CASE STUDY

TAKEDA IRELAND

Lean Manufacturing as a Strategy,
Paperless Manufacturing as a Result.

Takeda Pharmaceutical Company (TPC) Limited is a dynamic and growing Japanese pharmaceutical company that is committed to improving the health and quality of life of people around the world. Employing 14,500 people worldwide, Takeda is number one pharmaceutical in Japan and one of the world's top 100 companies.

Takeda Ireland Limited (TIL) was established as a 100% subsidiary of TPC in 1997. TIL has played a key role in the group's worldwide operations. TIL is over 155 000 sq. ft in size and manufactures solid oral dosage finished products such as tablets, capsules and granules. TIL's first commercial shipment (BLOPRESS/AMIAS) was in 1999 and since then TIL has served as TPC's main pharmaceutical production base for the European and U.S. markets. The TIL site is an FDA and IMB compliant facility which is licensed to manufacture the key blockbusters products:

- **Prevacid/Lansox (peptic ulcers),**
- **Actos (insulin sensitizer),**
- **Blopress (hypertension, cardiac failure),**
- **Rozerem (insomnia).**

Completed in 2000, this facility integrates the latest manufacturing technologies allowing for paperless manufacturing, reduced costs, improved quality and continuous improvement.

The Challenge

As a state-of-the-art manufacturing facility, Takeda Ireland was eager to find better ways to implement cost reduction strategy while improving operational performance and quality. Process automation, reduced human errors, improved yield, faster batch review, less paper volume, secured archiving, visibility on tasks to be performed and executed were among the key objectives.

When all the objectives were prioritised, the four top concerns of Takeda Ireland related to manufacturing were listed as:

- **Reduced costs**
- **Faster time-to-market**
- **Right the first time**
- **Complete and comprehensive audit trail**

The Solution

Takeda Ireland chose XFP-MES by Elan Software Systems to manage the entire production cycle from the receipt of raw materials to the shipping of finished products in 1999. The implementation of XFP includes material flow management, weighing and dispensing, directed manufacturing, equipment management, electronic batch records (eBR) and packaging.

At Takeda Ireland, XFP integrates with SAP and the LIMS systems making sure information is always accurate in all systems. Material consumption and reconciliation, dispense, inventory adjustment, flow management and batch information are pieces of information that are constantly updated among XFP, SAP and the LIMS systems.

Within XFP, Takeda easily supervises product packaging processes by controlling templates for packaging operations and labels varying according to shipping country, this additional control helps maintain GMP compliance.

The use of mobile devices such as WIFI hand held terminals and tablet PC's facilitate real time user task execution at the point of operation and eliminate human entry errors.

TIL chose XFP-MES by Elan Software Systems to implement an eBR on its site in 2006. The eBR is an electronic copy of the standard paper-based batch records use to control their manufacturing process. The advantages of eBR include better control and traceability through the use of electronic signatures, security and bar-coding, improved repeatability due to stricter control of key process parameters, and simpler review and storage of batch information.

SAP® Certified Integration

The Benefits

It took less than 12 months to deploy the eBR among Takeda Ireland's first production line. And the system has been demonstrating high returns on investment since then. The very first result was the reduction of errors, like wrong data input and wrong calculations with were having a direct impact on the cost of quality.

An essential for the project was to meet the requirements of data storage and security in accordance with Good Manufacturing Practice (GMP). The XFP-MES suite includes pre-defined electronic signatures, comprehensive security features and complete audit trails of user actions and executed eBR. It stores data in an industry standard database, providing a better maintenance of batch information. Last but not least, the use of XFP eBR has accelerated the batch release, enabling faster product shipment.

" XFP-MES solution from Elan Software is well aligned with a Japanese drug manufacturer. It provides the right lean manufacturing tool to improve operational performance while reducing costs. Besides, Elan Software has a deep expertise of pharmaceutical processes, giving them a true cutting edge."

Paul Blunnie, Plant Manager