

elets

Pharma CIO

SYMPOSIUM

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Vivanta by Taj-President, Mumbai

Innovations Reshaping Indian Pharmaceutical Landscape



Delegates at the inaugural ceremony of the elets Pharma CIO Symposium in Mumbai.

India is on the cusp of a momentous paradigm shift in healthcare. Where on the one hand there is a growing need to improve the existing health delivery system, while on the other hand a vibrant ecosystem is required to promote innovation and research and development to discover new molecules and reinforce India's reputation as a leader in natural medicines – an area that is of late witnessing a number of policy interventions.

Elets Pharma CIO Symposium held in Mumbai on April 21 offered a grand opportunity for Pharmaceutical CIOs, policy makers, regulators, industry experts and industry stakeholders to come together to deliberate, network and bring in unique synergies to the system and push forward digital adoption to drive innovations.

The first of its kind Pharma CIO Symposium examined the growth of Indian pharmaceutical industry from the perspective of how Information Technology is adding a

new dimension to the growth of the industry globally, even as experts stressed that to innovate continuously "is not a matter of choice anymore and has rather become a necessity".

Also came up for discussion India's proven capabilities in cutting edge disciplines like chemistry and biotechnology, which should be leveraged to make forays into innovations in drugs.

By an estimate, the industry is all set to expand at a Compound Annual Growth Rate (CAGR) of 16 per cent to \$55 billion by 2020. Much of this growth will depend on Indian pharma companies' capacity to adopt IT to drive their productivity, improve efficiency and maintain cost effectiveness.

With an eye on the changing scenario in the Indian pharma sector, Elets Pharma CIO Symposium has come as a major breakthrough, helping India develop a vibrant ecosystem to achieve its healthcare goals.

Inaugural Session

A Peek into Innovations in Pharma Industry



VR Shah

Deputy Commissioner

Food and Drug Control Administration, Gujarat

"Sharing the latest developments in Food and Drug Control Administration (FDCA) of Gujarat, VR Shah, Deputy Commissioner, FDCA-Gujarat said that FDCA along with some other state government departments have been identified under the Right of Citizen to Public Services (RCPS) Act. "The moment I receive an application, its acknowledgement has to be sent to the applicant within three days. If there are any documents to be furnished or there are some lacunas then we have to inform the applicants about them. An officer is designated to look into the grievances and is assigned a time limit to dispose off the case. If the officer fails to do so, the applicant has the right to sue him."



J Jayaseelan

Chairman

Indian Drug Manufacturers Association

"In 1970s, the government took two major decisions. The first was removal of product patents to enable Indian pharma industry grow. This helped us to do reverse engineering. The second major decision was government imposing restrictions on imports of drugs. Although these policies helped in the growth of Indian pharma sector, the negative impact was the migration of companies focused on R&D out of India due to removal of patent protection. In 2005, when we again became part of the global patent system no Indian pharma company could launch a single molecule on its own. One formulation can fetch, say, \$100 million which is good. But one new drug can help India earn as much as Rs 50,000 to Rs 70,000 crores from just one product."



Mayur Parmar

Food and Drug Control Administration (FDCA), Gujarat

"Pharma industry is the second most regulated industry in the world. When it comes to IT adoption, the industry is more reactive than proactive because regulations in always top of its mind. Consider a situation where one fine morning you find all the data on your computer is lost. That would still be fine as we can tackle it. But imagine that same thing happening with the health data of a person. Suppose a patient has been receiving cancer treatment through nano-robots and someone hacks these nano-robots. So, we need to take care of these challenges when we adopt IT."



Yugal Sikri

Chairman

Pharmaceutical Management, School of Business Management & Director, Pharmaceutical Technology Management, SPP School of Pharmacy and Technology Management, NMIMS University.

"Innovations are happening in india at a dramatic pace. In the last 10 years a lot of things have disappeared that we thought were part of our lives. We need to look at digitalisation and innovations from the perspective of fast changes happening around us. I don't think it's a choice. It's rather a necessity. It is mandatory for us to be digitally aware about what's happening around. Business is changing dynamics and it's important for us to keep pace with the change and understand the new lingo."

Key Takeaways

- In the area of ease of doing business, Gujarat government authorities have identified certain areas where officials need to deliver on the commitments.
- Earlier, when Gujarat FDCA officials used to go for an inspection the report could be submitted after about a week or 10 days. But now the report has to be submitted within 24 hours and the person inspected is able to see that report within the next 48 hours.
- All the agencies concerned will now be collectively setting out the dates for routine inspections and they will be conducting their respective inspections on a single day.
- The Central Drugs Standard Control Organisation (CDSCO) has opted for e-platform, through which each and every retailer and wholesaler will be connected to make available all the data about the stock of the medicines.
- The track and trace system of the inventory is enabling a drastic shift in the Indian regulatory functioning. It will be fully focused on technological innovation, capacity building of the officers as also of the small and medium sized manufacturers.
- It's high time that organisations have a department called digital education where every single employee of old age or middle age can learn the new lingo.
- Even the largest of pharma organisations do not have digital education department to make every single employee digitally enabled.
- Today, a mobile phone connects us to the people, organisations, and a large information highway (internet) which runs across the globe.
- Wearable devices are coming out in a big way. Innovative products like fibrotronic, which acts as a sensor to capture health data our body generates, have been launched recently. It means that everything is getting connected to the information highway (internet) -- thanks to the Internet of Things.
- Wearable devices are increasingly giving information about blood pressure, glucose level and all other relevant metabolic parameters constantly round the clock.
- In 2016, a contact lense was launched which measures the glucose level from the lacrimal fluid (tears).
- These devices are generating huge data -- structured as well as unstructured -- which is being used by AI to generate useful information.
- To store and archive the huge amount of data, cloud technology has come up, as also the discipline of analytics.
- In 2005, when India became part of the global patent system no Indian pharmaceutical company could launch a single molecule on its own, although the country did well in technological innovations like special pharma formulations.
- One formulation can fetch, say, around \$100 million for the country. But one new drug can help India earn as much as Rs 50,000 to Rs 70,000 crores from just one product.
- After India became a part of the global patent system, all the multi-national companies have started coming back to the country for R&D because of good availability of talent in basic sciences and information technology. Today, no R&D can take place without IT.
- For the next 30-40 years, India needs to focus on innovations and strengthen its roots in biosimilars and biotechnology.
- India is very good at pharma chemistry. In the first quarter of 2017, of the 171 ANDAs approved 55 were from India. Indian companies are continuously having 30-35 per cent of the ANDAs filed in the US. Every third ANDA is from India.
- The areas for future growth include R&D and biosimilar.
- The future growth potential of Ayurveda, Siddha and other traditional medicine systems is huge for India.
- Despite India being one of the leading the source country for natural medicines, China enjoys more than 90 per cent of the market share.
- India needs to find out the active principles in each herb. Concerted efforts are required to bring new molecules and products in traditional medicine systems.
- Pharma industry attracts the highest foreign direct investment. If it is taken up as a flagship industry it will help Indian economy to grow further.

Key Challenges for Indian Pharma Sector

- Before 2005 Indian pharmaceutical companies could meet the domestic needs, but after the patent system came into play only multinational companies could launch any new drug – although they are partnering with Indian companies for marketing purposes.
- Indian companies might do well in exports but with Generic Prescription Code to come into force, the Indian pharma industry needs to find a way to meet the impending challenges.
- In the active pharmaceutical ingredient (API) space, India has proven capabilities. But over dependence on China for 70-75 per cent of APIs will not augur well for India. Unfortunately, Indian manufacturers depend on China only for the cheap raw material and not for any technological reason.
- India has a price control mechanism in place. Since there is a control on the end product price, Indian manufacturers are unable to match the price offered by China.
- There are deliberations happening on imposing import ban on Chinese products, but unfortunately if you are going to put a lot of import burden on China APIs then most of the products may not be available for domestic consumption. Until we are able to make APIs at a comparable cost to China, we will not be able to provide the products at the price NPPA fixes.
- Unlike formulation business, API business is a 24/7 business. It is a high power intensity business. Power is a very important component where China has an edge over India as the cost of power in China is negligible. Any part of India cannot give that kind of power support to API industry.
- The current government had announced 2015 as the year of API. A lot of talks took place on this subject but the API industry is still on its own. Nothing happened fruitfully and a lot of decisions are still in the pipeline.
- There is requirement for a separate ministry for pharma industry, as regulatory part is looked after by the Health Ministry, export by the Commerce Ministry and pollution control by the Forest Ministry. The Pharma Department is part of the Chemical and Fertilisers Ministry. Since the Pharma Department is newly-formed, no responsibility has been assigned to it, so it does only price control.



Panelists during the inaugural session of elets Pharma CIO Symposium at Vivanta by Taj-President, Mumbai.

Industry Presentation

Technology Changing Dynamics of Business



Ajit Sodhi

Managing Partner & CTO
mySignatureBook

"Businesses are changing very fast owing to the accelerating rate of technological innovations and adoption, said Ajit Sodhi, Managing Partner & CTO, mySignatureBook, as he cited the example of telecom industry to put his point across to the audience.

"I give an example how the telecom industry was started. Way back in 1800s it took almost 80 plus years before we could see the dial up phone but the technological change from the dial up phone to Nokia popular model happened in much shorter time. But the smart phones came up very fast. Businesses are changing. Today Pfizer's competition is not from Eli Lilly but from Qualcomm," he said.

"GM Motors was at one point of time the world's biggest car maker. Ford and GM Motors were running the entire automobile sector.

They were the global leaders making lot of money. But today Tesla is the most valued company in the US," he added.

Tesla changed the whole business model of how a car is produced, sold and how the people are experiencing the whole utilisation of the car, according to Sodhi.

"Tesla is making only 70,000 cars a year, while GM is making five million cars a year. Nobody could have thought in their wildest dreams that GM will be caught behind. There are a lot more companies like these that are changing the whole economies. If you are not changing; and you are not digital your survival is on stake," he said.

Our vision ties off with the same thing. We are helping all those organisations which are trying to achieve their changed goals in a more secure and transparent manner, Sodhi added.

He also explained the best practices for digital adoption and how mySignatureBook can help in getting organisations digitised.

Key Takeaways

- Digitisation of pharma sector may reduce development cycle time and cost, evolve patient care model and comply with industry and country regulators.
- Change should happen quickly, but it cannot be haphazard. It has to be very accurate.
- All the companies which are 100 per cent digital are able to grow their revenues much easily as they are able to control their cost, and cost impacts their profits – pushing them further up.

Panel Discussion 1

Disruptive Innovations and New Technologies in Pharma Industry and Engaging Physician/Patient to New Digital Era



Jasmine Gorimar

Head-Technology
Boehringer Ingelheim

"It's very cliché to say that necessity is the mother of innovation, but what kind of innovation we are talking about? Is it only in the area of new drug development? No. Is it innovations in the area of consumerism? The consumer is changing, their behaviour is changing, their habits are changing... the whole environment is changing. Not only the internal Indian pharmaceutical environment is changing, but the global market is changing. Not only the pharmaceutical market but the behaviours across the industries are changing. We are talking about not only the changes in the area of consumerism but also in the area of supply chain management."



Atul Aslekar

Director
Nova Lead Pharma Inc

"Talking about disruptive technologies, he said that drug discovery and development is seeing a huge amount of data getting generated. "There are a number of opportunities to use big data and connect it way back to the design and development aspects of medicines. Particularly in the Indian context, as the digitisation ramps up, we are quite sure that we will have multiple data points which will give lots of insights to the pharma companies to provide India-specific solutions."



Gyan Pandey

Chief Information Officer
Aurobindo Pharma Limited

"Speaking about disruptive technologies happening in the pharma manufacturing, he said that disruptions are happening everywhere along with digitisation. "The two words that resonate on any forum are: disruptions and digitisation, which are intricately linked together. It is not that digitisation is a new concept but the whole automation or digitisation's impact is now connected across the processes end to end. This makes the world more connected. IT is involved in every aspect from ideation to drug discovery, manufacturing, and from supply chain to supplying drugs to the end customer. It is again involved in analysing all those data points to make it more efficient."



Amit Singh

Pharma Sales Director
South and South East Asia,
Elsevier

"Sharing Elsevier's experience of going digital, Amit Singh said that "Content is the king and we own a lot of content, but the challenge for us was to find out how we are going to position ourselves going forward in the future. So, the first part was how to go from print to E (electronic). That part is already done now. The next part would be how to use the data in terms of big data analytics or machine learning. A lot of these things are being taken up in the pharma industry as well. The whole idea is how we use the data once we have it in the digital format or machine learning format. We use the data to draw certain inferences. We believe in helping our customers in the pharma segment as well as doctors."



Anil Gidwani

Director
Dana Group

"Disruptive innovation is something which is connecting. The people at the bottom of the pyramid are using IT. This is disruptive. We are also getting transparent by using IT. The other important disruption is taking place in the monitoring space. We are monitoring trials, representatives and processes. Then you have feedback mechanism, which is getting fast."

On how to use IT disruption in the pharma industry, he said that in the marketing and sales division a sales representative can use an app and can give you an exact picture of his doctor visits. This eliminates the job of the area manager. If he has a question, he can send it across to the product manager and get the reply immediately. "Similarly, on the manufacturing side we can do even more. For example, we can measure the weight of the tablet, the variation between one tablet to another."

"Disruption in IT is introducing transparency. It brings us more closer to each other. Today, if FDA has a website where pharma companies can upload details of each and every batch produced with detailed specification of each and everything, FDA inspection becomes an online process."



Ajit Sodhi

Managing Partner & CTO
mySignatureBook

"In the next 5-10 years, we are going to see personalised care start happening in India. With computing power going up so fast and so cheap, it has become very fast and cheap to compute your human genome. We are already witnessing a lot of research and products coming up in personalised healthcare. With the computing power processing ability is so easily available in cloud that you can reach out to many patients and subjects. Research is also getting very fast and innovative."



Panelists deliberating during the panel discussion on 'Disruptive Innovations and New Technologies in Pharma Industry'.



Key Takeaways

- Google Health is putting in a good amount of investment to track individuals when they are not sick. The company is going to track people when they are very young and see how they are fairing in their health. Based upon that, they are going to collect a huge amount of data and the analytics will come into play.
- Very soon the accountability will be very high for physicians to see whether the services provided by them were really required or not. The tracking and traceability is going to happen very soon.
- Big IT companies like Google, IBM and Microsoft, etc are already making a huge amount of investments into healthcare applications to allow trace and traceability of the transactions that are occurring through Blockchain.
- Auto industry has been very fast in adopting changes on the digital platform. But in the pharma industry, this adoption has been a bit slow. The reasons could be seen from the business point of view or regulations.
- As pharma is the second most regulated industry in the world, it has to maintain proof of records over a period of time. In India, financial records are maintained till 8 years, but all the batch records of a particular drug till the time it is in the market. Most of the times, these records are on the paper.
- Focusing on data integrity and maintaining the record in the paper format will be very costly and also it may not be conclusive to prove to the auditors that there are no manipulations.
- The areas in pharma sector suitable for digitisation are the factory and the supply chain. If you talk about inventory management, the inventory carrying cost in the pharma is too high. If you have the right supply chain system where you have the visibility, better planning, better utilisation and self life, you can deliver in time and avoid millions of dollars of losses. It will eventually be beneficial for the society because drug companies will be able to provide drugs at lower costs.
- Today, in India we have about one million deaths because of medical negligence. The number in the US is also similar. So, if we can actually use the data, put a context to the data and help physicians a lot of quality in terms of measurable outcomes will come to medicine and that can help drive the next wave of growth for pharma.
- Currently, we are seeing the growth in pharma slowing down. The thing that can help Indian pharma get out of the current slowdown is the digital innovation.
- There is the need to use data to help physicians come out with more measurable outcomes.

Panel Discussion 2

Policies for the Pharma Industry -- Challenges and Opportunities



VR Shah

Deputy Commissioner
Food and Drug Control
Administration, Gujarat

"The scenario between 1970s and 1980s was an example of opportunity when India decided to follow the policy of "Patent to Process" and by reverse engineering the industry grew in leaps and bounds. But the period from 1994, after India became a signatory of TRIPS (Trade-Related Aspects of Intellectual Property Rights) with 10 years window, can be called as challenge because now pharma firms cannot replicate the products which are already in the market. This forced the pharma industry to either go for exports or domestic list of off-patent generic drugs. It also forced the pharma companies to start concentrating on R&D."



Panelists with their trophies at the elets Pharma CIO Symposium in Mumbai.



Dr Pravin Ghadge

Head-Clinical Development
Reliance Lifesciences

"New regulations and government policies should not be looked as roadblocks for the pharma industry. When we are developing molecules for the domestic market, we tend to be a little relaxed in presenting the data. But the new government policy requires manufacturers to present the data in a specific manner. So, whatever data we are gathering from clinical trials in India, that data is getting recognised elsewhere as well. It underlines the success of the regulatory authority."



J Jayaseelan

Chairman

Indian Drug Manufacturer's Association

"We are already the top exporting country in the pharma sector. The direct challenges for Indian pharma companies in this area include fast evolving international regulations, data integrity and other new concepts. The challenge of doing business in a regulated market is very high for Indian pharma companies. Suppose an Indian pharma company has invested Rs 500 crores in its facility for export. Now, an EU auditor coming for inspection and seeing some differences in the company's data will immediately issue an import alert on the company. To get an USFDA approval, a company needs to invest heavily and wait for three-four years before starting doing business. But because of one import alert, the entire export business of the company can come to a standstill."



Saisudha Patro

Managing Director
Mundial Pharmaceuticals Private Limited

"When we talk about the policies, we need to see whether these are beneficial to entrepreneur, investor or the new comer to the marketplace. As an Indian player, I may have the technology, knowledge and good labour, but still I am not so competitive because we keep on paying different types of taxes. Most of the efforts of the Indian pharma companies are diverted towards cost saving and increasing sales, rather than focusing on innovations and R&D."



Madhusudhan N Saraf

Principal and Professor of Pharmacology
Bombay College of Pharmacy

"Pharmaceutical industry is a knowledge-based industry and the most important component of it is human resource. Today, we are facing the challenge of availability of quality human resource. In spite of the fact that we have a number of educational institutions imparting pharma education, there is a big dearth of quality people who can cater to the industry. Industry-academic linkage is the need of the hour."

Key Takeaways

- The key initiatives of the Gujarat FDCA in e-governance space include two portals: DMLA and XLN.
- The XLN portal is especially designed for the chemist shops. Some 33,000 chemists in Gujarat are on this portal along with the drug inspectors and all FDCA officials.
- Any person can check the credentials of the nearest chemist shop and pharmacist on this portal. Nearly 14 states have replicated the XLN module.
- The XLN website is connected with the FDCA laboratory in Baroda, Pharmacy Council of Gujarat and Pharmacy Council of India. The moment a sample is considered not of the standard quality, all 33,000 stake holders get an SMS alert so that they can prevent using that particular batch of the product.
- Similarly, there is the DMLA website for pharma manufacturing firms. It facilitates firms to apply for a product and get permissions online. The database of 250,000 product permissions granted to the firms is also available there.
- Very few companies in India are going for eBMR (Evidence-Based Medicine Reviews). If Indian companies have to build their reputation in pharma sector, they need to adopt such global best practices.
- When the US and EU regulators see a small difference in the data, they are not bothered about the end-product quality. They tell the company that since you have not signed on a particular date as required, your data is not believable. So, the end product quality cannot be checked. This is a new learning for the industry.
- In the last three years, top 25 Indian companies have invested more than Rs 22,500 crores in the US. They have started their formulation facilities in the US. The reason for the step is that even if they get an adverse observation there, no import ban is imposed on them. The problem can be addressed much faster in the US than in India. But no company has an API facility there because it is a 'Red Category' industry associated with pollution.
- Egovernance and Digital documentation is going to help Indian pharma companies to meet the challenges of regulated markets.
- There are more than 10,000 pharma companies in India, out of which top 25 companies contribute 82 per cent of sales. Any policy the government introduces should think of small and medium pharma companies as well.
- The latest challenge for small and medium companies comes from the generic medicine code or the Uniform Code for Pharmaceutical Marketing Practices (UCPMP). Once the UCPMP comes in, all the small and medium marketing companies will slowly vanish.
- The small and medium companies should understand that they have to find out unique products like in naturopathy, or have products in bio-similar segment.
- Today, the consumers are becoming more aware and, therefore, over the counter medicines offer a good opportunity for the pharma industry to grow.



Key speakers discussing their ideas at the panel discussion on 'Leveraging IoT and New Age Technology for the Growth of Pharma Sector'.

Panel Discussion 3

Leveraging IoT and New Age Technology for the Growth of Pharma Sector



Mayur Danait
Chief Information Officer
Lupin

"Lifesciences industry is considered to be laggard when it comes to adoption of technology. It's not so proactive, as some of the other industries have been. In all fairness, there is a very strong reason for that. It is the second most tightly regulated industry. In the last couple of years, we have also seen a lot of industry headwinds. We have seen the R&D productivity falling across the world, competition increasing coupled with thinning margins and falling prices. We have also seen the cost of compliance going up, putting a lot of pressure on manufacturers. I think there are four areas where IoT will be relevant: one is drug discovery and development, while others include manufacturing and supply chain, sales and marketing, and pharmacovigilance."





Ravi Sharma
Chief Information Officer
Marksans Pharma Limited

"Speaking on the impact of Internet of Things on R&D, Ravi Sharma, Chief Information Officer, Marksans Pharma Limited, said, "IoT has a big role to play in organ on the chip in future because lot of studies have been done on the subject and there will be restrictions and people will not volunteer for it. If some kind of silicon chip is emedded in a human body, it will not have side effects but we will be able conduct most of studies on the molecule."



Devendra Dhawale
Director, CIO Advisory &
Digital Consulting
KPMG

"In 2012, a student whose name was Jack Andraka won the Smithsonian American Ingenuity Award for an early stage pancreatic cancer test. When he developed that test he did not have any facilities. What the organ on a chip is going to do for a researcher is going to promote a 'do it yourself' trend. If you are adept enough in R&D, there is a lot of innovation expected from this."



Sanjay Moralwar
Group CIO
Zydus Cadila

"Wherever you are required to collect data and there is a hinderence in collecting it, IoT will be utilised there. We don't have much R&D happening on animal healthcare in India. Countries in the Western world are already using IoT to collect animal health data through RFIDs and chips. Similarly, wearable patches is not a big market in India, but it is a big market in the US."



Key Takeaways

- IoT has great potential in manufacturing as it can play a big role in capturing data at source. It can help in adoption of proactive approach in ensuring that a failure does not happen.
- Pharma companies are under lot of pressure to serialise the products. A lot of investment

is being made in track and trace. The entire industry is looking at it from the compliance point of view. But there are lots of IoT devices available in the market today which can also capture information on the go about all the shipments.