# "Achieving sustainable operational excellence would be the key imperative for this industry"

...says Sayantan Roy, Software Business Leader, GE Intelligent Platforms. He discusses his views on IT adoption in the pharma industry and GE's role in the same.

Arshia Khan



#### Tell us about GE Intelligent Platforms' interest in the pharmaceutical industry.

GE has always been interested in advancing the state of the healthcare industry. GE Healthcare provides affordable, high quality healthcare to millions of patients worldwide. In the same vein, GE Intelligent Platforms (IP) endeavours to help pharma companies provide quality drugs at the right price to alleviate patients' pain. However, pharma companies cannot produce high quality drugs at such high cost levels that no one can afford them. They need to maintain their costs low, and that is where we step in. We help them optimise their costs, while assuring them the same high quality.

The industry is fast globalising, quality and regulatory compliance is attracting boardroom attention, and there is an urgent need to manage costs. We are well positioned to help the industry on all three counts.

## What are the biggest challenges the pharma industry faces today?

Globalisation and compliance have brought more focus on regulations such as FDA, GMP, etc and have also increased competition. This has resulted in margin pressure. No longer can one afford to leave Work-In-Progress (WIP) production and material as a black box disconnected from business systems. Quality rejection costs, operator inefficiency and energy costs are three important parameters, which every pharma company needs to control. Most

plants have a basic level of automation by way of Programmable Logic Controllers (PLCs) and Distributed Control Systems (DCS). But none of these automations focus on the above factors. Globalisation of industry now demands that not only the best quality drug reaches the patient but also the same is produced at the minimum cost.

## How does GE help address these challenges?

We recommend a step-by-step approach to protecting one's investment. As first step, we integrate all the plant data into a central repository and build a visibility of the plant operations with respect to the manufacturing Key Performance Indicators (KPIs). As a part of visibility, we also provide real-time dashboards capturing Overall Equipment Effectiveness (OEE), energy costs and other KPIs, which play a role in achieving operational excellence. The next step is benchmarking current performance against the past one captured in the repository and identifying the gaps. The third step is to identify the root causes of the gaps and optimising the process parameters. The last step is digitising the Standard Operating Procedures (SOPs) based on the gaps and findings.

These steps ensure that a pharma company produces a golden batch on a repeated basis and achieves sustainable operational excellence.

## Explain in detail about golden batch and digitising SOP.

The answer to the differences between a good and a bad batch lies in the plant data itself. One needs to capture this and put in the right context. The challenge here is integrating the process parameters data with quality data. Currently, quality data is analysed post the batch execution and the same is used for exception handling or quality assurance. But it does not help reducing waste, which decreases the yield. To avoid this, we offer process analytic and control tools that integrate the quality database with process data and identify the process parameters, which were responsible for a good batch and also compare them with process parameters in a bad batch. Thus, one can do the correction prior to the batch being rejected.

SOPs exist in every plant but seldom all of them are followed in totality. This what an ERP has achieved at a business layer where it has ensured digitisation of a workflow between all business functions. A similar digitisation is required at a plant level as well. We offer this layer at the plant level on a real-time basis, which ensures every operator becomes a smart operator and all the operations are carried out on a role centric basis.

# The general perception of such solutions is that it is way too expensive for the Indian market. Your take.

Not really, if you consider the total cost of ownership. Like I said earlier, we employ a

'stepped' approach to operational excellence; never a rip-and-replace one. And we use client's existing infrastructure to the maximum extent possible. More importantly, our solutions are completely modular, so our clients pick and choose the ones that they really need. They usually start with one production line or area and then scale to the entire plant, at times even multiple, geographically dispersed plants. Because our solutions operate on open technologies, they can connect to almost any brand of PLC or DCS. What heartens pharma COOs and CIOs most is their capability to connect to a variety or ERP systems (SAP, Oracle, Microsoft Dynamix), so they can connect their shop floor data to the top floor and derive decisions based on intelligent, real-time information, directly from their machines.

#### Have any pharma organisations realised the benefits of these solutions?

Yes. We have implemented these solutions at a few Active Pharmaceutical Ingredients (APIs) and formulations plants in India.

Moreover, given the global nature of the pharma industry today, I believe Indian pharma organisations would be as much interested in our references world-wide. We have implemented these at a number of sites for reputed global pharma organisations.

#### How much would it cost a pharma company to implement these solutions?

Investments in such solutions depend upon a number of factors – number of parameters to be monitored, number of processes to be controlled, number of machines or lines to be tracked, integration with other systems, etc. Hence, it is difficult to put a number on the investment. Each solution is customised to the plant requirements. A better way for a pharma company to look at such investment is to initiate a small pilot on a shared-cost basis, realise the benefits and then scale the pilot to a larger area.

#### What do you view as the next big thing in the industry?

Achieving sustainable operational excellence would be the key imperative

for this industry. Although the industry has grown well during the slowdown, the global competition is intense. The current macro-economic scenario of high interest rates, increasing cost of raw materials is adding further pressure on margins. Hence, pharma COOs and CIOs cannot afford large, disconnected WIP inventory as a black box any longer and need to integrate plant operations on a real-time basis with their business systems.

#### How will IT adoption in pharma look like five years down the line?

As Indian pharma companies scale and compete with global majors, their operations are bound to become more complex. Hence, they will increasingly adopt technology to simplify operations, manage risk and improve productivity. My recommendation to them is to start now than later. Start small, realise some quick benefits that help you build a business case and scale your technology investments faster. Of course, we would be glad to help.

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