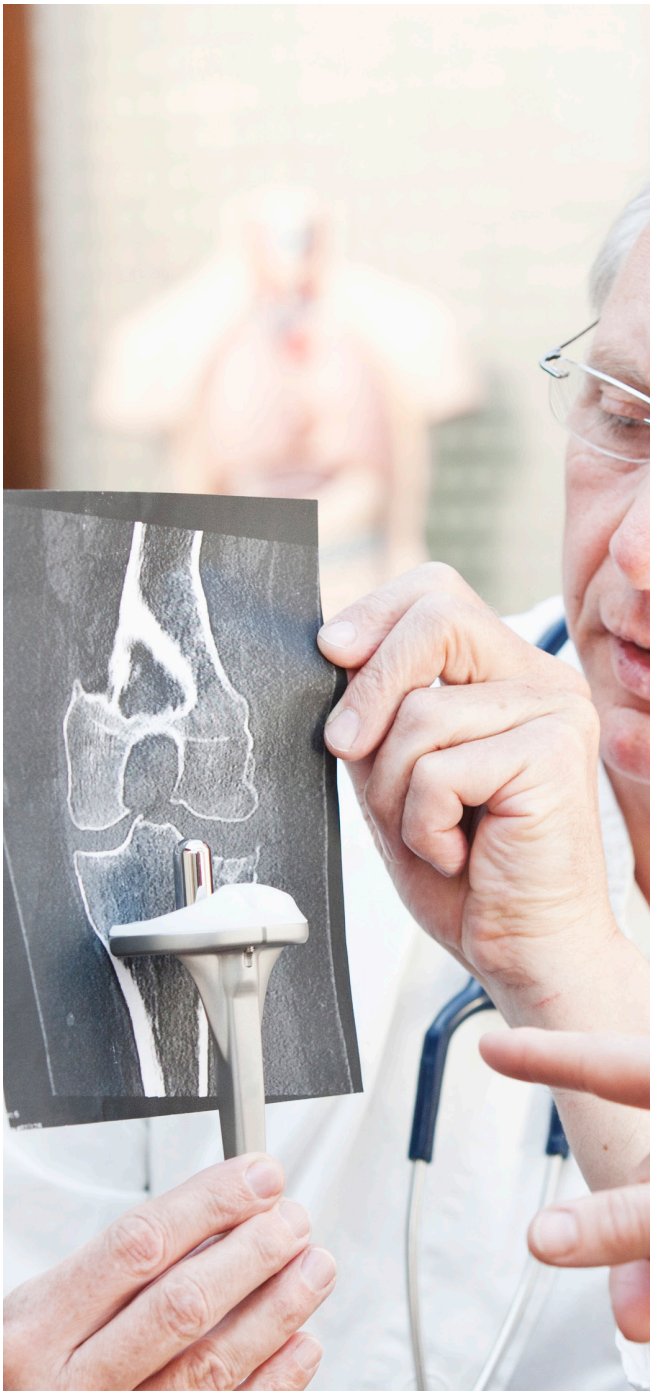
ENGINEERING

Industries eXcellence Global

CASE STUDY: DIGITALIZING COMPLIANCE FOR MEDICAL DEVICES



About the Customer

The customer is a leading global medical device manufacturer that designs, develops and produces products for different medical fields including cardiology, interventional radiology, orthopedics, electrophysiology and surgical management. The manufacturer was named among the top 100 medical device companies in 2018. They are also the sixth largest multinational producer of orthopedic products, including knee and hip replacement solutions.

Project Summary

Our Industries eXcellence team led the implementation of a complete state-of-the-art Manufacturing Execution System (MES) at the customer's flagship U.S. production plant in order to digitalize their data collection, automate documentation and replace their existing 25-year old legacy system. By the end of this initiative, our team had delivered a complete "top floor to shop floor" digital manufacturing solution, fully integrating the customer's new MES with their DNC, PLM and ERP systems.

Project Activities

- **Analysis of requirements to recommend best solutions**
- **Designed and developed new MES based on Opcenter Execution Medical Device Suite (previously Camstar)**
- **Designed and developed new DNC system based on Shop Floor Connect (SFC) for Siemens Teamcenter**
- **Integrated MES to DNC system to centralize management of all production data**
- **Integrated MES to existing ERP system to enable sharing of work order and production performance data**

Business Drivers

- **Replace legacy Manufacturing Execution System (MES)**
- **Manufacturing system synchronization**
- **Connect business floor to shop floor – improve transparency**
- **Move towards a paperless shop floor**
- **Create a single source of truth via one digital system as the central repository for manufacturing data, and make this data easily available to operators on the shop floor**

ENGINEERING

Industries eXcellence Global

More About The Project

Combining the requirements of traditional discrete manufacturing with a high level of regulatory control via FDA and international authorities, Medical Device Manufacturing presents a unique set of challenges. For this customer, meeting the quality requirements of the FDA involved tedious data collection and documentation processes that were being executed manually, on paper and requiring a high number of dedicated human resources. Every knee and hip replacement that left the customer's production facility had to be accompanied by an enormous amount of documentation covering every step of its lifecycle. The customer knew that the time and resources spent on creating medical device records manually were unsustainable to stay competitive, so they looked towards automation.

How did we help? First, our team of industry specialists led an in-depth analysis of the customer's requirements to better understand their most pressing challenges and recommend the right solutions to address them. The analysis identified electronic Device History Record (eDHR) Management as the best and most cost-effective solution to improve process efficiency while ensuring quality control and regulatory compliance at the same time. In order to enable eDHR and digitalize Work-In-Progress (WIP) on the shop floor, our Industries eXcellence experts designed, developed and customized an end-to-end MES solution to replace the customer's existing legacy system, as well as a new Direct Numerical Control (DNC) system to provide the link between engineering, manufacturing planning and the machines on the shop floor.

Our scope of work for this enterprise MES initiative included:

» Designing and developing new MES and new DNC system
» Integrating new MES to new DNC system to centralize management of all production data
» Integrating new MES to existing ERP system to enable sharing of work order and production performance data
» Leading the validation phase, implementing the 2 new systems and providing end user and system support

Engineering's Advantage

So, what is the real, measurable value gained by companies going paperless in the Medical Device Manufacturing environment? This customer is just one of a number of manufacturers in this sector with whom we are collaborating on similar initiatives. Simply put, the use of paper to meet the stringent data collection and quality compliance requirements in this industry leads to a significant waste of time and resources whose skills could be better utilized in more value-add tasks. One manufacturer we spoke with told us that in a plant of 600 people, 35 of them were dedicated full-time to walking from station to station and manually documenting data. Therefore, by going paperless, not only did our customer ensure consistent quality compliance, improve efficiency and streamline processes, but they will now be able to reallocate more of their resources and personnel to more complex and value-driving activities within the enterprise.

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

ENGINEERING
Industries eXcellence Global

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 USA
55 W Monroe Street
Suite 2575
Chicago, IL 60603

+1 630.625.0045

info@engusa.com

www.engusa.com