

process news

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A Focus On the Future





The Sanofi Pasteur facility in Marcy-l'Etoile is one of the company's main research hubs

■ Sanofi Pasteur, France

The Best Medicine

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

Sanofi Pasteur, the vaccines division of the Sanofi-Aventis 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 improving effec-

tiveness, Sanofi Pasteur decided to implement a manufacturing execution system (MES).

Response to public health needs

In vaccine manufacturing, it is essential to be responsive to public health needs. In the event of an epidemic, vaccine production must be geared up to tackle the outbreak by rapidly producing a large quantity of doses effective against the infection. At Sanofi Pasteur, the quality teams working closely with the heads of industrial operations determined that an MES would provide the required responsiveness through tight control of manufacturing processes. Following a review of available MES software, Sanofi Pasteur selected XFP, an independent software

XFP MES software benefits

- ▶ Reduced paper usage
- ▶ Consistency of production
- ▶ Improved batch repeatability
- ▶ Assured regulatory compliance
- ▶ Reduced cycle time
- ▶ Real-time lot tracking & traceability
- ▶ Enhanced data management

Siemens MES support for life science industries

- ▶ Dedicated Center of Excellence based in France
- ▶ XFP MES components and Simatic IT designed for life sciences
- ▶ Functions optimized for biological processing
 - Weigh & dispense
 - Master batch record
 - Electronic work instructions
 - Electronic batch review & release
 - Materials & lot traceability



Photos: Sanofi Pasteur

Vaccine production is a complex process and every production step must be completely traceable

component available from the Simatic IT MES portfolio. Sanofi Pasteur's vaccine production philosophy is to manage globally and implement locally. Consequently, the company decided to install XFP at selected Sanofi Pasteur sites in France and the United States.

The aim of Sanofi Pasteur in implementing an MES strategy was to move from its paper-based control record system to an electronic master batch record process with electronic work instructions. The ultimate goal of deploying XFP is to achieve a completely paperless manufacturing process with electronic batch release.

A biological manufacturing process

Vaccine production is a complex biological process. Skilled operators and scientists undertake the majority of the operations, including the culture of living cells, bacterial fermentation, and the purification and attenuation of the live vaccine. Each production facility is an isolated sterile unit operating under clean-room conditions. Because public vaccination programs involve administering to large numbers of people, everything possible must be done to prevent any undesirable effects of the drugs. To ensure the safety and quality of the vaccines, a highly stringent regime of inspections, quality audits, and lot traceability controls encompasses the complete production process. With a paper-based production data system, maintaining these

quality controls can be a cumbersome and time-consuming process.

Process excellence

XFP MES software is optimized for life science applications. It reduces paper use, guides the operators through the production processes, collects production data, and provides consolidated batch records with full traceability. Guiding the operators, whether they are running manual or automated processes, ensures consistency and repeatability. Vaccine production requires the gathering and processing of huge volumes of data for process control and quality assurance – up to 10,000 data points per batch. XFP software automates this process and provides real-time visibility of any process deviation, something quite impossible with manual, paper-based systems.

The deployment of XFP enabled Sanofi Pasteur to replace manual recording of production data with automated electronic batch records, with all the associated benefits. This gave Sanofi Pasteur the means to achieve the highest levels of quality, efficiency, and regulatory compliance in its production sites worldwide. ■

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