



IPSEN Clinical Supplies Tracking

« W4 BPM Suite allows our clinical and manufacturing teams to optimize their daily work, the clinical batches management, while supplying traced and centralized information with respect to the 21 CFR Part 11 rule. »

Hervé Bibas, Projet Manager, Ipsen

Solution Overview

Business sector
Pharmaceutical

Project goals

- > Formalize and optimize the treatment of supplies
- > Improve the collaboration between all the actors implied in the process
- > Follow and audit all actions made on all files
- > Identify all the products used in the studies

Products and technologies :

- > Platform: Unix Solaris
- > Data Server: Unix Solaris
- > Application Server: Websphere
- > Web Server: IBM HTTP
- > SGBDR : ORACLE

Concerned about securing and optimizing its R&D processes while meeting the restricting norms current in the pharmaceutical sector (among others the 21 CFR Part 11), IPSEN relies on W4 to optimize its clinical supplies tracking flow.



The order and the follow-up of the clinical lots are indeed very complex processes including numerous steps (more than 10) centered around 3 areas: production, clinical lots management and exchanges with outside organizations (Hospital Centers, chemists, doctors ...). With no homogeneity, these processes were done by hand, fax, mail... hence leading to the following major inconveniences:

- Dispersed information (technical specifications, orders, dispatches, acknowledgement of receipt forms ...) requiring individual management by the project managers ending up as a waste of time and with manual follow-up.
- No automatic integration with the data from the CTMS, the CAMM.
- A succession of manual steps (checking the files, completing the forms, signing and sending faxes, bringing the logs up-to-date, filing the faxes...).



contact@w4.eu - www.w4.eu



> IPSEN : Gestion logistique des essais cliniques

The Solution

At the end of December 2002, after a study of different market software packages and of internal options, IPSEN decided to set-up the reporting capacities with the workflow solution W4 BPM Suite (sending on-site follow-ups, monitoring the quantities ordered by therapeutic units, tracing dispatches ...).

There was no software package that answered entirely to the interface needs between the two different departments: manufacturing and clinical development. W4 BPM Suite allows managing this type of process change with repetitive tasks involving different users.

The Request for Proposal can be summed up as follows:

- Formalize and optimize the treatment of supplies.
- Improve the collaboration between all the actors implied in the process.
- Follow and audit all actions made on all files.
- Identify all the products used in the studies.

The Project

Once the project specifications were defined, an IPSEN project team including very different profiles and experiences devoted three and a half months setting out the user requirements in order to minimize the misunderstandings. It took only two months to define the technical requirements (database, LDAP interfaces, data format...) and four months to determine the detailed requirements with W4 and the integrator partner SQLI (formerly Aston) and to enter into the first development phase. At the end, three addenda and two additional clauses have been added to the Request for Proposal.

First summary before the first quarter 2004:

Even if the application built with W4 BPM Suite generates both administration and maintenance costs, it answers 100 % to the needs. Flexible, evolving, with a friendly interface, it integrates perfectly to the IPSEN information system. Moreover, it respects the 21 CFR Part 11 rule: all data entries are tracked, stored and available in a single view.

Second summary at the end of the second quarter 2006:

A further upgrade to the application built with the W4 BPM Suite went into production at the end of February 2006. This upgrade allows the system to handle blind studies (mix of active and placebo drugs) as well as open ones. "The system has now completed the pilot stage and is used for the packaging and dispatch requirements of all new studies, plus any existing long term studies that are deemed suitable. A future upgrade will increase the coverage of the system to include the return and destruction of the drugs." declared David Fowler, International Project Manager, IPSEN

A propos d'Ipsen

IPSEN is a mid-sized European pharmaceutical group focused on the development of innovative products in targeted disease areas: oncology, endocrinology, and neuromuscular disorders. This native French Group is today a worldwide one and markets over twenty products in more than 100 countries.

For IPSEN, R&D is a highly strategic activity. In 2005 169 M€ were invested (20.9 % of its sales) in 4 centers located in Paris, Boston, Barcelona

