8th Annual Conference on Pharmaceuticals & Medical Devices Sector

India Pharma and India Medical Device 2023

26-27 May 2023,
The Ashok, New Delhi

DAY 1: 26th May 2023 (Friday) **Theme: "Sustainable MedTech 5.0: Scaling and Innovating Indian MedTech"**	
09:30 - 10:00	*Registration*
10:00 - 11:00	**Inaugural Session**
11:00 – 11:15	**Tea-Break**
11:15 – 12:45	**Medical Devices CEO's Roundtable**
11:15 – 12:45	**Workshop on Materiovigilance Programme of India (MvPI)** • Materiovigilance Programme of India (MvPI): Current Development and Contemporary Challenges *(Dr V Kalaiselvan, Senior Principal Scientific Officer, IPC)* • Medical Device Adverse Event Reporting: Lesson's from Clinical Setting *(Dr Kavita Gulati, Director Professor, Vallabhbhai Patel Chest Institute, New Delhi)*
13:00 – 14:00	*Lunch*
14:00 -15:30	*Session 1:* **Practical Commercialization Strategies for MedTech: Pilot scale to Production scale**
	Session Brief: The objective of any start-up is to commercialize its technology in the shortest amount of time and as cost-effectively as possible. Any lost time is irreplaceable, as the start-up risks burning through existing funds. Even if successful, the time to profit under patent protection increases with each minute the technology remains non-commercial. As mentioned, researchers and investors typically have little experience in effectively or efficiently identifying, vetting and managing production facilities (national/international), sourcing raw materials, or locating specialized equipment and instrumentation. More importantly, this is not their core competency, and they usually lack the in-house resources to do all of this. Since time is of essence, a hit or miss approach is not strategic. **Medical Device Commercialization** Commercialization is traditionally a nine-step process from concept to launch. These steps do not have to be taken in the exact order; they can be taken in parallel or in a different order. As long as all of them are taken into account during the development and commercialization processes, they set the stage for the medical device's success, critical parameters impacting Medical Device Commercialization: 1. Phase of Planning (Sketch) 2. Patent Examination 3. Market Relevance 4. Regulatory Compliance 5. Quality Control 6. Application/Implementation 7. Human Factors and Usability 8. Business Development and Marketing 9. Launch

	The medical device market can provide great opportunities for manufacturers if they can successfully navigate the many requirements and multiple-step processes. This session will provide insights for a well-defined pathway for commercialisation and success for startups. It will also include analysis of National Medical Device Policy and understanding its role in steering growth of Indian Medical Device Sector, including startups. **Key Takeaways:** • Guidance towards Scaling manufacturing to meet commercial requirement. • **How to Ensure regulatory compliance of products:** Review of Medical Devices' Regulatory Requirements • Approach to get adequate funding for product development and manufacturing. **Session Chair:** • **Shri Rajesh Kumar Singh**, Secretary, Department for Promotion of Industry and Internal Trade. **Session Co-Chair:** • **Shri Manish Singh**, Principal Secretary, Government of Madhya Pradesh, Department of Industrial Policy & Investment Promotion. **Session Moderator:** • **Dr Taslimarif Saiyed,** CEO & Director, Centre for Cellular and Molecular Platforms (C-CAMP), Dept. of Biotechnology, Govt. of India. **Government Panellists:** • **Shri Naresh Pal Gangwar,** Additional Secretary, Ministry of Environment, Forest and Climate Change. • **Shri Amitesh Kumar Sinha,** Joint Secretary, Ministry of Electronics and Information Technology. • **Shri Chandan Kumar,** Scientist C & Deputy Director, Medical Equipment and Hospital Planning Department, Bureau of Indian Standards. **Industry Panellists:** • **Mr Chhitiz Kumar,** Business Head - Precision Diagnosis & Connected Care, Philips India Ltd. • **Mr Gurmit Singh Chugh**, Managing Director, Transluminia Therapeutics. • **Mr Rajiv Nath**, Manging Director, Hindustan Syringes and Medical Equipments Pvt. Ltd. • **Mr Aravind Viswanathan**, CEO, Transasia Bio-Medicals Ltd. • **Mr Aditya Banerjee**, Managing Director, B Braun Medical (India) Pvt. Ltd. • **Mr Manish Sardana,** President, Poly Medicure Ltd.
15:45-17:15	Session 2: **Propelling the Innovation and R&D Growth: Efficient Quality Management in MedTech**
	Session Brief: Research and Development (R&D) has always remained the cornerstone in the maintenance of market superiority by the developed countries. As we chalk the path of a more robust healthcare infrastructure post pandemic, the Indian Medtech sector will play an important part in the global arena. Indian medical devices market at present is valued at approx. $12 billion and is expected to grow to $50 billion in next 5 years. Better awareness and affordability, coupled with cost-effective skilled labour and government initiatives around improving access to healthcare and incentivising domestic manufacturing is pushing growth in this sector. To promote integrated research, development and commercialization in the MedTech, biologics and biosimilars sector the Department of Pharmaceuticals (DoP) has initiated **'Draft**

	Policy to Catalyze Research & Development and Innovation in the Pharma and MedTech Sector in India'. The **National Medical Devices Policy 2023** aims to build on these measures to facilitate the orderly growth of the medical device sector. The policy focuses on creating an enabling ecosystem for manufacturing and innovation, streamlining regulations, promoting training and capacity building programs, and fostering talent and skilled resources in line with the industry requirements. The policy covers six broad areas of policy interventions—regulatory streamlining, enabling infrastructure, facilitating R&D and innovation, attracting investments, human resources development, and brand positioning and awareness creation. **Key Takeaways:** • Analysis of National Medical Device Policy and Proposed R&D policy. • Understanding gap in current R&D ecosystem in MedTech. • Policy & Infrastructure support in enabling R&D • Center of Excellence for R&D • Research outcome linked fiscal Incentives for India and the world to support transformational and incremental innovation. **Session Chair & Keynote Address:** • **Dr V K Saraswat**, Member, Niti Aayog. **Session Moderator:** • **Mr Nikhil Bhaskar,** Partner, Boston Consulting Group. **Government Panellists:** • **Dr Anitha Thampi**, Director (Technical and Operations), HLL Lifecare Limited. • **Prof. Naresh Bhatnagar**, HoD, Centre for Biomedical Engineering, IIT Delhi. **Industry Panellists:** • **Mr Atul Grover**, Managing Director, Becton and Dickinson-India and South Asia. • **Mr Girish Raghavan**, Vice President, Digital Platforms & India Technology Center, GE Healthcare-South Asia. • **Dr Pramod Kumar Minocha**, Director (Technical), Meril Life Sciences • **Ms Chandra Ganjoo,** Group Chief Executive Officer, Trivitron Healthcare. • **Dr Ravi V,** Head Research and Development, Tata Medical and Diagnostics Limited. • **Mr Mudit Dandwate**, CEO & Co-Founder, Dozee.
17:30-19:00	Session 3: **Capacity & Skill building in MedTech: Industry-Academia Integration**
	Session Brief: India's medical and healthcare industry is rapidly advancing, driven by technological advancements and increasing demand for quality care. This has paved the way for a new breed of professionals - Biomedical Engineers. They are responsible for developing new instruments and technologies to diagnose, treat, and prevent diseases. Scope of Biomedical Engineering- designing and developing medical devices and systems. Biomedical Engineering is relatively new field that has emerged from the convergence of engineering and medicine. In India, biomedical engineering is still growing, but it holds much promise for the future. The reasons for this include:

- The growing healthcare sector in India presents a huge opportunity for biomedical engineers to develop products and solutions that can make healthcare delivery more efficient and effective.
- India has a large pool of talented engineers who can be trained to work in this field.
- The Indian government is investing heavily in research and development in this area, creating more opportunities for biomedical engineers.
- Biomedical engineering offers an interesting career option for those who want to combine their passion for engineering with their interest in medicine.

In MedTech manufacturing ecosystem also there in a need to accelerate adding skills programs for technicians and assistants starting from high school—HSSC is actively working on this; and invest in ongoing training including adherence to quality management systems and compliance standards. An important subject that needs to be emphasized is Quality Engineering which includes knowledge base around statistics, data management, technical writing skills that are important when firms try for other country FDA certifications. More courses around Bio Medical Engineering and Biotechnology would be needed. Female participation in workforce is about 11% as against general industry standards of 25+percent.

Key Takeaways:

- Mapping the gaps and building a future ready workforce.
- Industry – Government/Academia collaboration for the skill development programs.
- Policy intervention for Industry led skilling programs and certification.
- Designing of Courses for Product Development and Product cycle management.

Session Chair:

- **Shri K Sanjay Murthy**, Secretary, Department of Higher Education, Ministry of Education Government of India

Session Moderator:

- **Mr Lalit Mistry**, Partner & Co-Head, Healthcare, KPMG India.

Government Panellists:

- **Mr Ashish Jain**, Chief Executive Officer (CEO) at Healthcare Sector Skill Council (HSSC)
- **Prof. Amitabha Bandyopadhyay,** HOD, Biological Sciences and Bioengineering DSBE, IIT Kanpur.

Industry Panellists:

- **Mr. Bhaskar Malladi**, Head of Strategy, Agappe Diagnostics Ltd.
- **Dr Jitendra Sharma,** Managing Director & CEO, Andhra MedTech Zone Ltd.
- **Mr Sashi Kumar V, Managing Director,** Phoenix Medical Systems (P) Ltd.
- **Mr GVS Manyam,** Managing Director, Panacea Medical Technologies Pvt. Ltd.
- **Dr Ambuj Chaturvedi**, Head of Professional Education, Johnson & Johnson MedTech India.

Day 2: Saturday, 27th May 2023 Theme: Indian Pharma Industry: Delivering Value through Innovation	
10:00 - 11:30 hrs	**Pharma CEO Roundtable**
11:45 - 13:00 hrs	**Regulators Interaction Session with Industry for Pharma & Medical Devices Sector**
13:00 - 14:00 hrs	Lunch
14:00 - 15:30 hrs	**SESSION 1: Pharmaceutical industry as pillar of India's growth and quality as the key foundation growth driver**
	Session Brief: India's pharmaceutical industry has grown tremendously in the recent years, and overall outlook remains robust and positive. Over the last two decades, Indian pharma industry has grown exponentially while significantly contributing to foreign exchange earnings and playing a vital role in the development and manufacturing of cost-effective and high-quality drugs for the country and export purpose. With changing global economic scenario, the industry has touched **~USD 50 bn Mark in 2022**, with an equal contribution in both domestic market and export. Pharma Industry aspires to grow to **USD 130 bn by 2030** and **USD 400 – 450 bn by 2047**. Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics. The overall sector is represented by large Indian companies/ MNCs, and MSMEs which offer relatively lower cost without compromising on quality as is reflected by the fact India has the highest number of United States Food and Drug Administration (USFDA) approved pharmaceutical plants outside the US and also a significant number of World Health Organization (WHO) Good Manufacturing Practices (GMP)-compliant plants as well as plants approved by regulatory authority of other countries. The objective of this session is to explore the role of the pharmaceutical industries of every size and scale in India's growth and how quality remains the core focus in driving the industry's growth. This panel would also deliberate on various key growth drivers to attain 130 Bn USD mark while maintaining the **Pharmacy of the World** title. **Key Discussion Points:** • Indian Pharma industry role in driving India's economic growth • What kind of Innovations, quality, and global reach India should focus to contribute globally – more from value perspectives then volume • Strengthening of quality monitoring framework to attain required consistency. **Chair: Shri Rajesh Bhushan,** Secretary of the Ministry of Health and Family Welfare **Moderator: Ms. Smriti Mishra,** Partner, PwC

	Government Participants: • **Dr. Rajeev Singh Raghuvanshi**, Drugs Controller General of India • **Mr. Adil Zainulbhai**, Chairman, Capacity Building Commission, New Delhi /**Shri Shyam Bang,** Ex-Chairperson, NABCB & CMD Jubilant Life Sciences • **Prof. Dulal Panda,** Director, NIPER Mohali **Industry Panellists:** • **Mr. Kirti Ganorkar**, CEO - India Business, Sun Pharmaceutical Industries Pvt. Ltd. • **Mr Siddharth Mittal**, MD & CEO, Biocon Ltd • **Mr. Nikhil Chopra,** CEO/Whole Time Director JB Chemicals & Pharmaceuticals Ltd • **Mr. Kartik Rajendran,** Managing Director, Abbott Speciality Care • **Mr. Bhushan Akshikar** Managing Director, India GlaxoSmithkline Pharma • **Mr. Rodolfo Hrosz**, Managing Director, Sanofi India Limited • **Mr. V. Simpson Emmanuel**, Managing Director, Roche Products (India) Pvt. Ltd • **Mr. Rakesh Bamzai**, CEO and MD, Mylan Laboratories Ltd. (A Viatris Company)
1530-1545 hrs	**SHORT BREAK**
15:45 - 17:15 hrs	**SESSION 2: Digital Transformation Shaping the Pharmaceutical Industry Value Chain**
	Session Brief: Digital applications can be applied throughout the drug life cycle, from drug research and development through to clinical trials, digital production and digital marketing & Digital R&D. Pharma companies are experiencing a wave of innovations – from new treatment modalities to smart machines, advanced analytics, and digital connectivity. In this evolutionary world pharma industry would require strategies to capitalize on these innovations and advance quality, efficiency, resilience, and workforce agility in pharma operations. To transform Pharma operations, industry needs a roadmap to reinforce existing digital technology. While India's growth trajectory looks promising on the surface, it is evident that there is a significant gap between the strategic vision and operational realities and Indian pharmaceutical companies are facing a unique set of challenges that are creating significant pressure on them to transform their supply chains. India's pharma supply chain is crippled with end-to-end complexity and reducing this complexity can unleash an array of benefits. The fast-paced product proliferation in pharma has several implications for the supply chain, including higher manufacturing and distribution costs, more inventory, and a larger supplier base. The strategy of putting data first has already helped pharmaceutical businesses make a smooth transition to digital. In addition to the drug traceability, the use of blockchain has helped strengthen clinical data security and data privacy. On similar lines, pharma companies have relied on cloud security and centralised access systems to keep track of patient data and other information and Patient Reported Outcomes (PROs) supported decision making. As a result, pharmaceutical businesses are now poised to confidently embark on digital transformation programmes.

	Key Discussion Points: • What does a Digital Transformation in the Pharma Industry look like? • Opportunities and challenges related to the digitalisation process: to put a spotlight on what digital transformation means for the pharmaceutical Industry. • Real-world case studies of digital transformation in the pharma (By Industry Panellists) • New & emerging AI, ML interventions for achieving R&D and manufacturing excellence in Pharma Industry-An Integrated Approach • Key benefits of implementation of digital tools • Building robust quality and compliance system using digital interventions **Chair: Sh. S. Gopalakrishnan,** Special Secretary, (Health) Ministry of Health and Family Welfare GOI **Moderator: Dr. Mahesh Bhalgat,** COO Syngene International Ltd. **Government participants:** • **Shri Kamlesh Kumar Pant,** Chairman, NPPA • ***Shri Abhishek Singh**, CEO, NeGD/DIC- MeiTY* **Industry panelists:** • **Mr. Sanjiv Navangul**, MD & CEO, Bharat Serums and Vaccine Group • **Mr. Motoyuki Sakiyama**, Chief Executive Officer, Otsuka Pharmaceutical Co., Ltd • **Mr. Philippe Houben,** Head digital Transformation Boehringer Ingelheim • **Mr. Arjun Juneja**, COO, Mankind Pharma Ltd. • **Dr. Ravi Prakash Mathur**, Vice President Supply Chain, Dr. Reddy's Laboratories • **Dr. Dhananjay Bakhle,** Executive VP, Medical Research Lupin • **Mr. Lakshminarayana Neti**, Chief Operating Officer, Biological E. Limited
17:30 - 19:00 hrs	**SESSION 3: Leapfrogging into the future of Indian pharma: Capitalizing on global biosimilar opportunity**
	Globally, from 2017 to 2025, the biosimilars market is predicted to reach $46.0 billion, which is rising at a CAGR of 33%. By 2030, India will become the sixth-largest market for pharmaceuticals, and it has firmly established itself in the global biopharmaceutical market. Many of the Indian pharmaceutical companies are preparing to step into the global biosimilars market. Biosimilars are the subsequent adaptations of the original biologic medicines and, these are manufactured with the purpose to provide remedial effects which are similar to the original drug. In the upcoming decade, there would be an increase in the number of existing biologics going off patents which would provide an opportunity for several innovator firms to offer services, specially designed for biosimilars. Due to the increase in patent expiries for biologic drugs, there exists a valuable opportunity for the development of more productive biopharmaceutical industry in India. India pharmaceutical companies are enhancing their manufacturing skills, and for clinical trials, they are working together with pharmaceutical companies worldwide. Also, due to the cost advantage of lower manufacturing cost, India has more benefit than its contesting nations which will further create a favourable scenario for the biopharmaceutical market. The Indian biosimilar market

	includes product segments such as insulin, G-CSF, vaccines, erythropoietin, interferon-alpha, hormones, fibrinolytic and plasma proteins etc. Currently, the pharmaceutical sector is grappling with several issues like delays in clinical trial approvals, the new pharmaceutical pricing policy, a uniform code for sales and marketing practices, compulsory licensing, manufacturing quality, regularity uncertainty, reluctance in prescribing, complexities in the production and competition all of which need immediate attention. This session is aimed at discussing the key strategies to design and develop affordable biosimilars, regulatory challenges and way forward enabling India to emerge as leading player in this space. **Discussion Points:** • Measures to compete with other developed countries in terms of regulatory aspects and export of biosimilars. • Complexities in Production and opportunities in Biosimilars segment • Key Strategies to seize global biosimilar opportunity. • Design and development strategies for novel affordable biosimilar products **Chair – Prof. (Dr.) Y. K. Gupta,** Chairman, AIIMS Bhopal & AIIMS Jammu, Government of India **Moderator: • Dr Shirshendu Mukherjee -** Mission Director Grand Challenges Program of Bill and Melinda Gates Foundation, National Biopharma Mission **Government Participants:** • **Dr. V. G. Somani**, Joint Drugs Controller (India) • **Dr. Manish Diwan**, Head – Strategic Partnership & Entrepreneurship Development, BIRAC, Department of Biotechnology, Govt. of India **Industry Participants:** • **Mr. Susheel Umesh,** Chief Commercial Officer, Emerging Markets at Biocon Biologics • **Dr. P. M. Murli**, Founder & Chairman at Jananom Private Limited • **Dr. Sanjay Singh**, Chief Executive Officer Gennova Biopharmaceuticals (Emcure) • **Dr. Murali Ramachandra**, CEO Aurigene Discovery Technologies Ltd. • **Dr. Prabuddha Kundu,** Managing Director at Premas Biotech • **Mr. Dinesh Sathe**, COO, Reliance Life Sciences