

IPSEN



Less Paper in Manufacturing, More Productivity.

Ipsen is an innovation driven international specialty pharmaceutical group with over 20 products on the market and a total worldwide staff of nearly 4,000 people. The company's development strategy is based on a combination of products in targeted therapeutic areas (oncology, endocrinology and neuromuscular disorders) which are growth drivers, and primary care products which contribute significantly to its research financing.

The manufacturing site of Dreux, France produces more than 20 drug specialties including Forlax, Smecta, Tanakan and Ginkor. Spread over 37.5 acres and organized around dedicated manufacturing units, the Dreux manufacturing site accounts for 48% of the group turnover and manufactures around 7,000 batches each year.

The Challenge

7,000 batches are manufactured yearly on the Dreux manufacturing site, which translated into an equivalent volume of paper batch information. This became a tremendous amount of paper for the quality stakeholders to manage, validate and review.

Along with a continuous improvement strategy, the Ipsen group decided to deploy a Manufacturing Execution System (MES) with the ultimate goal to reach a fully paperless drug manufacturing facility. The main expectations regarding the software solution to deploy were: to shorten and secure batch execution, optimize batch release time and streamline master process design. A master process is an electronic model of a key manufacturing process, describing all the operations required to manufacture a drug, from the incoming ingredients until the batch release.

The XFP-MES solution is used daily to manage the manufacturing process of our FORLAX product line. First results were great. Error risks associated with manual tasks have been eliminated. Batch cycle time dropped by 20%. The batch release process has been greatly accelerated thanks to the review by exception feature. We expect even higher benefits with the completion of the deployment.

Ismaël Colnet, CIO

The Solution

Ipsen selected XFP Weigh & Dispense and XFP eBR from Elan Software to improve the productivity and quality of its Dreux manufacturing site.

The first step of the XFP deployment focused on the FORLAX manufacturing unit, a fast growing product within the Ipsen portfolio. Since the spring of 2007, XFP runs and tracks each and every one of the 2,500 FORLAX batches produced each year. XFP takes part in each step of the manufacturing process.

The MES system manages the weighing and dispensing of ingredients, as well as the receipt execution. For each work order, XFP displays the work instructions for each operator, provides real-time alerts in case of deviations and automatically generates the electronic batch record, gathering all the required information for batch release by quality assurance.

The XFP solution integrates seamlessly with the ERP system and automation (weighing, mixing and cleaning), optimizing the manufacturing process and providing full traceability.



The ERP system automatically provides XFP with work orders, items, batches and inventory. Along with the flow, XFP continuously updates the ERP with all relevant information such as material consumption and reconciliation, batch information, equipment and operator times. Double data-entry is eliminated. In the immediate future, the XFP MES from Elan Software will be deployed to all Dreux manufacturing lines.

The Benefits

The implementation of the XFP-MES solution has enabled Ipsen to achieve fully paperless manufacturing for its FORLAX line, in compliance with FDA 21 CFR Part 11, GMP and ISA88/95 requirements. As of today, the project goals, which are listed hereafter, have been successfully reached:

- **To shorten and secure batch execution**

Risks associated with manual tasks have been eliminated. Regulatory compliance is total. Batch execution cycles have dropped by 20%. XFP-MES provides full traceability at each and every step of the process and corrective actions are immediate.

- **To optimize the batch release**

The batch release process is much easier and faster using the batch review by exception feature. Complementary research and analysis times are reduced, information is available in real time, and deviations and undertaken actions can be consulted at all times. The archiving costs are greatly reduced since the batch information is now archived electronically. The gain in cycle time allows for lower FORLAX inventory and shorter delivery times.

- **To streamline the master creation**

XFP-MES operation process modeler is a great tool to deploy lean manufacturing strategies. User-friendly and powered with advanced modeling features, the XFP operation process modeler has enabled users to rapidly design manufacturing processes and easily maintain and revise them, with no IT skills required.