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## Industry Advancement

# Moving in the RIGHT DIRECTION

**India's pharmaceutical sector is well-known around the world. It stands third largest in terms of volume and 13<sup>th</sup> largest in terms of value. In this backdrop, the Government of India (GoI) is taking special efforts in upscaling the sector to its true potential.**

The two exhibitions—INDIA PHARMA 2017 and INDIA DEVICE 2017—organized by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, GoI in association with Federation of Indian Chambers of Commerce and Industry (FICCI), are a testament to the commitment of the government and industry to the sector. The combination of exhibition and conferences at the event brought

to the forefront the capability and innovativeness present in these two sectors as well as its determination to continuously better itself.

Ananthkumar, Minister of Chemical & Fertilizers and Parliamentary Affairs, GoI, actively engaged in the events and spoke candidly on the plans the government has to enhance the sectors. At one of the joint conferences—CEO Round Table—

he mentioned, “The medical device sector has asked for industry-friendly taxation, the development of medical devices parks, and simplification of various procedural issues.”

In order to make the sectors more competitive, he shared that the Union and State Governments will provide common facilities for these sectors, so that their manufacturing costs will come down by 30%. In-line with this,

he announced that a MedTech Zone will be built in Bengaluru.

### Expediting progress

Adding to this, Nirmala Sitharaman, Minister of State for Commerce and Industry, GoI, stated, “The government has decided to include the medical device sector among the 25 flagship industries to boost the ‘Make in India’ program and

*Continued on page 3*



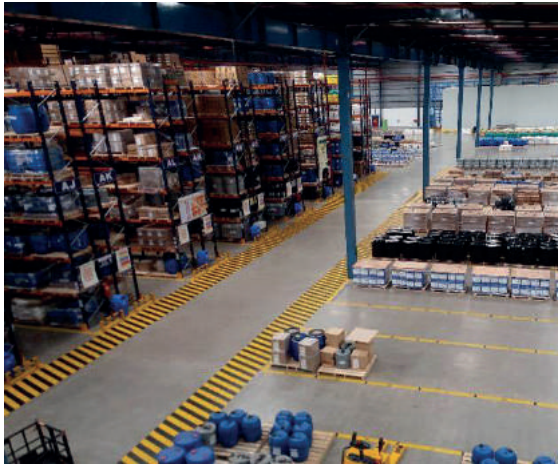
Some of the major initiatives taken by the government to promote the pharmaceutical sector in India are as follows:

- 11 National Institutes of Pharmaceutical Education & Research (NIPERS) will be transformed in innovation hubs to keep pace with the growing demand for highly skilled R&D professionals
- Plans to establish eight mini drug-testing laboratories across major ports and airports in the country to monitor drug quality
- Plans to establish six pharmaceutical parks and two medical devices parks involving an investment of \$4.61 billion
- Plans to setup venture capital funds, to boost drug discovery and strengthen pharma infrastructure
- Pharma Data Bank, an integrated pharmaceutical database management system launched to facilitate online filling of mandatory returns as prescribed in Drugs (Prices Control) Order, 2013

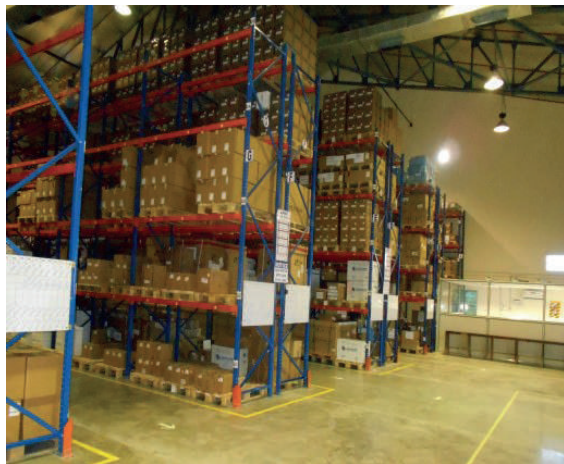




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\*ACTUAL SITE PICTURES





"The government has decided to include the medical device sector among the 25 flagship industries to boost the 'Make in India' program and reduce imports."

**Nirmala Sitharaman,**  
Minister of State for  
Commerce and Industry, GoI



"Union and State Governments will provide common facilities for pharma and medical device sectors, so that their manufacturing costs will come down by 30%."

**Ananthkumar,** Minister of  
Chemical & Fertilizers and  
Parliamentary Affairs, GoI



"With a double-digit growth in the last year, the pharmaceutical sector is all set to reach the mark of \$55 billion by 2020."

**Mansukh Mandaviya,**  
Minister of State Road  
Transport & Highways,  
Shipping, Chemicals &  
Fertilizers, GoI



"As a major supplier of affordable and quality medicines to the developed and developing world, the Indian pharmaceutical industry plays a crucial role in ensuring health outcomes."

**Jai P Prakash,** Secretary,  
Ministry of Chemical &  
Fertilizers, Department of  
Pharmaceuticals, GoI

Continued from page 1

reduce imports."

Also, for the first time, eight international regulators participated at the event throwing light on best global practices, policies, benchmarks for the pharma and medical device sectors.

Furthermore, to encourage the 'Make in India' initiative of this Government and bring in

Foreign Investments into the country, Mansukh Mandaviya, Minister of State Road Transport & Highways, Shipping, Chemicals & Fertilizers, GoI, advised that 100% Foreign Direct Investment (FDI) is allowed under the automatic route for Greenfield projects and 74% for Brownfield projects in the Pharmaceuticals Sector.

India is the largest provider of generic drugs—every fifth tablet, capsule & injections are manufactured here. For 2015-16, India's pharmaceutical exports amounted to \$16.89 billion. Jai P Prakash, Secretary, Ministry of Chemical & Fertilizers, Department of Pharmaceuticals, GoI asserted, "As a major supplier

of affordable and quality medicines to the developed and developing world, the Indian pharmaceutical industry plays a crucial role in ensuring health outcomes. The Government of India is keen to work closely with Industry for necessary reforms required for ease of doing business and 'Make in India' initiative."

## Educating Industry

# Advancing Brand INDIA

**India is the 'Pharmacy of the world'—supplying 70 percent of generic medicine to the USA and Europe.**

The program was an initiative of IDMA, in collaboration with NSF aimed at building 'BRAND INDIA' by developing Change Agents for Quality Excellence and for making India the centre of excellence for pharmaceutical manufacture. The intensive and challenging MBA style program provided participants with the necessary tools to overcome this challenge. The session had key representatives from IDMA and NSF, and the government shedding light on best practices in Quality Culture, Quality Management, regulatory compliance, manufacturing operations. It also covered topics such as leadership skills, skills in risk based decision making, advanced problem solving, crisis management, and lot more.

## Investments

# Attracting Investments

**The INDIA PHARMA and INDIA MEDICAL Joint Investors Meet was held concurrently with the exhibitions.**

The session involved showcasing investment case studies from the industry and analyzing them through a SWOT (Strength, Weakness, Opportunity, Threat) framework. The participants, included policy makers, foreign investors, industry leaders from the sectors, export organizations and delegates. The discussion held brought about extensive insights in how to make India a more attractive destination, incorporate ease of doing business further through policy changes and also showcased efforts made by the DIPPT to highlight India's competitive edge for a global market.

## Knowledge Sharing

# Learning from the Best

**As another means to enhance the pharma and medical device sectors, a joint plenary session—Pharma and Medical Devices Regulatory Meet: Achieving Global Excellence by Sharing Best Practices—was held at the INDIA PHARMA 2017 and INDIA MEDICAL DEVICE 2017.**

The session comprised MHRA from India and the globe (Singapore, Health Canada, Brazil, Russia, Vietnam, Parts of Africa, South Korea, Mexico, China), industry representatives of quality assurance, export agencies, trade and business officials from embassies and foreign missions. The conference brought to the forefront issues relating to trade as well as regulatory demands. Best practices for the sectors was also discussed. It proved to be an ideal platform for global knowledge sharing and networking.





## Deliberating Actions

# Stabilizing the Path to Success

India's pharmaceutical and medical device sector is on a growth trend and in order to keep this trend going INDIA PHARMA 2017 and INDIA MEDICAL DEVICE 2017 had several parallel panel discussion organized on various topics.

## INDIA PHARMA 2017

### Data Integrity Revisited—Challenges and Solutions

The session focussed on how data integrity is key to GMP compliance. It was noted that in order to pass aggressive audits by regulatory agencies it is very important for companies to inculcate good communication, culture and collaboration within its respective organizations. Challenges faced with data integrity as well as best data integrity practices were shared through clinical examples.



### Biopharmaceutical—The New Engine of Growth

The biopharma sector is bringing in several opportunities for expansion. To leverage these opportunities, the session discussed the future of the biopharma sector in the global market and what it meant for India. Government officials, trade and business officials, and industry delegates voiced their take on the same.



### Strategic Initiatives for Success in Developed and Emerging Markets

The panelist comprised government representatives and industry players, trade and business officials, regulatory body representatives. The session provided an interesting take on how current economic climates of certain countries may affect trade and growth. A big part of the discussion surrounded how global players could make use of emerging markets like India as a destination to manufacture for global sale.



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## INDIA MEDICAL DEVICE 2017

### Policy Interventions in Med Tech Sector

Panelists comprised government officials and industry player. The session was focussed on the main theme of 'Shaping the Future'. Policies and initiatives were shared by ministers representing relevant departments. Recommendations were also voiced by the industry to enhance ease of doing business to enhance the growth of sector and increase the adoption of medical technology in the Indian healthcare system.



### Scaling Med Tech Manufacturing in India

India has different states that provide infrastructure and reforms that companies can leverage to make investments. This session had state representatives from different states bring to light the various initiatives their respective states have for investors. Additionally, panelists from the industry shed light on recommendations that would help SMEs or startups to setup manufacturing facilities within a state. Cluster based development was also discussed as part of building ecosystems that encourage sustainability and profitability.



### Emerging Technologies in Indian Healthcare

The central theme of this discussion was how to enhance India's healthcare delivery system. Various possibilities, suggestions, pilot plans, scaling of pilots and adoption of new technologies was discussed. Additionally, to help manage assets and increase better working in care provision, the use of IoTs in the sector was also discussed.



### Supporting Innovation

## Partnering for Success!

The Incubation Centre IIT Patna is an exhibitor at the INDIA MEDICAL DEVICE 2017. Joseph Paul Arackalan, Assistant Manager, Incubation Centre IIT Patna, advises, "The exhibition brings together all contributors of the ecosystem, such as manufacturers, regulators, distributors, incubators, investors, academia and aspiring entrepreneurs under one roof which will facilitate ecosystem to evolve and mature and accelerate newer initiatives in the sector."

He voices that many companies starting in this sector face challenges in securing enough funds to survive. Also, it is difficult for them to get access

to the technology infrastructure required for product development. "The Indian Medical Devices sector is picking up momentum and is expected to grow. However, import dependence has to be reduced. Startup companies in medical electronic devices require engineering skills, healthcare domain skills, equipment for research and product development and support on regulatory approvals and funding. Typically, the 'idea to market' cycle is much longer in medical electronics when compared to IT or ITES services," informs Arackalan.

#### Providing essential support

The organization is looking

forward to meeting aspiring entrepreneurs and startups whom it can support. Any innovator or aspiring entrepreneur can submit their business proposal to Incubation Centre IIT Patna by sending it to [manager\\_ic@iitp.ac.in](mailto:manager_ic@iitp.ac.in). The organization will offer a 2 year incubation program if the proposal is suitable.

"The Incubation Centre IIT Patna is located in the IIT Patna campus in Patna, Bihar, and is well set up to support startup companies in Electronics System Design and Manufacturing and Medical Electronics. Along with up to 10 lakh seed funding, we offer fully furnished co-working space, state of the art laboratories, mentorship



Joseph Paul Arackalan,  
Assistant Manager,  
Incubation Centre IIT Patna

from IIT and AIIMS professors and successful entrepreneurs," states Arackalan.

Incubation Centre IIT Patna  
[www.iciitp.com](http://www.iciitp.com)  
Hall 2, Booth 9



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## Pain Management

## Cranial Electrotherapy Stimulation

Non-invasive treatment provides relief from stress, insomnia, depression, anxiety, PTSD.

The CES UltraQ is a Cranial Electrotherapy Stimulation (CES) device that helps treat stress, insomnia, depression and anxiety by indirectly stimulating tissue in the brain's hypothalamic area. This causes the brain to manufacture various neurohormones, restoring its state to pre-stress homeostasis. The premier unit alone features an original 100 Hz configuration with a knob control. To use the device, either place pre-gelled electrodes below each ear (after plugging the electrodes' wires into the unit's jack), or attach ear-clips, fitted with conductive rubber electrodes, to the earlobes, and current will be discharged through it. It is safe even when used at maximum intensity. Most people experience results almost immediately after treatment. Others notice a response after several days. This relaxed-but-alert state usually remains for an average of 12 to 72 hours after the first few sessions. With regular use, it is possible for the patient to habituate to this preferred state of consciousness. The treatment helps normalize sleep patterns, as well as helps in curbing depression, mood swings, irrational anger, irritability and poor impulse control.

## Usage

The device is to be used till symptoms disappear, most symptoms disappear by using it for an hour per day. It can be used for as long or as little and frequently because the device is not addictive. Owing to its size the device can be used doing daily chores and even at work. Its efficacy has been clinically confirmed through 28 established psychometric tests, computerized EEGs and topographical brain-mapping. Meta-analyses yielding positive results from the use of CES have been conducted at the University of Tulsa and the Harvard University School of Public Health. No significant negative side effect has ever been seen during a study or follow-ups of up to two years later.

Rithwik Pharma Pvt Ltd  
www.rithwikpharma.com  
Hall 2, Booth 85



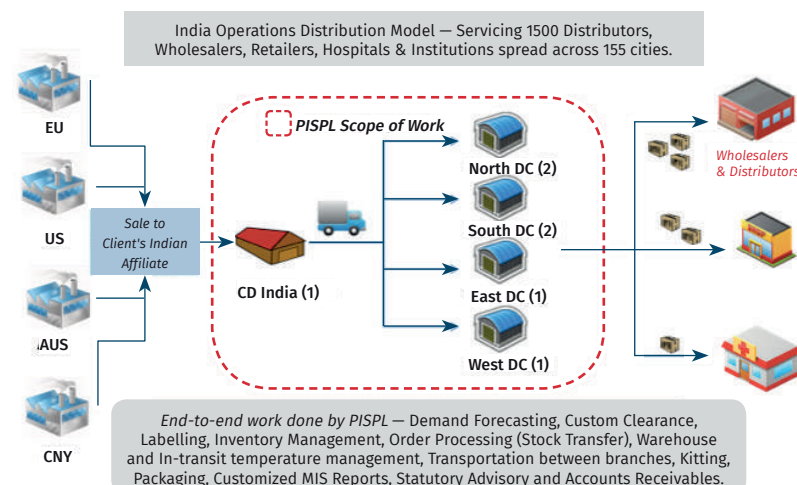
## Logistics

## End-to-end Services

Supply chain management acts as a competitive advantage.

The healthcare industry in India is constantly changing, presenting new challenges to healthcare companies every day. There is no 'one fit all' model, since compliance protocols in each state are different. As a result, the manufacturer needs to have a very specific go-to market strategy within the segments and states they operate in. Here's an example of a case study PISPL that enables its client to focus on their core area, i.e., sales and marketing.

Storage and movement of health care diagnostics reagents (kits) for a Global Healthcare company from the Central Distribution in Chennai to 6 Distribution Centers across India followed by end mile distribution to Wholesalers & Distributors, Retailers, Hospitals & Institutions.



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## CUSTOMER ENDORSED

Here are two testimonials by people who have used the device.

"For 15 years, I have had constant sleep problems. Using the CES Ultra machine, for almost three months now—usually on a weekly basis, I am able to get a good night's rest. Of late, I only use it when I find difficulty falling asleep. I turn the device on and within 30 minutes I am fast asleep."

Sherry from Chicago

"Within a few weeks of using the CES Ultra, I noticed a drastic improvement in my control over my emotions and the quality of my sleep. I use it in silence it for 30 minutes every day before going to bed. What a great product!"

Sidharth from Mumbai

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## Seals and bearings

## Opportunities for Collaborative Success!

INDIA PHARMA 2017 is scaling up opportunities to the pharmaceutical sector through emphasis on FDA and regulatory policies.



Ranjan Sen, Managing Director,  
Trelleborg Sealing Solutions India

Trelleborg Sealing Solutions offers a range of products—from the versatile elastomer O-Ring to complex multi-faceted PTFE based and polyurethane geometries—to the pharmaceutical sector.

According to Ranjan Sen, Managing Director, Trelleborg Sealing Solutions India, the size of Indian population, weak access to the healthcare resources and increasing medical tourism are some of reasons there is a boosting

demand for better healthcare and medical products in India. "The 'Make in India' initiative is helping by filling the gap between the demand and supply cycle by allowing global companies to build ventures and enter Indian market," advises Sen. "This will also help Indian companies to develop products that match the market standard at affordable rates. With the demand in the country for better technology, services and product, industry is expected to grow in future!"

## Overcoming challenges

Sen believes that the major challenges faced by the Indian medical device industry are matching the quality standard and capacity of the international companies and gaining the necessary drug approvals. "I think this event provides a platform for companies to showcase their strengths and focus in the industry. Furthermore, the event also broadens their perspective to the technological advancements, opportunities for growth and competence."

## Forging bonds

The company who is an exhibitor at the INDIA PHARMA 2017 show have witnessed new products that Indian device manufacturers are offering. One of the primary reason for participating at the exhibition was to find opportunities for growth through partnerships in India. "We firmly believe that the Indian market is maturing fast and so are the capabilities of the Indian manufacturers. They will need quality FDA approved partners to grow and Trelleborg could be one," concluded Sen.

Trelleborg Sealing Solutions India  
tss.trelleborg.com/in  
Hall 2, Booth 47

## Identification Solutions

## Process Optimization Solutions

The Indian pharmaceuticals market is set for high-growth; INDIA PHARMA 2017 provides the perfect platform that brings together all stakeholders of the market.

Markss Infotech Limited offers innovative, cost-effective automatic identification solutions for business and industry. The company, participating at INDIA PHARMA 2017, is showcasing solutions that help pharmaceutical companies enhance the efficiency and effectiveness of their manufacturing processes.

Priyanka Zunjarrao, Assistant Marketing Manager, Markss Infotech Ltd, informs, "We are displaying our solutions—the RFID based Vessel sterilization that identifies the material use in the vessel before the cleaning process; the Media Control Solution for Microbiology Labs and API Formulations; and the Print and validate system for Pharmacy Packaging."

Zunjarrao states that the company chose to participate at the exhibition as it showcases new technologies and machinery that will improve manufacturing processes within the sector: "The show provides insight into the future of the pharma sector, giving companies the option to get a competitive edge over competitors."

Markss Infotech Ltd  
www.markss.com  
Hall 2, Booth 59



Priyanka Zunjarrao,  
Assistant Marketing Manager,  
Markss Infotech Ltd

## Market Overview

## Peaks and Valleys of India's Pharmaceutical Sector

India's pharmaceutical industry has demonstrated remarkable growth via both organic and inorganic routes. The issues encountered at each step have proved to be turning points that have changed the mechanisms and prevalent trends of the sector. Presently, the market size of India's pharmaceutical sector is \$20 billion and is likely to touch \$55 billion by 2020.

India's pharmaceutical market is estimated to be the third largest globally in terms of volume and 13<sup>th</sup> largest in terms of value.

As in most other countries, India's medical regulatory structure is divided between national and state authorities. The Drug Controller General of India (DCGI) is the national authority responsible for regulating pharmaceuticals. The DCGI registers all imported drugs, new drugs, and biologicals in selected categories and is responsible for approving clinical trials and maintaining quality standards. Recent events indicate that tighter scrutiny by the US FDA (Food and Drug Administration) for

drugs shipped to the US is emerging as a key challenge for this sector, one that is causing delays in product approvals and launches. For the short term at least, this is likely to slow growth in India and other countries. Since India is home to one-fifth of the world's population, global pharmaceutical companies know that the country's market is a potential goldmine. Domestic pharmaceutical companies are collaborating and joining hands with global companies to expand their geographic footprint. In a connected world, what impacts one industry or country has global ramifications.

## Growth via mergers &amp; acquisitions

Although India's pharmaceutical sector is recognized as a leading producer of generic drugs and has state-of-the-art manufacturing facilities, at the granular level there are apprehensions about patent protection, quality, pricing, etc.

## Under the regulatory scanner

The US FDA focuses on the quality, efficacy, accuracy of data, and safety aspects for all companies shipping active pharmaceutical ingredients (API) and key drugs to the US. Indian generic drug makers account for a significant percentage of generic and over-the-counter drugs sold in the US. However, this percentage may decrease as some pharmaceutical companies in India have not met the standards stipulated by the USFDA. India's pharmaceutical sector has to carefully balance multiple issues such as public healthcare and adherence to rigid global regulatory laws while, and at the same time, remaining profitable

Source: ARC Advisory Group





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Trelleborg is a world leader in engineered polymer solutions that seal, damp and protect critical applications in demanding environments. Its innovative solutions accelerate performance for customers in a sustainable way. The Trelleborg Group has annual sales of SEK 30 billion (EUR 3.25 billion, USD 3.60 billion) in over 40 countries. The Group comprises five business areas: Trelleborg Coated Systems, Trelleborg Industrial Solutions, Trelleborg Offshore & Construction, Trelleborg Sealing Solutions and Trelleborg Wheel Systems, and the operations of Rubena and Savatech. The Trelleborg share has been listed on the Stock Exchange since 1964 and is listed on Nasdaq Stockholm, Large Cap.



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