



औषध विभाग
Department of
Pharmaceuticals



8TH
**INTERNATIONAL CONFERENCE ON
PHARMA AND MEDICAL DEVICE SECTOR**

**INDIATM
PHARMA
2023** | **INDIAMEDICALTM
DEVICE
2023**

26th- 27th May 2023
Convention Hall, The Ashok,
New Delhi



OVERALL PROGRAM

INDIA PHARMA & INDIA MEDICAL DEVICE

26th - 27th May 2023, Convention Hall, The Ashok, New Delhi

DATE / TIME | EVENT

Day 1 : Friday, 26th May 2023 | INDIA MEDICAL DEVICE 2023 Conference
"Sustainable MedTech 5.0: Scaling and Innovating Indian MedTech"

09:30 - 10:00 hrs.	Registration
10:00 - 11:00 hrs.	Inaugural Session
11:00 - 11:15 hrs.	Tea Break
11:15 - 12:45 hrs.	Medical Devices CEO Roundtable
13:00 - 14:00 hrs.	Lunch
14:00 - 15:30 hrs.	IMD Session 1: Practical Commercialization Strategies for MedTech: Pilot scale to Production scale
15:45 - 17:15 hrs.	IMD Session 2: Propelling the Innovation and R&D Growth: Efficient Quality management in MedTech
17:30 - 19:00 hrs.	IMD Session 3: Capacity & Skill building in MedTech: Industry-Academia Integration
19:00 onwards	Cultural Program & Dinner Hosted by Dr. Mansukh Mandaviya, Hon'ble Minister of Health and Family Welfare & Minister of Chemicals & Fertilizers, Government of India (By Invitation only)

Day 2 : Saturday, 27th May 2023 | INDIA PHARMA 2023 Conference
"Indian pharma industry: Delivering value through Innovation"

10:00 - 11:30 hrs.	Pharma CEO Roundtable
11:30 - 11:45 hrs.	Tea Break
11:45 - 13:00 hrs.	Regulators Interaction Session with Pharma & Medical Devices Industry
13:00 - 14:00 hrs.	Lunch
14:00 - 15:30 hrs.	IP Session 1: Pharmaceutical industry as pillar of India's growth and quality as the key foundation growth driver
15:45 - 17:15 hrs.	IP Session 2: Digital Transformation Shaping the Pharmaceutical Industry Value Chain
17:30 - 19:00 hrs.	IP Session 3: Leapfrogging into the future of Indian pharma: Capitalizing on global biosimilar opportunity





ABOUT INDIA PHARMA & INDIA MEDICAL DEVICE 2023

The Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India, along with the Federation of Indian Chambers of Commerce & Industry (FICCI) has been actively working towards growth of Pharma & Medical Device sector. Since the objective has always been to encourage and bring forward best technology solutions and manufacturing, therefore, Department of Pharmaceuticals announced India Pharma & India Medical Device series of events which is an annual activity. The 8th edition of International Conference on Pharmaceutical & Medical Device sector i.e **INDIA PHARMA 2023 & INDIA MEDICAL DEVICE 2023** is scheduled from 26th - 27th May, 2023.

The objective of India Pharma & India Medical Device 2023 is to:

- Endeavor to address industry issues and to create a platform to recommend solutions
- Facilitate sharing of knowledge and best practices
- Promote India as a Manufacturing hub in the Pharmaceutical and Medical Devices Sector
- Establish India as a premier global healthcare destination and attract investments
- Provide a platform to network and collaborate
- Identify new priority areas and deliberate upon them



PHARMA SECTOR OVERVIEW

The Indian pharmaceutical industry ranks third globally in pharmaceutical production by volume and is known for its generic medicines and low-cost vaccines. Market size of India pharmaceuticals industry is expected to reach US\$ 65 billion by 2024, and ~US\$ 130 billion by 2030. According to the government data, the Indian pharmaceutical industry is worth approximately \$50 billion in 2023 with over \$25 billion of the value coming from exports¹. Major segments of Indian Pharmaceutical Industry include generic drugs, OTC medicines, bulk drugs, vaccines, contract research & manufacturing, biosimilars and biologics.

Indian pharmaceutical industry plays significant role globally, supplying affordable and low-cost generic drugs to millions of people across the globe. The sector offers 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. India accounts for 60 percent of global vaccine production, contributing 40 to 70 percent of the WHO demand for Diphtheria, Tetanus and Pertussis (DPT) and Bacillus Calmette–Guérin (BCG) vaccines, and 90 percent of the WHO demand for the measles vaccine. There are 500 API manufacturers contributing about 8% in the global API Industry. India is the largest supplier of generic medicines and manufactures about 60,000 different

generic brands across 60 therapeutic categories and accounts for 20% of the global supply of generics. Because of the low price and high quality, Indian medicines are preferred worldwide, making it “Pharmacy of the World”.

India's pharmaceutical sector forms a major component of the country's foreign trade and has been consistently making trade surplus. The Government has put in place an investor-friendly Foreign Direct Investment (FDI) policy to promote investment in the Sector. In pharmaceuticals, up to 100% FDI in greenfield projects and up to 74% FDI in brownfield projects is allowed under the automatic route. The booming pharmaceutical industry of India is largely driven by cost-effective innovation when it comes to mass production of life saving drugs that are used by countries globally. During the Covid-19 pandemic, India was at the forefront of delivering essential drugs and vaccines to several nations. India's

With the immense potential for growth, pharmaceuticals sector is set to attain new heights in a post-pandemic world and elevate its position on the value chain by delivering affordable and quality-assured medicines and addressing the unmet needs of patients across the globe.



MEDICAL DEVICE SECTOR OVERVIEW

The medical devices sector in India is an essential and integral constituent of the Indian healthcare sector. The Indian medical devices sector's contribution has become even more prominent as India supported the domestic and global battle against COVID-19 pandemic through the large-scale production of medical devices & diagnostic kits, such as Ventilators, Rapid Antigen Test kits, Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR) kits, Infrared (IR) Thermometers, Personal Protective Equipment (PPE) Kits & N-95 masks.

The medical devices sector in India is a sunrise sector which is growing at a fast pace. The market size of the medical devices sector in India is estimated to be nearly \$12.5 billion and its share in the global medical device market is estimated to be 1.5%.

India is the 4th largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally.

Export of medical devices from India stood at US\$ 2.90 billion in FY2022 and are expected to rise to US\$ 10 billion by 2025. To increase domestic manufacturing of Medical Devices and growth of sector, Department of Pharmaceuticals has taken a lot of initiatives such as:

- **PLI scheme:** The government has launched the Production Linked Incentive (PLI) Scheme to boost domestic manufacturing in the medical devices sector. Under the PLI scheme for Medical Devices, till now, a total of 26 projects have been approved, with a committed investment of INR 1206 Cr (~\$147 mn) to enable growth and innovation in the MedTech industry and make India as the global hub for manufacturing and innovation in the coming years.
- **National Medical Device Parks:** The Government of India

has taken several steps to ensure the growth of a vibrant ecosystem of medical devices manufacturing in India over the past 5 years, states have committed to set-up dedicated MedTech parks where efficient domestic manufacturing at lower costs. The State Government of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh have been given “in-principle” approval to develop Medical Devices Parks & create a robust ecosystem for medical device manufacturing in the country.

- **Setting up of National Medical Device Promotion Council:** National Medical Devices Promotion Council (NMDPC) will be created to provide an impetus and boost to Indian Medical Devices manufacturing industry and support the 'Make in India' impetus for Medical Devices in India. The forum is headed by Secretary, Department of Pharmaceuticals.
- **Release of National Medical Device Policy:** The National Medical Devices Policy, 2023 is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality and innovation.

The Medical Device industry is highly capital intensive with a long gestation period and requires development and induction of new technologies. It also requires continuous training of health providers to adapt to new technologies. Most of the hi-tech innovative products originate from a well-developed ecosystem and innovation cycle which is yet to be fully developed in India.

The medical devices industry in India is poised for significant growth in the next five years, with the market size expected to reach \$50 bn by 2030. Hence, the future of the medical device industry in India is quite promising.



CONFERENCE PROGRAM India Medical Device 2023

“Sustainable MedTech 5.0: Scaling and Innovating Indian MedTech”

DATE / TIME	EVENT
	DAY 1, 26th May 2023, Friday
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
13:00 - 14:00	<i>Lunch</i>
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: <ol style="list-style-type: none">1. Phase of Planning (Sketch)2. Patent Examination3. Market Relevance4. Regulatory Compliance5. Quality Control6. Application/Implementation7. Human Factors and Usability8. Business Development and Marketing9. 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.

CONFERENCE PROGRAM India Medical Device 2023

“Sustainable MedTech 5.0: Scaling and Innovating Indian MedTech”

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	<p>Key Takeaways:</p> <ul style="list-style-type: none">• 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.
15:45-17:15	<p>Session 2:</p> <p>Propelling the Innovation and R&D Growth: Efficient Quality Management in MedTech</p> <p>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.</p> <p>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.</p> <p>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'.</p> <p>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.</p> <p>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.</p> <p>Key Takeaways:</p> <ul style="list-style-type: none">• 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.

CONFERENCE PROGRAM India Medical Device 2023

“Sustainable MedTech 5.0: Scaling and Innovating Indian MedTech”

DATE / TIME	EVENT
17:30-19:00	<p>Session 3:</p> <p>Capacity & Skill building in MedTech: Industry-Academia Integration</p> <p>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.</p> <p>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.</p> <p>In India, biomedical engineering is still growing, but it holds much promise for the future. The reasons for this include:</p> <ul style="list-style-type: none">• 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. <p>In MedTech manufacturing ecosystem also there is 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.</p> <p>Key Takeaways:</p> <ul style="list-style-type: none">• 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.

CONFERENCE PROGRAM India Pharma 2023

“Indian pharma industry: Delivering value through Innovation”

DATE / TIME	EVENT
	DAY 2, 27th May 2023, Saturday
10:00 - 11:30 hrs	Pharma CEO Roundtable
11:30 - 11:45 hrs	Tea Break
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:
	<p>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.</p> <p>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.</p> <p>Key Discussion Points:</p> <ul style="list-style-type: none"> • 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.
1530-1545 hrs	SHORT BREAK
15:45 - 17:15 hrs	SESSION 2: Digital Transformation Shaping the Pharmaceutical Industry Value Chain
	Session Brief:
	<p>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</p>

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	<p>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.</p> <p>Key Discussion Points:</p> <ul style="list-style-type: none">• 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
17:30 - 19:00 hrs	<p>SESSION 3: Leapfrogging into the future of Indian pharma: Capitalizing on global biosimilar opportunity</p> <p>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.</p> <p>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.</p> <p>Discussion Points:</p> <ul style="list-style-type: none">• 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

ORGANISERS



**Department of Pharmaceuticals,
Ministry of Chemicals & Fertilizers,
Government of India**

The Department of Pharmaceuticals was created on the 1st of July in the year 2008 in the Ministry of Chemicals & Fertilizers with the objective to give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, research & development, protection of intellectual property rights and international commitments related to pharmaceutical sector which required integration of work with other Ministries.



FICCI

FICCI is the voice of India's business and industry. Established in 1927, it is India's oldest and largest apex business organization. It serves its members from the Indian private and public corporate sectors and multinational companies, drawing its strength from diverse regional chambers of commerce and industry across states, reaching out to over 2,50,000 companies.

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