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Pharma**Bio**

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES *World*

Analytical Instruments and Laboratory
Equipment: Trends & Developments



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Process Industry's Gateway to Indian Market



Creating Analytical Instruments 4.0 for a Better World

This article reveals how Industry 4.0 can help Analytical Equipment Manufacturers and Pharma companies to improve their future financial performance, optimise investments and become globally competitive. The author then recommends 3 steps that are critical to initiate Industry 4.0 journey with existing assets, before making larger investments.

Analytical Instruments are used in multiple sectors for varied applications. According to one market research report¹, the global analytical instrument market is expected to grow at a rate of 8.4% CAGR. The analytical lab instruments market would grow at 7.3% and reach \$124 billion by 2023. The demand is driven by increased investment in R&D and quality control, while having an emphasis on cost reduction and productivity optimisation. The instruments also help in ensuring that processes adhere to regulations.

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Impact on Pharma and Analytical Instruments Industry:

Let us take the example of new product development in Pharmaceutical Industry. The process is an intensive one, given that it impacts lives. Testing, Validation, QC and Compliance are of paramount importance.

At the same time, there is a constant endeavour to get pharma products to the market in shortest period at least cost, both for improving healthcare and business.

What is changing though is the rapid transitioning of Healthcare to a new world of personalisation, with a laser-like focus on outcomes and value. For that, healthcare systems now need to understand additional data of exogenous factors such as environmental influences, behaviour, genetics, treatment outcome etc. to create and deliver value.

Science, Technology and Engineering streams too are converging, creating new opportunities and opening new pathways for doing business.

These changes will continually push pharma companies to adapt to agile research and flexible manufacturing. The need for bringing together traditional and new data through automation creates new growth opportunities for Analytical Instruments sector.

Three paradigm shifts emerge from the above scenario:

- Shift in Patient Experience (Generic to Personalisation)
- Flexible and Fast Innovation (In-house versus Partnership)
- Increased role of Digitalisation (Portable/Wearable/In-house equipment, Automation, Real-time Analytics, Connected Systems)

And these trends are not futuristic. Partnerships are evolving to speed up trials and develop personalised treatment by leveraging digital technologies, with a mix of high/limited volumes. This is evident from the partnerships announced, a few being mentioned below

- Oxford University- Astra Zeneca- Serum Institute (for Covid -19 vaccine)

Figure 1 summarises the shift that is taking place:



Figure 1 : Market forces are compelling pharma companies to adopt an agile and flexible approach while maintaining high quality and rigorous compliance.

- Aravind Eye Clinic- Google² (for AI backed health monitoring, beyond eye care)
- Gilead Sciences- Dr. Reddys (For drug manufacturing)

These shifts are perfect candidates for the industry to adopt Industry 4.0³ practices. At present, ISA-95 configuration of systems is well understood and adopted in the pharma sector.

While the ISA-95 and Industry 4.0 system configurations may appear similar, Industry 4.0 builds next level advantages through automated data aggregation and analytics that create additional insights. For a lab, such enhanced insights can strengthen Real World Evidence, minimising trial costs and delays. For manufacturing, it can create cost and response advantage where automation is supported by analytics. Importantly, it also addresses how our people can truly add value with their creativity and innovation.

Financial Perspective:

It is but natural for companies to closely monitor its financial health, especially in stressed times. The focus is not on investments, but on revenues, profit and cashflow. But once business stabilises, Industry 4.0 offers opportunities for future financial benefits.

Those companies which have started the journey are focussed on one or more of the following:

- Reducing costs related to transactions, maintenance, energy and waste through automation for improved outcome, process quality, and experience.
- Improve revenue forecast and cashflow management by using data analytics and cloud technology.
- Broaden the revenue generating product mix by designing smart digital solutions.
- Develop technology leveraged business models for revenue and sustained cashflow.

Understanding the Role of Industry 4.0 in your Value Chain:

Industry 4.0 has been initially presented as a technology focussed solution. As a result, the true benefit to process industry was not clear.

In reality, Industry 4.0 is about establishing an active collaborative network, connecting people and integrating processes. The approach enables information exchange that supports industry standards, both within organizations and throughout their value chain.

Figure 2 represents a simplistic version of what the future Industry 4.0 system would look like. It shows the multifunction involvement across the value chain. It also includes partners (CRO, CMO, CSO,

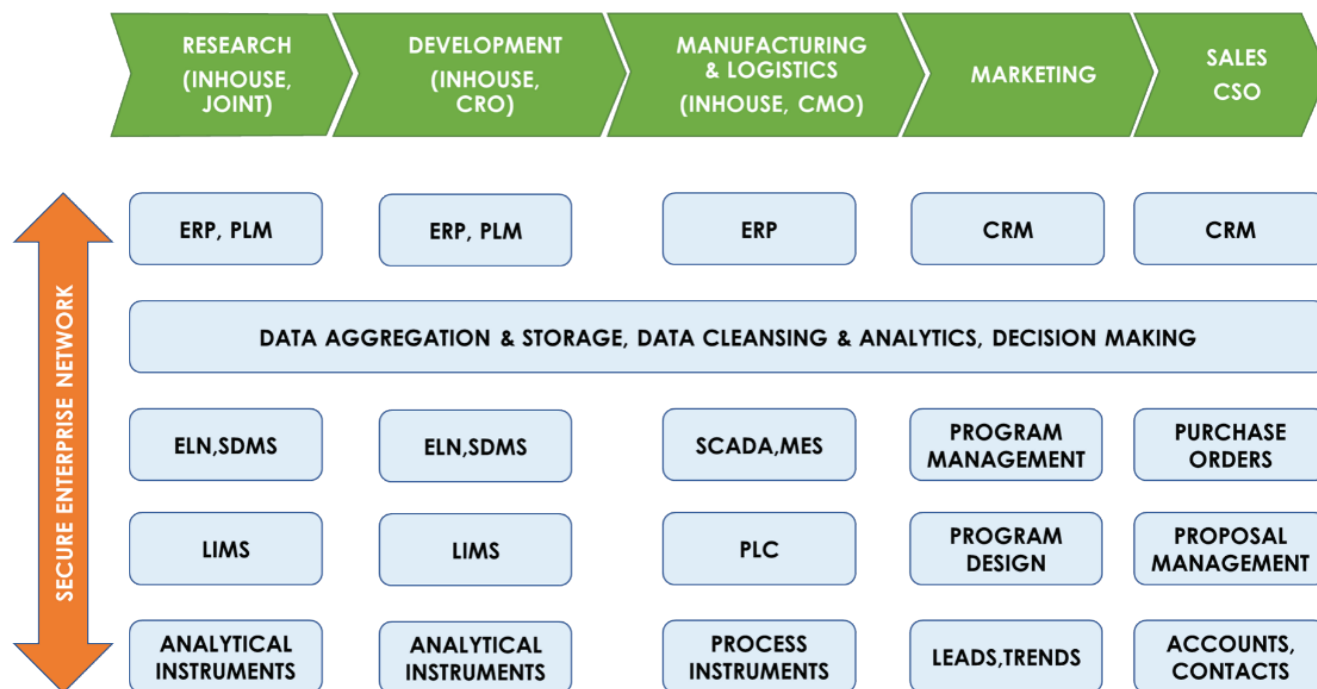


Figure 2 : The “Smart and Connected” approach of Industry 4.0 offers opportunities to meet the demands of market forces and create business advantage.

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material and equipment suppliers). If an organisation must compete globally and create a profitable business, rapid innovation and flexible manufacturing is necessary. This is where digitalisation provides speed across the value chain, while maintaining accuracy, quality, security and compliance.

3 important steps to unlock opportunities in Analytical Instrumentation 4.0

In a smart and connected economy, Analytical Instruments and smart sensors are already reshaping the way they function for labs and manufacturing activities. Convergence of science, technology and engineering has created sensors that are small, non-invasive

and can sample data more frequently. Embedded computing enables in-situ analysis. Results and data can be transported quickly via internet and 4G/5G technologies, for performing advanced analytics on aggregated data from multiple sources. Certain analytical instruments may thus move out of the lab. These scenarios create new possibilities and an important role for Analytical Instruments, in the Industry 4.0 world.

Manufacturers and users of analytical instruments should consider the following 3 steps.

Enhancing Existing Capabilities - Understand what Industry 4.0 is

Industry 4.0, when looked at in isolation,

can sound overwhelming to many. This feeling itself may stop you from taking the next step. However, once you understand the concept in its componential form (Figure 2), you shall more likely see how Industry 4.0 can help you to become future ready. But for that, Industry 4.0 skilling is needed at all levels. This helps in defining a thought-out strategy and roadmap. Companies should begin with small steps and experience quick wins, rather than a big initiative (not recommended).

The other important aspect is that Capability Development helps in building the right mindset and confidence amongst the staff. Rather than being concerned about the impact of digital technologies on job loss, it helps in stimulating creativity.

This componential implementation becomes the foundation for developing an adapting mindset and harnessing future business growth.

Embrace Big Data and Data Analytics:

Analysis of data is nothing new to pharma (or any other) industry. But when research, development and manufacturing are increasingly driven by collaboration and partnerships, then rapid multiple source data acquisition, management and sharing becomes extremely essential. Multiple sources include datasets such as clinical trial data, electronic medical records (EMRs), claims and billing data,

product and disease registries, and data gathered by personal devices and health applications. This approach to link data is called a “digital thread” that provides limitless opportunities for rapid and singular view of information.

Innovation - Think Industry 4.0 Solutions, not just Products:

Pharma industry is no stranger to Innovation. It is based on a rock-solid foundation of research. As first touch point, Analytical Instruments and smart sensors become vital in “Smart, Connected and Autonomous” world. Enhancing existing products or building new products that are Industry 4.0 compatible thus presents an opportunity, which will soon become a need. Companies can consider a mix of portable and inhouse products, automation accessories, equipment health prediction, software applications and data interoperability with other equipment.

Similarly, various processes within an organisation, when digitally enabled can yield real business results. It can improve quality, prevent downtime, improve safety to save costs.

As an example, the lab automation equipment manufacturer Inpeco, manufactures equipment along with Robotic modules, interoperability with other analysers and Data Analytics Software. We also see that research is enabling sensors to become miniaturised, non-invasive and connected. When such



Image Source:
<https://www.apple.com/in/apple-events/september-2020/>

technology matures, one can visualise emergence of “virtual” clinical trials and remote health management.

Apple’s Series 6 Watch⁴ announcement is a step in this

direction. Its miniature sensors associated algorithms and app, monitor SpO2 levels, apart from other parameters. Such advancements get many researchers and innovators interested. Imagine the explosion in availability of rich, contextual data for deeper analysis and research.

Innovation is not just about creating new products or services. Delivering them in an efficient manner and managing their performance is equally important. If you do not leverage digitalisation for marketing, sales and performance management, you will lose a chance to secure valuable insight and revenue opportunities that may be unfolding outside the organisation.

Summary

Market growth forecasts provides a great opportunity for the Analytical Instruments industry. Health and Safety of Humans and Planet are focus areas of every industry. Analytical Instruments will continue to find newer applications in different sectors.

Industry 4.0 will not just create business advantages but also free people from

repetitive tasks. We can then take advantage of human strengths like creativity and innovation to full effect.

Successful short-term results can be achieved using existing technology and data. However, the long-term results need innovation, patience and commitment to realise the full potential of Industry 4.0. This is primarily due to the time needed for devices, data analysis systems and re-designed processes to achieve maturity. All this is possible only if people are equipped with new skills and tools. The earlier you start, the earlier you can reconfigure people skills, business processes and business models.

When such systems are built, companies will create an immense competitive advantage on the global stage. ■

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