

# Going Paperless

Baxter - Full electronic Batch Record & Release with SIMATIC IT XFP



## SIMATIC IT

Answers for industry.

**SIEMENS**



“Before we implemented SIMATIC IT XFP at the Irish plant, the documentation department needed 3 to 4 days planning to print the paper batch template. Now this process takes less than 30 minutes and the systems sends the right instructions to the right operator. This is just one example among many. The cost reduction ratio is two and a half times better than our expectations.”

Douglas Bolster, Production Manager (e-batch), Baxter Castlebar.

## Paperless Manufacturing Across Multiple Sites.

Baxter implemented an MES system to be sure to manufacture products right the first time. Baxter Healthcare relied on SIMATIC IT XFP for Medication delivery and Renal divisions. The solution deployed includes Weighing & Dispensing, Material Management, electronic Work Instructions and Electronic Batch Record & Release.

### The customer

With approximately 46,500 employees worldwide, Baxter applies its expertise in medical devices, pharmaceuticals and biotechnology to make a meaningful difference in patients' lives. Baxter International Inc. operates in three main businesses: BioScience, Medication Delivery (MD) and Renal. This case study focuses solely on the MD and Renal divisions. Baxter MD is a leading manufacturer of intravenous (IV) solutions and administration sets, premixed drugs and drug reconstitution systems, pre-filled vials and syringes for injectable drugs, electronic infusion pumps in addition to other products used to deliver fluids and drugs to patients.

### The business challenge

Back in 2003, Baxter Medication Delivery and Renal Divisions in Europe were eager to implement an electronic batch system with the principal objectives of cost reduction, increased quality compliance, enhanced flexibility and acceleration of batch release.

#### **Error prevention and cost reduction**

The main goal was to avoid solution and product discard, via the automatic prevention of manual errors in production, specifically in mixing, printing and packing. The Irish plant of Castlebar operates with over 1,000 employees. As the manufacturing process is primarily manual, the process is always prone to human error.



## At a glance

### Company:

Baxter  
www.baxter.com

**Industry:** Life Sciences

### Solution:

- SIMATIC IT XFP

### e-Batch system at a glance:

- 765 trained users, 400 users every day
- 4000 new workflows per day
- 20 000 manual tasks are recorded every 24h
- 54 000 automatic background control tasks
- 150 PCs and toughbooks connected at any one time.

### Enhanced flexibility

All European Baxter MD & Renal plants plan for increased growth in products with numerous different product codes in each product type. This can involve complex production processes. One of the key objectives was to deploy a flexible system that could enable rapid change of the production schedule. In addition, Baxter needed the flexibility to change its batch record workflow as the manufacturing process changed.

### Full quality compliance

The electronic batch system must guarantee full compliance with internal standards, industry standards and customer requirements. As an example of an internal standard, the system should highlight any specific product code requirements such as unique sampling and inform the operators to take the right amounts of samples at the right time.

### Accelerated batch release

Previously, three days lead time was needed to pre-print the blank paper-based batch documentation. The large amount of paperwork completed by manufacturing for each batch led to a significant time in secondary batch review and also in returning paperwork for correction. This added additional unproductive time to the release cycle of the batch.

## The solution

The European divisions of Baxter MD & Renal selected the SIMATIC IT XFP solution to manage all production operations. The implementation of SIMATIC IT XFP

includes material flow and inventory management, weighing, counting and dispensing, directed manufacturing, daily equipment checks, mixing, printing, filling, sterilizing, electronic batch records (eBR), batch testing and reviews, packaging and labelling operations and finally data warehousing. All data is stored in a central repository available for use and review, enabling Baxter to perform trend analysis such as laboratory trends, scrap analysis and measure manufacturing output and scrap.

At Baxter MD/Renal Europe, SIMATIC IT XFP integrates with the ERP and LIMS systems making sure that 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 in SIMATIC IT XFP, the ERP and LIMS systems.

At the time of writing, the SIMATIC IT XFP solution is deployed at the Baxter manufacturing facilities in Ireland, Belgium, Italy, Spain and Canada. Ireland served as a pilot site and Belgium has become the MES excellence center.

## The pay-off

The implementation of a full electronic batch record solution has shown good returns. The e-batch system guides operators through the complete process, acting as an electronic router with controlled task execution and automatic calculations while recording all actions. Human error

risks have been significantly minimized, quality has increased. Examples of added control in the following areas had led to increased error reduction:

- All samples are tracked on the system preventing samples from being mislaid.
- Scanning of WIP into line cleared manufacturing areas/departments.
- Automated checks of Batch Number & Expiry for product labelling.
- Batch review by exception/deviation only.

It is now possible to manage more volume with less resource and better quality. Less storage space is required and a reduction in headcount has been achieved due to the continuous checking and interrogation of data. All samples are tracked on the system preventing samples from being mislaid.

Thanks to the traceability, electronic signature and security features, the system helps ensure total quality compliance with any industry regulations, including FDA. Finally, the new system has led to the reduction of batch release time and of course cost.

All data is gathered in one batch report, which is accessible at any time. Reviews are only done on exceptions, which translate into significant time and cost savings. Over 6,500 batches and 9,500 mixes have been released electronically in the Castlebar site. The Right The First Time ratio is above 99%. Cost savings account for more than \$250K per annum. Efficient paperless manufacturing has become the new motto of Baxter MD and Renal sites across Europe.

## Get more information

[marketing.simatic-it@siemens.com](mailto:marketing.simatic-it@siemens.com)

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