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DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology
Government of India

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Biotechnology Industry Research Assistance Council
(A Govt. of India Enterprise)

GLOBAL BIO-INDIA

For An Atmanirbhar Bharat

A REPORT



**Transforming Lives
Biosciences to Bioeconomy**

1-3 March 2021 | Digital Platform



DELEGATES
8400+

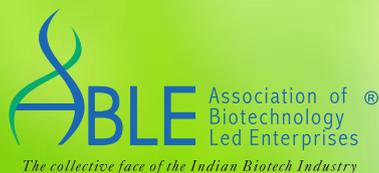
ENTREPRENEURS
& START-UPS
1000+

BIO PARTNERING
MEETINGS
350+

EXHIBITORS
150+

COUNTRIES
40+

PARTNERS



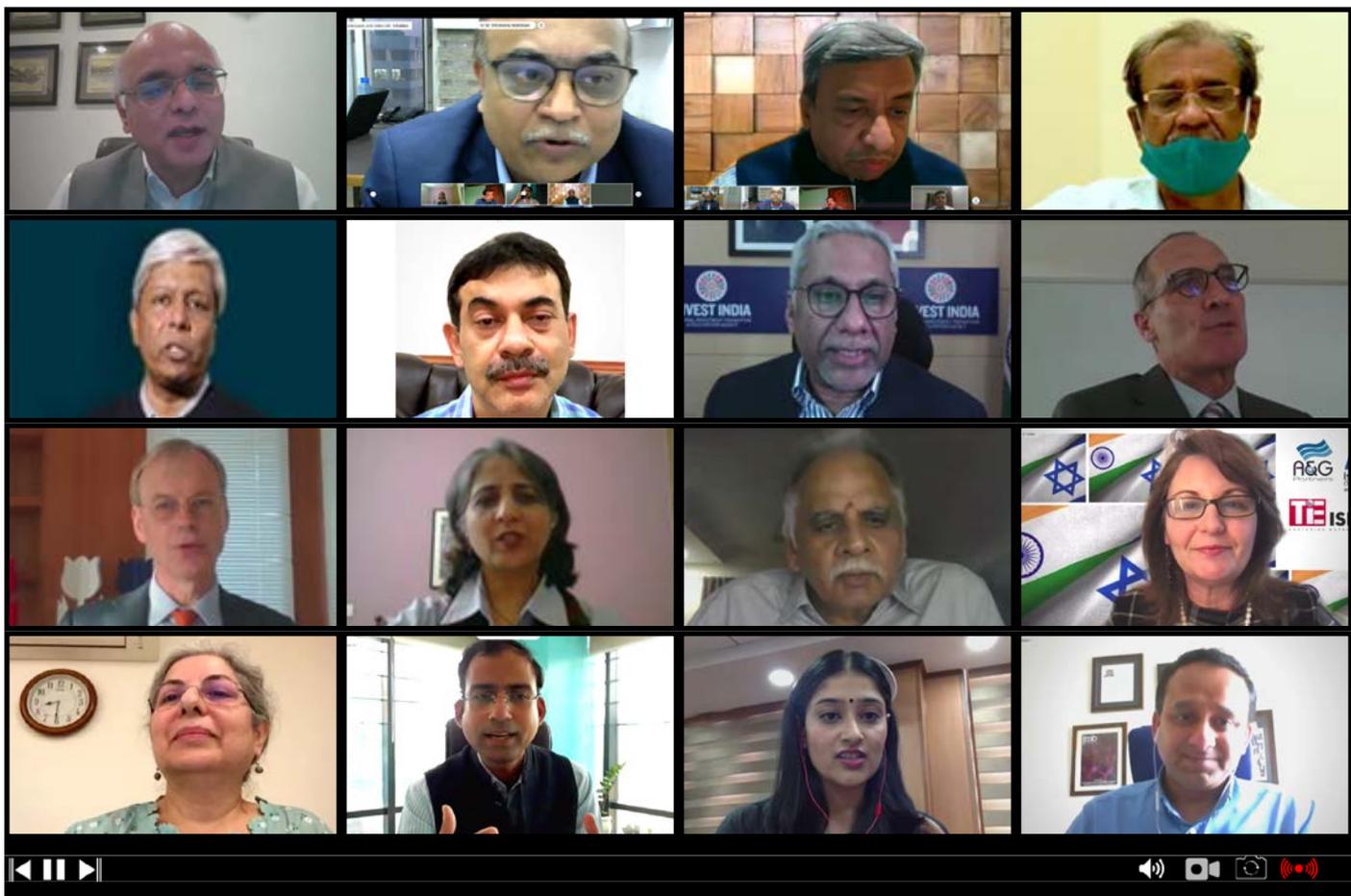
Confederation of Indian Industry

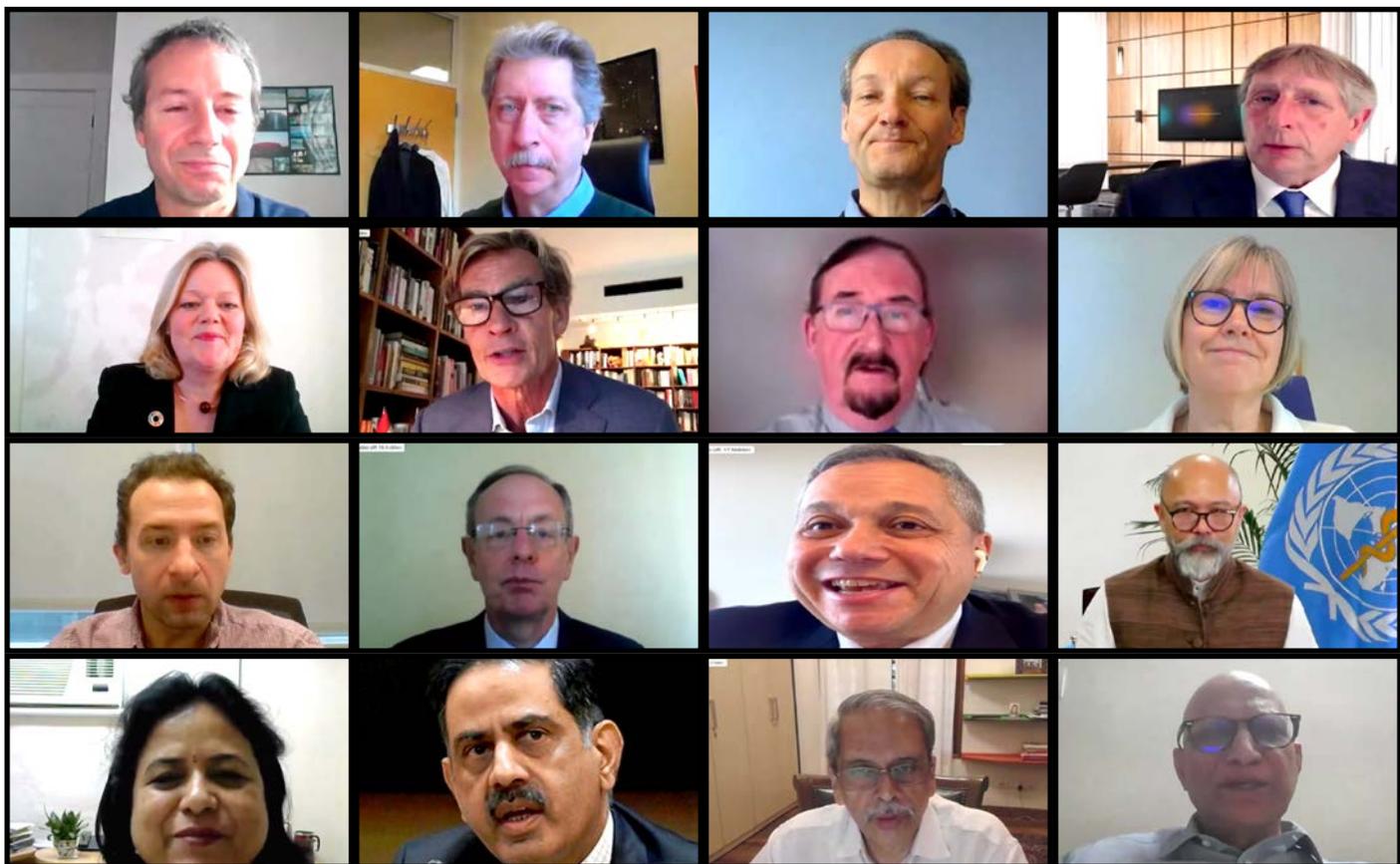


INVEST INDIA
NATIONAL INVESTMENT PROMOTION
& FACILITATION AGENCY

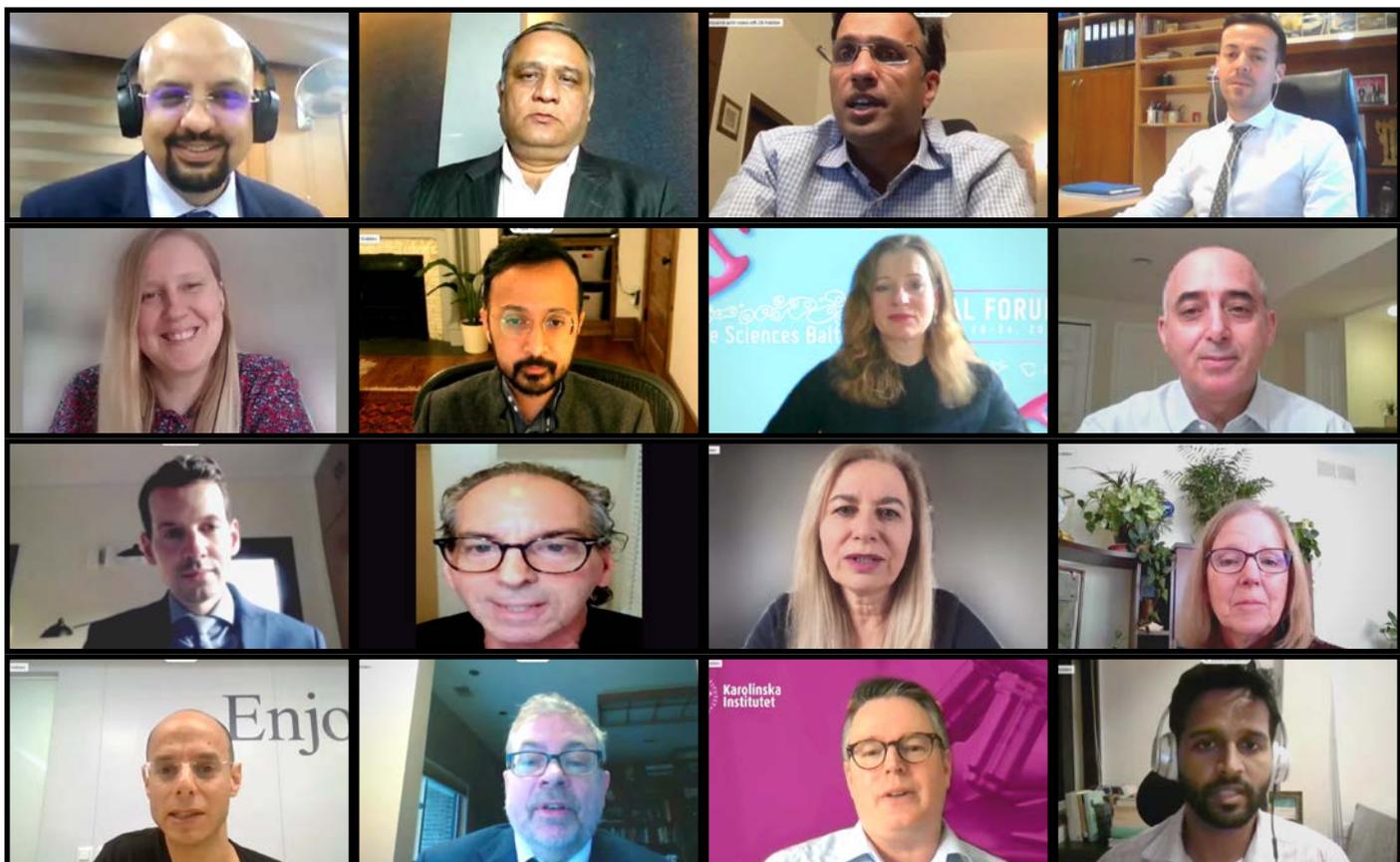


Global Bio-India 2021 Championing Indian Biotech Growth





Indian Biotech Industry Gliding Towards \$150 billion in 2025 For An Atmanirbar Bharat



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KEY TAKEAWAYS FROM **GLOBAL BIO INDIA 2021**

The second edition of Global Bio-India-2021 held through virtual mode. The three-day event, showcasing the strengths and opportunities of India's biotechnology sector at the national level as well as to the global community, came up with a large number of ideas through deliberations among experts in as many as 24 knowledge sessions. Here are some of the key takeaways

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NUGGETS
&
TAKEAWAYS**Phenomenal Potential**

With a \$70 billion output contribution to the GDP, which is slated to grow up to \$150 billion by 2025, including \$100 billion in bio-manufacturing, the Biotechnology sector truly has phenomenal potential in the future.

Promoting Indian Technologies

Industry and Commerce Department to promote Indian technologies internationally. Efforts to be made to work with the FDA to get the technologies more visibility at international fora at special fairs.

Out Of The Box

Startups need to be encouraged to experiment, to go beyond the run-of-the-mill thinking. We need to ensure that our startups are not afraid of failures. Failure also has its own importance, particularly in research and innovation, and invention.

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Boost To Ideas

The Project Development Cell will help us to come up with significant targeted support for the biotechnology sector for any good ideas that the startups may come up with.

Clean & Green Future

The interdependence of energy and health has been an important area of focus in the last few years and Prime Minister Modi has taken the responsible path of the sustainable energy transition for a clean and green future.

Major Biofuel Program

We have embarked on a major biofuel program in the country, which has huge investment opportunities.

Culture Of Science & Innovation

India stands as a powerful example for the world to showcase that embracing a culture of science and innovation can deliver progress on public health goals both within the country and globally.

Incentives For Research, Production

Introducing Research Linked Incentive scheme in line with the Production Linked Incentives schemes launched recently an excellent idea to work on.

\$150 Bn Bio-economy

To convert India into a \$150 bn bio-economy, appropriate enabling environment must be created that can cover the production, use, and trading of biomass.

From Import To Self-Sufficiency

The success story of diagnostics from 100% import to 100% self-sufficiency in less than three months and the development of two vaccines, all developed in less than a year with two emergency use authorizations is an indication of the Indian biotech sector's inherent strength.

New Is The News

India must focus on research to bring new vaccines, new drugs, new diagnostics, and new medical devices to the world markets to generate high-value IPs in order to raise its share in the global bio-economy.

Great Opportunity For All

At least 60% of the world's physical inputs could be made using biological means and 45% of the world's disease burden could be addressed by it. Thus, it presents a great opportunity for innovators, businesses, and policymakers.

AI, IOT & AR

The key trends which are taking place in the biotechnology segment are due to disruptive technologies like artificial intelligence, the Internet of Things, and augmented reality.

Automation, The Way Forward

To keep abreast of the new technology developments, life sciences companies will have to embark upon automating the whole process of drug evaluation to avoid delays and discrepancies.

Financial Factors

Lowering the cost of borrowing to set up plants in API hubs through tie-ups with multilateral financing agencies can go a long way in addressing the issue of finance.

GLOBAL BIO INDIA 2021 - BY THE NUMBERS

India Marches towards an Atmanirbhar Bharat

\$70.2 BILLION
Indian Bioeconomy

4237 Startups driving Biotech space in India

500

Innovative ideas supported by Department of Biotechnology in 1 year

Rs 50,000 CRORE
Budget allocation for National Research Foundation

60 Bio-incubators build over 640,349 square feet of incubation space for startups

260+ IPs filed by Indian biotechnology sector during COVID-19 pandemic

200+ Products and technologies launched in the market in 2020

12.3% CAGR of Indian Bioeconomy

\$150 BILLION Targeted growth of Indian Bioeconomy by 2025

1,000+ Startups (valued at over Rs 3,500 crore) receive financial support from DBT

60% Share of Biopharma by value in India's total Bioeconomy

40% Population employed in Bio Agri sector in India

60% India's share in global vaccine production by volume

1,900 Test laboratories functioning across the country

1 MILLION COVID-19 sample testing capacity built across India in just one year

\$58.37 BILLION FDI inflow of USD 58.37 Bn during April to November 2020

\$70 BILLION Current indicated investments for India

Supply Chain Reaction

A large number of companies are moving their supply chains on a fast-track basis. This is an opportunity for India to help in the global diversification of supply chains.

New And Emerging Diseases

The COVID-19 pandemic has reinforced the need for scientists and researchers to be always ready for such situations and continue working on new and emerging diseases.

Long gestation period

Biotech sector is relatively different from IT, FinTech, and eCommerce sectors. The biotech sector in particular has a longer gestation period. The ideas and innovations take longer to translate into a successful outcome.

Critical COVID Junction

On the COVID-19 front, we are at a very critical junction again because we had seen the number of COVID cases going up dramatically, while on the other hand fatigue has set in, which is prompting people and governments to behave normally.

Multi-disciplinary & Interdisciplinary

The research in biotech needs to be multi-disciplinary and interdisciplinary. So we need computer scientists, mathematicians, and chemists to work together rather than in silos.

FIVE PRODUCTS WERE LAUNCHED IN THE GLOBAL BIO-INDIA 2021



Emvolio: A portable, battery-powered refrigerator for Vaccine delivery from Blackfrog Technologies Pvt. Ltd.



Grippy: Battery powered prosthetic hand with a sense of touch and multi-grip control from Bionic Hope Pvt. Ltd.



KEYAR: Wireless intrapartum monitoring device with DAKSH mobile application for monitoring

risky pregnancies from Janitri Innovations Pvt. Ltd.



easyNav: Computer-guided Surgical navigation system for neuro-surgery

Happy Reliable Surgeries Pvt Ltd



VoDCa: Vortex Devices based on Cavitation Technology for waste water

treatment by Vivira Process Technologies Pvt. Ltd.

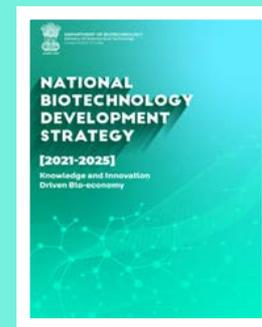
FORMAL ANNOUNCEMENT FOR SETTING UP OF PROJECT DEVELOPMENT CELL FOR BIOTECHNOLOGY

Dr.Renu Swarup, Secretary formally announced the setting up of Project Development Cell for Biotechnology at BIRAC by Department of Biotechnology in association with Invest India, the National Investment Promotion and Facilitation agency. The Project Development Cell would facilitate investments in the Biotechnology sector by providing a dedicated facilitation mechanism and would closely interact with potential investors and State Governments to identify suitable clusters/geographic locations for fast-tracking investments & project implementation.



NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY 2021-25

With the current growth trajectory of the sector we are confident that India will be within the top 5 countries globally and be recognized as a Global Biomanufacturing Hub by 2025, with the Sector growing exponentially to achieve a growth of \$150 Billion. This strategy document brings out this plan and also lays emphasis on the new initiatives to be taken along with certain policy changes which are required to deliver this target. The new strategy will allow the biotech sector to make a quantum jump in addressing these priority areas



KNOWLEDGE **Reports** & *VISION* **Documents**

INDIA BIOECONOMY REPORT 2021 BY ABLE

Hon'ble Minister for Commerce and Industry, Shri Piyush Goyal launched the 3rd edition of the BioEconomy Report, India BioEconomy Report (IBER) 2021 brought out by Biotechnology Industry Research Assistance Council (BIRAC) through its Make-in-India Facilitation Cell and the Association of Biotechnology Led Enterprises (ABLE). The report maps Indian BioEconomy status, FDI inflow, number of Biotech start-up/ Companies in India, Bioeconomy's contribution to GDP, contribution of various subsectors and policies that could trigger India's BioEconomy.



The report highlight that how COVID-19 has changed the entire dynamics of the role of Biotechnology and modern medical diagnostics. "With lockdowns, generally the businesses were affected and regular business models would have been relegated to defy the gravity. The study shows that sector has done well and didn't buckle down under pressure and record 12.3 percent growth," the report says.

REALIZING INVESTMENT POTENTIAL FOR INDIAN STATE BY INSTITUTE OF COMPETITIVENESS

This report is mapping the State-specific investment potential, which would highlight the strengths and areas of improvement for different states with regard to biotech policies and would also serve as a guidance for new policy initiatives, investors to assess potential at state as well as national level.

“The presented framework and the set of indicators have evolved as a result of extensive deliberations on possible means to better capture the innovation landscape. This process has evolved from constant stakeholder interactions with sector-level experts such as BIRAC and The Biotechnology Innovation Organization,” says Amit Kapoor, Honorary Chairman, Institute for Competitiveness, which brought out the report.



INDIAN PATHOGEN PRIORITY LIST

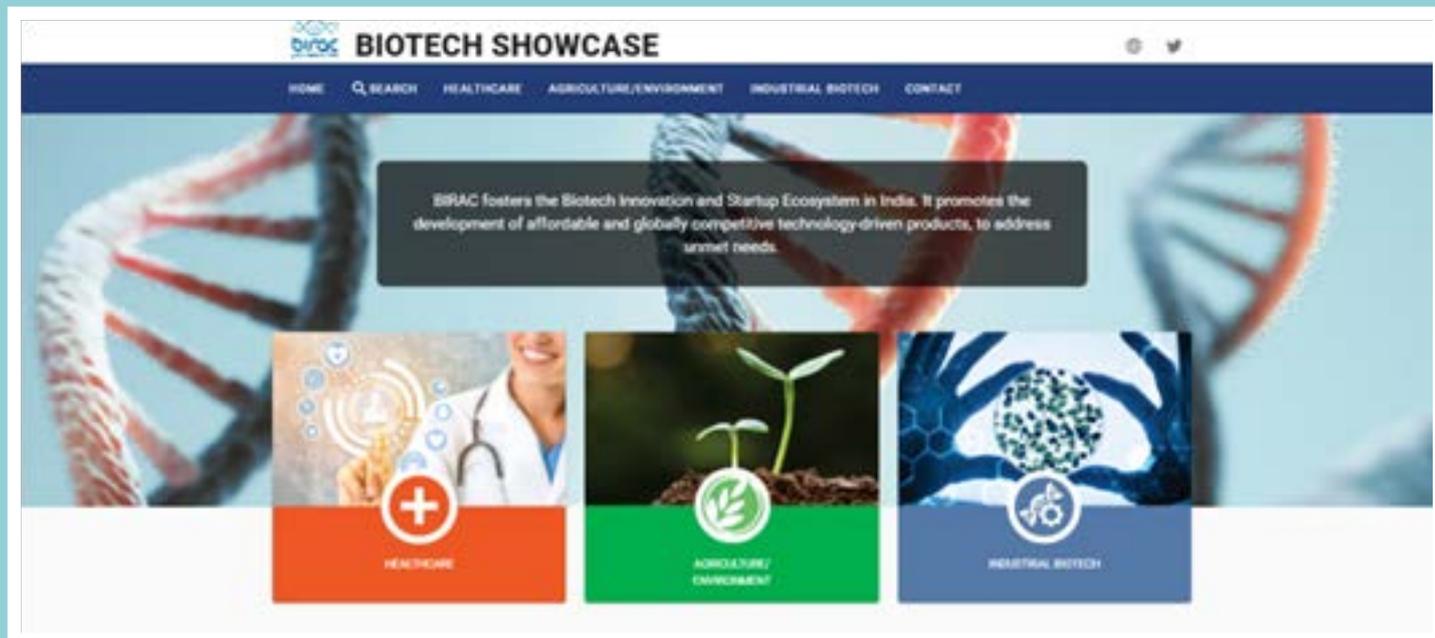
The WHO Country Office for India collaborated with the Department of Biotechnology to develop the list of drug resistant microbial pathogens of national relevance, in alignment with the global priority list of antibiotic-resistant bacteria to guide research, discovery and development of new antibiotics (WHO, 2017). This list shall help to facilitate prioritization of research and development of new and effective antibiotics from Indian perspective.

The report is aligned with WHO's Global Priority Pathogen List of antibiotic-resistant bacteria and was developed with inputs from AMR experts across different domains from across India to guide policy initiatives that incentivise basic science and advanced research and development through public funding agencies and private-sector investment in new antibiotics pipelines.



BIOTECH INNOVATIONS

Technologies Commercialized (150+) by Start-ups



TECHNOLOGIES UNDER DEVELOPMENT

This compendium is a compilation of the BIRAC supported innovations, products and technologies, new facilities, COVID initiatives and much more. This rich repository would provide insights into the innovative products and technologies supported by BIRAC and how these innovations have come a long way in solving problems in varied sectors.

It also details the initiatives taken by the organization in tackling the pandemic. “BIRAC innovators have also come up with potential COVID solutions that have been very helpful in the present scenario. The vibrant ecosystem offered by BIRAC has been very helpful in addressing the societal issues,” says Anju Bhalla, Joint Secretary DST and MD BIRAC.



LEADERS SPEAK

The second edition of Global Bio-India-2021, which was organized on a digital platform from March 1 to 3, saw the coming together of leaders from the biotechnology sector, policymakers, and members of academia in large numbers to provide useful insights into the developments in the sector, besides helping prepare a future roadmap to make it a key driver for India's aspiration of achieving \$5 trillion economy target

Leaders Speak

India Stands as a Shining Example of Innovation

India has done a commendable job in extending support to startups, strengthening government diagnostic capacity, and making rapid regulatory response

Calling biotech industry as the backbone of various industrial sectors, Vice President Shri Venkaiah Naidu, said that India stands as a shining example to the rest of the world, enjoying the culture of science and innovation that can help achieve public health goals both within India and globally. “I’m pleased to endorse that the global biotechnology is the backbone of various industrial sectors. In recent times, it is driving innovations in pharmaceutical sector, agriculture and food processing which has had a profound impact on the quality of human lives and has become the driving force of significant transformation,” said the Vice President.

He said the government’s mandate is to create a strong enabling environment for the growth of the biotech sector. “I am happy to acknowledge the efforts of the government in engaging with all the stakeholders for not only providing financial support, but also introducing key policy changes,” he added.

Speaking on the important learnings from the response during the crisis, he said that India did a commendable job in developing novel protection equipment, besides extending support to startups, strengthening government diagnostic capacity, and making rapid regulatory response.



SHRI VENKAIAH NAIDU
Hon'ble Vice President of India

India took a lead to help over 60 countries vaccinate their population groups. He said it was noteworthy that we were able to significantly improve our COVID-19 testing capacity to over 1 million samples every day through almost 1,900 laboratories across the country. He added that the government will support the development of a world-class biotech innovation ecosystem by creating incubation infrastructure and support mechanisms to enable the industry transition from research to commercialization.

The Vice President also pointed out that the COVID-19 pandemic has reinforced the need for scientists and researchers to be always ready for such situations and continue working on new and emerging diseases.

I MUST COMPLIMENT THE DEPARTMENT OF BIOTECHNOLOGY, MINISTER OF SCIENCE AND TECHNOLOGY FOR ADOPTING A PROACTIVE APPROACH AND SUPPORTING VARIOUS RESEARCH PROGRAMS IN MODERN BIOLOGY AND BIOTECHNOLOGY



Transforming Lives Biosciences to Bioeconomy

Atmanirbhar Bharat

\$150 Billion Indian Bioeconomy

by 2025 ❖ Industry & Academia

Collaboration ❖ India Fights COVID

❖ Bio Manufacturing ❖ Emerging

Technologies ❖ New Products and

Services ❖ Startup Ecosystem

❖ Labs2Market ❖ Women

Entrepreneurs Conclave ❖ BIRAC's

Innovators Awards ❖ Health Conclave

❖ Clean Energy Conclave ❖ Agritech

Conclave ❖ MedTech Ecosystem

❖ Learnings from Pandemic ❖ Global

Investors' Meet ❖ CEOs Roundtable

❖ Bioclusters across India ❖

Phytopharma and Traditional Knowledge

❖ Regulatory Corrections ❖ Indian

Pathogen Priority List

Leaders Speak

Biotechnology Will Build Bharat of Tomorrow

The success of Global Bio India 2021 is an indication of the success the biotechnology sector has achieved in the country

Recalling the words of Shri Atal Bihari Vajpayee, Dr Harsh Vardhan, Union Minister of Science and Technology; Health & Family Welfare and Earth Sciences, said that the former Prime Minister of India had predicted at the turn of the century that if 'IT is India of today then Biotechnology is Bharat of Tomorrow'.



DR. HARSH VARDHAN
Union Minister of Science & Technology;
Health & Family Welfare and Earth Sciences

"I would love to remember former Prime Minister of India Shri Atal Bihari Vajpayee at this particular moment because towards the beginning of this century when he was the prime minister of the country for six years, he brought science to the centre stage of Indian politics. That was a time when there was a huge boom in the IT sector. He had predicted that if IT is India of today then Biotechnology is going to be the Bharat of tomorrow. And this is what we are gradually witnessing as the biotechnology sector has been growing," the Minister said while speaking at the Inauguration of Global Bio India 2021.

He said that March 1 was a special day because it was the day when the country men were able to enjoy the benefits of vaccination against the COVID virus. "It is all because of the contribution of our scientists who have been supported so well by the Department of Biotechnology. And of course, our Prime

Minister Narendra Modiji, who blessed all of us during the fight against COVID through vaccine development and also by providing a fund of over Rs 900 crore under COVID Suraksha programme," said Dr Harsh Vardhan.

He appreciated the efforts of scientific and technology community by saying that they have done so well in terms of rising to the occasion. "The way they produced everything that was required, whether it was vaccine, diagnostic kits, drugs

or various other equipments, it's very difficult to describe the contribution of the scientists. This is a moment of great satisfaction for me as a minister for science and technology."

He also appreciated the growth of biotechnology sector in the country. "During the course of these five-six years as the science and technology minister, people from the industry used to tell me that we want to be \$100 billion bio economy by 2025. But they have in fact changed their goal. And it seems they are getting more confident talking about achieving their goal now. They are now talking about \$150 billion economy by 2025. And as I was told that already \$70 billion has been achieved," said Dr Harsh Vardhan.

The success of Global Bio India, he said, was an indication of the success the biotechnology sector has achieved. "I remember the Global Bio India conference in 2019. It saw the

2020 WILL NOT ONLY BE REMEMBERED AS AN ERA OF COVID WHEN THE WHOLE HUMANITY GOT DISTURBED, BUT THE YEAR WILL ALSO BE REMEMBERED AS AN ERA OF SCIENCE AND THE YEAR OF SCIENTISTS

participation of almost 30 countries with 3,500 delegates and around 300 startups in exhibitions, workshops, boot camps, round table and investors' meet along with so many global regulators. Looking at Global Bio India 2021, where there is participation from almost 50 countries, of over 8,000 delegates and more than 1000 startups, I think this is a huge indication of the success that we are achieving in this particular field, he said.

He added that with the involvement of Department of Biotechnology, CII and support by so many scientists and bio technologists and problem solvers like Dr. Kiran Mazumdar Shaw, I think Indian Biotech sector has a good chance of actually achieving the goal of \$150 billion by 2025.

The Minister said that suggestions like introducing Research Linked Incentive scheme in line with the production linked incentives schemes launched recently was a very bright idea.

He also praised the finance minister for announcing the National Research Foundation with a budget of Rs 50,000 crore in the Union Budget of 2021. "Economies have witnessed a down slide all over the world during this crisis. But the government announced almost 27 lakh crore of planned spending during the crisis. Even the health sector and scientific community got so much of support. The scientific community also paid back by devising all the things through the right approach and right strategy," said Dr Harsh Vardhan.

"We have lost many people all across the world, we lost so many of our dear friends to COVID. However, 2020 will not only be remembered as an era of COVID when the whole humanity got disturbed, but the year

will also be remembered as an era of science and the year of scientists, because we could see that scientists, irrespective of what their field was, what their domain was, what they were supposed to be doing, they all rose to the occasion," he acknowledged.

The Minister also said that although so many vaccines are still in the research domain, "there was one disease (COVID-19) which came in the last week of December 2019 and it took everybody by surprise. However, when we are talking in the first quarter of 2021, we have already got two vaccines in our country which we have already given to almost one crore 35 lakh people. And today we have got the guts, ability, potential and planning to vaccinate every person above 60 years of age in this country, and every person with a comorbidity between 45 and 69 years of age".

He said that as a doctor, he felt more contented with the developments of biotechnology because "this is something which is closest to the welfare of human being".

"This is an occasion to reaffirm our resolve that in times to come, we will certainly be able to achieve our immediate goal of a new India by 2022. That is the dream of our Prime Minister which he had spelt out in 2017. By 2020, we are already amongst the top two-three scientific nations of the world and among the first 15 countries on the Global Innovation Index. This is a great achievement. And a lot of it has happened during the last seven years under Prime Minister Narendra Modi. So he also deserves a lot of appreciation and support from all of us, and we all have to contribute to the realization of his dream of a new India," Dr Harsh Vardhan said.

Leaders Speak

Biotech Industry Unleashed its True Power During Pandemic

India was able to fight the COVID-19 pandemic owing to the concerted efforts of the government and the private sector together

The Science and Technology ecosystem in India has always been a dynamic and evolving area with the support of the Government of India through its different schemes and policies. However, in 2020, with the background of COVID-19 pandemic that was a source of trouble for all, the biotech industry unleashed its true power, resilience and capability, said Smt. Nirmala Sitharaman, Union Minister of Finance & Corporate Affairs.

Speaking at the inaugural of Global Bio India 2021, the minister said that India was able to fight the COVID-19 pandemic owing to the concerted efforts of the government and the private sector together.

“The government through the Department of Biotechnology and BIRAC has supported technology driven 3,500 plus entrepreneurs, startups, SMEs and so on. Through various operational models of cooperation, a network of 55 bio incubators with more than 550,000 square feet of incubation space has been built, which has helped innovators to create a pool of intellectual wealth,” the Finance Minister said.



SMT. NIRMALA SITHARAMAN
Union Minister of Finance &
Corporate Affairs

During the pandemic, she said that 260 plus IPs were filed and the government supported the launch of over 200 products and technologies in the market. “The government through Department of Biotechnology, its autonomous institutes and public sector undertakings, Indian Council of Medical Research and Council of Scientific and Industrial Research have been working relentlessly to mitigate the COVID-19 global health crisis, through development of diagnostics, vaccines, novel protection equipments, support to startups to scale up diagnostic capacity, and rapid regulatory response,” the Minister added.

She informed that a multi-pronged research strategy and action plan was evolved for immediate response, augmentation of COVID-19 tests across the country, as well as for long term preparedness to tackle the COVID-19 infection.

“India stands as a powerful example for the world as to how embracing a culture of science and innovation can deliver the progress on public health goals, both within the country and globally,” Smt. Sitharaman said.

INDIA STANDS AS A POWERFUL EXAMPLE FOR THE WORLD AS TO HOW EMBRACING A CULTURE OF SCIENCE AND INNOVATION CAN DELIVER THE PROGRESS ON PUBLIC HEALTH GOALS, BOTH WITHIN THE COUNTRY AND GLOBALLY

She said that the Indian biotech sector's efforts were in line with the Atmanirbhar Bharat vision of the Prime Minister. "India has taken a leading role in the manufacture of diagnostics, medical equipment, and vaccines, we were able to quickly build up our capacities for testing over 1 million COVID-19 samples every day, spanning almost 1,900 laboratories across the country," added the Minister.

The Department of Biotechnology and BIRAC (Biotechnology Industry Research Assistance Council) also initiated the COVID-19 Research Consortium to facilitate the holistic development of vaccines, diagnostics and therapeutics under the Mission COVID Suraksha. The initiative accelerated the development of indigenous vaccines in the country.

"Today the world is looking at India to supply much of the vaccines required for the pandemic. India is on the way to fulfilling this

promise, both for our population and for the rest of the world, with a clarion call given by Honourable Prime Minister for Atmanirbhar Bharat or self-sufficient India," she said.

Smt Sitharaman hailed biotechnology industry for rising to the occasion. "Both large and small companies in the biotechnology industry have risen to the occasion. From large manufacturers to startups, the innovation ecosystem in the country has come together to provide solutions for India and the world," the Finance Minister said.

She informed the audience that the Union Budget 2021 has increased outlays for the entire science and technology domain with the establishment of the National Research Foundation as proposed in the budget that is expected to fund research in the university ecosystem, across the range of disciplines, from science and technology to humanities. "It will further expand the scope of science funding in India," she said.

Leaders Speak

Startups Should Be Encouraged To Experiment

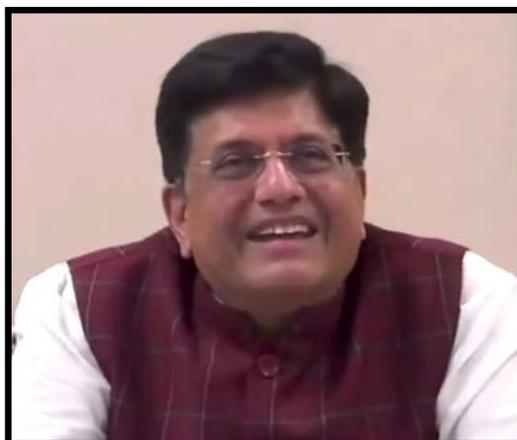
Innovations have to be affordable and accessible to the larger masses, and should have a significant impact on society by making the life of people easier, which Prime Minister Narendra Modi often refers to as ‘Ease of Living’

Indian startups need to be encouraged to experiment and to go beyond the run of the mill thinking, said Mr Piyush Goyal Minister of Railways, Minister of Commerce and Industry and Minister of Consumer Affairs, Food and Public Distribution, while addressing the Global Bio India 2021.

“We need to ensure that our startups are not afraid of failures. Failure also has its own importance, particularly in research and innovation and invention,” said Mr Goyal, adding that the synergy between the private sector and the government will truly be an enabler for the startup ecosystem in India.

“You really cannot have great innovation and invention coming up only through government initiatives. We do need to have all sections of business involved. But at the same time, government should act as an enabler as a service provider and as a support to the ecosystem,” he said.

He also pledged the Industry Ministry’s and Commerce Department’s complete support in promoting technologies developed by Indian start-ups internationally. “We can work with the FDA to get these technologies more visibility at international fora. We can even look



SHRI PIYUSH GOYAL

Union Minister of Railways, Commerce and Industry and Minister of Consumer Affairs, Food and Public Distribution

at special fairs to showcase the outcomes of the outputs of our startup ecosystem to other parts of the world,” said the minister.

He hailed the contributions being made by women entrepreneurs saying that “it’s very appropriate when we say that 40% of all our startups are being led by women, showing the world the strength of our brothers and sisters”.

Emphasizing that the Project Development Cell will come up with a significant targeted support for biotechnology sector

to promote any good ideas that the startups may come up with, Mr Goyal said the need of the hour is to engage more and more with rural India to tap new talent.

“The translations and language capabilities that DBT is trying to bring about, to help people in different languages whose mother tongue may be different, who may not be well versed with English, but may have good ideas will help us to really bring together the best that India has to offer,” the minister said.

He also stressed on developing affordable innovations. “All innovations have to be accessible to the larger masses, and should have a significant impact on society, on our lives, and make the life of people easier, which Prime Minister Narendra Modi often refers to as ‘Ease of Living’,” he added.

WHEN BIO-ECONOMY IS COMBINED WITH THE DIGITAL AND INFORMATION ECONOMY, IT RESULTS INTO BIOTECH

He was all praise for the efforts being put in by the Department of Biotechnology in building and strengthening the startup ecosystem in the country.

“Building Startups in Biotechnology field is not simple. It’s an uncharted territory with a lot of learnings a lot of stumbling along the way. But the results have been truly phenomenal, as against the target of 2000, the Department of Biotechnology has helped set up over 4,200 startups in this sector,” said Mr Goyal.

With \$70 billion output contribution to the GDP, which is slated to grow up to \$150 billion by 2025, including \$100 billion in manufacturing, the Biotechnology sector truly has a phenomenal potential in the future, he added.

“The dashboard and tracker approach will help the startups going forward,” the Minister opined.

He also took note of innovative products launched during Global Bio 2021. “The five selected products by young startups launched during Global Bio 2021 are reflective of the contemporary thinking that DBT is engaged in. Each of these products is relevant in today’s times. Be it vaccine distribution at the last mile, or be it the prosthetic hand using 3d printing launched here, all these products showcase the level of precision that technology can bring into improving people’s lives. However, we need to see how these can be made to scale and made more affordable.”

“Similarly, whether it’s the wastewater treatment or the switch device which helps medical monitoring of patients, or the device that gives location of surgical instruments, all

of this is reflective of India’s own campaign to become self-sufficient in modern technology, particularly in healthcare. And going forward, ensure that 1.35 billion Indians get a better quality of life, get better healthcare facilities,” Mr Goyal said.

He added that when bio-economy is combined with the digital and information economy, it results into biotech. “And I think that will truly be the defining moment for India’s future economic growth, for India’s engagement with the rest of the world, and demonstrate India’s capabilities as a powerhouse of innovation, invention, and research. Biotechnology has potential to really push the boundaries of high-tech research and new technologies,” he said.

Referring to the Bioeconomy Report 2021, Mr Goyal said that it addresses several very critical issues, including issues relevant to our farmers, the agriculture sector, which impacts the people of India the most. “It also looks at products like cotton, which impacts agriculture, and textiles, the largest job creator in the country and the largest foreign exchange earner in the country,” said the Minister.

Highlighting the significant role to be played by the biotechnology sector in future, he said that doctors have five existing dimensions for decision making, such as Symptoms, Events, History, Habits, and Reports. “Biotechnology will put together all these dimensions and create a layer of the sixth dimension and help different sectors in different fields, more particularly healthcare, to truly become the instrument of service to meet the needs of 1.35 billion people of India,” he said.

Leaders Speak

Clean Energy to Fuel Growth of Indian Economy

India has been developing next generation infrastructure and enabling sustainable and efficient energy availability and accessibility to the poorest of the poor for combating climate change as a responsible global citizen

The Department of Biotechnology and Biotechnology Industry Research Assistance Council have been instrumental in promoting the research and development in the area of clean energy, which is going to play a large role in fuelling the growth of the Indian economy, said Mr Dharmendra Pradhan, Minister for Petroleum & Natural Gas and Steel, in his address at Global Bio India 2021.



SHRI DHARMENDRA PRADHAN
Minister for Petroleum &
Natural Gas and Steel

“Clean energy is going to play a large role in fuelling the growth of the Indian economy and manage the ambition of our population. The interdependence of energy and health has been an important area of focus in the last few years and Prime Minister Modi has taken the responsible path of sustainable energy transition for a clean and green future,” said Mr Pradhan.

“The greatest common good for the cause of cleaner energy and low carbon economy will be guided by the well-defined energy transition roadmap with seven key drivers as outlined by Prime Minister in October last year. That essentially means it will be a healthy mix of all commercially viable options by maximizing deployment of energy

sources, including biofuels, and emerging fuels such as hydrogen available within the country,” the minister added.

Saying that the government has been consistently taking energy policy initiatives and taking meaningful measures to ensure energy security, Mr Pradhan informed the attendees that India has been developing next generation infrastructure and enabling sustainable and efficient energy availability and accessibility to the poorest of the poor for combating climate change as a responsible global

citizen.

“Natural gas will be a significant transition for us. We are taking all efforts to shift towards a gas-based economy and to increase the share of natural gas from current 6% to 15% by 2030. We are also developing a nationwide gas grid, and other gas infrastructure included LNG regasification terminals,” he said.

To draw up a road map for using hydrogen as an energy source, the National Hydrogen Mission was launched in the Budget 2021. The Minister said that oil and gas companies in India are already developing projects for use of hydrogen as a fuel.

He further added that Indian refineries have been upgraded to produce BS-6 fuel with an investment of Rs 34,000 crore, which will go a long way in reducing air pollution.

CLEAN ENERGY CONCLAVE ORGANISED DURING THE GLOBAL BIO INDIA IS FOCUSING ON THE INTERDEPENDENCY THAT MAY EXIST BETWEEN THE HEALTH OF AN INDIVIDUAL AND HOW CAN IT BE IMPROVED BY PROVIDING CLEAN ENERGY

Highlighting another important development, he announced that his ministry has embarked on a major biofuel programme in the country, which has huge investment opportunities. “Biofuels have the power to create a balance between our environment and economic development. In order to augment the stock availability and promote biofuels, we notified the National Policy on Biofuels in June 2018,” said Mr Pradhan.

“Major initiatives have been taken to boost ethanol plants that can produce energy from agricultural waste across 11 states at an estimated cost of Rs 14,000 crore. The bio refineries will significantly contribute towards ethanol blending programme for achieving 20% ethanol blending in petrol by 2025,” he added.

The Ministry of Petroleum and Natural Gas is partnering with several countries including Belgium, Finland and Italy for clean energy. Indian companies have been encouraged to work with their foreign counterparts for developing refinery projects exploring different biofuels for air and sea transport. The government is also encouraging setting up of a supply chain mechanism.

“It is planned to roll out 5,000 compressed biogas plants by 2023 with a return investment potential of \$20 billion. These plants are expected to produce 15 million tonnes of compressed biogas per annum,” he said.

He said that New Delhi Municipal Corporation and South Delhi Municipal Corporation have developed waste to energy facilities, which is expected to set a new path for decarbonisation by using domestically available resource.

He expressed satisfaction that the Clean Energy Conclave being organised during the Global Bio India is focusing on the interdependency that may exist between the health of an individual and how can it be improved by providing clean energy. “It is a matter of great satisfaction that our country is moving towards universal access to clean cooking which has seen a remarkable surge from 55% in 2014 to now 99.6%,” he added.

Touching upon the government’s Ujjwala Scheme, the minister expressed satisfaction that India is moving towards universal access to clean cooking. “Ujjwala program not only tackles the health and environmental problem due to kitchen smoke, but also empowers the woman and restores control to them over their destiny,” he said.

He announced that by July this year, the government plans to add another 10 million household under the Ujjwala Scheme, which he added “has set an example for the developing countries of the world”.

“The World Health Organization termed it as a decisive intervention to change the indoor air pollution being faced by women,” the Minister said.

“This year Global Bio India’s theme of Transforming Lives-Biosciences to Bioeconomy fits into the Government of India’s mandate for clean technologies. I’d like to congratulate all the innovators who are working in the space of clean energy and this innovation ecosystem,” Mr Pradhan said.

Leaders Speak

India has Come Out Stronger in Biotech Ecosystem

The success story of Indian Biotech ecosystem can be gauged by the fact that India attained self-sufficiency in terms of manufacturing necessary equipment and kits in less than three months after the pandemic struck

COVID-19 was a moment of reckoning, which provided Indian biotech sector a great opportunity to unleash the full potential of its innovation capacities, said Dr. Renu Swarup, Secretary, Department of Biotechnology, in her opening address at the Global Bio India 2021.

“When we last met in 2019. From then till now, tremendous progress has been made. And we have witnessed both challenges and opportunities. 2020s has been defined by a single word and that is COVID-19. This pandemic brought unprecedented challenges not only to our country, but globally. At the same time for technology sector, it was a moment of reckoning. It provided us a great opportunity to unleash the full potential of innovation capacities to tackle this pandemic. The Indian biotech industry has come out stronger, providing confidence to the society,” Dr. Swarup said.

Speaking about the Indian Biotech ecosystem, the Secretary DBT said that the robust ecosystem was built in the country over the last few years. “An enabling policy framework and the government’s various



DR. RENU SWARUP
Secretary,
Department of Biotechnology

initiatives were beginning to show the desired growth plan when the pandemic struck. This was taken as an opportunity by a vibrant biotech ecosystem, and all the stakeholders collectively responded to the clarion call of the honourable Prime Minister in our fight against COVID,” she added.

The success story of Indian Biotech ecosystem can be gauged by the fact that India attained self-sufficiency in terms of manufacturing necessary equipment and kits in less than three months after

the pandemic struck, Dr Swarup said. “Our vaccines developed in less than a year with two emergency use authorizations.”

“The vaccination began because of the special focus that we got under the Atmanirbhar Bharat and Mission COVID Suraksha. Be it bio repository, genome sequencing, therapeutics, or monoclonal we excelled in all these areas. But what we greatly excelled in was collaborations and the convergence of all of them together. So the country’s bio economy size has grown more than 12.3% and it has reached \$70.2 billion. In 2019, it was just \$62.5 billion and is now moving towards achieving the expected growth of \$150 billion by 2025,” the Secretary DBT projected.

WE ARE HOPING THAT THIS INNOVATION LED ENTREPRENEURSHIP, WHICH HAS CONTINUED DESPITE THE PANDEMIC, WILL REACH A MUCH GREATER HEIGHT AS WE MOVE ON

The share of bio economy in the GDP has also been rising, according to her. She hoped that with the sustained growth and sustainable innovative ecosystem India will be able to achieve its growth target for the sector sooner than later.

Pointing out some of the lessons learnt during the COVID-19 pandemic, Dr Swarup said that whether it was to provide diagnostics, PPEs, ventilators or vaccines, support systems have been created to allow the regulatory systems to eliminate various impediments related to the infrastructure development.

“To speed up the research and innovation is something that we would like to see going beyond the COVID. I’m very happy to inform you that the component labs, the universities, the industry, we all came together. And those initial hesitations that we saw in terms of collaboration are all on the side to get through the COVID solutions. We are also hoping that this innovation led entrepreneurship, which has continued despite the pandemic, will reach a much greater height as we move on,” she added.

More than 840 biotech start-ups were set up in 2020 itself despite the pandemic, Dr Swarup informed. “This takes our total number of startups in Biotech space to more than 4,000. It is 4,237 to be precise,” she said.

Adding that the focus was on addressing all issues ranging from scalability to sustainability, the Secretary DBT said that over this year alone, 400 to 500 new ideas have been supported by her department and more than 1000 startups have received financial support. These startups, she said, have been valued for more than Rs3,500 crore.

Dr Swarup also highlighted that the Department of Biotechnology could respond so quickly against the COVID pandemic because of the “wonderful foundation that has been set under the National Biopharma Mission, which was launched in 2018 in collaboration with the World Bank”.

“When we met in 2019, the event witnessed a lot of vibrancy and energy with more than 3,000 delegates in the Delhi Aerocity Ground. Today, we have more than 6,000 delegates, and participation has increased to 50 countries along with 10 state governments and more than 6,000 startups who are engaged with us through different events. We can feel this vibrancy, the Secretary DBT said. Moving forward, we are looking at working towards the \$150 billion bio economy. This network that we’ve established of knowledge translation clusters, creeping up technology clusters is based on the reports that we had, from the expert group and to public consultations”.

Leaders Speak

DBT One of the Most Investor-Friendly Departments

The Department of Biotechnology of the Government of India, unlike typical scientific departments, is probably one of the most investor-friendly departments, said Dr Guruprasad Mohapatra, Secretary, Department for Promotion of Industry and Internal Trade (DPIIT).

“The biotechnology department of the Government of India, unlike typical scientific departments, is probably one of the most investor-friendly departments I’ve seen because we interact very closely with many departments of Government of India. And more importantly is their focus on startups,” said Dr Mohapatra while speaking at Global Bio India 2021.

He added that very interestingly now the departments which are not very welcoming of startups are also welcoming them. “That indicates the solid commitment of our honourable Prime Minister, who sees a great future for startups in continuing this onward journey of the Indian economy,” he said.

“We have more than 42,000 registered startups in the DPIIT. There could be a few thousands who are not registered, but they exist. When the COVID started and we started taking the threat very seriously in India by forming Empowered Groups, I headed an Empowered Group on Procurement for COVID related devices. It could be PPEs, diagnostic kits, etc. I remember the transformation from an absolutely hopeless position in the early



DR. GURUPRASAD MOHAPATRA
Secretary, Department for Promotion of
Industry and Internal Trade (DPIIT)

March 2020 of not producing anything in India to producing adequately not only for India within three months, but also exporting all those items,” said Dr Mohapatra, while sharing his experience.

According to him during the pandemic the entire capability of the biotech industry came to the fore. “The Indian biotech sector is not only raising the health profile of the country, but also raising the investment opportunities in the country. Today, there are over 4,300 startups in the

biotechnology sector, which are likely to increase to around 10,000 by 2024-25. The bio-economy in India has grown from around \$51 billion in 2018 to \$63 billion in 2019. And even in the year of pandemic, the industry has registered an onward growth of around 12%,” he added.

The expected growth of \$150 billion by 2024-25, he said, is indicative of the possibilities of investment in this sector. “And this is where startups will play a very major role in promoting this agenda,” Dr Mohapatra observed.

Referring to the recent Global Investor Startup Summit, where the Prime Minister addressed the audience during the valedictory and interacted with nine National Startup Award winners, the Secretary DPIIT said, “The Prime Minister made two announcements at the event. One was setting up of a National Seed Fund Scheme. Honestly the idea for this seed fund scheme came from the Department of Biotechnology because they have a seed fund scheme of their own.”

THE INDIAN BIOTECH SECTOR IS NOT ONLY RAISING THE HEALTH PROFILE OF THE COUNTRY, BUT ALSO RAISING THE INVESTMENT OPPORTUNITIES IN THE COUNTRY. TODAY, THERE ARE OVER 4,300 STARTUPS IN THE BIOTECHNOLOGY SECTOR, WHICH ARE LIKELY TO INCREASE TO AROUND 10,000 BY 2024-25

Another major scheme, which the Prime Minister spoke about and is under active consideration of the Cabinet, is the Credit Guarantee Scheme for Startups. “Because that’s where the startups need a lot of financing. They require working capital, and that is where the banks and the non-banking financial institutions will play a major role,” he added.

The Secretary DPIIT also informed that some states like Kerala have already up for the Seed Fund Scheme to encourage early stage startups to go from a proof of concept stage to a marketing stage. “The National Seed Fund Scheme has been announced and it is being notified now. We are quite hopeful that with the active participation and support from all the ministries, particular Department of Biotechnology, startups will have a very able shoulder to rely on,” he said.

Saying that DPIIT is very supportive of startups, Dr Mohapatra highlighted the flow of investment coming from global organisations like Soft Bank, Sequoia Capital, DST Global, Google, etc., that has enthused Indian startups. “What we need to do is to identify those startups which require early stage

fund support and identify those startups which require venture capital support, and very systematically handhold them, listen to them, try to find out where the bottlenecks are in government and try to resolve those problems,” the Secretary said.

THE BIOTECHNOLOGY DEPARTMENT OF THE GOVERNMENT OF INDIA, UNLIKE TYPICAL SCIENTIFIC DEPARTMENTS, IS PROBABLY ONE OF THE MOST INVESTOR-FRIENDLY DEPARTMENTS I’VE SEEN BECAUSE WE INTERACT VERY CLOSELY WITH MANY DEPARTMENTS OF THE GOVERNMENT OF INDIA. AND MORE IMPORTANTLY IS THEIR FOCUS ON STARTUPS

Leaders Speak

Health Care Sector is at an Inflection Point

The health care sector as a whole globally is at an inflection point, this is a moment in time where it is up to us in the sector to make or break it, rise up to the expectations to do some good work or fail at it. There a sense of urgency and a sense of inevitability about it, said Ms S. Aparna, Secretary, Department of Pharmaceuticals, Government of India, while addressing Global Bio India 2021.

“This is a moment where we need to act, and act in a wise way based on our experience with a better appreciation of the potential that lies in this sector. The need for raising awareness about the importance of healthcare not just for individuals, but for communities across the globe is at an all- time high,” said the Secretary, Department of Pharmaceuticals.

She further added that the realisation that healthcare is not an isolated sector is also at an all-time high. “With the COVID 19 pandemic, people have understood that there is a trifecta of the economic, the natural and the human systems. And it was at that trifecta that the pandemic arose because of globalization and encroachment into the space of nature,” Ms. Aparna observed.

She said that she believes that more attention from the highest echelons of the power structure is directed towards health care, whether at the global level or at the national level or at local government levels. “This is a time I think, that we have also seen unprecedented levels of collaboration, innovation and resource mobilization,” the Secretary added.



Ms. S. APARNA
Secretary, Department of Pharmaceuticals,
Government of India

She pointed out that while collaboration across sectors, between public and private, was witnessed not only in India but in many other countries, India was a prime example of “frugal innovation”.

“The vaccine development and the process that powered the vaccine development in India is an example of innovation. Pharma products, medical devices, instrumentation all have seen innovation in the last year,” Ms Aparna said.

Speaking about resource mobilization, she said that it was for the first time that huge resources were being devoted by multilateral organizations apart from countries in the healthcare sector. “Therefore, I do believe that this is an inflection point.”

Highlighting the challenges faced by the medtech sector, the Secretary said that the medical devices sector is a relatively less attended sector within the overall healthcare sector. “However, I think we are making amends and the sector is growing at an adequate pace. We are devoting a lot of attention to medical devices over the last couple of years,” she admitted.

She further added that the medical devices sector needs to look at how it can manage the demand. “I think we need to raise the equilibrium from the current level to a higher order, where we are both able to produce a larger, wider range of products that meet patient demand. And we are also able to manage the ability to absorb the wider range of products that will be available,” she suggested.

**WE HAVE THE WORLD'S ARGUABLY THE LARGEST
HEALTH INSURANCE SCHEME IN INDIA,
WHICH PROVIDES FOR INSURANCE COVER WITH
UNPRECEDENTED LEVELS OF FLEXIBILITY
AND CUSTOMER CENTRICITY FOR ABOUT
500 MILLION INDIVIDUALS, OR 100 MILLION FAMILIES**

Speaking on the supply side of things, Ms Aparna said, "As far as government is concerned, we have now started focusing attention on providing support for infrastructure. So whether it is medical clusters or medical device paths that will soon be coming up or even incorporating the requirements of the healthcare sector into the national logistics policy. Probably two years ago, we would not have thought of ensuring that cold chain storage for vaccines is a part of our national logistics policy. But today, it would be foolish not to do so. So at every level of infrastructure, I believe we are paying attention. We are paying attention of improving competitiveness by providing incentives that will encourage investment in the sector and encourage growth at scale."

The Secretary informed that the FDI policy has already been relaxed for the sector. "We are very much ahead of the curve. We have improved incredibly over the last four to five years. And this is a time where India is also looking to be a part of the demand for diversification of the global value chain."

Calling for entrepreneurs in Medtech sector to take advantage of this global demand for diversification of the supply chain, Ms Aparna said that there is unlimited potential in this space.

"We have the world's arguably the largest health insurance scheme in India, which provides for insurance cover with unprecedented levels of flexibility and customer centricity for about 500 million individuals, or 100 million families. We have 150,000 wellness centres coming up. We

have policy decisions on public procurement, which should be able to give better articulation of the demand across the country," she added while highlighting the opportunities from the domestic demand point of view.

She said that specifically for the medical devices sector, there is a possibility that the government will be looking at non-traditional ways of providing public services through private sector participation when it comes to high end diagnostics like imaging and scans.

"At the junction of this supply and demand is governance through regulatory systems, taking care of quality of products, taking care of certification of products, taking care of testing capacities and pricing. This is that junction where government is most active. And I would appreciate today if the industry could look at the manner in which this bridge between supply and demand in the form of sector governance can be made very efficient, very transparent and very responsive," she said.

The Secretary reminded the healthcare service providers and suppliers of medical products, that in India "for us access, availability and affordability of healthcare and medical products will continue to be most important when we take policy decisions, how we are able to reconcile these goals is what needs to be seen."

"I believe if the sector is to reach its full potential, the needs of our patient population is to be met. We have to work together not only on what is to be done, but more importantly, how it can be done," she added.

Leaders Speak

Startups were Best Performers in COVID

The excellence created by the Department of Biotechnology over the years in creating an ecosystem of innovation has certainly helped during the pandemic time

Lauding biotechnologists and other stakeholders in the Indian biotechnology ecosystem, Dr V K Saraswat, Member, Niti Ayog, said that the best performance came from small startups during the COVID-19 pandemic as their contribution to find solutions was considerably huge.

“Modern biotechnology plays a crucial role both in the elucidation of the molecular causes of disease and in the development of new diagnostic methods and better targeted drugs. These developments have led to the birth of a new economic order that we call biotech industry. Today, it is associated mostly with small startup companies. In fact, during pandemic period, the best performance has come from these startups. While many of the other industries were going slow, I think it was biotechnology startup companies in this particular sector which came up in a big way and contributed considerably to find solutions,” said Dr Saraswat.

He added that the excellence created by the Department of Biotechnology over the years in creating an ecosystem of innovation has certainly helped during the pandemic time. “I would say that I think we have today a very,



DR. V K SARASWAT

Member,
Niti Ayog

very potent ecosystem as far as this technology is concerned.”

Touching upon the emerging global scenario in biotech, Dr Saraswat said the bio evolution is a \$2 trillion to \$4 trillion opportunity.

There are four areas of bio innovations which are basically being practiced globally, according to him. He listed out bio molecules mapping and engineering which involves understanding intracellular molecules; bio systems where researchers are mapping and

engineering the cells, tissues and organs; bio machine interfaces, where researchers are connecting nervous systems of living organisms to machines; and lastly bio computing, where researchers are using the cells and cellular components for computation. “The scope and the scale of potential impact on economies and societies of these research areas appear to be substantial,” he added.

“Some figures say that 60% of the world’s physical inputs could be made using biological means and 45% of the world’s diseases burden could be addressed by it. So there are transformative capabilities with application across various domains,” Dr Saraswat said.

Basically, he said, that it’s an area where innovators business and policymakers must act “if we have to capture the benefits of the bio revolution”.

AI WILL ACCELERATE DISEASE DIAGNOSIS, RESEARCH OF NEW PRODUCTS AND DRUG DEVELOPMENT; LOT FOR RELIABLE MEDICAL DEVICES AND REMOTE PATIENT MONITORING; AND AUGMENTED REALITY, WILL BOOST THE KNOWLEDGE TRANSFER PROCESSES AND GENETIC ENGINEERING POWERED BY TECHNOLOGY ADVANCEMENT

Adding that India is doing significantly well, but there's a lot more required to be done, Dr Saraswat said, "The Indian pharmaceutical sector is expected to grow at a CAGR of about 22.4% in the near future and medical device market is going to grow about \$25 billion by 2025. This is the kind of growth we are expecting. But the main game changer which is emerging in this particular sector is the synthetic biology."

The healthcare sector is one of the fastest growing sectors in the country, which is expected to grow by about \$372 billion by 2022.

He also pointed out that those days are over when scientists work on single technologies. "Everywhere it is the integration of technology, the convergence of foundational technologies like nano technology, biotechnology, information technology and cognitive sciences," Dr Saraswat observed.

"In fact, till very recently, we were not adding the cognitive sciences in this, but I think now it becomes the order of the day, which will transform the biotechnology into nano informatics, DNA computing, photonics, nano biomedicine, nano biotechnology synthetic biology, bio photonics, and this convergence will usher in a new era as far as the biotechnology research is concerned," he informed the audience.

According to Dr Saraswat, the key trends which are taking place in the biotechnology segment are due to the disruptive technologies. For example, the artificial

intelligence which will accelerate disease diagnosis, research of new products and drug development; the Internet of Things for reliable medical devices and remote patient monitoring; and augmented reality, which will boost the knowledge transfer processes and genetic engineering powered by technology advancement.

"Clinical research partnership with modernization will help patients be more consistent in terms of their dosage, regulatory automation. To keep abreast of the new technology developments, life sciences companies will have to embark upon automating the whole process of drug evaluation to avoid delays and discrepancies what we have seen during the COVID-19 pandemic period," he said.

Speaking about challenges, he added that the increased volume of life sciences research is certainly going to need standardization. "I think this is one thing which in the life sciences business is expected to move forward. This will certainly universalize the whole thing. Compliance management technology as the companies spread their business into the market will result in additional automating for the processes of global compliance," he predicted.

Touching upon government interventions, he said that budgetary allocation for the Union Ministry of Health grew by about 18.6% over five years. "For taking any research activity in biotechnology area, I think enough money will be made available," he added.

Leaders Speak

COVID Unleashed our Animal Instincts

The indigenously developed vaccines in India are amazing examples of how the time can be compressed and scientific and R&D mobilization can take place in an amazing manner

Touching upon areas that emanate from India's quest for Atmanirbhar Bharat in the context of biopharma, and pharmaceutical solutions for the people, Dr Vinod Pal, Member Health, NITI Aayog, said that the COVID 19 pandemic unleashed animal instincts, helping us realise that India can deliver on a fast track mode.

"Firstly, we learned that we have animal instincts that can be unleashed, and we can deliver on a fast track mode. I would like to emphasize that the speed with which the solutions appear was phenomenal. Over a period of 10 to 12 weeks, there were 96 Indian diagnostics in the market and the first one came up within three weeks of the COVID-19 pandemic," said Dr Pal.

He said the Indian bio industry did not just copy and paste the solutions, but also they embraced the most advanced technology. And therefore, it was evident that things can happen in a very speedy manner.

"Likewise, the indigenously developed vaccines in India are amazing examples of how



DR. VINOD PAL
Member Health,
NITI Aayog

the time can be compressed and scientific and R&D mobilization can take place in an amazing manner," Dr Pal added.

He said that initiatives in production, manufacturing and stockpiling are helping us reap the benefits. "What is remarkable is that this time around the DBT and the ICMR decided clearly that we will also like to see trials of the vaccine to take place in other countries. Their intention to have a global footprint for vaccines R&D journey was something which I felt very proud

of. And I think it did break the ceiling in a way," the Member of NITI Aayog.

He said that though India's efforts has not yet reached the final result, the effort that was made in this regard by reaching out to 10 countries in the neighbourhood and reaching out to several other countries beyond the neighbourhood, in terms of requesting them to test our vaccine on their population, to me was a path breaking phenomenon, added Dr Pal.

"It was part of a well thought out strategy backed by deep thinking and resources. So extending capabilities for trial beyond our own shores is something which has also been achieved in the course of our scientific journey for COVID-19 vaccine."

WHAT IS REMARKABLE IS THAT THIS TIME AROUND THE DBT AND THE ICMR DECIDED CLEARLY THAT WE WILL ALSO LIKE TO SEE TRIALS OF THE VACCINE TO TAKE PLACE IN OTHER COUNTRIES. THEIR INTENTION TO HAVE A GLOBAL FOOTPRINT FOR VACCINES R&D JOURNEY WAS SOMETHING WHICH I FELT VERY PROUD OF. AND I THINK IT DID BREAK THE CEILING IN A WAY

He also expressed his satisfaction on the way India's regulatory system responded, "in terms of ease of doing business and in terms of speed."

"Also on the translational side, taking decisions for the protocols, for treatment of patients, a systematic approach that was taken step by step as the evidence appeared is also something which will come handy in times to come," Dr Pal added.

He said that India has learnt important lessons "that we now need to take forward, as we move along into the next phase".

Mentioning that India realized the need for having a stable system for APIs during the COVID-19 pandemic, he said, "It laid bare our vulnerabilities in this period. But now we have specific production linked incentive scheme to give stimulus to the industry and address those gaps. Overall, I think it showed our true potential. And I would like us to use that potential to break fresh grounds and one area where I hope we can break fresh ground is the area of rare diseases."

"Another area which I like to flag today is the area of antimicrobial resistance, where again, the solutions should come from India. Because there is one dimension, which is

the responsibility of people like us, clinicians and hospitals, to make sure that there is antimicrobial stewardship and is tracking what we are giving when we are giving and so on," Dr Pal added.

He also underscored the need for searching new molecules. "We must also be repurposing the old molecules. We actually have technologies which could change this whole romance with the antibiotics, and therefore, I would like us to flag these two areas. Antimicrobial resistance as a priority has somewhat been pushed to the back burner, I would like this to come in the forefront. The solutions to antimicrobial resistance may not be in the classical chemistry, but in the more advanced biochemistry or biotechnology, and therefore I hope we can work in on these two areas," said the Member of Niti Ayog.

OVER A PERIOD OF 10 TO 12 WEEKS, THERE WERE 96 INDIAN DIAGNOSTICS IN THE MARKET AND THE FIRST ONE CAME UP WITHIN THREE WEEKS OF THE COVID-19 PANDEMIC

Leaders Speak

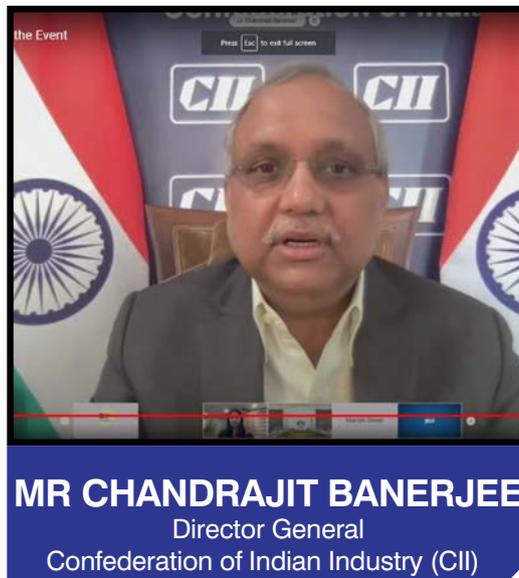
Bio Economy Most Critical Vehicle to Reach Circular Economy

Biotecnology is in the forefront of the technology, innovation, and creativity which are rapidly redefining the global economy. A bio-based economy is therefore most critical vehicle to reach the circular economy through sustainable development, said Mr Chandrajit Banerjee, Director General, Confederation of Indian Industry (CII) at the Global Bio India.

Speaking at the inaugural session, he said that it was a matter of great pride that India, true to its promise of being a pharmacy to the world, has successfully began the country wide vaccination exercise, while also supporting other nations by way of supplying indigenously developed vaccines.

“We have been an advocate of a bio-based economy for a very long time. And as we are aware, the biopharma segment alone contributes to more than 60% share of the total bio economy by value. The Indian pharma industry, along with biotechnology has the potential to grow easily up to \$200 billion by 2025,” he said.

He added that CII has been recommending the need for infrastructure development, environmental clearances and providing incentives to the API industry. “Already, we have initiated some of these by ways of developing a white paper on API advantage for India and expanding its focus to forging



partnerships between industry and academia,” Mr Banerjee informed.

Saying that the Global Bio India’s theme of ‘Transforming Lives - Bio Sciences to Bio Economy’ was very topical, he added that 2020 was an unprecedented year for nations across the world. “It was a time when we all had to realign, rethink and reimagine our growth opportunities. Under the leadership of Dr. Harsh Vardhan we saw India dealing with this huge challenge of the pandemic so very well.”

Speaking further, he said that Bio Agri is the second largest contributor to India’s bio economy, which is employing close to 40% of the population and contributing close to about 15% to the gross value added. “The sector remains very crucial to the overall stability of the Indian economy. I just wanted to mention that we are working on up-gradation of rural agricultural markets to work as primary aggregation points for farmers, where they can sell their products directly to the consumers or bulk buyers, retailers or processors,” he added.

The Director General of CII also said that CII as an institution has also aligned its agenda with the government’s vision of double farmers’ income. “We’re working through a multi-stakeholder approach. A circular economy adopted in the agriculture would prevent things like air pollution. The Food and Agriculture Centres across India’s food systems and our companies are already promoting a landscape approach to minimize farming impacts on nature,” Mr Banerjee said.

CII'S RELATIONSHIPS WITH A VARIETY OF TRADE AND BUSINESS AGENCIES ACROSS THE GLOBE CAN PROVIDE THE PLATFORM FOR INCREASED COLLABORATION AND INNOVATION, WHICH IS REQUIRED IN THE CIRCULAR ECONOMY ECOSYSTEM

“More and more agri companies are building capacity on sustainable farming practices that really support biodiversity conservation and livelihood enhancement,” he added.

Speaking about a CII commissioned report on Indian biotechnology, agriculture and industry that aims to define the industry's vision for 2025, he said there are three critical recommendations which we have included. One is laying out the role of various biotechnology companies in solving the agricultural challenges faced by the country. Second is forming single regulatory authority to govern all bio-agricultural domains falling under various ministries. The third is facilitating pooling of private investments for effective Research and Development utilization.

Touching upon the Indian blue economy, he said that India is the second largest fish producer in the world today. “So, we have suggested some steps to be taken up gently towards strengthening domestic contribution to the aquaculture sector. One of the things that we are talking about is strengthen cold supply chain facilities for movement and storage of products; the second is building hub infrastructure to handle fresh, chilled products and transport via trains; and thirdly, introduction of fish marks under the FSA to ensure the quality of the products,” he said.

He suggested that to convert India into a biotech or bio economy, appropriate enabling environment must be created that can cover the production, use and trading of biomass, ensuring that the relevant processes are sustainable and fair. “So to that effect, CII will really be very keen to support the development of such platforms of multi-stakeholder collaborations,” he said.

“Through our various delivery mechanisms and structure, we would be really keen to support a trickle down of elements of a circular economy to all our stakeholders and enhance its uptake across the country. The centres of excellence, which are focused on sustainability, have all initiated work on different elements related to circular economy, and the support and the guidance from the government would be of great value to take this forward,” Mr Banerjee added.

He further said that CII's relationships with a variety of trade and business agencies across the globe can also provide the platform for increased collaboration and innovation, which is required in the circular economy ecosystem.

“There is immense opportunity available for the country to claim its position as a global leader with opportunities for its citizens at all levels and geographies,” said the CII Director General.

Leaders Speak

We Must Recognise Strength of Research

Stressing on the importance of investing in research and innovation, Dr. Kiran Mazumdar Shaw, Executive Chairperson, Biocon, said that India must bring new vaccines, new drugs, new diagnostics and new medical devices to the world markets to generate high value IPs in order to raise its share in the global bio economy.



DR. KIRAN MAZUMDAR SHAW
Executive Chairperson,
Biocon

“I would like to take this opportunity to focus on one very important area, and that is on research and innovation. India accounts for 60% of global vaccine production by volume. India also accounts for 20% manufacturing of generic by volume globally. But when it comes to value capture, it is only 3%. I think this has to be corrected, and the only way it can be corrected is by investing in research and innovation,” said Dr Shaw at the Global Bio India 2021.

“We must basically bring new vaccines, new drugs, new diagnostics and new medical devices to the world markets. That would basically generate high value IP and contribution to what we are doing in terms of research and innovation,” she added.

She proposed that just as the government has introduced the Production Linked Incentive scheme, India also needs a research-led incentive scheme. “We must also make sure that the incentive scheme also covers academia. Because I think academia has a very important role to play in drug discovery.”

To further support her statement, Dr Shaw said that all the vaccines against COVID -19 that we’re talking about today have come from the academic research labs or small startups, which have actually been born out of academic institutions.

“I think we must realize and recognize the fact that whether it is the Pfizer or Moderna vaccine that came out of biotech startups, or whether it is the vaccine that came out of Oxford University and then licensed to Astra Zeneca, we

must recognize the strength of academic research. We must encourage Indian industry to partner with academia. And of course, we must invest in ensuring that academia also delivers on its potential of discovery, research and innovation,” she added.

Executive Chairperson of Biocon also hailed the contribution made by the biotechnology sector worldwide. “The second edition of Global Bio India is being organised at a time when the world actually celebrates the many successes of the biotechnology sector worldwide. The phrase bio economy was coined because of the impact bio sciences has on the world. We have seen the impact of bio sciences and biotechnology on disease control,” she added.

She also highlighted the immense importance of biotechnology beyond diseases. “When it comes to agriculture, biotechnology is playing a significant role in terms of food and feed production. Renewable energy is also relying a lot on the powers of bio sciences to generate clean power. We are also looking at environmental sustainability with a huge help from biotechnology,” Dr Shaw said.

JUST AS THE GOVERNMENT HAS INTRODUCED THE PRODUCTION LINKED INCENTIVE SCHEME, INDIA ALSO NEEDS A RESEARCH-LED INCENTIVE SCHEME

The bio-pharma sector has a huge role to play and that has been demonstrated in the vaccine sector itself, she added. “It has actually demonstrated the power of this technology to basically deal with a pandemic that could have actually impacted the economy, and that could have destroyed much more had it not been for the scientific community to come up with vaccines to take on this virus,” Dr Shaw said.

She also believes that biology is going to be a very important area for India to focus on. “When you look at the huge impact that bio sciences and biotechnology have on the world economy, it is no wonder that India is pursuing a very important strategy of creating a \$150 billion sector in the very near future,” she said.

Biotechnology has supported the fight against the COVID-19 pandemic through diagnostics, drugs and vaccines, The Biocon Executive Chairman said, adding that in the future the world will focus on biotechnology as a means to understand diseases better. “Whether it is about surveillance, genomic mapping of viruses, or whether it is developing vaccines and drugs to counter viruses, I think biotechnology has a major role to play,” she said.

Apart from that, India also need to focus on non-communicable diseases, she opined.

“So there’s a lot to be done. I believe that we can have an organized scheme that focuses on moonshots. We must identify five or six areas where we want to really catch up and deliver on cutting edge. So, whether it is vaccines, novel medicines, cell and gene therapy, drugs and diagnostics for rare diseases, or whether it is AI or drug delivery systems, we have to identify those areas, invest in those areas, incentivise that research, both within industry and academia. The research incentives

can be augmented with industry, academia partnership,” she recommended.

Dr Shaw was also optimistic that the Indian biotechnology sector can actually get its \$150 billion target sooner than anticipated. “This can be done not just in the area of pharmaceuticals, this can be done in the area of agriculture and renewable energy. I think biotechnology has a huge role to play in terms of generating biological batteries, which can be very interesting as a cutting edge technology.”

She also stressed that India needs data scientists and data analysts for high levels of computing power. “Quantum computing in biology is becoming a very important area and India should not lose our leadership position in this area.”

Citing the example of Korea, which has captured 40% of the global pharmaceutical manufacturing, Dr Shaw said that it became possible because the government of Korea very systematically and consistently invested over one decade into biopharmaceutical manufacturing. “India must also do the same because we already have this foundation laid for bio manufacturing, and we must actually build on that.”

She also cited the example of China, which has overtaken the US in terms of the number of patents filed annually. China has overtaken the US because of the huge amount of investment it has been making in research and innovation.

“I think India needs to definitely invest in research and innovation in its academic institutions and private laboratories. Indian industry today is spending only 6% of its revenues on research and innovation, while most innovative companies in the world are spending around 20% in research and innovation,” she added.

Leaders Speak

mRNA Based Technology is Amenable to Vaccine Development

Explaining how the Moderna vaccine for COVID-19 works, Dr. Andre Carfi, VP & Head of Research, Infectious Disease at Moderna, gave an overview of the efficacy of modern mRNA technology in fighting against viruses.

“The technology is based on the delivery of a messenger RNA to the cytoplasm of cells, where the mRNA can be taken up by ribosomes and translated into proteins and you can generate products in the different formats. It can be intracellular, a membrane bound or secreted, and therefore, the technology offers many opportunities in terms of targeting a disease. It results in an excellent immune response, and therefore, the technology is amenable to vaccine development,” Dr Carfi said.

In the context of Moderna mRNA Based Technology, he said that the sequence or the mRNA is optimized to result in optimal translation and protein expression. He said the technology not only provides stability, which is an important element, but also allows living nano particle to protect the messenger RNA, which is critical for delivering the mRNA to the cells and for escape of the mRNA from endosomes.

“We consider this as a platform technology, because you just need enzymes, a polymerase buffer and nucleotides, and then you generate the mRNA that encodes for the



DR. ANDRE CARFI
Moderna, VP & Head of Research,
Infectious Disease at Moderna

protein of interest,” he said.

He added that a critical element of the vaccine is that “if you’re trying to change the vaccine that you want to make, the only thing that you have to modify is the sequence of the messenger RNA, because everything else remains the same, both in terms of age and, and in terms of the processes. So this allows for faster development, and makes the technology well suited for a pandemic response”.

Dr Carfi said that even before working on the COVID vaccine, Moderna had a number of other candidates, both in the infectious diseases space and other therapeutics. “We started working on fluid that was more as a proof of principle that you can actually elicit immune responses in humans. But since then, we have started work on other respiratory viruses, such as Herpes viruses, etc,” he added.

Speaking on COVID vaccine development, he said, “It’s important to remember that during the development, we did not skip any of the clinical steps. Also in this case, there was a large investment from the US government that allowed us to really start manufacturing and preparing for the next steps.”

He added that the support from regulatory agencies was very helpful in moving the program forward. “So within 43 days, we already had the vaccine vial. This is a really the fastest development that I’m aware of,” Dr Carfi said.

Leaders Speak

We are Strong in International Collaborations

Speaking about Bharat Biotech India Limited's journey towards developing a COVID vaccine, Dr Krishna Mohan, the executive director of the company said that they were largely benefitted by strong international collaborations.

"We are strong at international collaborations. Especially, we have

benefitted significantly by the partnership we have with Oxford University, University of Maryland, with good support from both the Bill and Melinda Gates Foundation," he said.

As far as the COVID-19 vaccine is concerned, he said that the company has completed the phase one and phase two trials for its use in India. "We are the only ones who have a BSL three facility fully up and running," he added.

He also touched upon a wide range of vaccines that Bharat Biotech India is "quite proud of". "We have a range of vaccines. What we are quite proud of is especially the rota virus vaccine, because we have several patents on that. And we have one of the world's best products compared to even what is generally manufactured by the other two multinational companies. We are also proud to have the world's first typhoid conjugate vaccine," Dr Mohan said.

He informed the audience that it took a couple of years to build a facility keeping the cost of manufacturing in mind. "We're quite proud that we have built a production facility. It's not a lab. It's a production facility where both



DR. KRISHNA MOHAN
Bharat Biotech India Limited

the production as well as the quality control is done. In fact, this is the advantage that we have compared to several other multinational manufacturers, who have been authorized to and got their emergency authorization."

Speaking about the development of COVID vaccine, he said, "We got the strain in May. And as we speak, we have supplied 10 lakh doses to the Government of India. And what's very important, not so much the number of doses that we manufacture

which is increasing day by day, but what we are particularly proud of is the fact that we have six international publications and all in very reputed journals. This shows that you can do good science, even if you are in an industrial environment."

He expressed his gratitude towards Indian Council of Medical Research for helping it in the vaccine development. "We have immensely benefitted and cherish the partnership we have with the Indian Council of Medical Research. If it was not for this partnership, we could have never done challenge studies either in hamsters or monkeys, because most of us are used to doing routine studies in mice or rabbits."

He said that Bharat Bio India's vaccine works extremely efficiently in terms of the challenge studies. "We have completed our phase three trial in terms of vaccinating about 26,000 subjects, second dose has been given to all the subjects, we have completed the 14 day post-secondary use period to and Currently, we are in a case count situation where we're getting ready for an interim analysis," Dr Mohan said.

Leaders Speak

Biotech Sector has Longer Gestation Period for Ideas to Market

Presenting a perspective on how India's Biotech Ecosystem is positioned today for the national as well as international community, Dr. Manish Diwan, Head - Strategic Partnership and Entrepreneurship Development, BIRAC, said that biotech sector requires longer gestation period for the ideas and innovations to reach the market.



DR. MANISH DIWAN
Head, Strategic Partnership and
Entrepreneurship Development, BIRAC

"IT sector in the last 20-25 years has seen remarkable growth and India has been able to harness it which was in sync with the sectoral growth worldwide. There has been a steep growth curve in the IT sector and we observed establishment of large companies that not only contributed to India's economy and technology, but connected and became an international source of technology dissemination and technology implementation" said Dr. Diwan.

"But biotech sector is relatively different from IT, FinTech and e-commerce. Biotech sector in particular has a longer gestation period. The ideas and innovations need access to high end instrumentation, specialised infrastructure and takes longer time to translate into a successful outcome and the product that eventually comes out is tangible unlike software or an e-commerce platform" he added.

"The idea led by a team needs to be technologically sound. So that a team of people can come together and build

that idea. The thumb rule of innovation to a product in other sectors is about 1,000 days, but in the biotech sector it takes five to eight years and sometimes even longer to actually have the product in market" he said.

Dr. Diwan pointed out that for the biotech sector though there is a longer investment period, "You need a higher risk appetite and a patient capital, which is valuable. Most biotech startups are technology led innovations, where technology is protected

by an IP that stays with the company. So there is a longevity as well as sustainability of the operations for those who become successful and that is what sets the biotech sector apart from the rest of the sectors."

He mentioned that now the early signs of maturity are evident as seen from the buildup of a critical mass of startup pool of entrepreneurs and incubators in the innovation ecosystem. This has been achieved with a focussed effort from Department of Biotechnology, BIRAC, Biotech Industry and allied ministries and departments.

According to Dr. Diwan, In the present times when the COVID pandemic has stuck, the importance of biotech and healthcare sector has been recognised worldwide by everyone. "Not only India but all economies at large have been looking at the biotech innovation ecosystem that India has proudly delivered. On vaccine front we have created first in class vaccines, and we have contributed heavily through manufacturing, so that COVID vaccines become available not only for India, but for the entire world."

THE EARLY SIGNS OF MATURITY ARE EVIDENT AS SEEN FROM THE BUILDUP OF A CRITICAL MASS OF STARTUP POOL OF ENTREPRENEURS AND INCUBATORS IN THE INNOVATION ECOSYSTEM. THIS HAS BEEN ACHIEVED WITH A FOCUSED EFFORT FROM DEPARTMENT OF BIOTECHNOLOGY, BIRAC, BIOTECH INDUSTRY AND ALLIED MINISTRIES AND DEPARTMENTS.

Another positive development mentioned by Dr. Diwan was development of diagnostic kits. “In the beginning of pandemic, India was sending samples to other countries just to get the samples tested. But now we have transitioned from that stage to now, where we have created 100% indigenized kits and we are exporting these kits worldwide.”

From an import centric activity, we have converted it into a potential export activity and this is because we had a robust biotech ecosystem in place, and that has delivered” he added.

Explaining further Dr. Diwan said that India’s biotech ecosystem has passed the test of regulatory and market compliances.”From a perspective of commercial activity also such startups have demonstrated success too. But we have noticed that the investors are a little hesitant to come forward in large numbers.

We need to have a long term patient capital allocation for biotech sector in the country” He lamented.

On the challenges and the bottlenecks for investment in the Indian biotech sector, he said that DPIIT, DBT and allied ministries and departments can also address those challenges. From Global Bio India stakeholders consultations and feedback, “We will take the suggestions forward to create mechanisms and environment that is suitable for mobilization of private equity into the ecosystem, which is a large gap.

Dr. Diwan pointed out that at present examples of Series B or Series C funding are missing in the biotech sector. “Our innovative, bright startups are actually flipping over, registering outside India to attract funding support for their innovations, So, that’s one large gap which we clearly see in the terms of risk funding.”

Leaders Speak

We are at critical junction in fight against COVID

Looking at the global epidemiology of COVID, we are at a very critical junction again because of the increase in cases worldwide, said Dr Soumya Swaminathan, Chief Scientist, WHO, while addressing Global Bio India 2021.

“We are at a very critical junction again because we had seen over the New Year, December and January that cases had gone up dramatically, particularly in Europe, North America and Latin America. And then for the last four to five weeks, we had been seeing a decline in weekly cases. But then last week again the decline stopped. In fact, the increase started again. And Southeast Asia region is one of the regions to show the increase in cases, mainly driven by India, Indonesia, and Nepal,” cautioned Dr Swaminathan.

She added that probably it’s a COVID-19 variant that actually has taken over in most of Europe now as a predominant strain. “And then we also see the same thing happening in Latin America, where there’s a third wave. And there’s a lot of fear here that there may be a fourth wave as well coming through,” she said.

She also said that fatigue has set in, which is prompting people to behave normally and the governments wanting to open up



DR. SOUMYA SWAMINATHAN
Chief Scientist,
WHO

the economy, transport, and all other things which facilitate people to get together.

The Chief Scientist of WHO added that though there’s a sense of security because of the start of vaccination campaigns, “we have to be very careful right now on the messaging”, as vaccines have only reached minority of people globally.

Speaking about India’s COVID response, she said that it was an overall positive story as industry stepped up its efforts to fill in all the gaps that existed very early on. “The government departments also stepped up to play the role of supporting, facilitating and coordinating the development of new tools,” she added.

Dr Swaminathan hoped the “well-coordinated response that we’ve seen to COVID can be applied to other diseases, for example, tuberculosis or malaria, which actually take a much higher toll if you see in terms of mortality”.

She called for high level of commitment and allocation of funding and resources to apply lessons learned during the pandemic to other diseases as well.

“But then you really need coordination between the public and the private sectors, because there are certain things individual companies and individual Institutes can do. But there are certain things which cannot be done, which do need a national coordinated approach,” she pointed out.

AS INDIA BECOMES MORE AND MORE INNOVATIVE, WE NEED THE REGULATORY SYSTEM TO KEEP UP WITH THE GLOBAL PRACTICES SO THAT THE PRODUCTS ARE RECOGNIZED GLOBALLY

She also stressed on the need for harmonizing the entire system. “Nomenclature and definitions are important. Now the WHO has actually come out with a coordinate definition of what is the variant of interest and what is the variant of concern. And what are the tests that would need to be done in order to take a variant of interest, and then actually label it as a variant of concern. And that will be applied globally,” Dr Swaminathan added. She also stressed on the need to have a national bio-bank.

“For studies of antibodies, and for monoclonal antibody development, you would need to harvest the antibodies from a large number of individuals. But to do that, you need not only the blood samples, but it has to come from a very well characterized group of individuals. So you need all the metadata, the clinical data, the laboratory data, the epidemiological data, to back it up,” she said.

“Similarly, for genomic analysis, it can only be done when you have one good database in which you have the genomics of the virus, as well as all the other data that go with the clinical and epidemiological presentation,” added the Chief Scientist of WHO.

To achieve all this, she said that there is a need for different agencies to come together and agree on a system, which the private sector then collaborates with.

Speaking on regulatory system, she said, “Our regulators have really improved a lot over the last few years. For COVID, she said that benchmark criteria were laid out

in advance. “So, it’s important to articulate that in advance. But then you also need a transparency of decision making that actually builds a trust in the system,” Dr Swaminathan observed.

“As India becomes more and more innovative, we need the regulatory system to keep up with the global practices so that the products are recognized globally. The WHO has a system for benchmarking national regulatory authorities. This is a system which is trying to do away with the old system. There are four levels of maturity, and there are criteria and checklists for each of those. And then finally when you reach the most mature level of being a regulatory authority anything that comes from that system will be accepted by their peers and by other countries,” she said.

She also stressed on the importance of ethics for undertaking various types of studies.

THE WELL COORDINATED RESPONSE THAT WE’VE SEEN TO COVID CAN BE APPLIED TO OTHER DISEASES, FOR EXAMPLE, TUBERCULOSIS OR MALARIA, WHICH ACTUALLY TAKE A MUCH HIGHER TOLL IF YOU SEE IN TERMS OF MORTALITY

Leaders Speak

COVID vaccine is Testimony of World's Confidence in India

The COVID-19 vaccines manufactured in India is the testimony of the confidence that the other world leaders have in us, said Dr Suresh S Jadhav of Serum Institute India Limited, while explaining the COVID-19 vaccine journey from science to delivery at the Global Bio India 2021.

"I think it was no wonder that everybody was looking at India because of the track record of the vaccine manufacturers. And our capability of supplying almost more than 2 billion vaccine doses globally every year, covering more than 170 countries and 70% infant population every year, is the testimony of the confidence that the other world leaders had in the vaccine manufacturers of India," he said.

Dr Jadhav said that Mr Bill Gates made a statement that India's willingness to play a big role in manufacturing COVID-19 vaccine and allow it to supply to other developing countries will be a critical part of containing the pandemic globally.

"When the COVID struck in the late November or December in 2019, none of the new technologies could be really translated to see whether they could be used for developing the vaccine because if you were to use a new technology, then you were to do a efficacy trial, which cost hundreds and hundreds millions of dollars and no vaccine manufacturer was ready to invest that kind of money in a vaccine," he added.

Most vaccine developers, he said started working on different platforms. "You will be



DR. S.S. JADHAV
Serum Institute India Limited

surprised to know that there are almost about 365 different companies and laboratories that are working to develop COVID vaccine. Almost 10 vaccines are already licensed for emergency use. I think the Indian manufacturers were certainly not behind and today we are aware that two vaccines have already got the emergency use license in India," he added.

Speaking about challenges of R&D, he said there were great challenges to start with, "because when a company

thinks about starting a new product, they are to really identify the right platform technologies, proper analytical methods, selection of the right animal models, early proof of concept in preclinical studies, iteration in process development and validations clinical trial design, identifying right clinical sites, infusion of optimal representative population and availability of the safety data specially with respect to the novel vaccine technologies", Dr Jadhav said.

"You wanted to develop a vaccine in the shortest possible time, because this particular virus has affected the total globe, that means, the total 7.8 billion population was affected. And if you want to make a vaccine and make it available to everybody, it was really a huge challenge and effort by several manufacturers was required to do that," he said.

Other challenges he pointed out included infrastructure that can comply with GMP requirements, proper design of equipment as per the product requirement, alignment of processing units to handle large volumes, qualification of equipments, and finally, availability of the critical raw materials.

Leaders Speak

Messenger RNA-Based Vaccine Works Very Well in People

Highlighting the developments in RNA-based technology for vaccine development, Dr. Norbert Pardi of University of Pennsylvania, took the audience on a journey that could prove to be a game changer in development of vaccine against the novel Corona virus.

“The very first paper that demonstrated or suggested that in-vitro transcribed RNA could potentially be used for therapy was published in 1990. This was a beautiful science paper, in which the authors injected mice intramuscularly with in-vitro transcribed messenger RNA. The reporter genes and protein production from the RNA was clearly demonstrated by it. I think this was a very important discovery,” said Dr. Pardi.

He added that despite the important findings of this, most people remain sceptical about the therapeutic potential of RNA. And the field focused on other approaches, for example, DNA based approaches.

“The main concerns were the unstable nature of messenger RNA, it’s really high innate inflammatory capacity, and that allowed in-vivo translatability. But due to the technological advancements and very active research in the past 15-20 years, these issues have been resolved. And messenger RNA has become a very promising new therapeutic modality,” he said.

Dr Pardi also informed that RNA has four basic building blocks, which can actually



DR. NORBERT PARDI
University of Pennsylvania

be modified. He mentioned a groundbreaking paper published in 2005 that paved the way for the safety of messenger RNA based therapies or vaccines.

“A number of years later, the researchers had another important discovery. It turns out that incorporation of modified nucleotides in the RNA not only decreases immune activation, but it also increases the Translate ability,” he said.

Dr Pardi said that after he joined the research in the field, a company called Aqua Therapeutics was asked to formulate “our messenger RNAs into their special lipid nano particles”.

“The liquid nano particles have four components that are 60 to 100 nanometer sized particles. We really wanted to try it with the messenger RNA and they did that. We tested them after injecting mice intravenously. It really turned out that these lipid nano particles work very, very well, which is very favourable for immunization studies,” he added.

The liquid nano particle Platform has many critical advantages. It allows development of vaccines very fast as demonstrated by Moderna. They developed the source COVID to vaccine in 42 days. These vaccines work incredibly well in people.

**MESSENGER RNA
HAS BECOME A VERY
PROMISING NEW
THERAPEUTIC MODALITY**

Leaders Speak

India Is Miniscule When It Comes To Value of Biotech Products

Despite the Indian life sciences market growing at 12% against the global growth rate of 10%, India's share in terms of value of biotech products is miniscule compared to the global market, said Mr. Sunil Thakur, Partner, Quadria Capital, while presenting the Indian biotech landscape at Global Bio India 2021.



MR. SUNIL THAKUR
Partner, Quadria Capital

"We are very miniscule when it comes to value of biotech products that are being sold. We are just a little under 3% of the total global market," said Mr Thakur.

However, he also added that despite the low share of Indian biotech sector in the global market, its growth rate is much higher than the global growth rate.

"What constitutes this 12% growth of Indian biotech sector is basically the four big factors. First is the population which needs pharma products. Also, financing is now being done by government. Penetration of private insurance, increase in disease incidence, price inflation and the new product launches are among the factors responsible for this growth," he said.

"This is how we see the transition from 2015 to 2020. Where majority of the world has moved into established phase for biosimilars, we are much ahead in terms of the number of products that have been developed and are being sold in the market. We are in line with Europe, which obviously took a lead in adoption of biosimilars as against some of the other direct markets that are still catching up," observed Mr Thakur.

India has one of the highest numbers of biosimilars that have been approved globally if you exclude China. "What we also understand is that the number of molecules that are there under development are upwards of about 350. These are at various stages," informed Mr Thakur.

He also said that early stage companies in India are attracting attention of investors from across the globe. "There are quite a few startups that are working on regenerative medicine and they are attracting the attention of

investors. But the big challenge that we are seeing is that investors who want to come in for Series A or Series B funding, they don't have the confidence of a vibrant growth or investment market – a market that can take up their stake when the Series C or D happens. That's a real challenge that we are facing. If we can align with the government and other industry participants, I guess we would be able to create a very vibrant market for early stage companies," suggested Mr Thakur.

He said the future of biotechnology looks bright as there are quite a few successful companies "that we've come across". "Last year and even this year we expect a lot of deals to be announced. And these are deals of the size of \$200 and \$300 million. There are also successful, big size companies that are attracting attention of large global investors. And therefore what it means is that if we can provide support to the early stage companies, it will do wonders for this particular sector," said Mr Thakur.

Leaders Speak

India Working Towards Health Equity

Stressing on the need for an equitable recovery from COVID, Dr. Peter Singer, Special Adviser to DG, WHO, said that Indian products are working towards health equity with Indian bio sector innovating affordable and accessible products for society.

Citing the example of vaccine arrival from India in Ghana and Cote d'Ivoire, he said that it was a major milestone and amazing proof point of how Indian products are working towards health equity.

Adding that the focus on positioning India as a bio manufacturing hub to innovate affordable and accessible products for Indian society and for the global markets would be crucial for global health, Dr Singer said that he was proud of what the Indian biotechnology sector has been able to achieve in the past two decades.

"In 2007 I wrote a paper in Nature Biotechnology called 'India's Health Biotech at the Crossroads-the Balance Between Domestic and International Markets. And I feel so proud to see how that's developed and how certain issues have been addressed in such a beautiful way," he said.

Calling COVID-19 the worst crisis that hit the world in 100 years with more than 2.5 million deaths, trillions of dollars of economic damage, loss of jobs, and loss of livelihoods, 2021 will be the year of vaccines and vaccine equity. He also said that 2022 will be hopefully be the year of primary health care that would lead



DR. PETER SINGER
Special Adviser to DG, WHO

to equitable recovery with focus on diseases like hypertension, oncology and pneumonia.

"Each of these phases puts a very strong focus on equity—the pre-existing social inequities in the public health measures and the diagnostics, or the vaccine equity. Equity is at the heart of primary health care, and an equitable recovery towards the SDGs," Dr Singer added.

He said that according to vaccine equity tracker@pandemic.com, about 12.4% of the population in the high income countries have received at least one dose of vaccine compared to about 1.4% in non-high income countries.

"That's a tenfold difference. And that's not a situation of equity. Every country in the world should initiate the vaccination of at least health care workers and older people who are at higher risk. A key driver of this equity movement for vaccines and more generally going forward is health products is India," he said.

According to him, India is a model for is not only providing products and not only providing people hope, but it's also a model for the world and for other countries in self-reliance.

"In 2021, the year of vaccine equity, we would love to see even more collaboration with manufacturing capacity so we can improve the production of vaccines. And in 2022, it will be extremely important on the broader suite of health products to continue the incredible work done in the Indian innovation ecosystem," said Dr Singer.

Leaders Speak

We Need To Find Ways to Help Startups Innovate

Saying that India needs to find ways to help younger companies innovate and remove hurdles to make them productive and profitable, Dr Douglas Ry Wagner, President, International Agri Business, Alga Energy, stressed on a greater role of the in achieving this goal.

“Rapid innovation often really comes from young companies. I don’t like to think of them as startups, but there is an experience that one goes through as we age, and companies do as well. And at different points along that journey, companies have different challenges. And we need to find ways to have that innovation from younger companies, to help them over that hurdle that leads to the ability to manufacture and to become profitable. I think the government has a large role to play in this,” said Dr Wagner.

Alga Energy having business now in 15 countries around the world, including India, Dr Wagner believes the European Union offers a really good role model for making available resources, both academic and industry collaborations, as well as funding for bio manufacturing facilities.

“That’s where Alga Energy got its funding for its first bio manufacturing facility in Spain, via government funded programs, tax credits, investment in R&D, things like that. So I would strongly recommend my colleagues in India to look to some of the programs of the EU as a potential model for that,” he added.



DR. DOUGLAS RY WAGNER
President, International AgriBusiness,
Alga Energy

Besides funding, he said the young companies really need a “speed dating service”.

“They really do need to get the support of larger companies that understand how to get products commercialized in the marketplace and have that infrastructure to take those ideas and make them something of a reality. In India, we’ve been fortunate since I’ve worked there so long to come up with a great partner, who have a large manufacturing facility,” Dr Wagner told the audience.

“We were able to do that in record time. And largely that’s supporting what we’re doing in agriculture, but we also work in human nutrition, in biopharma, etc. And this manufacturing facility is enabling us to do that locally in India. But it really was the result of finding the right partner to allow us to be able to do that. That was important.”

“So how do we find how do we arrange those marriages? How do we help young companies arranged marriages is really critical,” he pointed out.

He also pointed out that agriculture represents about 30% of the world’s population. “We know how important this is in India with about 10% of the population of India being farmers. And the sort of longer term crisis that we have, we’ve had a lot of discussion around COVID, which has been an immediate challenge for the whole world. But the longer term crisis we have with regard to our environment, and really creating a sustainable ecosystem that allows us to survive and thrive not only through the present generation, but the future generations as well.”

YOUNG INDIAN BIOTECH COMPANIES NEED TO GET THE SUPPORT OF LARGER COMPANIES THAT UNDERSTAND HOW TO GET PRODUCTS COMMERCIALIZED IN THE MARKETPLACE AND HAVE THAT INFRASTRUCTURE TO TAKE THOSE IDEAS AND MAKE THEM SOMETHING OF A REALITY

He said that a huge amount of natural diversity can be tapped and brought to market in terms of sustainable solutions. “But when we try and bring those sustainable solutions to agriculture, we quite often run into the same regulatory pathway, that non-sustainable products over the last decades or over the last century have been brought to market,” Dr Wagner lamented.

He added that it has become a huge impediment “to our ability to revolutionize agriculture, to make the sustainability leaps that we need to make happen rapidly”.

He cautioned that we don’t have the luxury of waiting for decades. “Right now it takes about a decade or more than a decade in the normal pathways for many of these non-sustainable solutions to reach the market. But we need to be able to shorten that timeframe to market that will also help a lot of these younger companies.”

He called for ways to bring partnerships within India that can affect the world globally. “In particular, in agriculture, we need to find ways of speeding up the regulatory pathway for sustainable solutions,” said Dr Wagner.

Leaders Speak

We Have a Thriving Startup Environment

Switzerland offers a thriving environment to startup by providing early stage funding and investing in patents, said Mr. Michael Altorfer, CEO, Swiss Biotech Association, Switzerland, in his address at the Global Bio India.

“Early stage funding can really be amplified by subsequent grants and private equity funding as well. The second element where we invest is patents. Switzerland has continuously invested into patents that are providing world class coverage, which is high market coverage, and high technological relevance,” said Mr Altorfer.

“We want to make sure that we are also investing in emerging trends, whether it is AI, or cell based or gene based therapies. In AI, you can see that Switzerland has invested heavily in patents combining AI and biotechnology applications. The last segment that is critical for the forward looking investments is investments into manufacturing. Here again, we have attracted a lot of international companies and we love to collaborate,” he added.

He informed the audience that Switzerland invests primarily in manufacturing of complex biopharmaceuticals and is also increasingly into cell based therapies. “All this investment has led to a situation where the Swiss life science industry is a dominant exporter,” he said.

Speaking on R&D, Mr Altorfer said that for the first time in 2019, R&D spending of the biotech



MR. MICHAEL ALTORFER
CEO, Swiss Biotech Association,
Switzerland

companies was more than 2 billion Swiss francs. “Many of them invest in international collaborations. And it’s not uncommon that more than half of that money is actually invested in R&D collaborations internationally,” he added.

The country has also invested in education, and in framework conditions that foster innovation that has consistently allowed Switzerland to be in the top rankings when it comes to innovation and competitiveness. It also attracts international talent

to work in Switzerland.

“Switzerland offers a very comprehensive and world leading Swiss biotech hub in the heart of Europe, comprising more than 1000 biotech companies pretty much equally balanced in three segments—the developers of new drugs and therapies, the service providers, and the third segment is of specialized consultants,” Mr Altorfer added.

The Swiss biotech Association represents about 30% of all the biotech companies active in Switzerland. “We support them by developing favourable framework conditions by ensuring that they have access to the essential talents, funding and access to tech transfer. And equally important is the networking for international and national collaborations,” he said.

To facilitate collaboration the country has established a Swiss Biotech Directory, which is available online, and as well as in hard copy, where one can find an easy access to these 1000 companies and can look for keyword searches. “This allows you to find your way to the companies of interest for partnering,” he added.

Leaders Speak

Sweden Highly Values Innovation Partnership with India

“Sweden really highly values our long standing innovation partnership with India, and the collaboration within health and life sciences,” said Dr Jenni Nordborg, National Coordinator & Director of the Office for Life Sciences at the Government Offices of Sweden, in her remarks at the Global Bio India 2021.



DR. JENNI NORDBORG
National Coordinator & Director of the
Office for Life Sciences at the Government
Offices of Sweden

“The COVID pandemic has really truly underlined the importance of the role of life sciences, both in our daily lives and for the global economy. It has been also evident for the general public that how important research is for society to jointly build our knowledge base globally, and how important the industry is to health care and resilience as a whole,” she said.

As the National Coordinator for Life Sciences, she said her job was to drive development for Life Sciences with a mandate to drive the dialogue with the sector, both nationally and internationally.

“One year ago, our national strategy was launched. The strategy is a framework based on eight priority areas, but their long term perspective is really to boost both health and prosperity. The overall framework of the strategy is precision prevention and sustainability,” she informed.

She said that the world is definitely moving into a new era of precision medicine that will hopefully enable both prevention and build on sustainability globally. “In other words,

life sciences really contribute to improving health and quality of life and ensure a current economic prosperity. And it is the basis on which Sweden maintains our leading position as a knowledge and innovative nation. Advances in this field also mean advancing the Sustainable Development Goals,” she observed.

The Swedish competitive edge in life sciences can be summarized into five categories, Dr Nordborg added. “First and foremost, we rely on a strong collaboration culture. Secondly, we have the public health care system and

sustainable clinical infrastructure that really builds on world-class and long standing academic research, our efficient ecosystem, innovation hubs and collaborations between small and medium sized enterprises with large corporations,” she said.

Highlighting the strong startup community with a mix of life sciences and the tech sector, Dr Nordborg said that the hub for data driven Life Sciences is also encompassed in this Swedish ecosystem. “We have an extensive system of data resources, high quality registries, bio banks, with the traceability through our personal identification numbers,” she added.

One of the important aspect of Swedish healthcare system, she said was a wide society focus on both prevention and health. “Swedes are tech savvy people with a high level of trust in authorities. They are not only willing to participate in medical research, but also to share data to drive change. Life Sciences has long been a top priority for the Swedish government”.

Leaders Speak

Karnataka Number One State in Biotechnology

Presenting the biotechnology landscape of Karnataka, Dr. E.V. Ramana Reddy, Additional Chief Secretary to Government, Department of Electronics, IT, BT and S&T, said that in the India Innovation Index, which was recently rolled out by Nithya Yoga, Karnataka has been ranked number one for two consecutive years.

“We’ve worked hard to ensure that we have the number one position in the biotech area. We have about 70 plus biotech companies in the state. The biotechnology does not only prevail in Bengaluru, we have sectors beyond Bengaluru also, which houses a lot of companies like in Mysore, Mangalore, and in the region of Hubli-Dharwad,” said Dr Reddy.

To facilitate this entire ecosystem, Karnataka has 35 plus state and central research institutes. “We were the first state in the country to bring about a Bio technology policy vision 3.0. The state is home to 60% of country’s biotech company. And Karnataka has 54% of India’s biotech workforce. The state contributes 1/3rd of bio tech exports in the country,” he informed.

The Karnataka Information Technology Society plays a key role to enable the government, industry and academia collaboration and interaction which happens on a regular basis.

“Recently, the state government took up the initiative of understanding how we can



DR. E.V. RAMANA REDDY
Additional Chief Secretary to Government,
Department of Electronics, IT, BT and S&T

leverage this number one status in the bio economy in the next 5 to 10 years. In a bio economy report, currently the state stands at \$22.6 billion,” he said.

Dr Reddy pointed out that the state was strongly focusing on bio agri sector, biopharma, biomedical, bio services, bio industrial and marine biotech. “These are the sectors that we have tried to leverage. The state will work around its policies in the next five years in these areas,” he added.

Even during the COVID pandemic Karnataka continued to grow in developing new IPs, which registered a 2% rise during the period.

“We have enabled the policy ecosystem for existing players like Biocon. The industry is extremely excited because these policies and these roadmaps that the government basically facilitates is in collaboration and understanding the wish list of the industry. During the pandemic, we’ve understood that some of these areas are what the state can leverage. We already have a great startup ecosystem, a great research capabilities, and great talent and workforce to leverage next,” said the Additional Chief Secretary.

He also pointed out that some of the key aspects that have aided to this overall position of Karnataka being number one in the sector is the plug and play infrastructure that the state boasts of. The entire spread of Biotechnology is all over the state. “A Bio Life Science Park is coming up closer to Bangalore”. The state has an industrial policy of 2020 which also facilitates the ease of doing business for the startup ecosystem.

Leaders Speak

UK Has Ambitious Plans for Science and Innovation

Presenting an overview of what is happening in UK in terms of bio innovation and identifying areas of collaboration with India, Mr. David Golding, Head of Global Innovation Partnership, UKRI Innovate UK, said that a budget of 7 billion pounds allocated for UKRI Innovate UK underpins the UK government's ambitious plans for science and innovation.



MR. DAVID GOLDING
Head of Global Innovation Partnership,
UKRI Innovate UK

"Building on the world's leading universities, we have a strong productive innovation system, a thriving startup scene, and the leading private finance sector. The UK Government published an R&D roadmap last July, setting out the country's vision and ambition for science, research and innovation. And that includes investing in science research and innovation that will deliver both economic growth and societal benefits," he said.

Given the pandemic we're currently going through, the roadmap was supported by an unprecedented commitment to increase public investment in R&D to 22 billion pounds by 2025. That's almost doubling of investment in R&D. "It's the UK government's vision to make the country the best place in the world to be a researcher, innovator, or entrepreneur," said Mr David Golding.

"For startups, we have a very thriving startup scene in the UK. In the ranking of the Global Startup ecosystem Silicon Valley is still in first place. But New York and London are now joint second. But I think it's worth saying that it isn't just about London, the startup

ecosystem has strengthened across Cambridge, Oxford, Manchester, and Edinburgh, to name but a few. And clearly Cambridge, Oxford and the likes of Edinburgh are very strong in life sciences and biotech," he pointed out.

The UK is also the third in the world for tech unicorns just behind the US and China with 77 companies valued at over 1 billion pounds. "It shows the strength of the tech sector in the UK, which has actually grown 44% in recent years and

six times as fast as the UK's economy," Mr Golding said.

An important factor in this growth story, he pointed out was that international workers actually make up almost half of the UK tech workforce. "We're expecting announcements by the UK Government around the visa system and hopefully opening up opportunities for scientists, researchers and those from the tech sector," he said.

Despite the COVID pandemic, he said the tech sector in the UK continues to perform really well. "The bio economy in the UK has continued to grow. And it's a large part of the UK economy with over 220 million pounds and accounting for over 5.2 million jobs," the Head of Global Innovation Partnership at UKRI Innovate UK said.

Speaking on government priorities, he said, "The government's economy strategy launched a couple of years ago is to focus around a number of priority areas, such as creating new forms of clean energy and new routes to industrial chemicals, producing smarter, cheaper materials such as bio based plastics and composites, reducing plastic waste and pollution."

Leaders Speak

Ancient Wisdom coupled with Biotechnology Will Help Indian Herbal Market

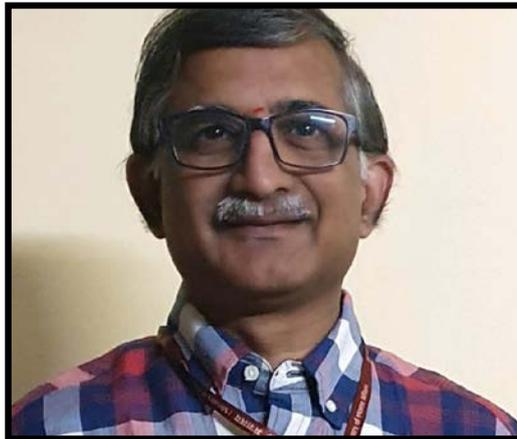
Speaking on the development of business opportunities in sunrise sectors, and scope and challenges specifically in the COVID situation, Dr JLN Sastry, Chief Executive Officer, National Medicinal Plants Board, Ministry of AYUSH, Government of India, said that India has a big opportunity in areas like trade in typical aromatic agents, where we look at a \$11-billion business opportunity by 2026, which was about \$5.2-6 billion in 2017.

“Ancient wisdom coupled with the support of biotechnology will make Indian herbal market number one by 2030 by overtaking the traditional Chinese medicine,” said Dr Sastry. He added that India being the second largest exporter of herbal medicines, which is 1/6th of the China’s global business, there is a potential for an exponential growth in the area.

“It is an industry with appetite that’s the kind of scenario we have in front of us,” Dr Sastry said.

He also added that we need to carefully analyze the value of the herbal medicines being low, which means that the in the international scenario is more for homeopathy when compared to it. It suggests that opportunity is plenty for India.

“DNA studies is a big opportunity, where backed by scientific studies of herbal varieties will give a global space to Indian companies. Then, another opportunity is for protocol development, especially for the tissue culture protocols,” he said.



DR. J.L.N. SASTRY
Chief Executive Officer, National Medicinal
Plants Board, Ministry of AYUSH,
Government of India

“Identifying under which conditions particular resources will be useful, and post harvesting practices, are something other very important areas. There are post harvest practice for black pepper, turmeric and dry ginger. Post-harvest practices take the raw material to the next level of value added product, which is again an opportunity. Extracts and volatiles always are looked upon as value added products,” Dr Sastry observed.

He added that organic cultivation itself is a value addition. “So, when you look at the agro practices as organic cultivation, you look at exponential growth of two to three times without doing anything by organic cultivation. It is a big opportunity without spending anything.”

By reducing the excess of chemical fertilizers and pesticides, you’re increasing the value of the product by three times, he opined, adding that the industry must look at these low hanging fruits which doesn’t require any plan except discipline.

Touching upon the storage techniques, he said that they also have a major role to play.

Speaking about challenges, Dr Sastry pointed out that development of agro techniques is not that easy. “We need to spend some time and document everything and everything needs to be streamlined. Many times we get just get carried away by looking at only biotic stress. It may be aquatic stress. Each species has its own behaviour, therefore it’s very difficult,” he said.

Leaders Speak

European Commission has Tradition of Cooperation with India

European Commission has a long standing strong, mutually supportive tradition of research and innovation in cooperation with India, said Mr Patrick Child, Deputy Director-General, Research and Innovation, European Commission, at the Global Bio India 2021.

“The recent 13th meeting of the EU-Indian Joint Steering Committee on Science and Technology Cooperation, which took place in the last few days, confirmed the growing importance of the EU India strategic partnership, and the important role of research innovation collaboration,” said Mr Child.

Highlight a few specific examples, he said that there is a very successful network of European and Indian incubators that was launched in Bangalore in 2018. “This provides an excellent opportunity for incubators and accelerators, from both the EU and India to collaborate on health and energy topics of mutual interest. Under the European Union’s Research and Innovation framework programme Horizon 2020, we have a flagship program of EU-India Cooperation on Integrated Local Energy Systems. This was launched in 2020, and has already produced two large programs with 11 million Euros in joint funding,” Mr Child added.

The systems focus on local energy networks in India and in Europe, seeking novel ways to make energy supply cleaner and more efficient.



MR. PATRICK CHILD
Deputy Director-General
Research and Innovation
European Commission

The Deputy Director-General of Research and Innovation at European Commission pointed out that India and European Commission has a very long history of successful collaboration on energy projects, ranging from offshore and solar renewables, grid integration and energy efficiency.

“Taken together, this important portfolio of projects, I believe, will result into novel solutions, encompassing local integration across different energy sectors, while increasing the share of renewables in the energy mix, and boosting our shared commitment to energy efficiency,” he said.

He also underscored the important role being played by the International Bio Economy Forum, of which India was a founding member. “This forum continues to be a valuable place for us to cooperate on important topics like sustainable bio refineries,” Mr Child added.

He highlighted the importance of international cooperation, which he said, is essential for us to address global climate challenges, and to make progress on the sustainable development goals of the UN Agenda 2030.

“We’re very happy to be working alongside India and other partners internationally in initiatives such as Mission Innovation. This global coalition of 24 partner countries in the European Union represents and brings together publicly funded investment into energy, research and innovation worldwide. And collectively, we’re committed to increasing the public investment in clean energy to install affordable Clean Energy Solutions,” said Mr Child.

Leaders Speak

India Builds On Its Strengths to Partner with the World

India continues to remain one of the most open economies in the world with private sector having the ability to play an important role in each and every sector of the economy to fulfill the ultimate vision of Prime Minister Narendra Modi of an Atmanirbhar Bharat, said Dr Deepak Bagla, CEO, Invest India.

Speaking at the inaugural of Global Bio India 2021, Dr Bagla said, "It's amazing the level of innovation and entrepreneurship, which we are seeing around us. 4,300 startups are already there in biotech itself. We've seen the entire effort in the past close to a year that kept us all going. A lot of it has to do with the ultimate vision of the honorable Prime Minister. It is a vision where India builds on its strengths to partner with the world and brings out the best for its own self sufficiency."

Putting the stellar performance of the Indian biotech sector in numbers, he said the sector closed the financial year 2020 with an FDI of \$74 billion. "It's the highest ever FDI we've got in our history. But what's interesting is that over 90% of that \$74 billion came in through the automatic route, which meant that investors did not require any specific approvals for that," added Dr Bagla.

Close to 43% of the FDI came in as Greenfield investment, he added. "India today is one of the top Greenfield destinations in the world. During the lockdown for the first eight months starting from April, the total FDI India received was \$58.39 billion. During the complete lockdown when borders were sealed globally with no aircrafts flying, Indian managed to get



MR. DEEPAK BAGLA
CEO, Invest India

\$58.39 billion. Let me put it in perspective. The previous year when everything was hunky dory, in those first eight months, we'd got \$47.67 billion. So even during the lockdown, we saw India increasing its stake," said the CEO of Invest India.

He attributed the reason for this surge to the diversification of supply chains. "I'm seeing a large number of companies moving their supply chains to India on a fast track basis. In fact for each of the investors we have a dedicated Relationship Manager. We help them with their

business plans and getting them grounded. My total book on indicated investments was about \$70 odd billion dollars," he said.

He added that the opportunity was well established before India went into the lockdown. "We were the largest, youngest and fastest growing economy with the largest market opportunity. We will remain the youngest at least for the next 100 years. The story during this lockdown was that we had the Prime Minister himself leading the charge," Dr Bagla said.

Highlighting the steps taken by states, he said, "A number of states have said that if you are a small or MSME Enterprise, you don't require any approvals to start up your business. Come and start right away and you can keep getting your approvals for the next 36 months."

Besides that, now there will be a single window system which Invest India will be launching in the next 90 days that provides a single platform to allow entrepreneurs get all state government and central government approvals by filling up a single form, informed Dr Bagla.

Leaders Speak

India Needs To Build Capacities for a Future World

India needs to come up with new models, such that it allows maximum participation in the research in creating world class products in the country, said Mr Kris Gopalakrishnan, Chairman Axilor Ventures & Co-founder Infosys.

Speaking at Global Bio India 2021, he said, “Building capacities for a future world. That

is what India truly represents. A very large ecosystem is coming together to make this happen. Look at the vaccine issue itself. The two vaccines that came first, the Pfizer and the Moderna vaccine, suited the developed countries but not the rest of the world, both from a cost perspective as well as from a logistics perspective. So, it’s really left to countries like India to think about science and research products that will serve the entire world rather than just 10% of the world.”

He added that India needs the confidence to build the capacity. “We need to be ready. When something is available and if you don’t occupy that space it will be occupied by somebody else. So this is our opportunity and we need to grab this with both hands. I’m very confident about the capabilities that exist in our scientists and researchers. I’m very confident that all biotech ecosystem players will come together,” he said.

According to Mr Gopalakrishnan, sometimes it’s possible that an opportunity exists, but everybody works at cross purposes.”But here we have seen that all the ecosystem players are coming together, working together to



SHRI KRIS GOPALAKRISHNAN
Chairman Axilor Ventures &
Co-founder Infosys

make sure that the goal is achieved. One of the reasons why Indian IT services industry is world class is because while building our companies, we also built industry. We work together. NASSCOM is a good example of how competitors came together to build an industry. I see the same thing happening with biotech,” he observed.

He added that he was optimistic that biotech can achieve \$250 billion economy by 2025, which will be about 5% of India’s GDP.

“That’s definitely a goal that we should aim for because there is a need for this. And we need to come up with new ways new models of doing this.”

Apart from building capacity, he said the Indian biotech industry must also create capability. “I strongly believe that in the next probably 20 years, we will have to find cure for cancer and other incurable diseases. This is a very exciting period and there is clearly a role for India in doing this,” he said.

Speaking about innovation and entrepreneurship ecosystem, he said that we need to identify the best of our students. “Now, all the research work needs to be multi-disciplinary and interdisciplinary work. So we need computer scientists, we need mathematicians, and we need chemists. The global education system works in silos. So, we need to make sure that our computer scientists understand biology or physicists under understand biology. Biology has now become central to not the work that we are doing. In fact, if you look at the latest in AI and machine learning, the ideas are coming from our understanding of the brain,” he said.

Leaders Speak

DBT Building Capacities in Biotech

Speaking about the role of Department of Biotechnology in building capacities across the country for early or late translational research and also for industrial development through various schemes and programs, Dr. Alka Sharma, Advisor DBT, said that building capacities for future was one of the key components of the tech development strategy launched in 2007, which has now set the target of achieving \$150 billion bio economy by 2025.

“The DBT formulated tech development strategy in 2007. Building capacities for future was one of the key components of this strategy. This strategy was revisited in 2015. And now as per the current strategy, the target is to achieve \$150 billion bioeconomy by 2025. DBT started its journey of translational research in industrial development mainly from 2000 onwards. The establishment of biotech park was the fastest scheme to promote and support earlier translational research in biotech sector in partnership with the states. After that, a number of schemes have been launched for capacity building,” said Dr Sharma.

In 2003, the DBT partnered with various state governments to establish Biotech Parks to help the innovators translate research into products and services by providing necessary infrastructure support, facilitating networking amongst various stakeholders and providing entrepreneurial opportunities even in remote places in the country. So far nine parks have been established in states such as



DR. ALKA SHARMA
Advisor/Scientist 'G'
Department of Biotechnology

Uttar Pradesh, Tamil Nadu, Karnataka, Kerala, Telangana, Assam, Jammu and Kashmir and Chattisgarh, informed the DBT advisor.

“An exclusive automatic path for women entrepreneurs is functional in Tamil Nadu. DBT has restructured the existing scheme of tech parks and has come up with the revised national biotechnology park scheme for setting up biotechnology incubators in consultation with the stakeholders. As per this revised scheme, DBT would provide financial support to

young companies,” she said.

Dr Sharma said that DBT has realised that deeper engagements of our industries would add tremendous value to the product development chain. Accordingly, the DBT has proposed establishment of enabling institutional mechanisms to bring university research and industry expertise into the main stream of innovation, translation and commercialization. “The guidelines for implementation of a project cluster have also been finalized and we have invited a number of proposals from various groups across the country and they are now under evaluation,” she added.

SO FAR, NINE BIOTECH PARKS HAVE BEEN ESTABLISHED IN STATES SUCH AS UTTAR PRADESH, TAMIL NADU, KARNATAKA, KERALA, TELANGANA, ASSAM, JAMMU AND KASHMIR AND CHATTISGARH

Leaders Speak

Developing Antibiotic Resistance Drugs a Big Challenge for Industry

Share his own experiences and understanding about the role of industry in the area of neglected diseases, Mr. Pankaj Patel, Chairman, Zydus Cadila, said the biggest challenge the industry faces today is in terms of financial risk in developing antibiotic resistance drugs.

“Developing drugs into certain areas are significantly higher, whereas in the case of

antibiotic, it's actually negative return. I think that's why we need to collectively work to find out how do we make systems so simple and transparent to make sure that we can develop antibiotic resistant drugs at a much lower cost,” said Mr Patel.

He added that about \$1.5 billion dollar is what generally is required to launch a new antibiotic drug and it takes about 10 to 12 years to do it. “Now that where the NPV becomes completely negative for the pharmaceutical industry, and that's why you will find less and less pharmaceutical company is getting involved into it because they do not have any other support available. A lot of money is basically spent on the earliest phase and late phase clinical studies mostly,” he said.

He suggested that a push and pull mechanism is needed to make antibiotic resistance drug production a viable option.”The push mechanism would be to give research grants for specific things. We can give tax incentives, we can create public private partnerships. And of course, non dilutive funding can be provided. The other pull mechanism could be kind of excellent regulatory pathway,” Mr Patel said.



MR. PANKAJ PATEL

Chairman,
Zydus Cadila

He observed that we all have learned during COVID times that regulatory timelines can be significantly compressed. Not only for COVID but we also need to now do it for every other thing which is happening in the drug research and healthcare.”

Mr Patel also believes that pricing is a major challenge and premium pricing can improve the returns. “Some kind of guaranteed revenue could also make sure that people will get more interest. What I see is that the Indian pharma industry has

capability to do things. So, we have significant capability in the work, whether it is vaccine, or new chemical entity or peptides or biologics, or even stem cell. We also have development capability and of course manufacturing capability. We also have capability to clinical trials,” he pointed out.

He informed the audience that his company is running an antibiotic resistance programmes for various diseases. “We have a molecule on which we're currently doing a DNA study to see its efficacy on a specific drug resistance bacteria. We are also working on another molecule which is again in the candidate profiling stage and it will be mostly used for lung infections, UTI, skin and gonorrhoea diseases. We are also working on tuberculosis and there we have two different molecules,” he said.

A PUSH AND PULL MECHANISM IS NEEDED TO MAKE ANTIBIOTIC RESISTANCE DRUG PRODUCTION A VIABLE OPTION

KNOWLEDGE SESSIONS

Global Bio India 2021 saw around 25 knowledge-packed sessions with participation from 230 speakers who shared their knowledge, wisdom, and perspective to enrich the 8000+ participants cutting across various sectors

Atmanirbhar Bharat Conclave: For India and the World

ATMANIRBHAR BHARAT FOR RESILIENT INDIA

There's a huge potential for India to emerge in a leadership role in areas like gene therapy, and leveraging artificial intelligence and machine learning

The session focused on how the Indian biotech sector can strengthen the “Atmanirbhar Bharat” vision of Prime Minister Modi by helping the country develop resilience and self-sufficiency in not only healthcare sector but also ensure food security and energy security while creating quality jobs for the skilled Indian youths.

Highlighting the achievements of the sector in mitigating the effect of COVID-19 pandemic, the eminent speakers spoke on how India can utilise its experience during the pandemic by turning challenges into opportunities.

The session saw release of National Biotechnology Development Strategy 2021-25 report and BIRAC's Technical Compendium 2021.

The biotechnology sector, which has grown at a CAGR of over 12% in past couple of years, has been contributing around \$70 billion to the Indian GDP, expressed its hope to further expand its goal of achieving \$100 billion size by 2025 to \$150 billion. The eminent speakers during the session underscored that the industry has the potential to reach its goal, but also surpass it given the right government policies and support system.

NEXT STEPS

- There is a huge opportunity for India to emerge in a leadership role in areas like gene therapy, AI and bio-computing
- International cooperation with countries like Switzerland and Sweden to develop cutting-edge technologies is the way forward for India
- Solutions in synthetic biology will be the game changers for the Indian bioeconomy
- Coordinated efforts between government, Industry and academia is the key to help India achieve \$5 trillion economy
- India accounts for 60% of global vaccine production by volume and 20% manufacturing of generic, but when it comes to value capture, it is only 3%. This has to be corrected.
- India needs to invest in research and innovation to bring out new vaccines, new drugs, new diagnostics and new medical devices to the world markets to generate high value IPs
- Biology is going to be a very important area for India to focus on in near future
- Indian biotech industry is spending only 6% of its revenues on research and innovation, while most innovative companies in the world are way ahead in terms of investing in R&D

THE BIOTECHNOLOGY SECTOR, WHICH HAS GROWN AT A CAGR OF OVER 12% IN THE PAST COUPLE OF YEARS, HAS BEEN CONTRIBUTING AROUND \$70 BILLION TO THE INDIAN GDP, AND IS HOPED TO FURTHER EXPAND ITS GOAL OF ACHIEVING \$100 BILLION SIZE BY 2025 TO \$150 BILLION

The speakers also expressed their satisfaction on the way India's regulatory system responded to the COVID-19 crisis in terms of ease of doing business and in terms of speed.

They called for the need for the Indian Biotech ecosystem to show the same level of confidence as it has shown during the pandemic in addressing the challenge of other communicable and non-communicable diseases by developing affordable and effective solutions.

The speakers also touched upon the emerging global trends in biotech, and discussed ways to make India a world-class global biotechnology hub.

The healthcare sector is one of the fastest growing sectors in the country, which is expected to grow by about \$372 billion by 2022. The Indian pharmaceutical sector is expected to grow at a CAGR of about 22.4% in the near future and medical device market is expected to grow about \$25 billion by 2025, this calls for developing solutions based on synthetic biology as well, opined the experts.

Listing out the priorities for the next phase of evolution of the India biotechnology sector, they also said that emerging areas like Artificial Intelligence, bio machine interfaces, and bio computing will help the sector increase its

share in the global market and pave the way for the industry's future.

The experts made it clear that all stakeholders, whether it is government, industry or academia, will have to work in tandem in order to make India's goal of becoming a \$5 trillion economy a reality.

The international speakers too underscored that how strong and growing bilateral partnership in science and technology and innovation with India is defining their relationship. They said that their joint investment agenda is to focus on water, agriculture and health and also creating competencies for India to strengthen competitiveness in global markets.

The experts said that they could feel how things are moving incredibly rapidly in India when it comes to science and innovation in tackling difficult issues like the climate crisis.

It was also highlighted during the session that there's a huge potential for India in collaboration other developed and developing economies to emerge in a leadership role in areas like gene therapy, and leveraging artificial intelligence and machine learning in the drug development process. They said that the experience during COVID-19 has underscored the role of global cooperation to find effective solutions.

India Fights COVID

WORLD AT CRITICAL JUNCTURE IN FIGHT AGAINST COVID

India's COVID response was an overall positive story as the industry quite successfully stepped up its efforts to fill in all the gaps that existed when the pandemic struck, but the world is again at a critical junction in the fight against the virus

This session showcased how India was able to contribute towards global fight against COVID-19 through vaccine development and coming up with novel diagnostic solutions and equipment in a record time.

The session was graced by representatives from WHO, Serum Institute India Limited and Bharat Biotech India Limited, among others to share their experience through vaccine development and help develop better insights into the global pandemic, which still rages on in many countries across the world.

The experts said that India rose to the occasion to streamline its systems and reached out to the global players to help create vaccines against the novel Corona virus in record time.

The experts hailed India's COVID response by saying that it was an overall positive story as

the industry quite successfully stepped up its efforts to fill in all the gaps that existed when the pandemic struck.

However, they also lamented that at this point in time the world is at a very critical juncture again because of the increase in cases worldwide. They also suggested that though there's a sense of security because of the start of vaccination campaigns, we need to be very careful on the messaging, as vaccines have only reached minority of people globally.

The experts called for high level of commitment and allocation of funding and resources to apply lessons learned during the pandemic to other diseases as well.

The session also highlighted the need for harmonizing the entire system to identify right solutions as common nomenclature and definitions were important.

NEXT STEPS

- There is a need for coordination between the public and the private sectors, because there are certain things individual companies and individual Institutes can do. But there are certain things which cannot be done, which do need a national coordinated approach
- To win the fight against Corona Virus, there is a need for different agencies to come together and agree on a system, which the private sector then collaborates with
- Researchers need metadata, clinical data, laboratory data, and epidemiological data, to back their research up. Therefore, a national bio-bank is the need of the hour.
- Indian companies need to develop different kinds of platform technologies for vaccines



Mr. Martin van den Berg

Ambassador, Embassy of Netherlands in India, Nepal and Bhutan

COVID-19 really shows us that the world needs international collaboration in science in technology and innovation. And I think it also highlights the importance of international value chains to rapidly bring solutions to the market.

Dr. Kiran Mazumdar Shaw

Executive Chairperson, Biocon



If India wants to be a leader, India will have to seriously invest in research, innovation, manufacturing, and of course, accessing capital through global markets with a sense of determination, and capabilities.



Dr. Ralf Heckner

Ambassador, Embassy of Switzerland in India and Bhutan

We put the money where our mouth is. About 3.4% of our GDP goes into research and development.



Prof. M Vidyasagar

Chair, NBDS Formulation Group, Distinguished Prof IIT -Hyderabad

We aim to increase our bio economy from its current \$70 billion size to \$150 billion in the next five years. This is slightly more than doubling the size of the bio economy. And this requires a compounded annual growth rate a little bit ahead of 15%.

Mr. Junaid Ahmad

Country Director, World Bank

Rich countries and regions that are associated with global value chain show greater production capacity than countries and regions that are solely looking inwards for production. Interestingly, the firm's related to global value chain, are greater creator of women's employment than firms that are not part of a global value chain.

Additional Focus: mRNA vaccine

THE MANY CRITICAL ADVANTAGES OF MRNA PLATFORMS

These platforms have many critical advantages like allowing development of vaccines very fast, which was recently demonstrated by Moderna, which developed the COVID vaccine in just 42 days

Experts during this session discussed the aspects of mRNA technology-based vaccines and its advantages over vaccines based on other platforms. The field experts took the audience on a journey that could prove to be a game changer in development of vaccine against the novel Corona virus. They said that scientists had for the first time shown that in-vitro transcribed RNA could potentially be used for therapy back in 1990 and since then a lot of progress has been made in the field.

They said that most people remain sceptical about the therapeutic potential of RNA, but due to the technological advancements and very active research in the past 15-20 years those issues have been resolved

and messenger RNA has become a very promising new therapeutic modality.

Talking about the mRNA platforms, they opined that these platforms have many critical advantages like allowing development of vaccines very fast, which was recently demonstrated by Moderna, which developed the COVID vaccine in just 42 days and the product works incredibly well in people.

Further, the experts highlighted that how this platform technology is convenient because you just need enzymes, a polymerase buffer and nucleus types to generate the mRNA that encodes for the protein of interest. Also, a critical element of mRNA vaccine is that allows minimal modification to produce other vaccines.

NEXT STEPS

- The mRNA technology offers many opportunities in terms of targeting a disease. It results in an excellent immune response, and therefore, the technology is an amenable way to vaccine development
- Self-amplifying mRNA vaccines come with a lot of advantage in terms of manufacturing capabilities
- Incorporation of modified nucleotides in the RNA not only decreases immune activation, but it also increases the Translate ability



Dr. Pankaj Patel

Cadila Healthcare Ltd

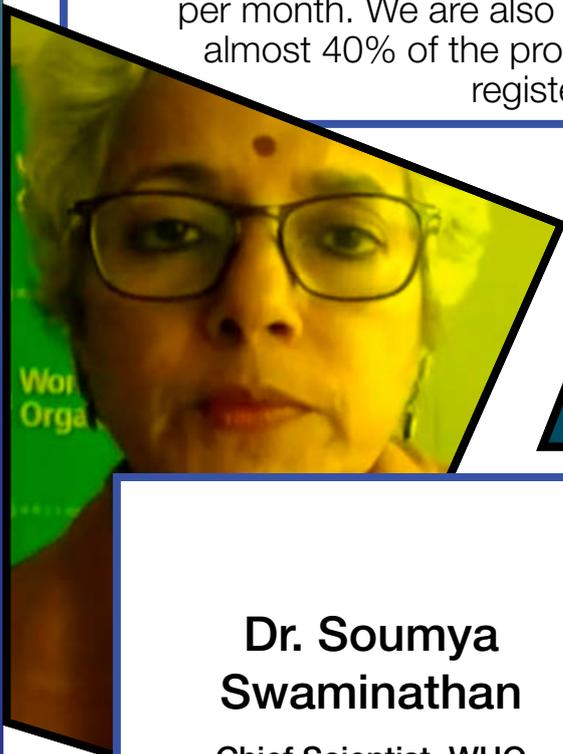
The future success of pharma industry would lie on the innovative capability of Indian manufacturers.

We have been looking at their startup formation. Biotech companies continue to register in the startup category at an average rate of 70 companies per month. We are also very happy to report that almost 40% of the promoters of 4,237 startups registered in 2020 are women.



Dr. Suresh Narayanan

Chief Operating Officer, Association of Biotechnology-Led Enterprises (ABLE)



Dr. Soumya Swaminathan

Chief Scientist, WHO

Well-coordinated response that we've seen to COVID can be applied to other diseases, for example, tuberculosis or malaria, which actually take a much higher toll if you see in terms of mortality.



Dr. Guruprasad Medigeshi

Translational Health Science and Technology Institute

As a pandemic response, academia has really risen up to the occasion and has delivered. But I think collaborations should not happen as a pandemic response, but it has to be the norm.

International Investors Meet

A VIBRANT INDIAN BIOTECH ECOSYSTEM

India was quick to come up with novel innovations and vaccines, which bears the testimony of the potential of its biotechnology sector

This session focused on showcasing the opportunities in the Indian biotechnology sector and discussed the various investment trends, challenges and opportunities for startups, global venture capital, private equity funds in the biotech sector in India.

Speaking at the session, experts tried bring a perspective to showcase how India's biotech

ecosystem is positioned today at the national as well as the international level. They made an effort to showcase the maturity and the critical mass in the innovation ecosystem of India that has been achieved over a period of time with a focused approach from Department of Biotechnology, Biotech industry, research bodies and allied ministries and departments of government, and the IT and the e-commerce sectors.

NEXT STEPS

- Create mechanisms and environment that is suitable for mobilization of private equity into the ecosystem
- At present no Series B or Series C funding readily available in the biotech sector, which is forcing innovative, bright start-ups to register outside India to attract funding support, which needs to be changed
- India needs to identify those startups which require early stage fund support and identify those startups which require venture capital support, and very systematically handhold them
- Investors who want to come in for Series A or Series B funding, they don't seem to have the confidence of a vibrant market that can take up their stake when the Series C or D funding happens

HIGHLIGHTING THE DIFFERENCE BETWEEN THE BIOTECHNOLOGY SECTOR AND OTHER SECTORS OF THE ECONOMY, THE EXPERTS HIGHLIGHTED THAT HOW THE IDEAS AND INNOVATIONS IN BIOTECH NEED A LONGER GESTATION PERIOD TO REACH THE MARKET, WHICH REQUIRES INVESTORS TO WAIT PATIENTLY FOR RETURNS ON THEIR INVESTMENTS

Highlighting the difference between the biotechnology sector and other sectors of the economy, the experts highlighted that how the ideas and innovations in biotech need a longer gestation period to reach the market, which requires investors to wait patiently for returns on their investments.

It was also highlighted during the session that how India was quick to come up with novel innovations and vaccines, which bears the testimony of the potential of its biotechnology sector.

Speaking about the startup ecosystem in the biotechnology sector, the experts were hopeful that it would include over 10,000 young firms by 2024-25, contributing significantly in the bio-economy of India.

Highlighting the efforts being made by the Government, the experts said that initiatives like National Seed Fund Scheme and Credit Guarantee Scheme for Startups are already in place and will go a long way in helping them grow.

Pioneer the Possible - Precision Health

INDIA-SWEDEN DIALOGUE ON PRECISION MEDICINE

The session explored the collaboration opportunities between Indian and Swedish industry, researchers, agencies, incubators and start-ups in Precision Medicine and Data-Driven Life Sciences, and paved the way for policy development and learning between Sweden and India to transform lives

The session highlighted the agreement between experts from both India and Sweden that their collaborations and friendship needs to be further deepened, as innovation and health are perhaps the two strongest drivers at the moment in this very dynamic bilateral relationship.

“The pandemic has shown that we must build new partnerships between the public and private sectors and find innovative ways for business investments and innovation to contribute to sustainable development,” said Niclas Jacobson, Deputy Director-General and Head of the Division for European Union and International Affairs, Ministry of Health and Social Affairs, Government of Sweden, while addressing the session.

NEXT STEPS

- India and Sweden must build new partnerships between the public and private sectors and find innovative ways for business investments and innovation
- Given India and Sweden’s respective strengths, the area of precision medicine promises the possibilities of cooperating with data and life sciences in many different ways
- The scientific research is increasingly getting multidisciplinary and India and Sweden bring synergies in terms of varied areas of scientific research and innovation
- Going forward, one area that requires the most convergence in terms of different areas of sciences is the area of precision health care
- There is the need to utilize health data in a new way so as to make health data accessible
- The promise of precision health is based on ability to predict better, be more preventive, and be more individualized

IN THIS LAST ONE YEAR, WE ALL BATTLED THE PANDEMIC AND DELIVERED WONDERFUL SOLUTIONS FROM SCIENCE AND TECHNOLOGY. AND THESE SOLUTIONS CAME BECAUSE OF THE CONVERGENCE OF DIFFERENT AREAS OF SCIENCE. WE ARE HOPING THAT GOING BEYOND THIS PANDEMIC, WE WILL CONTINUE WITH THIS CONVERGENCE, COLLABORATION AND COMMITMENT

Elaborating further, Ambassador Klas Molin, Embassy of Sweden in India, emphasized that he believes that given India's and Sweden's respective strengths, the area of precision medicine promises the possibilities of cooperating with data and life sciences in many different ways.

"The global pandemic has put this area of research and application firmly in the spotlight, not only today, but for times to come. And the way we see that public-private partnership in the last one year or so has really been intensifying all over, including in India, people are looking towards researchers and entrepreneurs for solutions," said Ambassador Tanmaya Lal, Indian Embassy in Sweden.

Dr Renu Swarup, Secretary, Department of Biotechnology, underscored that precision healthcare has always been one of the most important priority areas in various bilateral cooperation discussions. "In this last one year, we all battled the pandemic and delivered wonderful solutions from science and technology. And these solutions came because of the convergence of different areas of science. We are hoping that going beyond this pandemic, we will continue with this convergence, collaboration and commitment. And one area that requires the most convergence is the area of precision health care," she said.

THE PROMISE OF PRECISION HEALTH IS BASED ON ABILITY TO PREDICT BETTER, BE MORE PREVENTIVE, AND BE MORE INDIVIDUALIZED

Dr Jenni Nordborg, National Coordinator & Director of the Office for Life Sciences at the Government Offices of Sweden, stressed that precision medicine will be a game changer for a lot of the things that we do for the future. “Today, when we’re moving towards precision medicine implementation, we need to utilize health data in a new way to have health data accessible and scientists be able to work with real world data,” Dr Nordborg said. She also emphasized the need for artificial intelligence in health data, and innovation in policy when it comes to implementation of precision medicine.

Citing the long standing cooperation with Sweden, which is now more than a decade long partnership, Dr Alka Sharma, Senior Adviser, Department of Biotechnology, said that India and Sweden are pursuing joint activities for advancing the benefit of science in both the countries. “The collaboration has resulted into a large number of good quality publications. We have worked together on many priority areas on health research, clean energy, and in promoting startups and entrepreneurship across both the countries. The latest effort was digital health care, which is being jointly promoted enhancing accessibility and affordability of health care across both the countries,” she said.

Dr Richard Rosenquist Brandell, Director, Science for Life Laboratory (SciLifeLab) and

Coordinator, Genomic Medicine Sweden, said that there is a potential to exchange research insights and data between Indian and Swedish organizations to engage in joint training and education programs to help embed precision medicine principles in research practice, as well as clinical industry and policy levels.

Dr Anurag Agarwal, Director, CSIR-Institute of Genomics and Integrative Biology (CSIR-IGIB), India, emphasized that the promise of precision health is based on ability to predict better, be more preventive, and be more individualized. “And all of that will take data, it will take whole genome data, it will take clinical data, it might take many other types of data. But most of all, it must be representative of the population to which it is being applied,” he said.

Dr Lotta Ljungquist, CEO, Cytiva and Testa Center, said that to be able to further implement and integrate precision medicine in the health sector new innovation platforms are needed. “With many Indian companies now developing ambitious precision medicine research activities, the time is just right to partner up with Sweden and use its strengths in areas such as molecular profiling and AI solutions. By showcasing indigenous Swedish Life Science Solutions, and the benefits of sharing platform technology and information, we will create a common ground for new innovative platforms,” Dr Ljungquist said.

INDIA-SWEDEN COLLABORATION HAS RESULTED INTO A LARGE NUMBER OF QUALITY PUBLICATIONS. WE HAVE WORKED TOGETHER ON MANY PRIORITY AREAS ON HEALTH RESEARCH, CLEAN ENERGY, AND IN PROMOTING STARTUPS AND ENTREPRENEURSHIP

Dr Sudeep Gupta, Director, Tata Memorial Centre Advanced Centre for Treatment, said, “In centers like ours every day 1000s of images are generated, including those comprising diagnostic radiology such as radiographs, CT scans, MRI scans, PET scans, mammography and others. We also generate an enormous amount of data with other techniques like immune histochemistry, multi parameter, diagnostic flow cytometry, and creating bio banks, including imaging bio banks that are linked to associated clinical information is an enormous stockpile of data that is waiting to be mined, including AI techniques such as traditional neural networks and others.”

Anders Blanck, CEO/Director General at The Swedish Association of the Pharmaceutical Industry, LIF, said that precision medicine now has a much wider approach from having been almost exclusively focused on genomics to now being applied in a broader context with a whole healthcare chain from diagnostics to treatments. And that means that precision medicine is becoming an integrated part of healthcare. And the possibility of using precision

medicine tools such as advanced diagnostics for more individualized treatment choices is actually a reality in several therapeutic areas such as lung cancer and rare diseases.

Anuradha Acharya, CEO Mapmygenome, was of the opinion that soon we will start seeing that there is a lot of consumer based information that we will have to start considering when it comes to precision health, because we will start to see a lot more data coming in from continuous monitoring devices.

Dr Björn Arvidsson, Managing Director STUNS Life science, said that we need to break down precision medicine into components that are more easily adoptable by the organizations responsible to carry out the integration. “I see three things—the health data, which is the foundation for it all, reimbursements, and the education and training.”

He added that precision medicine requires the attention to patients as unique individuals taking into account the personal health history, their lifestyle and potential genetic contributions.

Startup Conclave

STARTUPS DRIVING INNOVATION IN BIOTECH

The session dedicated to startups sought to understand the key factors that can provide major thrust towards encouraging the growth of Start-ups and develop better insights into the challenges they face

In the 2016 action plan for the Startup India, the Prime Minister had given the Department of Bio Technology a specific target of creating 2000 startups by 2020. However, by 2020 there are more than 4,300 that are currently driving innovation and research in the sector, acknowledged experts during the session focused on startup.

The COVID pandemic was not only about challenge but also a year of opportunities for

the science and technology field to deliver when it mattered the most. The startups in the biotech sector rose to the occasion and played a crucial role in helping India achieve 100% self-reliance in diagnostics in less than three months. The session dedicated to startups sought to understand the key factors that can provide major thrust towards encouraging the growth of Start-ups and develop better insights into the challenges they face.

NEXT STEPS

- Biotech sector has now 59 incubation centres supported by DBT alone. Going forward, the number would be increased to 225
- Great innovations and inventions will come up through the involvement of all sections of the business. Government should act as an enabler and as a support to the ecosystem
- The Industry and Commerce Ministry will promote technologies developed by Indian startups internationally by helping them to get more visibility at international fora through special fairs
- There is a need to focus on bright ideas coming from rural india

THE CONCLAVE ALSO SAW THE RELEASE OF THE CONSOLIDATED INDIAN BIO-ECONOMY REPORT BASED ON THE LATEST DATA REPRESENTING THE BIOTECH SECTOR'S CONTRIBUTION TO THE BIOECONOMY. THIS WAS FOLLOWED BY THE ANNOUNCEMENT OF THE PROJECT DEVELOPMENT CELL (PDC) JOINTLY IMPLEMENTED BY DBT, BIRAC & INVEST INDIA

The conclave also saw release of the consolidated Indian Bio Economy Report based on latest data representing the Biotech Sector's contribution to the Bioeconomy. This was followed by announcement of The Project Development Cell (PDC) jointly implemented by DBT, BIRAC & Invest India, which will function to identify potential investors in the biotechnology sector within & outside India.

The experts said that steps like Project Development Cell initiative will go a long way in converting ideas to reality for startups and further strengthen the existing ecosystem, which has evolved over two decades.

The discussions during the session were held around:

- How to facilitate innovations on the entire product development chain
- Success stories of the top 10 BIRAC supported commercialized startups working among different sectors like Healthcare, Agriculture, Environment, and Industrial Biotech
- Best practices, activities, initiatives, achievements of the partner country's Biotechnology sector and providing an opportunity to showcase representative countries as a sourcing and exporting destination to Indian as well as International Biotechnology industry
- Opportunities and incentives provided by State Governments' in India

First Hub

EMPOWERING BIOTECH ENTERPRISES

Created with a vision to stimulate, foster and enhance the strategic research and innovation capabilities of the Indian biotech industry, particularly start-ups and SME's, the FIRST HUB has been strengthening and empowering the emerging biotech enterprise to undertake strategic research and innovation, and address nationally relevant product development needs

The FIRST HUB Session, dedicated to a facilitation unit established by Biotechnology Industry Research Assistance Council, a PSU of Department of Biotechnology, Ministry of Science & Technology, GOI, resolved queries raised by Startups, Entrepreneurs, Researchers, Academicians, Incubation Centres, SMEs, etc. The queries were mainly concerned with Regulatory pathways and Regulation, Funding opportunities, Mentorship, Investment opportunities, Market access, Industry Academia partnerships, Intellectual Property, etc.

One of the first queries raised by a participant, who has made a COVID diagnostics solution, was regarding the regulatory pathways.

“The problem we are facing is concerned with ICMR validation because our diagnostics is for the antigen detection through ELISA. In the

ICMR portal, there is a direct application but we can't make it through the portal because there is no provision for the antigen analyzer test. And correspondence through emails is taking a lot of time and there is no clarity on that. Secondly, in case of the antibody detection kit, we found on the portal a disclaimer that ICMR portal will only accept standalone kits for SARS COVID and ICMR will not be able to undertake validation of ELISA kits meant for detection of neutralizing antibodies against SARS COVID. So, under this circumstances, we are not clear whether the ELISA kits meant for antibody detection against the virus will get validated through ICMR or not,” asked the participant.

Answering to his query, experts asked him to reach out to them and promised to put him in touch with the program officers who are handling diagnostics for COVID.

It was also revealed that initially ICMR used to do the validation for all the test kits because there was no other system in place in the country. But now there are parallel systems like DBT institutes, and ICMR is not the only nodal agency doing validation of test kits.

The next query was raised on testing and standardization process concerning a milk augmentation detection device. The participant, whose company has developed a paper based device where paper strip can be dipped in milk to give concentration of chemicals present in it. "We have a camera based solution as well, where we take the image of the paper strip that can show the concentration of the chemical. We are working with dairy companies, who want to use this device at procurement level. But we are also looking at taking it to consumers as well and we want to get it certified," informed the participant.

The experts said that there were already several standards published regarding testing of milk and related products for the purpose of detecting and quantifying data exchange. So, they advised the participant to refer to Indian standard number 1479.

"There are parts of this which are available in public domain, and you can download it from the website and see whether it is the same set of tests which you are doing or is it something innovative. In case the innovation is around test methodology then Food and Agriculture Department's dedicated sectional committee which deals with the dairy products can be approached," said the experts.

The next query came from the developer of an oral hygiene device for those who are not able to brush by themselves. For example bedridden elderly, or those who are quadriplegic. The participant wanted to know how to assess that their prototype, which has components like pumps and other things, is standardized and is eligible for taking the product to clinical trials. Also, he wanted to know that what type of lab testing is expected in such a case.

The experts told the participant that the IEC standard is the applicable standard in this case. "What I can map now according to what you have described and this can be tested in one of our laboratory here in AMTZ which is in Vishakhapatnam," said Dilip Kumar, Scientist -D and Head- Standards & Innovations, AMTZ.

There was also a query regarding ethical clearance of handed stereographs for Indian ethnicity, where the participant asked, "If I have to get secondary data of the patients or x rays, so from where I have to get ethical clearance, whether getting medical clearance from ICMR is valid in private hospitals as well? The second part of the query is that in case if I have to take the radiographs and if the data that is available is unfortunately not adequate, or is not compatible with the data which I really required if I have to take radiographs for children, then what kind of ethical clearance is needed, and whether the ethical clearance needed for government hospitals is different from private hospitals?"

Replying to the query, Dr. Jerin Jose Cherian, Scientist-D, ICMR, said, "It doesn't seem to have any regulatory implications. So what I would suggest to you is, you know, most Institutes where there is medical research ongoing, they have themselves affiliated to either the Department of Health Research, or the regulators office, which is the CDC. So now, there are two types of regulations for institution ethics committees it's for biomedical research and also for regulatory clearances. So depending on your requirement, you can actually identify the institution where you have the ethics committee. You don't have to come to ICMR or any other institute. Just reach out to your own institute where they have ethics committees and get them to review it. And then if they allow you to carry on with your research, then that should be adequate."

Building Entrepreneurial Culture

GRASSROOT INNOVATIONS FOR SOCIETAL GOOD

Grassroot innovations are community-led solutions holding potential to offer sustainable solutions for larger societal good. This session was designed to discuss the initiatives, opportunities and challenges towards building a strong entrepreneurial culture with special focus on grassroot innovations

During this session, the experts and leaders in the domain highlighted recent policy initiatives and the future outlook for this important area. The session also saw participation from five grassroot innovators who shared their inspiring stories with the audience.

“We are the only country in the world where grassroot innovations are part of national

innovation system. In most of the other countries, the national innovation system includes only the R&D in formal sector. In fact, the new science technology and innovation policy draft has an eloquent statement on not only grassroot innovations, but also people’s knowledge, community knowledge, and traditional knowledge, which can provide affordable, and accessible solutions to meet the needs of our society,” said Prof. Anil Gupta, Founder, Honey Bee Network, SRISTI, GIAN & NIF, while opening the session.

NEXT STEPS

- In the field of research if our aspirations are tall then it will result into big changes. There is the need to create entrepreneurs to transform India’s biosciences into bioeconomy
- The scope of social entrepreneurship is quite huge, as it is connected with all stakeholders of the society including entrepreneurship, technology and environment
- Social enterprises are problem solvers but the most important aspect of it is that all these solutions cannot be copycat solutions
- As the world is changing so fast, women entrepreneurs need innovations that can reduce their drudgery and take care of the efficiency, environment and naturalresources without taking away employment
- BIRAC’S e-YUVA scheme’s intent is to create technologies to implement at the grassroot level. It also seeks to make it possible for our youth to relate with the problems at the tier-2 or tier-3 city levels

IN THE WORDS OF OUR PRIME MINISTER, 'THE TIME FOR INCREMENTAL CHANGE IS GONE. WE REQUIRE TRANSFORMATIONAL CHANGE.' WE NEED TO CREATE ENTREPRENEURS TO TRANSFORM BIOTECHNOLOGY INTO BIO-ECONOMY

Grassroot innovations have played a crucial role in the development of our society for centuries. The organized grassroot innovation movement in India is comparatively a recent phenomenon which started around 30-40 years back. Professor Gupta and Dr Mashelkar have played a very critical role in this movement by bringing together grassroot innovators and helping them get organised. CSIR, which was one of the first institutions set up to promote science and technology in the country, has also been responsible for majority of development in the field that we see today," said Dr. ShekharMande, DG, CSIR.

Dr. R A Mashelkar, National Research Professor and Former DG-CSIR, said that everybody has the potential to do innovation. "Minds on the margins are not marginal minds. This is the vision that has been guiding us. In my new book 'Leapfrogging to Pole-Vaulting'; I have argued that in the field of research if our aspirations are tall then it will result into big changes. In the words of our Prime Minister, 'The time for incremental change is gone. We require transformational change.' We need to create entrepreneurs to transform biotechnology into bio-economy," Dr. Mashelkar said.

"It was my privilege that I was associated with the research, training and teaching of social entrepreneurship. When I started my career, social entrepreneurship as an academic

discipline was in a nascent stage and I have seen its journey from close quarters. We contributed by creating the curriculum for social entrepreneurship academic programmes and outlines of research in the field. Secondly, we have contextualized social innovation in this regard. One of the biggest challenges in this process was linking human dignity with enterprise creation," said Prof Satyajit Majumdar of Centre for Social Entrepreneurship, School of Management and Labour Studies, Tata Institute of Social Studies.

Reema Nanavati of Self-Employed Women's Association of India (SEWA) highlighted that for 18-19 lakh members of SEWA who are all social entrepreneurs, innovation is a coping mechanism.

Dr Manish Dewan of BIRAC highlighted the work being done by his organisation to promote social entrepreneurship in India. "BIRAC'S e-YUVA scheme's intent is to create technologies to implement at the grassroot level. It also seeks to make it possible for our youth to relate with the problems at the tier-2 or tier-3 city levels so that technology can penetrate across the country to the last mile. We are creating e-YUVA Centres and e-Yuva fellows and these will be the torchbearers of grassroot innovations helping link scientifically validated technology with the more mature system in the country," he said.

Health Conclave

HARNESSING THE POTENTIAL OF INDIAN HEALTHCARE SYSTEM

There were also deliberations on topics ranging from how to make technology choices in healthcare setups, to how Indian patients' behaviour can be changed

This session discussed that how COVID-19 pandemic overwhelmed healthcare systems globally and proved that awareness about healthcare cannot be seen in isolation. The experts highlighted that how India stood as the prime example of frugal innovation in the world, besides suggesting ways as to how entrepreneurs can set up distribution networks that are internationally competitive and can intersect the markets where Indian made products needs to go.

The deliberations also touched upon licensing pathways that the government can introduce to enable young entrepreneurs cut short the time to market.

Speaking on challenges, the experts said that while health technology assessment exists in India since 2012, it has not got integrated into approvals of medical devices, particularly in health programs.

NEXT STEPS

- The health care sector globally is at an inflection point, this is a moment in time where it is up to us in the sector to make or break it
- Medical devices sector is a relatively less attended sector within the overall healthcare sector, which will certainly going to change
- Medical devices sector needs to look at how it can manage the demand
- Government has now started focusing attention on providing support for infrastructure. So medical clusters or medical device pathways will soon be introduced
- The requirements of the healthcare sector will be incorporated into the national logistics policy

THE EMINENT SPEAKERS SHARED THEIR WISDOM WITH STARTUPS AND BUDDING ENTREPRENEURS ATTENDING THE SESSION AS TO HOW FAILING EVIDENCE GENERATION OR WRONG PATHWAY FOR CLINICAL TRIALS IN AN UNKNOWN SUBJECT CAN LEAD TO PRODUCT DELAYS

The experts also tried to find ways to mitigate the huge range of potential risks that comes with emerging med tech. Deliberations focused on the steps that can be taken from a patient safety perspective and what should emerging medtech companies need to keep in mind while designing their products.

The eminent speakers shared their wisdom with startups and budding entrepreneurs attending the session as to how failing evidence generation or wrong pathway for clinical trial in an unknown subject can lead

to product delays. They also highlighted that Indian innovations have to compete with large number cheap products, therefore Indian startups need support of procurement and market access.

There were also deliberations on topics ranging from how to make technology choices in healthcare setups, to how Indian patients' behaviour can be changed, as they often access the entire healthcare services in a reverse chain.

Clean Energy Conclave

CLEAN ENERGY FOR A HEALTHIER FUTURE

The experts at the session showcased that how access to reliable affordable clean energy can have an immediate and transformative impact on quality of life and contribute significantly in access to basic services like health, education and livelihoods

Clean energy is at the core of India's quest for sustainable energy security. Due to its demand size and dynamism, there are tremendous opportunities and technology challenges to provide reliable, affordable and sustainable energy to India. Due

to India's growing population and economy, the country is in a unique position to adopt and rely on many cleaner resources. Thus, many initiatives have been undertaken by the Department of Biotechnology through national and international collaborations to achieve this goal.

NEXT STEPS

- Mission Innovation Program to work on solutions for community building around clean energy
- A roadmap needs to be created on how can India set up important missions in areas like biomass, marine and hydrogen energy
- More efforts need to be made in areas like cooking solutions to tackle indoor pollution which impacts maternal and child health
- European and Indian incubator initiative launched in Bangalore in 2018 provides an excellent opportunity for incubators and accelerators from both the EU and India to collaborate on health and energy topics of mutual interest
- The International Bio Economy Forum continues to be a valuable place for cooperation on important topics like sustainable bio refineries
- The greatest common good for the cause of cleaner energy and low carbon economy will be guided by the well-defined energy transition roadmap
- India has been developing next generation infrastructure and enabling sustainable and efficient energy availability and accessibility to the poorest of the poor for combating climate change
- Natural gas will be a significant transition for India in its quest for clean energy solutions
- The National Hydrogen Mission launched in the Budget 2021 to draw up a road map for using hydrogen as an energy source

THE EXPERTS AT THE SESSION SHOWCASED THAT HOW ACCESS TO RELIABLE AFFORDABLE CLEAN ENERGY CAN HAVE AN IMMEDIATE AND TRANSFORMATIVE IMPACT ON THE QUALITY OF LIFE AND CONTRIBUTE SIGNIFICANTLY TO ACCESS BASIC SERVICES LIKE HEALTH, EDUCATION, AND LIVELIHOODS

The session on clean energy was attended by experts and thought leaders to highlight:

- Opportunities and challenges associated with more than 100 projects aiming to achieve sustainability in energy sphere
- Successful demonstration of technologies like Fuji ethanol, carbon converting sewage treatment technologies, high value chemicals, materials and bio polymers, etc
- Finding ways to successfully implement and promote idea generation and commercialization of sustainable technologies
- Projects being supported under the Mission Innovation Program
- Clean energy incubators and innovative solutions they are able to come up with
- How to make clean energy accessible to populations, which is a prerequisite for quality health and is fundamental to universal health care coverage and achieving the Sustainable Development Goals.
- Innovative, efficient and affordable solutions for clean cooking in rural community settings for healthy community

The experts at the session showcased that how access to reliable affordable clean energy can have an immediate and transformative impact on quality of life and contribute significantly in access to basic services like health, education and livelihoods. They also discussed the potential of off grid energy solutions that can expand access to modern energy services in a timely and environmentally sustainable manner.

Women Entrepreneur's Conclave

WOMEN ENTREPRENEURS: THE POWER TO TRANSFORM

Women have time and again proven their mettle when it comes to running enterprises. Today, India boasts of 13.5–15.7 million women-owned enterprises, representing 20% of all enterprises. However, this number needs to be boosted. India's Bioscience sector shows a ray of hope with at least 40% workforce constituting women in different roles. Top women entrepreneurs serve as a role model to young women who want to follow their dreams

There is no denying the fact that women across the world are driving transformation with unflinching determination and diligence. The Indian Biotech sector in particular, which has seen a large number of women entrepreneurs, is setting the example for women empowerment. The session dedicated to Women Entrepreneurs was attended by many noted women who have proven their mettle in the field and continue to be the role model for future generations.

The conclave focused on:

- Perspectives of women leaders from across the globe, highlighting the challenges as well as the learnings from their respective experiences and insights
- Various initiatives and measures taken by India to boost women entrepreneurship

- Issues of women in leadership positions and gender equity
- Opportunities for women as part of the workforce
- Value chains that are dominated by women

The panel of experts discussed how some of the inherent biases exist in the way we look at products and services that are associated with women, especially in areas like beauty and lifestyle products and services. And when it comes to something like biotech, there is a deeper scrutiny from investors who like to ask more questions about mitigate risks, and less on the vision of women entrepreneurs, the experts pointed out.

They also pointed out that how invisible women are in any kind of design and testing, as many medical and other consumable products and never tested on women.

NEXT STEPS

- There's enough business case for companies to step up their efforts in designing products and services keeping women in mind
- Industry can factor in gender analysis to allow more diversity on investment teams
- There is a gender disparity when it comes to women in leadership roles. It is a common sight that the CEOs in companies, or even in

academia top researchers or top directors are all men. This needs to be changed.

- Gender balance is important because it brings the diversity of diverse views to an organisation
- There are few women in top positions because the pipeline of women in workforce does not have a strong base. This needs to be improved



Mr. Sashi Kumar

Managing Director,
Phoenix Medical
Systems Pvt Ltd

Many medical products cannot be directly put on a patient as we have seen in COVID vaccine case. Even if we want to ramp up and go into the market fast we cannot do it unless and until we get the product into a proper evidence building.

Mr. Amit Chopra

Managing Director – India and
South Asia,
Thermo Fisher Scientific

I think one thing COVID has done is that it has ignited the innovative startup ecosystem. The government and private sector partnership has really taken off. I think now there’s a huge opportunity for India and the Indian startup ecosystem to partner global companies to have free flow of technology and innovation both ways and achieve scale.



Dr. Peter Singer

Special Adviser to DG,
WHO

In 2021, the year of vaccine equity, we would love to see even more collaboration with manufacturing capacity so we can improve the production of vaccines. And in 2022, it will be extremely important on the broader suite of health products to continue the incredible work done in the Indian innovation ecosystem.



Mr. Jasvir Singh

Regulatory- Scientific
and Government
Affairs Leader South
Asia, DuPont India Pvt
Ltd (IFF–International
Flavors & Fragrances)

A working group can be created to look at all the regulatory barriers which exist across sectors and review them on an annual basis and see the progress being made based on an objective parameter.

CEO Roundtable

NAVIGATING INDIA'S FOOTPRINT AS A GLOBAL BIOTECH DESTINATION

CEO roundtable that convened during the Global Bio India 2021 included representatives from the Indian government and Biotech Industries for a discussion focused on how India is making progress to become a Global Biotechnology destination for the whole world.

The discussions revolved around:

- The strong ecosystem created in the last 20 years that helped India deliver COVID solutions
- Ways to position India as a strong bio-manufacturing hub for innovative, affordable and accessible products for the society and also for global markets.

NEXT STEPS

- The target of making India a 150 billion bio economy can be achieved by anchoring it around the bioeconomy size. Vaccines within biopharma and biologics would be the key contributor of this growth.
- India has a huge opportunity to create real world evidence for Biologics as well as for vaccines. And that actually means that it needs investment in research
- Vaccines getting developed in the developed world can be launched in India in a much more faster supported and enable regulatory mechanism. But this will require parallel regulatory approval rather than sequential regulatory approval
- The adult vaccination ecosystem must include additional adult vaccines in that network, which will then take care of diseases like influenza and meningitis
- Commercial players need a sustainable and predictable price in the country's procurement mechanisms
- Building an ecosystem that promotes partnerships between startups and large enterprises is the way to go in India
- Strengthening the Indian IP system and promoting clean manufacturing is very important for the future of Indian biotech
- The risk assessment capabilities for sectors like food processing industries, or industrial enzymes needs to be taken on par with global levels

IT WAS ALSO HIGHLIGHTED DURING THE CONCLAVE THAT HOW A VERY STRONG FOCUS ON EQUITY IS REQUIRED, ESPECIALLY WHEN IT COMES TO COVID VACCINATION AROUND THE WORLD AND HOW INDIA CAN PLAY A CRITICAL ROLE IN ENSURING THAT

- Strengthening a strong education, research and translation ecosystem across the country
- Government plans to have knowledge translational clusters and technology propellers on the catapult model, as well as setting up of bio manufacturing zones.
- How to replicate the response to the COVID pandemic in other sectors like agriculture, industrial bioenergy, biofuels and many others.
- Identifying priorities and take them on a mission mode.
- Identify challenges and policy enablers, which can help further strengthen the ecosystem.

Speaking during the session, the experts agreed that positioning India as a bio manufacturing hub to innovate affordable and accessible products for Indian society and for the global markets would be crucial for global health.

It was also highlighted during the conclave that how a very strong focus on equity is required, especially when it comes to COVID vaccination around the world and how India can play a critical role in ensuring that.

Phytopharma and Traditional Knowledge

USING TRADITIONAL KNOWLEDGE TO FIGHT DISEASES

Focus on medicinal plants and traditional knowledge can make a huge difference when it comes to contribution towards the bio economy of the country

The session provided useful insights into the phytopharmaceuticals and Traditional Knowledge from AYUSH perspective focusing on the opportunities of innovation from business and regulatory aspects, and process of drug development through Traditional systems as well as scope and challenges prevalent in this sector.

Speaking during the session, the experts said that focus on medicinal plants and traditional knowledge can make a huge difference when it comes to contribution towards the bio economy of the country.

The session discussions were held around:

- How different regulatory framework are available for both traditional medicine as well as Phytopharmaceutical drugs
- How now the Department of Biotechnology is involved in both traditional knowledge based drug discovery and pharmaceutical drug discovery
- How biotech intervention can play a role in leveraging traditional knowledge on herbs and medicinal plants
- The existing gaps, what needs to be done to fill them and what are the future plans for the sector

NEXT STEPS

- The enormous traditional knowledge available in the Himalayan region will be documented and used for discovery of new drugs
- The sector needs to have a very developed platform for knowledge sharing and empowerment
- The indigenous knowledge systems can be used to develop nutraceutical dietary supplements that can lead to commercialization
- Integration and innovation is the need of the hour for the development of drugs from tradition knowledge
- The use of medicinal plants has increased, and therefore, we need identification and screening of products, profiling of phytochemical and identification of metabolites



Dr. Pulok Kumar Mukherjee

Director, Institute of Bioresources and Sustainable Development (IBSD), Imphal

We have to validate our own knowledge on the traditional medicines, which may be qualified or non qualified. And those validations can be based on the explorations of the traditional medicines and then development of the drugs.

Dr. Mohd. Aslam

Ex-Adviser Department of Biotechnology, Govt. of India

DBT has signed an MOU with Ministry of AYUSH for creating a pipeline of products, along with identifying material and for many other things. In this, biotech intervention can play a major role along with other ministerial departments under the program on translational research.



Dr. Ravindra Singh

Assistant Director (Chemistry), Central Council for Research in Ayurvedic Sciences (CCRAS)

A new class of drug has been introduced in India called the Phyto pharmaceutical drugs. So, these are the standardized fractions with the definite number of bioactive phytochemical compounds, which can be used as a medicine for prevention or prevention of any disease or disorder.”



Dr. Madhu Dikshit

National Chair, Translational Health Science and Technology Institute, Fardidabad

We understand that the public acceptability is the key for any drug and we know that there is a high acceptance for the herbal medicines all over the world.

State Focus: Biotech Clusters

THE GREAT STATE OPPORTUNITY IN BIOTECH

Each state highlighted their projects to the entire international community to bring in foreign direct investments. More than 20 states and union territories have come up with their own biotechnology policies, which will boost the growth of biotech sector

Leveraging India's ever-growing Biotechnology sector, the State focused Biotech Cluster session brought forth a special segment on 'Opportunities and Incentives provided by State Governments' in India. This session presented an opportunity for companies to understand extant and upcoming policies, incentive packages, industrial clusters, regulatory ecosystem, research & development opportunities, and other details, which are imperative to their investment decisions.

There was representation from at least four states to showcase their strengths in the growing opportunities in the biotech sector. The session reflected all the good work that the states are doing, like promoting ease of doing business, bringing out biotech state policies, bringing out policy frameworks

that can help get the regulations in place, single window clearances and incentivization the sector.

The experts said that to facilitate the biotech ecosystem, while the central government is bringing in next layer of incubation system, that is technology clusters, to help companies and younger startups with access to common facilities, these parks are created in the states would propel their growth.

Each state highlighted their projects to the entire international community to bring in foreign direct investments, as well as large enterprises in India to converge and scale.

The session helped the companies to understand the upcoming policies, incentive packages, industrial clusters, research and development opportunities and other details which are imperative to investment decision by companies.

NEXT STEPS

- More than 20 states and union territories have come up with their own biotechnology policies, which will boost the growth of biotech sector
- Odisha is setting up a Biotech Park and a center of excellence in marine biotechnology to boost the bioeconomy of the country
- Karnataka is also coming up with the Bengaluru Biotechnologies Park and a Life Sciences Park, which is going to come up at a cost of Rs 5000 crores
- Telengana has got itself positioned as the vaccine capital of the world and more than 800 Life Sciences companies have planned investments into this space
- In Punjab too the Plant Life Sciences Park at the Knowledge City in Mohali is another initiative which will go a long way in strengthening the Indian biotech sector



Mr. Dushyant Thakor

Vice President,
Invest India

The National Single Window System that will be coming up in few months will really transform the journey for investors. Also, the National Land Bank, whose integration has been done with the Industrial Information System will make the journey very easy for an investor.



Mr. Adrián GUTIÉRREZ

Science & Technology
Counsellor, Embassy of
Spain, Representative
of CDTI | India, South
& Southeast Asia |
Overseas Network
Govt. of India

In terms of size, our companies are pretty small. More than 65% of all biotech companies are micro or SMEs, meaning that they have less than 10 employees. Spain boasts a good network of buyer regions scattered across the country, each of them with its own areas of specialization.

Mr. Jayesh Ranjan

Principal Secretary, IT, Electronics & Industries, Government of Telangana

Telangana is one of the top ranking states in terms of ease of doing business. But most importantly, it is hopefully India's first and largest biotech manufacturing and R&D cluster, which is called the genome bank.



Mr. Santosh Kumar Sarangi

Principal Sec., Dept. of Science & Technology, Odisha



Odisha has been doing pretty well in the ease of doing business as well as in the innovation index. We have more than 150 biotechnology companies as on date, who are operating in Odisha in the areas of bioagri, bioindustry, biopharma and a whole range of R&D units.

If you're looking for an ideal congenial ecosystem, to develop your ideas, and to establish yourselves in Europe, France is an ideal destination for you. Because

France provides several opportunities and initiatives.



Mr. Srinivasa KAVERI

Director, CNRS
Office in India ,
Embassy of France

Country Focus For Ecosystem Connect

INTERNATIONAL CONNECT FOR STRONG ECOSYSTEM

The session saw participation from Switzerland, Netherlands, Lithuania, Sweden, Finland, UK, France, Germany and Russia.

The session provided an excellent forum to participant to get insights into the best practices, activities, initiatives, achievements of the partner country's Biotechnology sector. It paved the way for attracting joint ventures and collaborations between enterprises from India and other countries.

The session saw participation from Switzerland, Netherlands, Lithuania, Sweden, Finland, UK, France, Germany and Russia.

The discussions and presentations were mainly focused on:

- Emerging trends, infrastructure, R&D spending and international collaborations
- How investment in education fosters innovation
- Collaboration opportunities

The experts said that the COVID pandemic has truly underlined the importance of the role of life sciences, both in our daily lives and for the global economy. They also added that the world is moving into a new era of precision medicine that will hopefully enable both prevention and build on sustainability globally.

NEXT STEPS

- Precision medicine will be a game changer driven by data and this calls for new modes for collaboration from thriving ecosystems
- It is imperative that going forward we fully utilize the infrastructures and the collaborative ecosystems to speedily build new knowledge and share it globally
- Early stage funding can really be amplified by subsequent grants and private equity funding as well
- Investing in science research and innovation that will deliver both economic growth and societal benefits



Mr. Bhargav Kotadia

MD, Sahajanand Medical Technologies Private Limited

India has some phenomenal institutes and research institutes. But still, when we compare the kind of collaborations our counterparts in Europe have, I think there's a big scope of improvement here.

Ms. Annapurna Das

Country Head, Sanofi Pasteur



We need much more accelerated review and approvals of our vaccines or biologics coming from the rest of the world to India and vice versa, to make India the biologics or biotech manufacturing hub.



Mr. Suresh Vazirani

Chairman & Managing Director, Transasia-Erba Group

Every penny spent on prevention is worth at least 100 pennies you will spent on cure.



Dr. S.S. Jadhav

Serum Institute India Limited

Our capability of supplying almost more than 2 billion vaccine doses globally every year, covering more than 170 countries and 70% infant population every year, is the testimony of the confidence that the other world leaders had in the vaccine manufacturers of India

Mr. David Golding

Head of Global Innovation Partnership, UKRI Innovate UK

For startups, we have a very thriving startup scene in the UK. In the ranking of the Global Startup ecosystem Silicon Valley is still in first place. But New York and London are now joint second. But I think it's worth saying that it isn't just about London, the startup ecosystem has strengthened across Cambridge, Oxford, Manchester, and Edinburgh, to name but a few.

Session on Diagnostic

A BIG SUCCESS STORY

During the past one year, several new indigenous in vitro diagnostics test for COVID-19 detections have been launched successfully

On one side, COVID-19 presented a mammoth challenge to us in the form of mortality and morbidity, while on the other hand, it made three long standing desiderables of the Indian diagnostics ecosystem come through in a single stroke: convergence and collaboration between industry and academia for space development; commercialization of innovative AI with the products; and an unparalleled support and guidance from the regulatory machinery of the country.

During the past one year, several new indigenous in vitro diagnostics test for COVID-19 detections have been launched successfully ranging from those based on RT PCR immunochromatographic Eliza and the CRISPR technologies. The Indian IVD market

is estimated to have recorded a year on year growth of more than 30% during the calendar year 2020, which is close to double the rate at which the industry has grown in the past decade.

During the first half of 2020, COVID-19 related products added close to Rs 3400 crores to the market size. During the second half of 2020, the number of tests being performed per day increased rapidly to reach 10 to 11 lakh tests per day. As a consequence, the second half of the year is estimated to have added nearly Rs 3,900 crores to the IVD market taking the size of COVID-19 related products to a total of Rs 7,300 crores during the year 2020.

The session on Diagnostics was held to celebrate this huge success story and to carry forward the lessons learnt during the pandemic.

NEXT STEPS

- No crisis should go waste and key learnings must be imbibed and retained. The task before the Indian diagnostics ecosystem is not to let the ball drop in the year 2021 and thereafter
- India needs to put more power behind the industry-academia collaborations
- Steps should be taken to accelerate innovation and indigenisation
- Government needs to keep the regulatory pathway agile to position the Indian IVD industry on a path to stable and robust growth
- DBT in collaboration with National Biopharma Mission has established a COVID-19 Research Consortium to facilitate the holistic development of diagnostic ecosystem across the country



Prof. G. Padmanaban

Former Director, IISc & Senior Science Innovation Adviser

We need to have a series of workshops between potential entrepreneurs who are seeking ideas, with established investigators, who didn't get into translation, and would be very happy to share their ideas. There are many fine patrons, but we all know that hardly 2% of the patrons get exploited.

Dr. Maurice Moloney

Founder and Managing Partner, Agritecknowledge LLC, Spain

Throughout this pandemic, the agriculture and food system has delivered spectacularly. We have not seen any degradation in the food supply or the quality of food during this very traumatic period. And I've got to say, in part that is attributable to agricultural biotech.



Mr. Anand Anandkumar

Bugworks



Access to pathogens in India is fantastic compared to my peers in Boston, or the Bay Area.

Prof. Neena Mitter

Director, QAAFI Centre for Horticultural Science
Director, ARC Research Hub for Sustainable Crop Protection



When I think of agriculture, really in the last few years, including the pandemic, have changed the way we think about weather, growing, producing, harvesting, distributing, consuming food and fiber. All those definitions have taken a little bit of a new nuance and meaning.

When you look at the biotech sector today, one thing which is very obvious is the large number of very talented entrepreneurs. I think there's no doubt when you look at talent and skill, we have really excellent people in the

country. And that's reflected in the large number of startups.



Prof. Rishikesh T. Krishnan

Director, IIM-Bangalore

Blue Economy

BLUE ECONOMY-A BIG OPPORTUNITY

The session discussed feasible strategies to support innovative technological interventions to tackle problems associated with NTDs and AMR

The sea is undoubtedly a treasure of assets for humankind. As the world population is increasing, so are the demands and the needs, and there may be a time when land alone will not be able to provide us optimal resources. Turning to the ocean is surely indispensable. Oceans could be of crucial importance in ensuring food security, health security and energy security.

India being surrounded by this resource has an immense opportunity of exploring this resource. Blue economy or marine biotechnology as we know it, is focused on research and development of technological applications of living marine organisms and their derivative. It also encompasses the protection that is needed for the marine environment for future generations.

The session on Blue Economy focused mainly on:

- Potential the development of blue economy holds for our country

- Initiatives in the form of Department of Biotechnology run programs with strong linkages
- Discussions and dialogues with focus on technological development in the area of aquaculture and marine biotechnology
- Exploration of ways for coastal area prosperity
- Sustainability of marine ecosystems
- Ways to exploit lagoons, mangrove forests, and seagrass beds, which are potential biological resources
- How rapid urbanization is creating a lot of conflicts with the natural resources leading to loss of flora and fauna
- Science and technology interventions to save bio diversity of mangrove forest areas
- Using biotechnological options for developing transgenic plants

NEXT STEPS

- Although the Indian coastline accounts for 80% of the world's mangrove areas, it comprises about 40% of the species which are reported globally. It means we are facing a rapid loss of species in the last 25 years. This needs to be changed.
- Salt concentration available in the coastal ecosystem can be utilized for saline agriculture to grow productive species
- A bacteria from the coral reef systems of Andaman Nicobar Islands has been identified and patented for developing livestock vaccines. It is ready for next stage of commercialization
- Seaweeds is another useful resource that is available in the coastal areas of India and can be utilised as a dietary supplement



Dr. Nivedita Gupta

Head Virology UNIT, Indian Council of Medical Research, New Delhi

There were some of the activities which ICMR found pretty challenging, and going for multi-stakeholder engagement DBT could bring in all the indigenous manufacturers to start manufacturing commodities in India. And this journey has been exemplary. There has been no looking back.

Dr. Alka Sharma

Adviser/Scientist 'G', Department of Biotechnology

First indigenous kit for diagnosis of COVID-19 has been developed with support from BIRAC. we have also established purchase method where we have shared facilities to manufacture a large number of diagnostic case. A fully indigenous antibody antigen detection kit is in the market, as also an antibody and antigen detection kit.



Mr. Navin Khanna

ICGEB

Indian scientists are very good in romanticizing science. But we don't know the crystallization of science, which means that we do science for the sake of science, and never make money out of science.

Dr. Madhur Gupta

WHO

WHO has been engaged in the last many months now in coordinating a global research effort to develop diagnostic tests through the WHO emergency use listing process, not only for diagnostics, but also therapeutics and vaccines.

Ensuring Quality

OVERCOMING CAR-T CELLS CMC CHALLENGES

CAR-T cell therapies despite showing promising results in clinical settings, requires robustness, scalability, and standardization of the manufacturing processes, to reduce costs and establish safety and efficacy

Biopharma is evolving at each stage. It was initially purified protein, then more complex monoclonal antibodies, and today it is having more complicated advanced therapies. The CAR-T cell therapy is an emerging treatment for several types of cancers. In CAR-T cell therapy, the patient's own T cells are modified to make them attack cancer cells or any other specified target. However, CAR-T cell therapies despite showing promising results in clinical settings, requires robustness, scalability, and standardization of the manufacturing processes, to reduce costs and establish safety and efficacy. Key considerations for ensuring manufacturing consistency and quality in product development are control of the quality of raw material components

and control of procedures and analytical methods to reduce the nonbiological sources of variability.

The session focused on overcoming quality challenges in CAR-T cell technology highlighted:

- how to bring this expensive technology to our country
- what government of India has done so far in CAR-T cell technology, especially the Department of Biotechnology
- the approach to develop an affordable CAR-T cell technology in India
- novel approaches to increase safety and specificity of the treatment
- good manufacturing practices, etc

NEXT STEPS

- There is a need to make CAR-T cell affordable for most patients in India keeping in view the potential therapeutic applications of this technology
- An initiative has been taken by DBT to develop CAR-T cell technology at an affordable price in the country
- Need to address some side effects that have been reported, such as cytokine release syndrome and non specific toxicity.
- Address the issues of lack of availability of clinical grade vectors and also difficulty in expansion and scaling of DNA of immune cells
- indigenous method for large scale manufacturing of CAR-T cells needs to be developed since it is a major bottleneck in implementation



Dr. Uday Bhaskar

Scientist F, Indian National Centre for Ocean Information Services, Hyderabad

We have a mission to provide data, information and advisory services to the society, industry, government and scientific community through sustained ocean observations, focused research, information management and ocean modeling.



Dr. G. Dharani

Scientist F, National Institute of Ocean Technology, Chennai

There are classes of natural compounds coming from marine systems are antibacterial, antifungal, antiviral, anti-cancer, and anti-diabetic.

Dr. Ajay Parida

Director, Institute of Life Sciences, Bhubneshwar

In the Indian context, the coastal ecosystem is a major system. India has 7,500 kilometer-long coastline that includes two islands, then we have 200 nautical miles of exclusivity. There is a link between land and the diverse marine ecosystem with estuaries and coral reefs.



Dr. Shilpi Gupta

BIRAC

Initiatives have been taken by DBT to establish the state of art for marine biology and biotechnology for exploring ocean resources towards the efforts for harvesting the blue economy.



Ms. Taranjeet Kaur

Manager, Entrepreneurship Development, BIRAC

BIG is one of a kind opportunity available to individual entrepreneurs and early stage startups for funding high risk innovative ideas. It has been one of the most significant stimulants for the entrepreneurship. It has empowered several aspirational entrepreneurs to pursue early proof of concept and embark on the startup journey.

Agritech Conclave

AGRITECH FOR A SUSTAINABLE FUTURE

A recent report has projected a market potential of \$24 billion for Agri-tech by 2025. But the impact of agri tech at the farmers' level is not as pronounced as one would like to see

Agriculture plays a pivotal role in India's economy by contributing around 16% towards country's GDP. And the current financial year, India's food grain production is estimated to reach to an all time high of more than 300 million tons. While much of this increase in production can be attributed to the hard work of our farmers, research undertaken by the agricultural scientists and farmer friendly initiatives of the government, agri tech startups in their own small way have contributed in this effort by addressing various challenges across the spectrum of agriculture value chain.

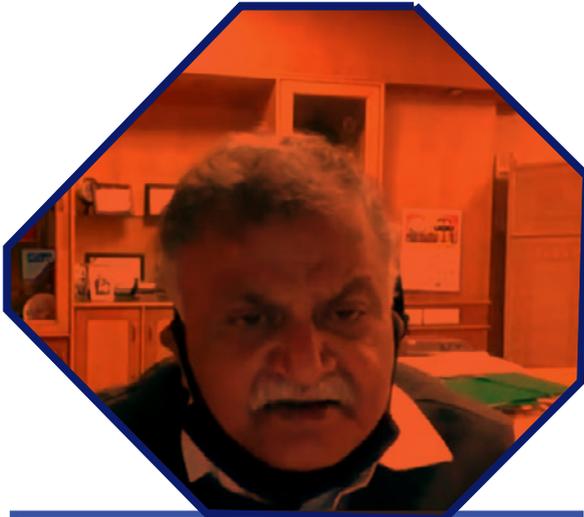
A recent report has projected a market potential of \$24 billion for Agri-tech by 2025. While government is making every possible effort to promote entrepreneurship and

agricultural sector to produce a policies, setting a regulatory focus incubators and accelerators and providing required financial, IP and regulatory support for product and technology development, right from idea generation to commercialization, the impact of agri tech at the farmers level is not as pronounced as one would like to see.

The session focused on all these issues provided an overview of plans to link up with initiatives in the agricultural sector. The panel discussions with agri tech start-up ecosystem leaders and stakeholders were held to help understand how Kissan Hub and Agri Biotech Clusters can be leveraged to further the growth of agribusiness-based start-ups and SMEs in the country that can better address the needs of our farmers for Atmanirbhar Bharat Abhiyaan.

NEXT STEPS

- There is a need to resolve the major challenges of testing and validation of product and technologies confronted by startups in agri-tech
- In view of the problem often experienced by the agritech startup in scaling up of their innovations. To address the issue of scaling and catalyzing the commercialization process, DBT has proposed to come up with a nationwide network of agri biotech clusters
- The government needs to intervene to reduce the time it takes to commercialize technologies
- Also, there are gaps in technology transfer and application and lack of access to facilities that are very critical to startups and small and medium enterprises
- The sector needs to go beyond the proof of concept stage to technology refinement
- Having access to manufacturing hubs, marketing, and regulatory compliance are some of the issues that the government needs to look into



Dr. Guruprasad Mohapatra

Secretary, Department for Promotion of Industry and Internal Trade (DPIIT)

The Indian biotech sector is not only raising the health profile of the country, but also raising the investment opportunities in the country.



Mr. Rajiv Nath

Forum Coordinator, AIMED, Managing Director, Hindustan Syringes & Medical Devices Ltd

I feel that the policy makers can definitely help the entrepreneurs in the area of creating templates of agreements. The templates will help entrepreneurs in terms of negotiating with an academic institution or with a industry, which will help them conclude agreements rapidly.

Dr. Naveen Nischal

Co-founder, Meddo | Cygnus | Voice of Healthcare

Although NABH is a quality benchmark, there are a lot of hospitals which are not NABH accredited. But they are good and provide good quality services.



Dr. Manish Diwan

Head, Strategic Partnership and Entrepreneurship Development, BIRAC



There is a longevity as well as sustainability of the operations if you become successful. And that is what sets the biotech sector apart from the rest of the sectors.

We've been trying to look at new ways of supporting startups across sectors. From a very small initiation in January 2016, today we have startups coming

from each state and each union territory of the country.



Mr. Anil Aggarawal

Joint Secretary, DPIIT

AMR & Neglected Diseases

A NEW BEGINNING

The session discussed feasible strategies to support innovative technological interventions to tackle problems associated with NTDs and AMR

Considering AMR as a National priority under the National Action Plan endorsed by the Government of India, the Department of Biotechnology (DBT) has initiated a major Mission on Antimicrobial Resistance. As envisioned under this Mission, the Department in collaboration with the WHO Country Office for India has developed the AMR-specific Indian Pathogen Priority List (IPPL), which will help in prioritizing the research and innovation needed to target AMR pathogens according to national as well as international needs.

The session discussed feasible strategies to support innovative technological interventions to tackle problems associated with Neglected Tropical Diseases (NTDs), Antimicrobial Resistance (AMR), and other infectious diseases in India.

The discussions during the session focused on:

- The regulatory landscape, which plays an important role for innovation of new therapeutics and tackle the problems of AMR and neglected tropical disease
- Ways to streamline the processes through regulatory provisions, regulatory interventions in terms of amendments, and also in terms of preparing guidelines on regulatory pathways and continuous engagement with the stakeholders
- Improving transparency, accountability and also predictability
- Timelines for disposal of applications for clinical trials and approval of new drugs
- How to accelerate approval of a new drug considering the serious life threatening diseases

NEXT STEPS

- New Drugs Clinical Trial Rules, published by the Government of India in March 2019, enables the developer to develop new therapeutics
- The timeline for approval of any clinical trials is 30 days and if no reply is received from the regulators within 30 days, then it will be considered deemed approved
- The biggest challenge for an innovator in India is to create global clinical trial networks for AMR that needs to be addressed
- There is a need to focus on antimicrobial resistance, which is a slow-moving silent global pandemic. It is a global health and development threat causing an estimated 10 million deaths per year and will have \$100 trillion impact on the global economy by 2050



Ms. Gauri Singh

Dy Director General,
IRENA

It's important that policymakers in energy and health have conversation because otherwise we work in silos. When you're in health, you think of only Health Solutions and when you're in energy you think of energy solutions only.



Prof Ambuj Sagar
IIT Delhi

As one thinks about the design of any program for public good, one has to be very clear on what the objectives are. There's an enormous set of synergies between energy and health and we need to be thoughtful in our approach.

Mr. Shashi Shekhar

Ex-Secretary,
Ministry of Water Resources,
Current PSA Fellow

The relationship between air pollution and premature mortality and a number of other diseases is getting established particularly in India. A 2017 Lancet study estimates about 1.24 million deaths in India can be attributed to air pollution.



Mr. Sunil Thakur

Partner,
Quadria Capital

"There are quite a few startups that are working on regenerative medicine and they are attracting the attention of investors."



Dr. Alexander Melerzanov

MD, PhD, Deputy Director for Post diploma Education and International affairs, MIPT Moscow, Russia

We have created a system startups that allows them to reach different scientists. We also established two national level centers for artificial intelligence and genomics. And using this, we get all our students, together with mentors from the industry who have reached a very high level of product development. And this way, we are trying to reach the goals of creating new medicines, new agricultural products, and new medical devices, and so on and so forth.

Early Stage Success Stories

BIG LEAP TO THE FUTURE

Biotech Ignition Grant provides a funding support of Rs 50 lakhs for a period of 18 months as grant. It infuses several efforts from creating awareness about the scheme, access to specialized infrastructure, technical and business mentorship, to regulatory guidance platform to showcase networking events to get connected with different stakeholders

Biotech Ignition Grant (BIG) launched by DBT/BIRAC in 2012 is one of the rare opportunities available to individual entrepreneurs and early stage start-ups for funding risky innovative ideas. BIG has revolutionized the landscape of early stage funding in biotech sector by supporting 550+ innovative ideas. Many of these have reached the market and have created intellectual wealth, raised investments, won national and international awards & accolades.

The session discussed the successful case studies of few early stage start-ups supported through BIG and deliberated on the current challenges faced by them. Experts gave their perspective on the strengths and weaknesses

of the ecosystem to help it move quickly to the next level.

The highlights of the session were:

- Details of schemes for various groups of researchers and entrepreneurs
- How to work out the logistics to connect potential entrepreneurs with established investigators
- How to integrate subject matter specialists in a project team when developing solutions using newer technologies like AI, IoT, and 3d printing
- Help young entrepreneurs to have a way out in terms of licensing the idea to some big player after phase one, or proof of concept stage

NEXT STEPS

- We need to find why startups in biotech sector are getting stuck at pre commercialization stage, or sometimes even at the pilot stage
- Government and supportive agencies need to make regulatory processes smoother and easier to navigate for startups
- The challenge of creating a sufficiently strong Manufacturing infrastructure which can work with talented startups to take their products to market needs to be tackled on an urgent basis
- Clusters could be built around some of the existing incubators and accelerators who can work with startups
- There is a regional skew with lot of concentration of the startups around large cities. This needs to be changed.



Prof. Melanie J Welham

Executive Chair, BBSRC, UKRI Engineering Biology

Biology is really about how we push back the frontiers of knowledge and how we can then use that knowledge to create a healthy, prosperous and sustainable future.

Mr. Neeraj Jain

Country Director, PATH

There are about 56% health facilities in India which don't have regular supply of electricity. So, there's a challenge of energy being available at health centers. I'd put anganwadis and health centers together because actually both of them are providing health.



Dr. Sangita Kasture

Scientist 'F', Department of Biotechnology, Govt of India



The energy efficient technologies for communities and health facilities can bridge the gap between clean energy sector and health sector.

Prof. Ajay Pillarisetti

Department of Environmental Health, Emory University



We've seen this massive transition towards LPG in India. Now that we've provided that access, which is a critical first step in getting people connected to a clean energy source, the next thing to do is how do we get people to actually use the LPG and to transition to it fully like any other improved cooking technology.

We fully understand the importance of development of new anti-microbials antibiotics, and also the drugs which are actually specific for neglected disease.



And considering that we are, you know, taking all measures from a regulatory point of view.

Mr. A.K. Pradhan

Deputy Drugs Controller of India

Enhancing Capacities in MedTech Ecosystem

TO SPEARHEAD THE NATIONAL BIOPHARMA MISSION

The session was a congregation of the representatives of facilities that have been supported under the National Biopharma Mission. It is a mission programme of the Department of Biotechnology with the support of the World Bank for a \$250 million grant over a five year period

The discussions during this session focused on perspectives of speakers representing the funded facilities to provide relevant information and details about the capabilities of the facility. A panel discussion attended by researchers, start-ups and large companies that are developing novel medical devices; technical experts and other medical devices industry stakeholders, was also organised as part of the session, wherein experts discussed the possible gaps in the medical device industry and the

solutions provided by the facilities to address those specific gaps.

Highlighting the achievements of the Department of Biotechnology, Dr. Kalaivani Ganesan, said that DBT has laid a robust foundation for the medtech ecosystem in the country. "The sector is import driven and dominated by multinational players. In the year 2008, DBT wanted to promote the indigenous medtech innovators and entrepreneurs. So it launched the National Bio Design program. Today, we have 200 entrepreneurs trained and more than 50 products developed and about 20 successful startups formed through this initiative."

NEXT STEPS

- India has to now accelerate developing indigenous novel affordable devices which are suitable for our own population, and our requirements
- It's high time for the medtech industry to become a global player in the same way as India built its pharma industry, and the vaccine industry

THE IIT KANPUR HOUSES THE FOURTH METRIC FACILITY FOR PROTOTYPING. THIS LAB SPECIALIZES IN DEVELOPMENT OF MEDICAL DEVICES RELATED TO HOSPITAL EQUIPMENT, GUIDANCE SYSTEMS FOR THE BLIND

She added that another landmark initiative of the department is the promotion of indigenous manufacturing, for which DBT supported establishment of a critical component research center, which is known as the Kalam Institute of Health Technology. “Today, it stands as a classic example of a successful medtech venture in the country,” Dr. Ganesan said.

Among the metric facility supported under NBN, the first of the full prototyping facilities is at Bangalore, which specializes in different areas of micro fluidics related medical devices. They provide services such as designing of devices, photo lithography, PDMS, fabrication, 3d printing, etc. Another lab located at Aurangabad has established a prototyping facility that provides services such as 3d printing, CNC, etc, primarily working in the areas of electronics based medical devices and wearable medical devices.

The NFL technology incubator located at Mangalore houses the metric design and rapid prototyping facilities and they provide different kinds of services such as PCB prototyping, rapid prototyping, using 3d printing and also bio printing specifically related in the area of dental applications.

The IIT Kanpur houses the fourth metric facility for prototyping. This lab specializes in development of medical devices related to hospital equipment, guidance systems for the blind, etc.

Prof. B. Ravi of BETiC Lab, IIT Bombay, who was the moderator of the panel discussion, said that it was high time for India to become self-dependent in medtech, as well as show some of our neighbouring countries the path for affordable health care. “The devices that we import today are worth Rs. 50,000 crores and almost 80% of them are imported from Western countries. These are highly expensive devices and are not affordable for the general public. So, there’s no doubt in our minds that India has to now accelerate developing indigenous novel affordable devices which are suitable for our own population, and our requirements,” he added.

Dr. V. Premnath of Venture Center, Pune, said that it’s high time for the medtech industry to become a global player in the same way as India built its pharma industry, and the vaccine industry. “We have the great potential to be a global player in the same way as our generic pharma and our vaccine manufacturing industries. In the med tech space, I also hope our entrepreneurs and innovators try to lead the way in terms of innovative products, which basically have global standing. These kinds of facilities are going to be the key for that, because facilities such as these are actually in many ways meant to reduce your cost of development, your risk taking ability, and therefore encourage a lot more innovative activity.

Talking about the IIT Kanpur medtech facility, Prof. J. Ramkumar of IIT Kanpur, said that their prime focus is only on non-invasive prototyping facility. “We are moving towards getting ISO 34 485 certificate. IIT Kanpur has three strong points--one is the faculty member, two is the students, and the third is the startup ecosystem. Depending upon the requirements of the startup company, we try to map and attach them with a faculty member and students who help in improving the prototype. The startup ecosystem tries to guide the students for all the other facilities,” he said.

Prof. Ramkumar also added that they try to handhold the startup company right from the virtual stage. “We try to work along with them, try to improvise their product, try to do optimization simulation and then try to take it forward for prototyping. We also help them in doing reverse engineering of the existing part of whatever is available in the market and try to identify the differences they can make so that the product will be unique,” he said.

Prof. Akhter Hussein, Dean of dental college at Yenepoyya University, Mangalore, said, “Mangalore is a very beautiful small coastal city, which is a hub of education with a large number of medical, dental and engineering colleges. Hence, we have an opportunity to cater to these institutions. We have been primarily inspiring our students or post graduates and staff to periodically conduct talks in creativity and lateral thinking leading to innovations. We have 50 patents to our credit and quite a few are in the pipeline. We aim to translate ideas into innovations and products which can reach the market to solve the healthcare problems. Some of the projects that we have completed so far are novel physiotherapy and rehabilitation equipment, oral hygiene appliances, animal surgical table, modular dental trays, and infusion models, etc.”

He added that the facilities offered by the university include industrial product design, 3d modeling and simulation facility equipped with advanced 3d scanner and high end computing, among others.

Dr. Feroz Mustafa from Center for Cellular and Molecular Platforms said that his Bangalore

THE RAPID PROTOTYPING FACILITY ESTABLISHED IN GOREGAON COMES WITH THE ADVANTAGE OF A COMPLETE ACADEMIC ENVIRONMENT ALONG WITH THE RICH INDUSTRIAL EXPERIENCE. SO, WORKING WITH US WILL IMPROVE YOUR TIME TO MARKET AND THE DEVELOPMENT IS DONE AT APPROPRIATE COST

facility is an incubation center which has been working in the area of biotech. “We are aiming to set up a one stop solution from design to pilot scale fabrication of plastic microfluidic diagnostic devices,” he added.

“Micro fluidics is basically using very small volumes of fluids, typically nano data to microliter, or sometimes even lower quantities in channels, which are about 10 to hundreds of microns and bits to make measurements. So this has a lot of advantage like you can make devices with small flow footprints, you use low volumes of samples and reagents, and the analysis times are faster. You can also miniaturize laboratory based procedures and this is especially useful for diagnostic,” he further informed.

Mr. Vishwas Kurundkar, Netra Accelerator Foundation, Maharashtra, said that the Rapid Prototyping facility established in Goregaon is an industry-academia partnership and comes with an industry segment which is an academic institute.

“We are offering services to startups, entrepreneurs and researchers to create a rapid prototyping facility as per their design. Our facility comes with the advantage of a complete academic environment along with the rich industrial experience. So, working with us will improve your time to market and the development is done at appropriate cost,” he added.

INDIA HAS TO NOW ACCELERATE DEVELOPING INDIGENIOUS, NOVEL AFFORDABLE DEVICES. IT'S HIGH TIME FOR THE MEDTECH INDUSTRY TO BECOME A GLOBAL PLAYER IN THE SAME WAY AS INDIA BUILT ITS PHARMA INDUSTRY, AND THE VACCINE INDUSTRY

According to Dr. Jaleel Akhtar, who heads the EMI EMC test facility at IIT Kanpur, his facility specializes in the automatic sign and components. "This project is about developing a facility for EMI testing of metadata. As per international regulatory requirement, you are not allowed to sell any product in the market, including medical devices, unless you conform to EMI EMC testing as per ISO standards. A lot of startups coming up with new medical devices are not aware about this fact. So they think, once you are done with the prototype, that's fine. But that's only the beginning," he said.

He also added that most of the medical devices are electronic products, and are high speed digital devices. "As a thumb rule, any digital device having high clock frequency will give emissions and the emission goes higher and higher as the clock frequency goes up. That's why it's very vital to check the emission of these devices, as not doing so can be fatal to a person's health, especially in a hospital environment," Dr. Akhtar said.

Mr. Milind Joshi, Scientist F at SAMEER–Mumbai, said that his institute is working in the field of electro magnetics, EMI EMC testing for more than 20 to 25 years. "Ours is a premier research organization under the Ministry of Information Technology working in the field of RF micro EMI, EMC, linear accelerator and photonics. Sameer happens to be amongst the first few organizations that started working in the field of EMI EMC compliance testing. We started our test activities way back in 1984 and later expanded them to Mumbai, Kolkata, Vishakhapatnam and intend to expand to few other cities as well," he added.

Dr. Ramamoorthy from Palamur Bioscience Pvt. Ltd. said that his is a biological testing laboratory located near the Hyderabad Airport. "We are basically undertaking animal testing studies, toxicology studies, safety assessment and exploratory Studies. We are also undertaking some basic research studies by using various range of animals. We have been approved by the Government of India for production of Beagle dogs, farm pigs, goats and sheep, etc," he said.

Building Capacities for Future India

BUILDING CAPACITIES FOR FUTURE

This session highlighted the existing initiatives geared towards capacity building and drew recommendations for building India as the global bio manufacturing hub

Various ministries and agencies of the government has built an ecosystem that currently nurtures more than 3,000 startups in biotechnology. With a target to reach \$150bn by 2025, the ecosystem could be expanded to support 10,000 startups by 2025. This session highlighted the existing initiatives geared towards capacity building and drew recommendations for building India as the global bio manufacturing hub in the near future.

The session also saw e-inauguration of three facilities under National Biopharma Mission.

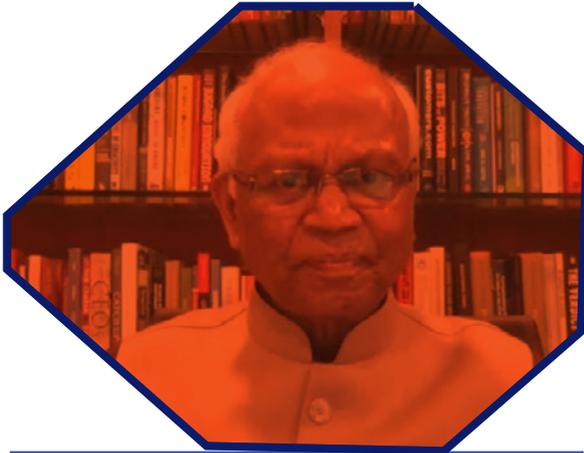
The experts focused on:

- The important role of DBT in building capacities across the country for early or late translational research
- Ensuring industrial development through various schemes and programs

- Partnerships between the DBT and various state governments to establish biotech parks and other necessary support infrastructure
- Finding ways to nurture innovation from ideation to commercialization
- How to facilitate individual researchers at undergraduate level as well as large companies through various funding mechanisms
- Ways to mobilize private equity into this challenging sector
- The role of skill development through dedicated high end skill development facilities like technical workshops, evangelization workshop, business strategy, the go to market strategy, and development strategy at various stages of development
- The importance of building capacity to innovate in times of crisis

NEXT STEPS

- COVID era has set the benchmarks of being competitive without compromising on the global standard, which will be shift in whatever work or whatever offerings we are going to make in the near future
- Cutting across various tech domains, our startups have started hitting upon the problems both from the societal as well as those faced by industries at large. This needs to be further supported
- Young students need to be aware of the role that Sustainable Development Goals play in the future of technology and innovation
- We have only 13% women entrepreneurs in our country. We need to ensure that we have at least 50% women entrepreneurs in our country
- We have a demographic dividend and technology. Now we need to ensure that we bring these benefits to a fast growing economy



Dr. R A Mashelkar

**National Research Professor
and
Former DG-CSIR**

I think the time for incremental change is gone. We require transformational change. For example, the Jan DhanYojna was drastic policy reforms that brought in financial inclusion for crores of people in India who did not have a bank account before.

Ms. Anat Bernstein-Reich

**Managing Director, A&G Partners,
Israel**

When a scientist works in an Israeli lab, immediately it is converted into a patent. The thought is how we can commercialize it. And then the scientist take it from the lab bench to the Science Park next to his institute and start his startup based on research done in the academia. This is the sort of ecosystem that allows entrepreneurship in general, but also women entrepreneurs, to take their lab research and commercialize it.”



**Ms. Agnė
Vaitkevičienė**

**Vice President,
Lithuanian Biotechnology
Association, Lithuania**

There are women leaders that could show and be a role model for other young scientists and entrepreneurs who seek their ideas to be brave. So we started this platform with inspirational speakers, to present their stories, and we will follow it with a mentorship program as well. We have very few women leaders in our small country of Lithuania. So, we really want to make it an international program for women to get more motivation and inspiration.

Our vision is really to make sure that infections are treatable for everyone, everywhere. The emphasis is really on ensuring that the treatments we develop are accessible. I think this is extremely important in the context of COVID-19, where increasingly, we see that our access to countermeasures are extremely critical in dealing with emerging infectious diseases, outbreaks and pandemics. We really need to see microbial resistance in the same light.



**Dr. Manica
Balasegaram**

**Executive Director,
GARDP**

Emerging Technologies

EMERGING TECHNOLOGIES - KEY TO A RESILIENT FUTURE

The session sought to develop understanding of integration of evolving manufacturing and analytical technologies to address user requirements for development of robust buy processes at reduced cost and increase efficiencies

Biological Science is expanding its knowledge frontiers speedily, the progressing insights into biological processes offer a broadening array of options to develop incremental and differential innovations across the medical, agricultural and industrial biotechnology sectors in pursuit to anticipated demands of emerging technologies. This session was organised to understand the technologies that would help us address the needs of tomorrow.

The Department of Biotechnology already has supporting programs in various emerging areas like genome technologies, nanotechnology, artificial intelligence system biology, alternate medicine and targeted therapeutics, stem cell research, etc. With experts from both India and abroad giving their perspectives on how India can leverage these emerging technology foilds, it was one of the most interesting and exciting sessions at Global Bio India 2021. The session sought to develop understanding of integration of evolving manufacturing and analytical technologies to address user requirements for development of robust buy processes at reduced cost and increase efficiencies.

NEXT STEPS

- New and emerging technologies have had immense impact during the COVID-19 pandemic on whether it's vaccines, or therapeutics or medical technologies. In future, we need to be prepared for developing new modalities that we have been sucessfully done in the past one year or so to build a resilient future
- Synthetic Biology is applying engineering principles to biology, thinking about designing, redesigning, and creating biological devices, systems, components and processes. It is an important technology to focus on
- Engineering biology is about realizing the potential that synthetic biology offers, but sort of encapsulates on a wider ecosystem and the capabilities that you need to really support exploitation of that knowledge to deliver societal and economic benefits. It offers real opportunities for the transformation of our future
- Discovery research continues to be really important and underpins all the new technological themes
- We need to continue to think about bio inspired design by engineered systems and cells and novel materials
- Bristol Synthetic Biology Center has developed a new technique whereby they've used synthetic biology to engineer bacteria to generate peptides. This is very different to the chemical synthesis of peptide which is normally used, it has much lower economic and environmental costs
- The Nottingham Synthetic Biology Center has brought together a consortium of partners across academia and business to successfully transform waste from carbon dioxide into animal feed protein.
- The concept of delivering peptides orally is easier to administer



Dr. Taslimarif Saiyed

**CEO and Director,
C-CAMP**

Building capacity is a way to actually be prepared for innovation to respond in times of crisis and for the betterment of society at large.



Mr. R. Ramanan

**Mission Director,
Atal Innovation Mission**

Indeed, never in the history of India, and never in the history of the world has science, technology, innovation, and entrepreneurship become center stage as of now. And it has been tremendously fulfilling to find that the Government of India had actually launched a series of innovation and entrepreneurship related building capacity for future and this has come to the fore in the present COVID-19 crisis.

Mr. Sanjeev Malhotra

CEO, CoE-IoT, Nasscom

We can expect that it will be almost mandatory by law to take a second opinion from a software whenever a doctor is diagnosing you. The amount of time the doctor has to spend with the patient is so limited that the services of software will be mandated after some time. That's the direction we are moving in.



The agri biotech sector has a lot to contribute towards the ambitious goal of \$150 billion strong Indian biotech sector. While we have seen in the past, the BT cotton has been the major output from this sector, the potential of agri biotechnology as a growth driver remains untapped. With the emergence of agri-based entrepreneurships and advancements in biotechnology, this is the right time to explore the opportunities for the sector towards catalyzing greater economic growth with a focus on sustainable agriculture measures that can benefit smallholder farmers and rural communities.



**Dr. Kiran K
Sharma**

**Chief Executive Officer,
Agribusiness & Innovation
Platform, ICRISAT
Director, CGIAR Research
Program on Grain
Legumes & Dryland
Cereals (CRP-GLDC)**

Learnings from Pandemic for Future Collaborations US-India in Bio- Pharmaceutical

FOCUS ON OPPORTUNITIES FOR US-INDIA COLLABORATION

The discussions during this session were structured in a way so as to focus on the opportunities for collaboration between Indian and the US in the important area of Bio-pharmaceutical, which has been at the forefront of the global fight against COVID

The participants in the discussions during this session included a number of innovative companies in the space of vaccines, biologicals, advanced therapies like cell and gene therapies, etc.

A top government official said, “We have learned how to tackle this pandemic with

regards to providing the diagnostic or immunological or any kind of reporting solutions in a rapid manner, while not losing the sight of the performance effectiveness, which is required. We had to increase our efforts and utilize the adaptive design model for the pilots and also work hand in hand with many regulators across the world and also internally.”

NEXT STEPS

- India needs to continue using the collaborative and adaptive design approach to overcome the challenges being posed by the COVID-19 pandemic
- Regulatory harmonization in the time of new therapeutic and vaccine development is critical when clinical trials are simultaneously launched around the world
- The underpinnings of pro-innovation policies need to remain strong, consistent and predictable
- Sound infrastructure, health financing models, robust and strong government procurement models that are inclusive of the spectrum of therapeutics and vaccines for the entire patient population are critical for fighting the COVID-19 pandemic
- There is the need for an incredibly strong, unshakeable and fully transparent disease outbreak surveillance system, not just for human diseases, but animal diseases, environmental quality and food systems, all of which are interconnected
- Some sort of government-private collaborations are needed to develop a single source of information to collect authentic and current information for incidence and prevalence rates of various diseases in India
- It is important for companies in India and in the US to make sure that there is a strategic partnership. and governments should actually enable creation of such partnerships

COVID-19 HAS TAUGHT AN IMPORTANT LESSON ON THE NEED FOR AN INCREDIBLY STRONG, UNSHAKEABLE AND TRANSPARENT DISEASE OUTBREAK SURVEILLANCE SYSTEM

He added that India could come out with an array of solutions. “In the beginning of the pandemic India did not have a single diagnostic kit in our country, but today we have more than 300 diagnostic kits in various categories. Simultaneously, when it comes to plasma and disease or even the vaccines the same model was adopted. Many products were made available not only for the Indian community but also for the global community. The experience has been extremely good, and using the collaborative and adaptive design approach has been the learning. We want to build on this and continue with this particular theme,” he said.

According to experts, COVID-19 was declared a public health emergency of international concern in January 2020, and a pandemic by the WHO in March 2020. “The COVID-19 has been a global challenge. The availability of safe and efficacious vaccines, COVID-19 diagnostic kits for early detection and therapeutics are crucial in effective management of the pandemic. So accordingly, the Department of Biotechnology along with its PSU has made concerted efforts for development of detection, treatment and prevention tools in order to facilitate development of vaccine diagnostics and drugs for COVID-19. The DCGI has developed a rapid response regulatory framework to expedite processes.”

Speaking during the interactive discussion between Govt of India and US Biopharmaceutical Industry, experts said, “Certainly lessons that we’ve learned from previous pandemics, and key principles that

form pharma and the biopharmaceutical industry are critical. We see COVID-19 continue to mutate, and we continue to see the rise of antimicrobial resistance and other threats on the horizon.”

They also pointed out that a strong health system, which includes infrastructure from the frontline workers to hospitals, to delivery systems, to pharmacies, to the entire ecosystem is also critical. “Health financing models, robust and strong government procurement models that are inclusive of the spectrum of therapeutics and vaccines for the entire patient population, are critical. As we continue to see the real burden of health crippling economies, crippling family ecosystem, those investments on the front end to mitigate the health risks are critical.”

Another expert said, “We’ve been in India proudly for more than 20 years, and today we have more than 2000 colleagues across the country at more than 40 sites. We’re serving customers who are directly responding to the pandemic. Most notably, we just announced the first made in India COVID test last week, which we were making in Bengaluru. The Serum Institute is a long time customer, we are really proud of the work that they’re doing on behalf of Indians and the whole world.”

They added that the disease has taught an important lesson that there is really the need for an incredibly strong, unshakeable and fully transparent disease outbreak surveillance system, not just for human diseases, but animal diseases, environmental quality and food systems, all of which are interconnected.

Regulation and Policies for Global Convergence

HARMONIZING THE CURRENT GLOBAL REGULATORY PRACTICES

This session was focused on discussing the possible ways of harmonizing the current regulatory practices of different countries, which was one of the key objectives of Global Bio India 2021

“The basic premises for the approval of drugs are safety, quality and efficacy. The process of drug approval globally is based on the data obtained through scientific experiments designed to ensure safety, quality and efficacy of pharmaceuticals. The session seeks to find ways to have a harmonized approval procedure globally,” said Dr. Nitin Jain, Scientist-F, Department of Biotechnology, Gol.

The session was divided into three parts. Starting with introduction of the Indian regulatory systems, and challenges faced by the biopharmaceutical industry in the thermal process, the second part saw discussions on enhancing the regulatory facilitation for global convergence. Lastly, there was an open house discussion to seek answers for questions like how can we announce the regulatory facilitation? And are there any policy changes that have occurred for harmonization and convergence?

NEXT STEPS

- There are few areas like preclinical studies where we need to look at challenges more deeply
- There is the need to rethink the issue of animal studies as in advanced market it has been accepted that it is extremely difficult or next to impossible to extrapolate the immune responses to the human system
- With the dynamics changing in the global regulatory system, Indian biopharmaceutical industry currently has to formulate different regulatory strategies
- It is time that India now moved from animal toxicology studies and replace it with in vitro studies for at least well-established products
- There is an imminent need to have a mutual convergence with a lot of countries, especially in the emerging markets. So the best way out is to find a mutual recognition trade treaty
- There is still scope for improvement in Biosimilar guidelines, which were last update in 2016
- The post approval change guidelines for Biologics, which are also applicable to biosimilars and were issued in 2010, require updation
- Time lines on the CDC portal need to be defined for approval of applications which have to be done physically. For example, post-approval changes

THERE IS AN IMMINENT NEED TO HAVE A MUTUAL CONVERGENCE WITH A LOT OF COUNTRIES, ESPECIALLY IN THE EMERGING MARKETS. THE BEST WAY OUT IS TO FIND A MUTUAL RECOGNITION TRADE TREATY

Introducing the Indian regulatory system, Dr. V.G. Somani, Drugs Controller General of India, Central Drugs Standard Control Organisation (CDSCO), said that as far as India is concerned, medicine brands are regulated by the central as well as the state regulatory authorities. “The federal structure is regulated by the Cosmetic Act. The responsibilities of institutions at the federal level include clinical trials, approvals, regulation of import, registration of sale and an additional responsibility of the regulation of ethics committees. The standards of scientific publications are also regulated by the central government. There are other standards within federal bodies which are also taken into consideration when it comes to the medical devices. The most important job is making the regulation that is applicable all across the country,” he added.

Presenting the perspective of industries, Dr. Akshaya Odak, Head – Regulatory, Lupin Biotech, said that since India’s guidelines and the international guidelines are getting harmonized it is going to help medicine makers. But there are a few areas like preclinical studies where we need to look at challenges more deeply.

Sharing his views the regulatory roadblocks, Dr. Krishna Prasad, General Manager, MJ Biopharma, said, “Our Indian regulatory pathway is actually a truncated version of the US or the European pathway, which is based on the totality of evidence. So while we are emphasizing on the preclinical, clinical

efficacy and safety, apart from the CMC, there are a lot of gaps that we need to look into. What is essentially happening is that with the dynamics changing in the global regulatory system, Indian biopharmaceutical industry currently has to formulate different regulatory strategies. One strategy is for India, one is for the emerging markets, which has already adopted the EU pathway, and the other two is for US and Europe. Earlier Indian regulatory system was fairly well accepted by most of the emerging markets, but in the last couple of years the situation has completely changed. Now is a perfect time to update our biosimilar guidelines as a part of convergence by refinement in two areas,” he said.

Dr. Bobby George, Head – Regulatory, Reliance Life Sciences, suggested that with respect to the biosimilar guidelines, which were last update in 2016, there is still scope for improvement. “The post approval change guidelines for Biologics, which are also applicable to biosimilars, and which were issued in 2010, require updation so that it is more harmonized with the international requirements,” he

The session also saw regulators from the UK, WHO, Switzerland, DBT, CPCSEA, Bureau of Indian Standards and Government e-Market Place share the regulatory practices followed by them and the efforts taken by the regulators to harmonize and make the regulatory process transparent across the world.

Closing Ceremony

MAPPING GLOBAL BIO-INDIA 2021

Global Bio-India 2021 objective was to transforming India from bio sciences to bioeconomy. It showcased the strength of India and global partnerships



The curtains were drawn on a highly engaging and successful second edition of Global Bio India on March 3. It was a totally different experience as the event was organised virtually. “On behalf of Department of Biotechnology, I take this opportunity to thank DBT and other officials along with our partners who worked hard to organize this event and make it a huge success in such a short period of time. A total of 30 sessions were organized over the course of three days, with active

participation of more than 8500 delegates 1000 plus startups as well as entrepreneurs. More than 180 exhibits with more than 50 participating countries was also a remarkable feature of this event,” said Dr. Sundeep Sarin from DBT.

He hoped that this edition of the event was an enriching experience for all the participants and the learnings from it would go a long way in supporting the goal of bio sciences to bioeconomy.

A TOTAL OF 30 SESSIONS WERE ORGANIZED OVER THE COURSE OF THREE DAYS, WITH ACTIVE PARTICIPATION OF MORE THAN 8500 DELEGATES, 1000 PLUS STARTUPS AS WELL AS ENTREPRENEURS. MORE THAN 180 EXHIBITS AND 50 PLUS PARTICIPATING COUNTRIES WAS A REMARKABLE FEATURE OF GLOBAL BIO INDIA 2021

Dr. Manish Diwan from BIRAC said that the event was able to mobilize people from across the biotech sector not only from India, but the biotech community at large across the world. “We had about 23 to 25 sessions, in which were brought not only people from India, but also from outside India. We had about 230 speakers who shared their knowledge, wisdom, and perspective to enrich us, out of which 50 of them were from other countries. We had 10 participating ministries and departments. In these three days, while sessions were going on we also had Investors Connect meeting where 140 meetings happened between investors and startups,” he informed. Over 23 awards were also rolled out during these three days.

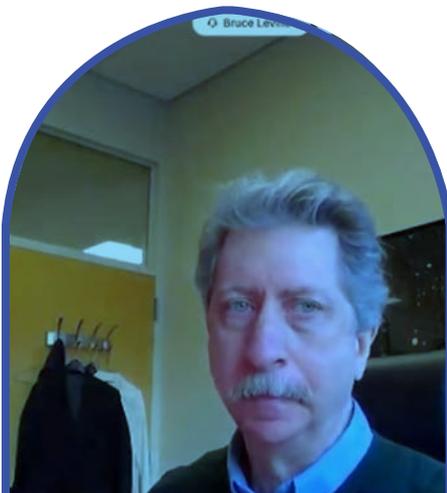
Anju Bhalla, Joint Secretary, DST & MD, BIRAC, said, “When events like this are conducted with so much aplomb, so much success, such collaborative efforts, I think we can believe in the ability of our community, the larger community of Indians to work together and get done what they have resolved to do. I think that is the one big learning from this event.”

“I want to especially thank and congratulate madam secretary for her vision, visionary leadership, and unwavering guidance in making sure that the goal of bio sciences to bio economy is achieved, and we also contribute

to a \$5 trillion economy objective of India. I also want to congratulate joint Secretary DBT, MD BIRAC for her truly remarkable support, and making sure that all these comprehensive insights from across multiple departments were shared on the virtual platform. And finally, the support from CII, who have managed to put together this virtual platform, and ensuring the smooth execution across different geographies, and multiple agencies, has been remarkable,” said Varun Sood, CEO, Invest India.

In her closing remarks, Dr. Renu Swarup, Secretary, Department of Biotechnology, praised the biotech community for collectively own the goal of transforming India from bio sciences to bioeconomy. “We collectively took this decision that we have to showcase the strength of India and we have to showcase the strength of our partnerships--national and international. Each of our international partners who joined us, I would like to take this opportunity to thank you,” she said.

The final remarks were made by Dr. Bhuvnesh Shrivastava from BIRAC, who congratulated all the participants, both national and international, and organizing partners for their support during the event.



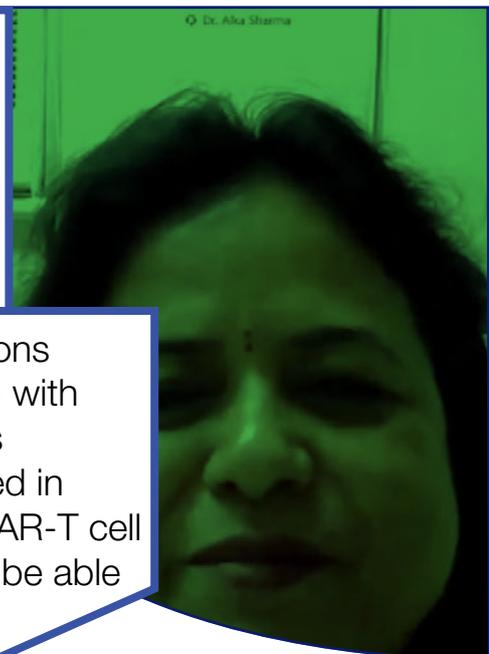
Prof. Bruce L. Levine

University of Pennsylvania,
Perelman School of Medicine

You need the scientific development to be able to commercialize, if you do scientific development, but it doesn't go anywhere, how is it benefiting patients, and you need that regulatory and quality oversight, to be able to facilitate that.

Dr. Alka Sharma

Scientist G,
DBT



With researchers and institutions working in close collaboration with highly focused objectives, it is hoped that the groups involved in development of practice or CAR-T cell technology in the country will be able to take the leap forward in a timely manner.



Dr. Rahul Purwar

Department of Biosciences &
Bioengineering,
IIT Bombay

Regarding CMC, there are multiple steps actually to manufacture the CAR-T design and given our infrastructure as well as even the reagents raw material availability, cold chain supply, it was not excellent. Those were the very big challenges to optimize all the essays and the manufacturing processes.



Dr. Fouad Atouf

US Pharmacopeia

In the area of therapies, we recently were endorsed to be a center of excellence for advanced therapies within the Asia Pacific economies that doesn't cover India. But I think some of the program there can be also expanded and extended to India.



AWARDS & **Innovations**

During the three-day Global Bio India 2021, 23 Awards were rolled out to recognise the contributions made by startups and entrepreneurs in developing solutions that helped India navigate through the challenges posed by the COVID-19 pandemic

BIRAC Innovator Awards

BIOMEDICAL DEVICES & DIAGNOSTICS

4S MEDICAL RESEARCH PVT. LTD.



Dr. Shomeshwar Singh

See Sound Live: Speech Development in Deaf

- Assistive technology that empowers a deaf child or adult to learn to speak without surgery or implants
- It has the potential to become for the deaf, what Braille is for the blind, today
- See Sound Live has been conceived, prototyped, trialed, patented and commercialized completely in India by 4S Medical Research Pvt. Ltd

BIOMEDICAL DEVICES & DIAGNOSTICS

VOXELGRIDS INNOVATIONS PRIVATE LIMITED



Dr. Arjun Arunachalam

Lightweight, Ultra-fast, Next Generation Magnetic Resonance Imaging (MRI) scanner

- World's first fully mobile, low liquid helium, full body, high field human MRI scanner that can be mounted on a truck and taken to the remotest parts of the country
- Scanner is extremely cost-effective and will result in a 3-4 X increase in Return on Investment (ROI). Lightweight and compact, this scanner can be installed on any floor of a hospital.
- Only entity in India to develop such cryogenics for large scale superconducting magnets that can be used in MRI scanners.

THERAPEUTICS, VACCINES & DRUG DELIVERY

HIMEDIA LABORATORIES PVT. LTD. (COLLABORATOR: ICT, MUMBAI)



Dr. Vishal Warke



Dr. Ratnesh Jain

Chemically Defined Serum-free Media (CDSFM)

- Developed a novel and cost-effective clone specific CDSFM and feeds for Biosimilar production in Herceptin & Avastin monoclonal antibody producing CHO cell clones, thereby becoming the only Indian company that manufactures clone-specific customized CDSFM
- The need to be indigenous in this range of products is a prime step to become "Atmanirbhar" in the protein therapeutics business, which is worth several billion dollars

AGRICULTURE, VETERINARY SCIENCE AND AQUACULTURE

INDO-AMERICAN HYBRID SEEDS (INDIA) PVT. LTD.



Dr. Devaraja Achar

Double disease resistant aromatic & non-aromatic cytoplasmic male sterile (CMS) lines for bacterial blight and blast

- The test cross F1 rice hybrids derived from gene pyramided CMS lines showed promising yield of more than 8.0 tons/ha with commercial desired grain qualities, suitable for large paddy growing areas of western, central, northern and north east parts of India
- The rice growing farming community will get benefited from double resistance F1 rice hybrids with assured yield and less dependence on fungicides and bactericides

ENERGY, ENVIRONMENT & SECONDARY AGRICULTURE

MALLIPATHRA NUTRACEUTICAL PRIVATE LIMITED (COLLABORATOR: SIR M VISVESVARAYA INSTITUTE OF TECHNOLOGY, BANGALORE)



**Dr. Mousumi
Mondal**



**Dr. Priya
Narayan**

Malli's Cordyceps

- Developed a novel process for growing worlds costliest endangered medicinal mushroom cordyceps in an artificial environment which grows much faster than the naturally available cordyceps
- The innovation involves a process of growing these mushrooms on both vegetarian and non-vegetarian substrates which is at par with the naturally grown Cordyceps in terms of active ingredients
- Developed various formulations like health drinks, infusions, capsules etc., comprising of cordyceps for nutraceutical applications

ENERGY, ENVIRONMENT & SECONDARY AGRICULTURE

KANPUR FLOWERCYCLING PRIVATE LIMITED



Mr. Ankit Aggarwal

Fleather - Animal-free leather made from floral-waste

- Developed the world's first alternative to animal leather- made from floral waste and farm stubble- „Fleather”.
- Built on the principles of biomimicry, Fleather is a breakthrough material that performs like animal

leather and can be customized for aesthetic expression, flexibility, density, and strength.

- Fleather not only cuts down several traditional downstream leather tanning processes but also helps provide better job opportunities to women from the marginalized sections of society.

BEST Startup Awards

AGRICULTURE & ALLIED AREAS CATEGORY

SNRAS SYSTEM PVT. LTD.



Mr. Suvadeep Sarkar
Founder & CTO

Product - Bluebox - A cost effective recirculatory aquaculture technology

Bluebox is a Nano aquaculture system which is a power efficient single unit Recirculatory aquaculture system consuming only 900 square feet of area having ability to produce up-to 80 kg per meter cube. It offers 30x more productivity and 4x reduction of mortality in aquaculture.

The startup has received several awards & recognitions as well as an order from Bank of Baroda of worth 4m USD for 60 systems in Sangli, Maharashtra.

MEDICAL DEVICES & DIAGNOSTICS CATEGORY

INACCEL TECHNOLOGIES PVT LTD.



Mr. Siraj Dhanani
Co-founder & CEO

Product - Neonatal CPAP

InnAccel is a start-up driving indigenous innovation in MedTech. Over the last 5 years, startup has developed a portfolio of innovative products across Critical care, and Maternal and child care.

- Saans is world's 1st infrastructure independent, portable, easy to use, neonatal CPAP device, which can be used both in hospital and in transport settings.
- Fetal Lite is a next-gen f-ECG based FHR monitor

that accurately identifies cases of fetal distress in clinical and non-clinical remote/in-home settings

- Saans Pro is a novel CPAP and HFNC system for COVID-19 patients iv VAPC are is the world's first intelligent, automated, and closed-loop secretion and oral hygiene management system for ventilated ICU patients
- Saans CPAP helmet is a novel CPAP helmet interface to prevent cross-infection of nursing staff in COVID-19

MEDICAL DEVICES & DIAGNOSTICS CATEGORY

TEST RIGHT NANOSYSTEMS



Mr. Shubham Rathore
Founder & CEO

Product: Portable Raman Spectrometer

The device provides Multiple Excitation Laser Modules, On-site Analysis, Real time Analysis Options: Probe based/ free space/ microscope coupled. It is a portable probe system and requires single-hand operation.

Test Right focuses on developing import substitutes.

- Portable spectrophotometer has widespread application in diagnostics and water testing

applications. On field Sickle Cell Anemia testing with Shanmukha Innovations IISc Bangalore startup is one of many such examples. Portable Raman spectrometer is being evaluated by Punjab Police to be used as Narcotics Detector to curb the menace of rampant addiction in the state. Another version of Raman device monitors the processes in a reaction tank of pharma drug or chemical and thus helps in improving the understanding and quality of the drug.

BIRAC'S BEST BIO-INCUBATOR AWARD

UNDER MATURE CATEGORY THE AWARD GOES TO
IKP LIFE SCIENCE INCUBATOR



- IKP LSI supported by BIRAC is set up with the mission to create a world-class ecosystem for fostering Biotech innovation in the country
- It has incubated 80+ start-ups in the Biotechnology domain
- Supported 400+ innovation projects from 300+ start-ups through various programmes
- IKP has a panel of over 100 domain specific mentors

BIRAC'S BEST BIO-INCUBATOR AWARD

UNDER EMERGING CATEGORY THE AWARD GOES TO
ASPIRE BIONEST BIOINCUBATOR



- ASPIRE BioNEST, supported by BIRAC is 20,000 square feet plug-and-play life sciences incubator supports startups in agriculture, healthcare, pharma, and allied areas
- It was setup in the year 2017
- The centre offers all the high-end sophisticated lab equipment for the Life sciences based startups
- Since its inception they have been able to nurture and support around 30 incubatees

MALLIPATHRA NUTRACEUTICAL PRIVATE LIMITED



Dr. Mousumi Mondal

- Mallipathra Nutraceutical has developed novel technique to grow Cordyceps mushrooms on non-vegetarian and vegetarian media in an artificial environmental condition within 60 days, as opposed to 365 days in nature.
- The product Cordycep is a super food that has several miracle medicinal molecules like Cordycepin and Cordycepic acid and acts as a Detoxifier & improves overall health, a potential antioxidant and antiaging agent, improves stamina, enhances immune system, increases vitality, Improves lungs and respiratory functions.
- It was also launched as an immunity booster during COVID19 by Hon Deputy CM of Karnataka.

WOMEN Entrepreneur Award Winners

HIDAA LIFE SCIENCES LLP



Ms. Menaka Gurnani

- Hidaa Life sciences has developed a natural vitamin D source product called, "D'bello ®," which is chemical free, 100% vegan, whole food nutrition from vegetable, cost effective and cooking stable.
- Vitamin D deficiency (VDD) that can lead to conditions such as rickets, osteoporosis, cardiovascular diseases, diabetes, depression, stunt growth in children etc. They are targeting the Vit D Deficiency with a vegan source.

DUOSISBIO-INNOVATIONS PVT. LTD.



Dr. Ruby Gupta

Duosis Bio Innovations has developed a product called "Jellnex", a novel, cost-effective and sustainable source of edible hydrocolloid by utilizing tamarind seeds. Jellnex will replace Pectin in food industries. Currently, Pectin is imported to India.

Organizer



सत्यमेव जयते

DEPARTMENT OF BIOTECHNOLOGY

Ministry of Science & Technology

Government of India

The Department of Biotechnology (DBT) is an Indian government Department set up in 1986 under the Ministry of Science and Technology facilitating research, capacity-building, technology and enterprise development in the field of biotechnology in the country. The DBT has 16 autonomous institutes all over the country working on R&D in frontier areas and two public sector undertakings promoting bio-entrepreneurship and commercialisation of technologies. In attaining its mission, the DBT actively collaborates with more than 20 countries globally and has enabled efforts of more than 15000 Indian scientists resulting in about 6000 key publications and IP; over 250 technologies



www.dbtindia.gov.in

[@DBTIndia](https://twitter.com/DBTIndia)

Organizer



Biotechnology Industry Research Assistance Council
(A Govt. of India Enterprise)

BIRAC is a Section 8 “Not-for-profit Company” set up by Department of Biotechnology, under Ministry of Science & Technology, Government of India, as an interface agency to promote Industry-Academia interface. Mandate of BIRAC is to nurture and empower the Biotech Innovation Ecosystem in India. To serve various dimensions, BIRAC operates mainly in 3 verticals i.e. Investment schemes, Entrepreneurship Development & Strategic Partnerships. BIRAC works closely with all partners - National and International to leverage the strength and expertise, mobilize resources and extend the outreach of its activities for innovative affordable product development addressing the unmet need.



www.birac.nic.in

[@BIRAC_2012](https://twitter.com/BIRAC_2012)

Partner



Confederation of Indian Industry

The Confederation of Indian Industry (CII) works to create and sustain an environment conducive to the development of India, partnering Industry, Government and civil society, through advisory and consultative processes.

CII is a non-government, not-for-profit, industry-led and industry-managed organization, with over 9000 members from the private as well as public sectors, including SMEs and MNCs, and an indirect membership of over 300,000 enterprises from 294 national and regional sectoral industry bodies.

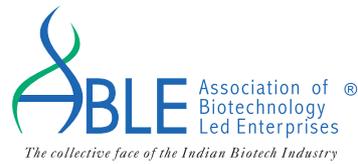
For more than 125 years, CII has been engaged in shaping India's development journey and works proactively on transforming Indian Industry's engagement in national development. CII charts change by working closely with Government on policy issues, interfacing with thought leaders, and enhancing efficiency, competitiveness and business opportunities for industry through a range of specialized services and strategic global linkages. It also provides a platform for consensus-building and networking on key issues.

Extending its agenda beyond business, CII assists industry to identify and execute corporate citizenship programmes. Partnerships with civil society organizations carry forward corporate initiatives for integrated and inclusive development across diverse domains including affirmative action, livelihoods, diversity management, skill development, empowerment of women, and sustainable development, to name a few.

As India marches towards its 75th year of Independence in 2022, CII, with the Theme for 2021-22 as Building India for a New World: Competitiveness, Growth, Sustainability, Technology, rededicates itself to meeting the aspirations of citizens for a morally, economically and technologically advanced country in partnership with the Government, Industry and all stakeholders.

With 62 offices, including 10 Centres of Excellence, in India, and 8 overseas offices in Australia, Egypt, Germany, Indonesia, Singapore, UAE, UK, and USA, as well as institutional partnerships with 394 counterpart organizations in 133 countries, CII serves as a reference point for Indian industry and the international business community.

Partner



ABLE-Association of Biotechnology Led Enterprises is a not-for-profit pan-India forum that represents the Indian Biotechnology Sector. It was launched in April 2003, after industry leaders felt a need to form an exclusive forum to represent the Indian Biotechnology Sector. ABLE is a founding member of the International Council of Biotechnology Association (ICBA).

ABLE has approx. 250 members representing all verticals of the sector like agribiotech, biopharma, industrial biotech, bioinformatics, investment banks, Venture Capital firms, leading research and academic institutes, law firms, equipment suppliers and students.

The primary focus of ABLE is to help accelerate the growth of the Biotechnology sector in India to attain 100 billion USD by 2025, through partnering with the Central and State Governments in their biotechnology initiatives to deliver optimal policies and create a positive regulatory environment, encouraging entrepreneurship and investment, providing a platform for domestic and overseas companies to explore collaboration and partnerships, forging stronger links between academia and industry and by showcasing the strengths of the Indian biotech sector.

ABLE thus catalyses a symbiotic interface between the industry, the government, academic and research institutes and domestic and international investors.

ABLE's objective is to work in consensus with all stake-holders, towards ensuring an effective, enabling and supportive environment for the Indian biotechnology sector to substantially contribute to India's economic and social growth by providing access to affordable healthcare, food and clean and sustainable energy.

ABLE uses a multi-pronged strategy to deliver its objectives that includes Advocacy, Promoting entrepreneurship, industry-Academia linkages, International outreach through showcasing Indian public and private biotech sectors and Organizations at International fora, among others.

Partner



Invest India is the National Investment Promotion and Facilitation Agency of India and act as the first point of reference for investors in India.

As the national investment promotion and facilitation agency, Invest India focuses on sector-specific investor targeting and development of new partnerships to enable sustainable investments in India. In addition to a core team that focuses on sustainable investments, Invest India also partners with substantial investment promotion agencies and multilateral organizations. Invest India also actively works with several Indian states to build capacity as well as bring in global best practices in investment targeting, promotion and facilitation areas.

Invest India, set up in 2009, is a non-profit venture under the Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, Government of India. Our Service Offerings:

Business Planning & Advisory

- Policy and incentives advisory
- Market expansion strategy
- Expansion advisory

Strategy & Implementation

- Market entry strategy
- JV and strategic partner search
- License and compliance advisory

Long-term Partnership

- Expansion advisory
- Policy impact analysis
- Facilitation

 www.investindia.gov.in

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Partner Country



Switzerland.



Kingdom of the Netherlands

Partner States



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सत्यमेव जयते

Ministry of Science & Technology
Government of India



सत्यमेव जयते

Ministry of Health and Family Welfare
Government of India



सत्यमेव जयते

Ministry of Earth Sciences
Government of India



सत्यमेव जयते

Micro, Small & Medium Enterprises
Government of India



सत्यमेव जयते

Ministry of Ayush
Government of India



सत्यमेव जयते

Office of the Principal Scientific Advisor to the
Government of India



सत्यमेव जयते

Department of Health Research
Government of India



सत्यमेव जयते

Department for Promotion of Industry
and Internal Trade



सत्यमेव जयते

Department of Science & Technology
Government of India



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COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH
(विज्ञान एवं प्रौद्योगिकी मंत्रालय, भारत सरकार)
MINISTRY OF SCIENCE & TECHNOLOGY, GOVT. OF INDIA



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INDIAN COUNCIL OF
MEDICAL RESEARCH
अनुसंधान परिषद



भारतीय कृषि अनुसंधान परिषद
Indian Council of Agricultural Research
(Ministry of Agriculture and Farmers Welfare)

Industry Partners

Platinum



Diamond



Gold



Silver



Biological E. Limited
Celebrating Life Every Day



Bronze



Partnering Investors



Knowledge Partners



Participating States



Supporting Partners





Global Bio-India 2021

Transforming Lives
Biosciences to Bioeconomy

1-3 March 2021
Digital Platform

Global Bio-India Secretariat

Make in India Cell

Biotechnology Industry Research Assistance Council

1st Floor, MTNL Building, 9, CGO Complex, Lodhi Road, New Delhi-110003

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Organisers

