The Best Medecine:

Sanofi Pasteur - MES software in vaccine manufacturing

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"The objective of Sanofi Pasteur is to meet public health needs with a reliable supply of vaccines in response to global demand. In order to improve quality and regulatory compliance, accelerate cycle times and improve operational excellence, we decided to implement a manufacturing execution system (MES) in pilot facilities"

Laurent Bilhaut, Sanofi Pasteur, IS Manufacturing - MES Team manager

Mass producing vaccines at highest quality standards with MES

Sanofi Pasteur uses the SIMATIC IT XFP manufacturing execution software to better meet public health needs - with enhanced quality, better flexibility, total compliance and improved operational excellence.

The customer

Sanofi Pasteur, the vaccines division of the Sanofi Group, is a world leader in vaccine manufacturing. The company produces vaccines protecting against 20 infectious diseases and manufactures over 1.6 billion doses per year across 10 production sites.Vaccine production is a complex and lengthy process. It can take up to 22 months to produce a vaccine, and strict process and quality controls must be applied at every stage. The objective of Sanofi Pasteur is to meet public health needs with a reliable supply of vaccines in response to global demand. In order to improve quality and regulatory compliance while accelerating cycle times and reducing cost, Sanofi Pasteur uses the SIMATIC IT XFP manufacturing execution software to better meet public health needs – with enhanced quality, better flexibility, and increased operational excellence. Sanofi Pasteur decided to implement a manufacturing execution system (MES) on its pilot facilities.

The solution

In vaccine manufacturing, it is essential to be able to support public health by responding to unanticipated needs, outbreaks, epidemics and bioterrorism. It is also critical to produce large quantities. Indeed, Sanofi Pasteur produces more than 1.6 billion doses of vaccine per year.

At a glance

Company:
Sanofi Pasteur
www.sanofipasteur.com

Industry: Life Sciences

Key Challenges:
- Implement a full MES solution integrated with SCADA
- Reduce the use of paper on the shop floor, a possible object of contamination and pollution
- Guide operators in the management of their activities
- Reduce errors through earlier identification of deviations
- Apply GxP directives at lowest possible costs

Solution:
- SIMATIC IT XFP

Key Benefits:
- Reduced errors
- Improved batch reproducibility
- Enforced regulatory compliance
- Reduced cycle time
- Real time track & trace
- Better process control
- Enhanced data management through advanced process data warehousing

To constantly improve customer satisfaction and meet regulatory demands, while keeping business highly competitive, the quality teams work closely with the heads of industrial operations. Together they identified that the implementation of Manufacturing Execution System software, MES in short, would ensure that processes correspond to good manufacturing practices while accelerating cycle time and effectiveness.

Sanofi Pasteur selected the SIMATIC IT XFP software, an independent software component available from the SIMATIC IT portfolio, Siemens MES flagship product. The intention of Sanofi Pasteur is to move from a fully paper-based batch record process to electronic master batch record process with electronic work instructions. The ultimate goal of the MES strategy of sanofi pasteur is to reach a full paperless manufacturing process with electronic release of the batch.

Vaccines like most Biotech rely on biological manufacturing processes
In vaccine manufacturing, production methods are based on biological processes. Working with "living matter" complicates the control of the process and lengthen the cycle:

- The process is complex, especially the manufacturing of the bulk.
  The bulk production process is based on a sterile biological batch. It means cell and viral culture, bacterial fermentation, inoculation, harvest, purification, inactivation/attenuated live vaccine and so on...
  Most the process is manual performed by trained operators and scientists.
- The environment is complex with a production process under sterile conditions like clean rooms, aseptic process, containment areas and dedicated building. Indeed, a sanofi pasteur production site is made up of several mini factories, each building being dedicated to one single vaccine production.
- The regulatory compliance is even more stringent than in other pharmaceutical manufacturing.
  Quality requirements dominate the production activities and management since vaccination is a preventive health policy and vaccinated population must be protected from undesirable effects. This translates into continual inspections from health authorities and full traceability, complete data collection and quality assurance systems. It is compulsory to have a batch record documentation that trace all actions performed.

The pay-off

MES as a pillar for "Process Excellence"
The deployment of SIMATIC IT XFP, a Siemens MES software dedicated to Life Sciences, throughout sanofi pasteur production sites in France and North America will help:

- Reduce the use of paper of the shop floor, a possible object of contamination and pollution
- Guide the operators in the management of their activities whether manual or automated tasks. The MES Software sends the right electronic instructions to the right operator at the right time, performed automatic controls and calculations, communication with the control and ERP levels and move along the process.
- Control the collection, storage and availability of production information. Vaccine manufacturing implies huge volume of data to track and trace for process control, compliance and batch release. For example, the dengue vaccine requires to collect 1000 to 10 000 pieces of information per batch, like process parameters (temperature, Ph, Oxygen concentration,...), events (alarms, thread holds), in process controls, samples, equipments and materials (ID, status,...), personnel (who, when, what),...
- Reduce errors and accelerate cycles through real-time identification of deviations
- Apply specific GxP guidelines at the lowest possible costs. The MES Software provides full traceability and controlled manufacturing, and cross checking
- Accelerate and accurate the generation of the Manufacturing Batch Record, including data review and approval.

Get more information

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