Global Innovation Summit 2021

Accelerating the innovation journey of the Indian life sciences industry

Summary and Recommendations

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1 Acknowledgements

IPA would like to acknowledge all the stakeholders who committed their time to provide insights on India's pharmaceutical and life sciences innovation journey and helped make the Global Innovation Summit 2021 a grand success.

We would like to thank the Hon'ble Prime Minister of India for delivering the keynote address and inaugurating the Global Innovation Summit 2021. We thank the Hon'ble Minister for Chemicals & Fertilizers and Ministry of Health & Family Welfare for his opening remarks.

We would like to thank the Secretary, Department of Pharmaceuticals for her overall guidance for the Summit. We also thank NITI Aayog, Ministry of Health & Family Welfare, Ministry of AYUSH, Department of Pharmaceuticals, Department of Biotechnology, Department for Promotion of Industry and Internal Trade, Council of Scientific and Industrial Research (CSIR), National Institute of Pharmaceutical Education and Research (NIPERs), Biotechnology Industry Research Assistance Council (BIRAC), Drugs Controller General of India (DCGI) and National Pharmaceutical Pricing Association (NPPA) for their support in organizing the Global Innovation Summit 2021.

We would like to thank our organizing partner, Invest India and all our association partners, Federation of Indian Chambers of Commerce and Industry (FICCI), Associated Chambers of Commerce and Industry of India (ASSOCHAM), Confederation of Indian Industry (CII), Organisation of Pharmaceutical Producers of India (OPPI), Indian Drug Manufacturers' Association (IDMA) and The IndUS Entrepreneurs (TiE),

A special thanks to IIM-Ahmedabad for leading the development of the Indian pharmaceutical industry innovation index. We also thank our knowledge partners, McKinsey & Co. for conceptualizing the Global Innovation Summit 2021.

Finally, IPA also acknowledges its Executive Council for their continuous support and guidance throughout this effort. The Global Innovation Summit 2021 would not have been possible without their timely involvement and commitment.

2 Executive Summary

The Global Innovation Summit 2021 was the first iteration of the Indian life sciences industry's flagship event focused on R&D and Innovation. The theme for the two-day event was **"Discover in India: Accelerating the innovation journey of the Indian life sciences industry".** It was inaugurated by the Hon'ble Prime Minister of India, Shri Narendra Modiji and spanned 12 sessions and more than 40 speakers. The summit was attended enthusiastically by over 3000 participants and received over 80,000 impressions over the two-days. The participation spanned stakeholders from across the Government, Regulators, Industry, Academia, Investors and Media.

The Summit stayed true to its objectives of:

1. Taking stock and provide recommendations to strengthen India's innovation landscape
2. Sharing learnings and best practices from the global innovation landscape
3. Encouraging "Discover in India" by providing a forum for entrepreneurs and researchers to showcase their breakthrough ideas / science

Summit was kicked off with the Hon'ble Prime Minister of India, Shri Narendra Modiji, sharing his vision of India becoming an Innovation Hub for the life sciences industry. In the subsequent sessions, thought leaders from across the Government and the Industry alike, talked about how India can leverage its strong starting position, both in terms of the talent and the industry and accelerate its innovation journey. Global thought leaders took to the platform to share best practices from across the world as well as potential ideas / imperatives for India. This was followed by 2 panel discussions where the panelists deliberated on the fundamental building blocks of an innovation ecosystem i.e., Enabling Regulatory Landscape and Funding support for Innovation respectively. Second day was kicked-off with the Grand Innovation Challenge, where some of the leading innovators of the country pitched their ideas to a panel of experts and industry luminaries. This was followed by the unveiling of the 'Innovation Index', a monitoring and evaluation framework to track India's progress on its innovation journey. Subsequently, leaders from across industry and academia came together in a panel discussion to deliberate on the enablers required for promoting industry-academia collaboration at scale. This was followed by another panel discussion, where several of the Indian and Global industry leaders talked about their individual aspirations as well as what it would take to building an enabling ecosystem in the country.

In summary, there were 5 key imperatives for India came up across these sessions / discussions:

- **Creating an enabling regulatory setup:** A fundamental enabler for a vibrant innovation ecosystem is a strong and efficient regulatory setup e.g., having a 'single window system', elimination of multiple regulatory bodies, establishing detailed guidelines, ongoing dialogue between the regulator and the industry etc.
- **Ensuring robust funding / investments:** The Government could create immediate and direct impetus through initiatives such as research-linked incentives, grants, subsidies as well as higher tax aids for R&D. Further, financial markets could be supported in offering incentives for investing in innovation e.g., pathway for private equity, offering innovation bonds, enabling crowd / P2P funding.

- **Enabling Industry-Academia collaboration:** Critical to ensure translatability of research happening in the labs to the market. It will require enabling infrastructure such as technology transfer offices, industry sponsored centers of excellence, incubation centers to encourage industry-academia collaboration, provision for exclusive licensing deals etc..
- **Putting in place a robust implementation framework:** A dedicated cross-stakeholder core committee must be set up to oversee the progress India makes on this front. It should be responsible for, supporting collaboration, continuous dialogue, cross-stakeholder initiatives etc.
- **Monitoring progress and impact:** The "Innovation index" is a holistic yardstick to track progress across the building blocks as well as desired outcome of delivering more and world class innovation coming out of India. The index should be refreshed annually as a means for monitoring progress and to think through any course corrections that might be required. Further, Innovation Summit can serve as a platform for bringing together the various stakeholders to review the index and discuss and align on the way forward.

3 Inaugural Session

Addresses:

- **Welcome Address by Shri Samir Mehta (President, Indian Pharmaceutical Alliance)**
- **Remarks by Shri Pankaj Patel (Chairman, Cadila Healthcare)**
- **Remarks by Dr. Mansukh Mandaviya (Hon'ble Minister for Heath & Family Welfare and Chemicals & Fertilizers**
- **Address by Shri Narendra Modi (Hon'ble Prime Minister of India)**

Key Highlights:

The Global Innovation Summit, serving as the flagship event for R&D and innovation in India can lead the transition from "Make in India to Discover in India"; under the overarching theme of Atmanirbhar Bharat.

The Indian pharma industry has been making a difference in people's lives for over 20 years. Employing nearly 3 million people and generating a trade surplus of US$13 billion the Indian pharma industry has been a key driver of economic growth. Rightly called 'Pharmacy of the world' – India supplies 60% of the global vaccine demand, and critical drugs to 150+ countries. India today is polio-free. During the times of the Covid-19 pandemic, India has gone as far as developing indigenous vaccines for Covid-19; and has exported 6+ crore doses of vaccines.

India's vision is to move to $130 bn size by 2030. India, despite its strong position in generics drugs, is yet to demonstrate its capabilities in innovations, biotech. In October 2021, the government released a draft document outlining the policy to catalyze R&D in pharma and med-tech in India. The policy reflects India's commitment to encourage R&D in pharmaceuticals and medical devices. The industry has got a major boost through investments worth over INR30K

crore. Building an innovation ecosystem will be a gamechanger for the country and a big leap forward in this decade.

The Hon'ble Prime Minister highlighted 2 areas to be explored carefully –

1) API requirements need serious attention as was identified during the Covid-19 pandemic. Domestic manufacturing of key ingredients for vaccines and medicines must be ramped up to reduce dependence on other countries for key raw materials. Investors and innovators are keen to work together to overcome this challenge.

2) Elevating the quality / manufacturing of India's traditional medicine products. There is a need to popularize traditional medicine with global standards. The government is working with the WHO to set up global center for traditional medicine in India. The PM concluded by espousing the cause of "Ideate in India, Innovate in India, Make in India and Make for the world".

4 Policy thrust for innovation

Addresses by:

- **Ms S Aparna (Secretary, Department of Pharmaceuticals)**
- **Prof Vijay Raghavan (Principal Scientific Advisor, Government of India)**
- **Dr. Vinod Paul (Member, NITI Aayog)**

Innovation is extremely critical, going forward. New opportunities are opening in biologics, biosimilars. For example, global biosimilar opportunity is expected to grow to ~$70 bn over next 5 years. India is witnessing an inflection point where industry effort should be matched with patient needs while remaining grounded in access, affordability and quality. To capture these opportunities, the Indian pharma industry can focus on drug delivery, drug development, process improvements through automation, use of AI/ML, data analytics. The Indian pharmaceutical sector is well poised to work towards this goal.

Government bodies play a huge role in fostering innovation. The shift in focus to innovation will need active involvement of government bodies such as Department of Biotechnology (DBT), Department of Science and Technology, Council for Scientific and Industrial Research (CSIR). For example –

- Leverage 'Make in India' and 'Startup India' programs as policy levers, moving forward.
- Continuation of national Bio-pharma Mission, and Mission Covid-Suraksha, conceptualized by DBT, which turned out to be a great facilitator for innovation in vaccines.
- Pursuing the National Biotechnology Development Strategy (2021-25) which will also be one of the catalysts for change, going forward.
- Research-linked Incentives Scheme by NITI Aayog which would incentivize risk-taking in discovery and translation of new drugs, biologics, vaccines, and other moonshot areas (through tax reductions, etc.).

Policy interventions to foster innovation have been outlined in the draft R&D policy with 3 focus areas –

- **Creation of a regulatory landscape in the country** that encourage and enables innovation and research in product development, elevating them to global standards of safety and quality
- **Incentivizing public and private investment in innovation** through a combination of fiscal and non-fiscal measures.
- **Build an enabling ecosystem designed to support innovation**. Three main components proposed for building robust ecosystem including Strengthening academic industry linkages collaborating across institutions and sectors and Building supporting infrastructure

The industry can gain competitive advantage and become the pre-emptive country of choice to serve the world through 2 key takeaways –

1. **Adoption of new technologies** that allow manufacturing of different kinds of drugs, with our increased understanding of biotech, advances in computing power, excellent interface with IT
2. **Understanding of human biology**, profiling of people and genetic interactions, giving us the opportunity of delivering personalized medicine to people

Going forward, the industry should be willing to take risks even in the face of high failure rates. The **need for quality and methodological rigour** such as high sample sizes, among others is paramount. Traditional medicine and Ayurveda cannot be neglected either and the same methodological rigor from modern medicine must be applied to Ayurveda as well.

5 Global Best Practices for Driving Innovation at Scale

Address by Mr. Jake Henry (Senior Partner, McKinsey & Company, and co-leader of McKinsey's Global Life Sciences Practice)

Key Highlights:

The **key trends shaping global innovation landscape** were discussed in this session. Life expectancy is twice as long as it was 100 years ago, and its rapid increase has to be credited to innovation in pharma and healthcare. 4 key trends may continue to propel Innovation in Lifesciences –

1. Continued disease burden and unmet medical need – Increased incidence of age- and lifestyle-related diseases such as cardio-vascular disease and neurological disorders.
2. Proliferation of technologies & platforms to drive innovation, e.g. CAR-T cell therapy for solid tumors, gene editing, etc. Around 40% of pharma pipeline today is composed of biologics (2nd wave) and next-gen (3rd wave).
3. Elevated levels of funding availability, supporting new wave of innovation – Biotech VC Funding, Deals, and IPOs reached their highest levels in 2020.

4. Emergence of a larger ecosystem of players driving innovation – Share of annual NME launches from established pharmacos has gone down from ~80% to 60%, and share of first launches has gone up from ~10% to 30%, from 2016-2020.

The learnings on building a vibrant innovation ecosystem were discussed next. Innovation in Lifesciences space is fairly concentrated with few geographical clusters (e.g. Greater Boston, UK Golden Triangle), driving bulk of the research globally. 5 key building blocks emerge as the cornerstones for a thriving innovation hub, as evident from the journeys of these successful innovation clusters –

1. Enabling regulatory and policy landscape, e.g. simplified and transparent review process.
2. Robust funding support, e.g. tax incentives and grants to fund research
3. Strong research talent pool, e.g. research-linked incentives and grants to attract top global talent
4. Industry-academia collaboration, e.g. platforms to bring research to market such as tech transfer offices
5. High quality infrastructure, e.g. innovation hubs comprising academic institutions, R&D centers of global pharmacos, startup incubators, etc.

The concluding area focused on **reflections for India, as it looks forward to accelerating its innovation journey**. India has a vibrant Lifesciences Industry that has made significant contribution to addressing global health needs (e.g. addressing upto 60% of global vaccine demand) and the country's economic outcomes (e.g. trade surplus of $13 bn). Shifting the focus to innovation, including new entities such as NMEs, BLAs, represents the next S curve for the Indian pharma industry.

6 Global Experience Sharing: Accelerating Innovation that Matters

Address by Prof. Robert Langer (David H. Koch Institute Professor, MIT)

Address by Dr. Martin Holst Lange (Executive Vice President, Head of Development, Novo Nordisk)

Key Highlights:

The session began with the factors that lend MIT its edge as a strong Lifesciences innovation hub. The institute fosters innovation fundamentally through good role models in the form of successful entrepreneurs, industry leaders, top notch researchers which is one of the advantages of the undergraduate research program. There have always been strong ties to industry. They have a terrific Technology Transfer Office, one of the best in the world, with 400+ US patents issued and 100+ license agreements just in FY21. There is also an Industrial Liaison Program involving thousands of companies which visit the campus and interact with students.

The story of Prof. Langer's research in drug delivery went against all conventional principles but ended up disrupting the industry; and led to the establishment of the company Moderna (which developed a successful mRNA Covid vaccine).

Academia and industry could derive the following key messages

- Essential to aspire for big innovation leapfrog than incremental improvement
- Don't constrain yourself within the realms of conventional wisdom – it isn't always correct
- Lay the strong foundation for a thriving innovation-focused culture by enabling exposure to multiple disciplines for young students / researchers
- There is no quick and sure-shot formula for success – have the appetite to take risks and be tolerant of failures
- Don't give up at the first sign of hurdles – if you genuinely believe in your idea, be prepared to move forward in spite of criticisms.

Key Highlights:

Innovation always stems from an **unmet patient or physician need**. **Novo Nordisk's innovation model** is built on dedicated disease understanding and focused innovation – 12 new products in less than 10 years enabled by strong collaboration between academic and commercial partners. The underlying principles of the model are –

- Fundamental understanding of the physiology of the human body is required to propel innovation
- Never underestimate the importance of basic research – 80% of their drugs are based on innovation from basic research
- Ensure patient access through focused product development; overall enabled by strong industry-academia collaboration

An innovative mindset could add value to an existing technology – In the diabetes space, stable insulin that can be stored without the previously necessary refrigeration requirements; is a good example.

It is also necessary to think about **innovation of processes** so as to be responsible to society and reduce our environmental footprint. With the advent of AI and digital tools, it is possible to accelerate research and clinical development.

7 Panel Discussion: Creating Regulatory Ecosystem to support Innovation

Moderator: Dr. Kiran Mazumdar-Shaw (Executive Chairperson, Biocon)

Address: Mr. Rajesh Bhushan (Secretary, Ministry of Health and Family Welfare)

Panelists:

- Dr. Rajesh Gokhale (Secretary, Department of Biotechnology)
- Dr. V G Somani (Drugs Controller General of India)
- Mr. Dilip Shanghvi (Managing Director, Sun Pharmaceutical Industries)
- Mr. Glenn Saldanha (Managing Director, Glenmark Pharmaceuticals)
- Dr. Sanjay Singh (CEO, Gennova Biopharmaceuticals)
- Mr. Kamlesh Pant (Chairman, National Pharmaceutical Pricing Authority)

Key Highlights:

The session emphasized the theme – "Idea to market journey of any innovation is directly proportional to regulatory controls", e.g. digital innovations outpace pharma by a factor of 10. The Covid-19 Pandemic has catalysed a change in the long pharma approval processes which saw drugs and vaccines being approved in less than a year. The concept of Emergency Use Approvals (EUAs), Rolling Reviews and Parallel Phase 1, 2 & 3 clinical development all of which played a significant role in regulatory acceleration; should now be amalgamated into the system through regulatory reforms.

Streamlining the regulatory process –

- The major challenge to innovation from a regulatory standpoint is the regulatory processes being multi-pronged and scattered with multiple organizations in between – e.g. submission of application for market authorization, import license etc. is sequential as opposed to parallel.
- Pre-submission and pre-approval meetings between industry and regulator would help make regulatory pathways very clear. Backward integration is also extremely necessary to cut down on delayed timelines resulting from import of raw materials, etc. A single window system is needed with all submissions made to one body
- Define guidelines objectively, e.g. how much data is actually needed for a phase 1 trial.

Challenges in investing in novel molecules – Historically it was easier to do phase 1 and phase 2 studies outside India. India is a potential destination for huge number of clinical trials due to its large patient pool.

Applying differentiated price control based on R&D investment –

- A big challenge is how to recoup investments in failed products through pricing for a successful product
- Market-based pricing based on value to patient's unmet needs while ensuring affordable access is fundamental
- There has to be a continued dialogue between the NPPA, DoP and other bodies to manage pricing for stimulating innovation. This is fundamental in a knowledge-driven industry.

8 Panel Discussion: Funding for Innovation and R&D

Moderator: Mr. Satish Reddy (Chairman, Dr. Reddy's Laboratories)

Panelists:

- Mr. Deepak Bagla (Managing Director and CEO, Invest India)
- Mr. Sanjay Murdeshwar (Managing Director, Novartis)
- Mr. Ramesh Swaminathan (CFO, Lupin)
- Dr. Prem Pavoor (Partner and Head of India, Eight Roads Ventures)
- Mr. Shashank Singh (Partner and Head of the India Office, Apax Partners)
- Mr. Matthias Evers (Senior Partner, McKinsey & Company, and co-leader of McKinsey's Global Life Sciences R&D)

Key Highlights:

Role of Government in facilitating funding access –

- Risk associated with investing in innovation is very high; and Indian organizations do not have the deep pockets necessary to further this journey alone. An increase in government funding support for drug development is imperative to be in line with mature innovation hubs like US (~35%); and China (~40%)
- Accounting standards of India v/s US also seem to be working against us – e.g. In the US, if a financial investor is willing to take R&D risk, it is off the pharmaco's books but India requires it to be recorded as a liability in the pharmaco's books
- An ecosystem view is necessary for funding as well, because after the early-stage, pharmacos, investors, and the equity market has to come in for late-stage funding
- Direct government support through tax deduction, research grants, etc. For example, Direct research grant up to 85% of R&D expenses in Israel; 230% super tax deduction for SMEs in the UK
- Research-Linked Incentive Scheme will be of benefit to drive increased investment in innovation

Attracting private funding – The most important element is talent. India has just 1,500 PhDs in biochemistry, whereas the US has 15,000. It is an imperative to create success stories of having world class universities, top quality talent that stays in India, etc. which would motivate investors to invest. The first opportunity area for attracting funding is to leverage our skills in data and digital. The second area, again building on India's strengths is transitioning from classical research in Chemistry to an era of new technology platforms.

Setting up non-fiscal enablers for easier funding access – The regulatory bottlenecks to funding must be dealt with first; and a focused strategy similar to Singapore, UK, etc. is necessary. Crowdfunding, P2P lending, etc. are examples of creative ways to raise capital for research.

9 Grand Innovation Challenge

Moderator: Mr Anirudh Roy Popli (Partner, McKinsey & Company, and Leader of McKinsey's India Life Sciences R&D)

Panelists:

- Dr. Srivari Chandrasekhar (Director, CSIR-IICT)
- Mr. Pankaj Patel (Chairman, Cadila Healthcare)
- Mr. Axel Baur (Senior Partner, McKinsey & Co, Leader of McKinsey's Asia Life Sciences and Healthcare practice)
- Prof. Arvind Sahay (MN Vora Chair Professor of Marketing and Entrepreneurship, Indian Institute of Management, Ahmedabad)

Day 2 opened with the Grand Innovation Challenge – an event of the shark tank format, where innovators pitched their ideas to an expert panel. Having shortlisted 10 extremely creative ideas out of 50+ entries based on overall impact, credibility of past research, and current stage of research; the selection was exceedingly difficult. The novel, cutting edge ideas presented during the challenge are given below –

Name of Applicant	Organization	Source	Idea
Dr. Pankaj Kumar Singh Dr. Nitin Pal Kalia	NIPER Hyderabad	Academia	Development of 1-8 cineole nanoemulsion bearing Amphotericin B against Mucormycosis “The Black Fungus”
Prof. Ajit R. Kulkarni Dr. Adersh Asok Ms. Sayoni Sarkar	IIT Bombay	Academia	Engineered safer ZnO based multifunctional sunscreen active ingredient for skin care and cosmetic applications
Dr. Guhan Jayaraman	Dept. of Biotechnology, IIT Madras	Academia	Production of Controlled Molecular Weight Hyaluronic Acid
Dr. Anant Narayan Bhatt	Division of Molecular and Radiation Biosciences Institute of Nuclear Medicine and Allied Sciences, DRDO	Academia	2-DG as an anti-viral drug (therapeutic/ adjuvant) for viral Outbreak
Aarti Sevilimedu Kiranam Chatti Kishore Parsa Srinivas Oruganti	Dr. Reddy's Laboratories	Industry	Affordable Disease modifying therapies for Rare Diseases
Dr Narendra Vutla and Dr Rajan Verma	Abbott Healthcare	Industry	Sustained Release formulations for better patient compliance
Girish Daginakatte	Aurigene, Dr Reddy's Laboratories	Industry	Novel Oral Small Molecule Antagonist of CD47 for Cancer Immunotherapy
Dr Indu Pal Kaur	University Institute of Pharmaceutical	Academia	CurPro S: Wound dressing sponge (S) containing nanocurcumin (Cur) and live

Name of Applicant	Organization	Source	Idea
	Sciences, Panjab University Chandigarh		Lactobacillus Plantarum (Pro) for infectious wounds
Sudip Roy (Founder) and Jayant Kumar Singh (Founder)	Prescience Insilico Private Limited	Industry	State-of-the-art software platform (PRinS3) to develop modular applications to design and repurpose drugs. The platform helps in accelerating drug discovery by reducing the time needed to design and develop a new drug using cutting edge technology like artificial Intelligence, cloud-based supercomputing, and highly quantitative physics-based methodologies.
Pijush Giri Daman Yadav Dr. Devendra Verma Dr. Debasish Pattnaik	ENVISAGE MEDTECH funded by BIRAC	Industry	Highly Biocompatible and Injectable Hydrogel for Prevention of Post-Surgical Adhesions

Recognitions to the following projects:

Academia

1. 'Production of Controlled Molecular Weight Hyaluronic Acid' by Dr. Guhan Jayaraman
2. 'CurPro S: Wound dressing sponge (S) containing nanocurcumin (Cur) and live Lactobacillus Plantarum (Pro) for infectious wounds' by Dr. Indu Pal Kaur

Industry

1. 'Novel Oral Small Molecule Antagonist of CD47 for Cancer Immunotherapy' by Girish Daginakatte
2. 'State-of-the-art software platform (PRinS3) to develop modular applications to design and repurpose drugs' by Sudip Roy and Jayant Kumar Singh

10 Building Innovation Ecosystem in India

Address by Mr. Amitabh Kant (CEO, NITI Aayog)

Key Highlights:

Over the last few years, India has been a pioneer in providing access to high quality and affordable medicines, both domestic and globally. It is now time to shift the focus to R&D. Integration of innovation into national policies is crucial, e.g. the draft R&D policy to catalyze innovation in pharma and medtech is a good starting point. The government is focused on enhancing the culture of research in India. These efforts have helped India rise to the 46th position in the Global Innovation Index, 2021 from 48th position.

The government has also taken initiatives to boost the pharma sector –

- **The government is developing centers of excellence** through various institutions such as NIIPER, CSIR, to foster scientific talent in the country
- **Incentivizing investment into innovation through production-linked incentive schemes**, for APIs, KSMs, formulations, etc. with a financial outlay of 6940 cr – e.g. the PLI 2 scheme will increase investment in production and contribute to product diversification through high value goods in the pharma sector.
- **Encouraging startups/ entrepreneurs through schemes** such as Biotechnology University Research Joint Industry Translation Cluster, etc.

The progress India makes in innovation has to be tracked. The innovation index developed in collaboration with IIM-Ahmedabad should be helpful in this direction.

11 Innovation Index and framework for innovation ecosystem

Address by Prof. Arvind Sahay (MN Vora Chair Professor of Marketing and Entrepreneurship, IIM Ahmedabad)

Key Highlights:

The Innovation Index was put together by stakeholders across industry and academia. The Index has two dimensions – 1) Qualitative or perceptual, and 2) Quantitative.

Data for both qualitative and quantitative parts were gathered across five avenues – Regulatory and Policy landscape, Funding support, Capability, Infrastructure and Talent, Global Collaboration, and Output Dimension (No of NMEs, NBEs,). The perceptual data was gathered through a survey sent to industry leaders, people in academia, researchers from NIIPERs, AIIMS, CSIR, etc. and even investors and venture capitalists who have invested in the pharma and biotech space. The quantitative data was gathered from secondary sources such as WIPO, Indian government data on number of postgraduates, USFDA, etc.

The qualitative index showed that India had improved from 2018 to 2021, from 4.02 to 5.26 (perceptual scores), contributed majorly by improvements in regulatory & policy landscape and research outcomes such as novel drugs and new modalities.

The quantitative index came out to be 2.46 in 2018 and 2.79 in 2021 respectively, with the improvement driven mostly by regulatory improvements and advances in capabilities, talent and infrastructure.

The Composite Pharma Innovation Index for India was calculated by combining the 2 indices as 3.08 in 2018, and 3.78 in 2021. This will serve as the benchmark against which progress in pharma innovation would be measured.

As next steps,

- The key focus areas that require attention as directed by the index are government and private funding support, global collaboration, and number of NMEs, NBEs, etc. registered from India
- The Indian pharma innovation index calculation exercise must be conducted periodically

12 Panel Discussion: Promoting academic-industry collaboration

Moderator: Dr. Y K Gupta (President, AIIMS Bhopal and AIIMS Jammu)

Panelists:

- Dr. Vaidya Rajesh Kotecha (Secretary, Ministry of AYUSH)
- Dr. Paul Nkansah (Senior Director, Corporate Partnerships Johns Hopkins Technology Ventures)
- Dr. Anil Koul (Vice President, Global Public Health Discovery Research, Johnson and Johnson)
- Dr. S. Chandrashekhar (Director, CSIR - Indian Institute of Chemical Technology, Hyderabad)
- Dr. B Suresh (President, Pharmacy Council of India)
- Dr. USN Murthy (Director, NIPER Guwahati)
- Mr. S Sridhar (Managing Director, Pfizer)
- Dr. George Patani (Hon. General Secretary, Indian Drug Manufacturer's Association)

Key Highlights:

There were four key themes that fell under the umbrella of 'how best we can boost industry-academia collaboration' –

Government role in fostering industry-academia collaboration –

- Ministry of AYUSH supports research institutes and COEs which has resulted in good translation of research outcomes. e.g. recently the medicine AYUSH 64 for mild to moderate Covid patients was transferred to industry and was made available country-wide
- All NIPER institutes across the country have identified targeted areas of research for specialization. NIPER Guwahati is providing pre-clinical data to traditional healers with almost 120 formulations in hand for proper testing, so that they finally make it to the market.
- The Bayh- Dole Act or Patent & Trademark Law Amendment Act, enacted in 1980 in the US for moving academic discoveries into the commercial landscape via exclusive licensing deals; has led to over 10,000 startups arising from IP generated in academia' resulting in 200 new drugs and vaccines. It is estimated to have contributed over $1 Tn to the US economy over four decades.

Support for translation from lab to market –

- In 2014, Johns Hopkins received an investment of $76 Mn and a tech transfer office was set up to centralize commercialization and translation – included licensing, sponsored research and partnerships, etc. Now they have about 50 partnerships with the industry across sectors and are averaging 144 licenses in a year which was double the number in 2014. The culture of innovation is therefore an extremely important element

- Partnerships also have to be strategic, e.g. In Johns Hopkins, partners have to fulfil requirements such as education of post-docs, curriculum development, etc. besides licensing of technologies.

Proactive role of industry and learnings from global peers –

- In J&J, the mantra for R&D is 'Open Innovation' – be receptive to ideas and innovations from all avenues. J&J set up five innovation centers across the globe where the main objective was to tap into the academic research in those areas. This has led to J&J's R&D output in the last ten years being extremely successful
- Another initiative is J-labs which are bio-incubator spaces where anyone with an idea can use the infrastructure for their work. This became a huge support system for early-stage companies that now have valuations in billions. The industry must go to academia, not just to hire but also to promote their research and ideas.

Incubation of startups – Pfizer's partnership with IIT Delhi is exemplary, having nine startups, two of which are close to commercialization. Pfizer is also trying to bring in other partners for proper coaching, mentoring startups in terms of regulations, funding, etc.

13 Experience Sharing Session

Address by Mr. Andrew Plump (President, R&D, Takeda Pharmaceutical Company)

Key Highlights:

The Biopharma innovation boom continues – FDA CDER averages ~40 annual novel drug approvals in last decade. Profits are also necessary to drive innovation and in the last five years, the industry has seen record investments each year especially in early-stage products.

Human genetic data is a key lever for target discovery and validation, and also in improving development success. There is still an element of basic biology that also supplements the cutting-edge technology and discoveries which is required going forward. The cell and gene therapy journey is just beginning, and over the next ten years this will change the face of human health.

Healthcare innovation must be driven globally; and focus across the healthcare ecosystem is critical –

- Ensure data sharing between industry, regulators, academia, providers, payers, and policy makers
- Align with regulatory policies globally
- Establish incentives to reduce manufacturing costs across supply chain
- Embrace data and digital technologies

Address by Mr. Werner Lanthaler (CEO, Evotec SE)

Key Highlights:

Evotec had a presence in India from 2010-12 with about 200 chemists. Now it is an organization of about 4000 scientists with over 2000 PhDs globally working in the biopharma industry. The learning from the three years in India was that quantity of talent cannot compensate for being outpaced by technology. Thus, emphasis was laid on technology evolution including human-relevant and prediction technologies. Therefore, India should be playing an innovation game and not a lower cost game.

The next big question is that of translatability, e.g. More than 70% of academic biotech data cannot be translated into an industrial process. The creation of a culture with focus on relevant experiments is required. China and the US always had adequate financing sources available in the market while Europe and India fell behind; and now have to catch up. It is an amazing opportunity for India due to its huge and motivated talent pool, and the global market is endless as there are 3300 diseases still waiting for cures.

14 Panel Discussion: CEO Panel Discussion

Moderator: Mr Gautam Kumra (Chairman of McKinsey's offices in Asia, McKinsey & Company)

Panelists:

- Mr. Christopher Viehbacher (Founding Partner, Gurnet Point Capital)
- Mr. Dilip Shanghvi (Managing Director, Sun Pharmaceutical Industries)
- Mr. Glenn Saldanha (Managing Director, Glenmark Pharmaceuticals)
- Mr. Nilesh Gupta (Managing Director, Lupin)
- Mr. Pankaj Patel (Chairman, Cadila Healthcare)
- Ms. Samina Hamied (Executive Vice Chairperson, Cipla)
- Mr. Satish Reddy (Chairman, Dr Reddy's Laboratories)

Key Highlights:

The discussion was centered around four key themes –

Catalyst role of innovation hubs –

- Innovation hubs have globally been the frontrunners of innovation. However, going forward, with advancements in technology allowing people all over the world to work together remotely,

the importance of geographical co-location may diminish. India can therefore think about reinventing the model and bring stakeholders together virtually

- A few centers in India may be necessary as a catalyst to attract global talent, and we can slowly transition to a non-physical model
- Government play an important role in creating innovation hub which can be catalyst as In other markets, for e.g. China and USA.

Streamlining regulatory and policy measures – The new R&D policy talks about streamlining regulatory processes and also attempts to provide a collaborative environment to properly utilize resources. The deployment of a single-window system for regulatory approvals must be expedited as it would significantly debottleneck innovation in India.

Cracking the funding conundrum –

- The government has to play a role in funding as innovation requires a scale of funding that private players cannot afford. Government schemes have to be well designed and leveraged across the stages of development of a product
- As India has to compete at a global level as products developed in India have to be the best even compared to global standards.

Unlocking quality of talent –

- India has a huge talent pool, but quality of talent needs to be augmented. Curriculums need to be updated, and we need to provide academia access to industrial trainings.
- The industry and the government have to work together to offer an environment that is attractive to top Indian talent, e.g. rewarding researchers through incentives and grants. The overall group agreed that bringing top talent back to India was a crucial step.

15 Way Forward

The Innovation Summit saw a confluence of perspectives and experience sharing from across a broad spectrum of stakeholders spanning, the Government, the Regulators, Industry, Academia, as well as Investors. As India sets out on this multi-year journey to achieve its aspiration of becoming a leading innovator in the life sciences space, there are several learnings from the journeys of other countries / hubs that can be leveraged. Several of the speakers and panels explored these learnings and drew out the imperatives for India:

- **Creating an enabling regulatory setup:** A fundamental enabler for a vibrant innovation ecosystem is a strong and efficient regulatory setup e.g., having a 'single window system', elimination of multiple regulatory bodies, establishing detailed guidelines etc. Further it is critical to ensure that there is an ongoing dialogue between the regulator and the industry e.g., pre-approval meetings, more frequent industry meets, rolling reviews etc. should be considered going forward.
- **Ensuring robust funding / investments:** The Government could create immediate and direct impetus through initiatives such as research-linked incentives, grants, subsidies as well

as higher tax aids for R&D. Further, financial markets could be supported in offering incentives for investing in innovation e.g., pathway for private equity, offering innovation bonds, enabling crowd / P2P funding. Further, as an indirect enabler, it is critical to enhance the credibility of Indian talent to assure / motivate investors to fund innovation in India.

- **Enabling Industry-Academia collaboration:** A key challenge today is the lack of translatability from lab to market. It is critical to set up enabling infrastructure such as technology transfer offices, industry sponsored centers of excellence, incubation centers to encourage industry-academia collaboration. Further, curriculums should keep pace with the ever-advancing industry and provide institutions with direct access to industrial trainings and resources. Inspiration can be drawn from the Bayh-Dole Act in the US that propelled academic research into the market through exclusive licensing deals, resulting in over 10,000 startups born from IPs generated in academia.
- **Putting in place a robust implementation framework:** A dedicated cross-stakeholder core committee must be set up to oversee the progress India makes on this front and should be responsible for:
    - Supporting collaboration and continuous dialogue between various stakeholders
    - Identifying and enabling any cross-stakeholder initiatives or course corrections required to ensure India continues to progress well
- **Monitoring progress and impact:** The "Innovation index" is a holistic yardstick to track progress across the building blocks as well as desired outcome of delivering more and world class innovation coming out of India. The index should be refreshed annually as a means for monitoring progress and to think through any course corrections that might be required. Further, Innovation Summit can serve as a platform for bringing together the various stakeholders to review the index and discuss and align on the way forward.

Innovation is at the core of the life sciences industry India's thrust on innovation will help it evolve from "Make in India" to "Discover as well as Make in India, for India and for the World".