



MADE
IN
ASIA

Innovative automation strategies for Asia's emerging biopharmaceutical manufacturing hub.

Pharmaceutical manufacturing has historically been less innovative than its research and development counterpart, owing in part to regulatory constraints and the rigorous process of validation, which discourages continuous improvement. Today, however, conventional pharmaceutical facilities have given way to the next generation of life sciences or biopharmaceutical facilities, and significant opportunities now exist for improving manufacturing processes and quality assurance through process innovation.

All biopharmaceutical manufacturers are faced with the challenges associated with meeting rising demand, especially in developing world areas, and regulating their product quality to comply with stringent world standards. Operational excellence plays an important part in overcoming these challenges, and the right standards-based process automation solution can help achieve and sustain that operational excellence throughout the lifecycle of a manufacturing facility.

The biopharmaceutical sector is expanding rapidly in Asia, most notably in China, Japan, Korea, Singapore and India, and in particular for the Contract Manufacturing Organisation (CMO) sector we are seeing a significant increase in the number of large, highly automated facilities being built in the region. These CMOs allow companies to focus on their research and development core competency, while the CMOs themselves can focus on optimising manufacturing processes.

Choosing the right partner

The design and implementation of automated manufacturing facilities in accordance with current good manufacturing practices (cGMP) requires the use of an integrated systems approach in order to build quality into the process, and improve the efficiency of both the manufacturing and regulatory processes.

The right process control strategy can:

- Prevent or mitigate the risk of sub-standard quality
- Reduce waste and rework
- Improve safety and reduce human errors
- Reduce energy costs
- Increase availability and throughput

These factors all contribute to the bottom line by reducing operational and compliance costs. Choosing a process automation vendor is therefore a strategic decision when constructing a new facility with operational excellence as a key objective. While advanced process automation technology is an important component in operational excellence, the success of an accelerated project start-up depends, to a large extent, on industry expertise and the project execution capabilities of the chosen partner.

The biopharmaceutical industry has always been one of Emerson's core global focus industries, and the company has worked with numerous biopharmaceutical customers – including Eli Lilly, Biogen-Idec, Genzyme, Novo Nordisk and GlaxoSmithKline, to name but a few. In Asia Pacific, the growing list of customers includes Biocon, Ranbaxy Labs, Novartis and Celltrion Inc.

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Powerful system functionality and industry expertise forged in hundreds of projects worldwide are some of the core values that Emerson provides to biopharmaceutical manufacturers. The Emerson team delivers a single-source solution to engineer efficient new plants or to analyse and streamline existing processes. Parallel to industry trends, the company's first centre of excellence for life sciences outside of the North American market is in Singapore, which underscores its commitment to the region's industry. Endorsed by, and developed in cooperation with the Singapore Economic Development Board, this centre of excellence is part of a worldwide validation consultation service group, and is backed by Emerson's regional capabilities to execute large-scale projects as the main automation contractor (MAC).

Emerson's Asia Pacific operations have been based in Singapore since 1965, and over the years the engineering team has acquired more than 400,000 engineering hours of project experience. Asia Pacific is a major growth region for Emerson, and the company has invested over the years in developing comprehensive capabilities and facilities such as project management, staging, application engineering, systems integration, and testing and validation, to serve its customers in the region.

Emerson can provide an effective automation strategy for emerging biopharmaceutical manufacturers, leveraging the industry expertise and experience of the Asia Pacific centre of excellence. The company has successfully executed large-scale projects on an accelerated schedule by networking its global industry experts across continents. Seamless coordination and rigorous global processes help provide quick response to customer needs and mobilise the necessary resources for the successful delivery of any project. ■



A CASE STUDY

Celltrion Inc is South Korea's first large-scale biopharmaceutical manufacturing facility. The 23-acre facility is equipped with a total bioreactor capacity of 50,000 litres, and is designed for expansion to 150,000 litres. Celltrion produces vaccines and therapeutic proteins for its global clients and is designed to comply with the cGMP standards of the FDA and European Medicines Agency (EMA).

Emerson's PlantWeb digital plant architecture, centred on the DeltaV system, is recognised throughout the life sciences industry as a leader in process automation based upon superior batch handling capabilities, an FDA-approved audit trail, and open, interoperable integration capabilities with operations and business applications such as MES and ERP software.

Celltrion was also looking for a committed partner with organisational depth and global experience, who would be able to effectively and efficiently deliver on set project objectives, and also support it beyond successful project start-up.

The Emerson Asia Pacific life sciences team, together with the local Korean engineering team, worked closely with Celltrion to include best practices in the project execution plan: prototyping, design reviews and quality audits are utilised, project issues were identified early and pre-emptive measures were taken to avoid additional costs and project time.

A class-based modular engineering approach was used, and this significantly reduced time spent on configuration, testing and validation. Productivity tools, such as a project builder library, were used to save engineering, documentation, testing and validation time, which was made possible through leveraging past standards developed in other projects.

This class-based approach reduced the time required to configure a multi-stream process. System configuration can be done only once, and then can be used for all other similar equipment. In fact, the project team was able to save up to 40 percent of engineering and validation time.

This strategic partnership between Celltrion and Emerson addressed process automation and validation issues, allowing Celltrion to improve time-to-market and quality with ease. It brings technology, engineering and partnership together with a single objective – delivering results.

More large-scale facilities like Celltrion are likely to be constructed in Asia as the biopharmaceutical industry flourishes in this region. To supply their global clientele with world-class contract manufacturing services, CMOs must continually optimise their manufacturing and regulatory processes. Emerson has the industry expertise and integrated automation solutions to enable them to do so.