ENGINEERING
THE DIGITAL TRANSFORMATION COMPANY

Industries eXcellence

CASE STUDY: DIGITAL MANUFACTURING FOR PHARMACEUTICALS

About the Customer

The customer is a global pharmaceuticals company and manufacturer focused on the treatment of rare diseases like hemophilia and primary immunodeficiency. The company's products are available in more than 100 countries across core therapeutic areas including Hematology, Immunology, Neuroscience, Lysosomal Storage Disorders and Oncology, amongst others.

Project Summary

Engineering Industries eXcellence has worked with the customer over the past 7 years to help them digitalize their manufacturing, automating processes and reducing the use of paper by 90% at facilities across North America and Europe. Our team of experts continues to work with the customer as part of a multi-year, multi-site effort to design and implement a full-featured manufacturing execution solution with electronic batch records at various existing and greenfield plants around the world.

Project Activities

- **Designing and deploying a customized Manufacturing Execution System (MES) for batch record management based on Siemens Opcenter Execution (SIMATIC IT) eBR Software**
- **Providing consulting and technical leadership before, during and after system go-live at plants across the U.S. and Europe**
- **Supporting computer system validation of new system according to GAMP standards**
- **Delivering software end user training and support**
- **Providing remote MES administration, maintenance and IT support services**

Business Drivers

- **Achieve paperless manufacturing process**
- **Global standardization of plant systems**
- **Reduce rework, deviations, research time and costs through automated error checking and process controls**
- **Improve regulatory compliance driven by built-in cGMP features and complete manufacturing traceability**
- **Improve process visibility with built-in GxP reporting and genealogy features**
- **Ensure internal end user adoption and acceptance**

ENGINEERING
THE DIGITAL TRANSFORMATION COMPANY

Industries eXcellence

More About The Project

With one of the most challenging and stringent regulatory environments of any industry, pharmaceutical manufacturing requires meticulous adherence to quality standards and process controls. Today, patient safety is the number one priority, as it should be. However, the complexity of government regulations has created many challenges for the manufacturers of modern pharmaceuticals.

The extreme focus on quality slows everything down. Completed drugs take longer to get into the hands of patients. New drugs take longer to be developed. New technologies take longer to be adopted. Quality control is expensive too, and it contributes to driving up costs for both the manufacturers and the patients.

The customer is a leading global biotechnology manufacturer who faced these same challenges. Our Industries eXcellence team worked with the customer to help them digitalize their manufacturing on an enterprise scale, automating their processes and reducing the use of paper by 90% at their production facilities across North America and Europe. To achieve this transformation, our team of experts led a multi-year, multi-site effort to customize and implement a full-featured Manufacturing Execution System (MES) with Electronic Batch Records (EBR) management capabilities at various existing and greenfield plants.

Thanks to the digitalization of their manufacturing process, the customer's operations have become significantly more efficient and controlled. Digital Manufacturing means most quality checks happen in seconds, not hours. This speeds up production and enables the customer to produce more medicine at higher quality specifications. As a result, medicine that is critical for those suffering with some of the most debilitating diseases in the world can get to more people, faster and at a lower cost to both the manufacturer and the patient.

Engineering's Advantage

Engineering has had a consistent presence in the life science industry, including pharmaceutical and medical device manufacturing, for over a decade. The industry has historically been characterized by a reluctance to change processes and adopt technology due to regulatory constraints and pressures. This approach has started to change in recent years, however, as the FDA and international regulatory agencies have started to embrace innovation more and more. Engineering Industries eXcellence has been on the forefront of this transformation, guiding manufacturers and facilitating the adoption of Industry 4.0 technologies aimed at improving quality, reducing patient risk and increasing data transparency.

From basic data collection to quality control systems to full-blown 21CFR11-compliant MES systems with EBR, Engineering is one of the few system integrators in the world that has the industry experience, technological expertise and global capabilities necessary to help your pharmaceutical manufacturing business thrive in the digital era.

Would you like to learn more about this customer case study? Contact us at info@indx.com.

ENGINEERING
Industries eXcellence

Industries eXcellence is a division of the Engineering Group, a global software maker, system integrator and provider of innovative technology solutions and services. Our division specializes in the digital transformation of the manufacturing and transportation sectors. We design, build and implement solutions that drive process automation, operational efficiency, supply chain optimization and intelligent data analytics for leading industrial enterprises worldwide.

CONTACT

Engineering Industries eXcellence
55 W Monroe Street
Suite 2575
Chicago, IL 60603

+1 630.625.0045

info@indx.com

www.indx.com