# Express Pharma and Ansys organise virtual summit on accelerating process scale-up with simulation

Experts share insights on how simulation and modelling can bring significant benefits to the pharma sector such as process efficiency, reduced time-to-market and higher levels of safety for patients

By Lakshmipriya Nair On Sep 18, 2021

LATEST UPDATES EVENTS


Read Article

With growing competition, pharma manufacturers must gear up to build competitive advantage to retain their market leadership. In this scenario, Computer Modelling and Simulation (CM&S) provides much-needed leverage to scale up production as they

move from small pilot studies to progressively larger clinical trials, then finally into large-scale production of drugs.

Pharma manufacturing systems are highly variable with each system having different levels of interdependence and variability and simulation helps untangle the chaos and bring out data-backed solutions. This leads to improved process efficiency, reduced time-to-market and most importantly, higher levels of safety for patients.

Therefore, **Express Pharma,** in association with **Ansys,** recently hosted a virtual summit focusing on '*Accelerating the Process Scale Up – Get it first time right!'*. Held on **August 17, 2021,** the event focussed on the advantages that can be ushered in pharma manufacturing through simulation and other technological innovations.

The event brought together industry experts and leaders to provide unique insights and recommendations to bring out various simulation led strategies aimed towards reducing the cost, accurately modelling and understanding process complexities while maintaining product differentiation and improving the time to market of the drugs.

It commenced with a welcome address by Viveka Roychowdhury, Editor, Express Pharma and Express Healthcare. She set the context for the sessions to follow by highlighting some advantages of simulation.

Roychowdhury informed, "As per various industry studies, simulation leads to an overall four times reduction in product cost and nine-fold reduction in development cost. It results in 2.5 times reduction in the number of change orders which eventually leads to 67 per cent improvement in new product introduction rate for pharma companies."

She added, "Above these benefits, the main advantage of in-silico trials is that simulations studies allow us to observe the effects of new drugs or treatment options in a virtual setting without impacting animals or humans."

## Building cost and time advantage

Sauri Gudlavalleti, Head R&D, Dr Reddy's Laboratories delivered an insightful keynote address on, "*Cost and Time Reduction Focus to Build Competitive Advantage for Indian Pharma*."

Speaking on the importance of the pharma sector and its role in changing people's lives for the better, he showcased how life expectancy has increased significantly with the advancements of medical science and the pharma industry.

Further, he pointed out that the pharma sector is a highly specialised and knowledge-intensive industry with huge R&D investments. However, this is an industry that could use quite a bit of in-silico work because there are a lot of complexities in drug development, manufacturing, and other stages. Therefore, it is better to reduce reliance on physical experiments and replace them virtually for better outcomes.

Giving an overview of the many complexities across processes and functions in the pharma sector, he said that new technologies and digitalisation can be the answer to tackle them effectively. He also spoke on the new approaches to reduce complexities and improve outcomes such as process modelling and simulation, advanced manufacturing technologies, advanced analytical technologies and sensorisation.

### Simulation-driven innovation

The subsequent speaker, Thierry Marchal, Program Director – Healthcare Solutions, Ansys gave a presentation on '*Simulation-Driven Innovation in Pharma Industry*.' He started by pointing out how imperative it is to make healthcare more affordable and accessible. Emphasising that the pharma industry has to find ways to make drug development more cost-efficient, he said that the traditional trial-based methods of delivering a drug to market have become very costly.

He opined that the 'one-size-fits-all' approach of drug development will be replaced by outcome-based personalised medicine and we were entering the era of in-silico medicine. He said that healthcare is still an underserved industry as far as modelling and simulation is concerned, but Ansys, with its new-age solutions, can be a good partner in leveraging their huge potential.

Marchal also gave a few examples of how Ansys' models add value to every stage of drug development and manufacturing such as the dissolution process, equipment sizing decisions, granulation and tabletting. Elaborating on their advantages, he said that they can usher better outcomes, reduce time and effort, ease tech transfer, eliminate errors and cut down uncertainties.

### Accelerating pharma process scale-up with simulation

Next, Nandan Kulkarni, Director – Medical Devices, Cipla shared real-life examples that showcased the role of simulation in accelerating pharma process scale-up and technology transfer.

He said that the COVID-19 pandemic has brought a paradigm shift to the ways things were being done in the industry, be it the way we synthesise, tech transfer or bring a product to the market. Now as Industry 4.0 plays out, pharma processes are undergoing a transformation. He advised that scale-up and tech transfer needs a holistic approach to get it first-time-right, be it drugs or medical devices.

Citing an example, he explained how Cipla dealt with the challenges in the scale-up of an in-house designed and patented digital spirometer called SpiroFy and the advantages accrued by being first-time-right.

A key message from his presentation was that scale-up involves more than just sizing calculation. It is vital to make a template of the best practices and standardise the scale-up process. Likewise, building deep organisational capabilities with statistical and engineering acumen is very important as well.

His presentation highlighted that as the industry shifts towards complex dosage forms and medical devices; it has to focus on aspects such as a holistic framework to integrate simulation-based scale-up, quality assurance parameters and quality by design. He also stressed the need for skill sets and capabilities in process simulation tools.

### Simulation for digital transformation

Subsequently, a fireside chat on Simulation for Digital Transformation of Pharma Manufacturing ensued. Birendra Kumar David, Director, Dr Reddy’s Laboratories and Hemant Punekar, Healthcare Expert-India, Ansys, participated in this session moderated by Roychowdhury.

The conversation initially revolved around how to adopt simulation processes within pharma organisations and the benefits of selecting a good partner to ease the adoption curve. David explained that building the right mindset is crucial while implementing a new technology and a good partner can help with this as well.

He also advised companies to focus on low-hanging fruits first while opting for simulation initially. He asked them to identify the areas where simulation can make an impact and then choose the right technology that can help. He went on to elaborate

how Dr Reddy's partnered with Ansys to gradually adopt certain modules of simulation and modelling solutions in some key areas and informed that the early gains they received built more trust in these solutions and accelerated the process of adoption.

Punekar spoke on how simulation tools are being utilised by pharma/biopharma companies across the globe to simplify and speed up multiple processes. He cited examples of how different companies have used simulation to accelerate culture development, build plant-scale tanks from the lab-scale tanks without going through the pilot-scale etc.

Speaking on the challenges that hinder pharma companies from adopting simulation and modelling more extensively, Punekar reiterated the need for a mindset change.

He opined that change agents or champions who understand the potential of simulation are needed to drive transformations. He also said that as understanding about the potential of simulation improves, adoption too will grow as the industry will be surer about the return on investments.

A key takeaway was that simulation can be of tremendous help in making real-world decision-making and mitigating risks, thereby enabling significant time and cost savings.

Post these sessions, the speakers addressed a few questions raised by the audience. The queries were wide-ranging and addressed different aspects of simulation and modelling, such as scalability and economic feasibility of these solutions, cost-benefit ratio and so on.

*lakshmipriya.nair@expressindia.com*

*laxmipriyanair@gmail.com*

analytical technologies | Ansys | Cipla | digital transformation | Dr Reddy's | Express Pharma | pharma manufacturing | Process Scale Up

Lakshmipriya Nair