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## Making API production cost effective with technology

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India is now poised with a unique challenge of standing on its own feet in API production as well as saving the world by providing lifesaving medicines.



The Indian Pharma industry is seeing an unprecedented demand to step up research and production initiatives. India contributes a grand share in global generic market up to 50% as per recent market survey. In US alone, Indian Pharma sector has bagged more than 40% of market share. Export market may further increase by another 8-14% in next 3 years as per KPMG.

However, with rising cost of APIs and heavy dependence on API imports, India must find a way to meet the demand without hurting the bottom-line. Lockdown of markets and international borders has led to a shortage of APIs and KSMS. If not addressed now, it will affect Indian pharma's ability to continue to meet the surging demand. To take complete advantage of the current market demand, Indian Pharma must accelerate the production work. Amidst all this, to make India self-reliant, Indian Government started promoting the concept of "Make in India."

Can India become self-reliant in API production is the big question to be answered. India is now poised with a unique challenge of standing on its own feet in API production as well as saving the world by providing lifesaving medicines. Every adversity carries an opportunity within itself. Even in the current pandemic situation, there is an opportunity for Indian Pharma sector to pause, reconsider, and make collective efforts for a better tomorrow and promote "Make in India." If Indian Pharma wants strong foothold in API production, it must replace person dependent and paper dependent processes with technology.

### **Why Indian Pharma Needs to Become Self-reliant in API Production?**

Indian Pharma industry is the largest provider of generic medicine in the world. Globally, it ranks #3 in production and #13 in value. 60,000 generic brands are produced, and 3000 Pharma companies are present in India, with around 10,500 manufacturing units. With such a huge global presence and potential to produce API locally, Indian Pharma sector still showed interest in importing raw materials from other cheaper sources. Cost effectiveness and pricing policies are the predominant players that caused this major shift of mindset in the industry. Understandably, companies chose to import cheaper API than produce locally to have a better price margin. The risk of facing issues with unknown impurities is also overlooked for the same reason. Regulatory bodies, thus, whip the Pharma sector with more stringent processes of auditing to ensure product quality. The main aim of regulatory authorities is not to let the price margin and impurities affect the lives of millions. This is causing many more concerns to the Indian Pharma sector.

With the current pandemic situation, the harsh reality of India's dependence on other countries for API has come to light. Bloomberg states that around 70% of India's API imports come from China. Almost \$2.4 billion is spent on procurement of API from China. Apart from such a huge outflow of cash from the country, there is another problem that Indian Pharma sector currently faces - API shortage. The scarcity of APIs led to a sharp incline in the API prices almost to 100% which affected the price and cost of drug production. This has once again raised the need for Indian Pharma to become self-reliant in API production. It has also raised the need for Indian Pharma to look at digitalization and automation of processes as the best alternatives to reduce costs and enhance product quality.

### **Financial Support from Government for Full Fledged API Production**

Indian Government is now showing keen interest in reviving the local API production units. The "Make in India" concept is gaining more predominance. Through an investment package of \$1.3 billion, it encourages Pharma companies to come forward and produce API in India. It also aims to keep already established companies intact in the country. It works against the movement of production units to some other countries. Manufacturing clusters, low cost production technologies are some of the measures to be taken immediately. Government ideally wants to increase API production in India to cut the over dependence on other countries.

Indian government is focusing on creating a conducive atmosphere and incentivizing Pharma companies that engage in API production. Supply chain management and reorganizing the supply chain and production units in the country would keep India prepared for any future pandemic situations.

### **Automation & Digitalization of Pharma Industry**

Overlooked in the past, but fast becoming a priority, digitalization must be a close next priority in pharma's strategic initiatives. Compliance issues, risk of data loss, wastage of time and effort, transcriptional errors, etc. are some of the issues commonly

found in Pharma companies following manual procedures. Digitalization was in the wish list of Pharma sector from many years. In the current situation, to promote “Make in India” and enhance API production, adopting new technology is the immediate and right answer to scale properly.

There is a paradigm shift in the way the world is functioning currently. Some Pharma companies who were vigilant have adopted various new technologies to ensure product quality. Quality being the primary requirement in Pharma industry, every Pharma company needs to tread the same path. Remote working, E-audits, reduction in person & paper dependency are the new norms of the day. Many of the Pharma processes except production site can be managed remotely. Some Indian Pharma companies are using robotic process automation (RPA) to automate certain repetitive processes and reduce the human presence in the laboratory. Smart glasses and such other equipment also facilitate quicker manufacturing and reduced person dependence. This newly enabled remote working option has helped numerous employees to work to their full potential with minimum risks.

Regulatory authorities are also avoiding the risk of virus spread by going for E-Audits. FDA, MHRA, and other regulatory agencies are encouraging Pharma companies to digitalize their processes. Digitalization will ensure smooth flow of audit process as data will be readily available for any clarification. The whole audit process can be completed quickly and efficiently. Many sites in India have efficiently cleared the FDA’s E-Audits using digital tools. Adoption of new technology and automation of processes ensures enhanced product quality and compliance. It relieves Pharma companies from major burden of worrying about regulatory audits.

### **Key Role of Technology in Scaling Indian Pharma**

Digitalization is the only and most important tool that can enhance Indian Pharma sector’s capabilities and push it to the next level. Pharma companies can leverage IT solutions for digitalization of various processes with applications like Laboratory Information Management System (LIMS), Document Management System (DMS), Quality Assurance Management System (QAMS), Batch Record Management System (BRM), Electronic Notebooks (ELN), Electronic Logbooks (eLog), Competency Management System (CMS), Instrument Interfacing and Integration with EDAP, Engineering Services Management System (ESM), etc. These applications aim at ensuring better quality and compliance consistently. They also make the production processes cost-effective which is the need of the hour.

Using these applications, Pharma companies can automate their review and approval process, digitalize workflows, channelize quality analysis process, and achieve much more. These applications ensure 100% removal of transcriptional errors, delay in documentation, and many such issues that usually lead to increased production costs. The Pharma IT solutions, mainly in the categories of quality control, quality assurance, manufacturing would give the required boost for local API production. This will also lead to easy collection of quality metrics.

As discussed above, Indian Pharma is doing exceptional business in generic medicines. With proper channelizing of resources and leveraging available IT solutions, they can reduce the production costs, ensure quality and compliance, and manage pricing of API components.

One important point for Indian Pharma leaders to focus on is the type of application or tool that best fits their necessity. Many eminent businesses in India have shouldered the responsibility of making API production cost effective by providing numerous Pharma IT solutions. By using these different solutions, profit margins can also be increased. As the manual processes can be lessened, there is more data security and reduction in redundant work. Complaint processes and right tools at the right time would ensure better product quality and yield. In a nutshell, automation & digitalization of processes is the most efficient way of making API production cost effective.

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