

BAXTER MD & RENAL



❏ Paperless Manufacturing Across Multiple Sites in Europe.

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 company also provides IV nutrition solutions, containers and compounding systems and services, general anesthetic agents and critical care drugs, contract manufacturing services as well as drug packaging and formulation technologies.

Baxter Renal is a leading manufacturer of products for peritoneal dialysis (PD), a home therapy for people with end-stage renal disease, or irreversible kidney failure. These products include a range of PD solutions and related supplies to help patients safely perform solution exchanges, as well as automated PD cyclers that perform solution exchanges for patients overnight while they sleep.

"Before we implemented XFP-MES 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

❏ A Focus at Baxter Ireland Pilot site for the European roll-out of XFP

- 8 full paperless production lines
- 18,500 tasks completed in 24 hours
- 54,000 system controlled tasks in 24 hours
- 765 trained users
- Over 400 users per day access e-batch
- 800 product codes used by XFP
- 150 PCs/Toughbooks connected to XFP

The Challenge

Back in 2003, Baxter Medication Delivery and Renal Division in Europe was 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. For example, errors in the weighing or mixing stage could lead to finished product being discarded with additional costs having been added.

▪ 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 and complicated production processes. One of the key objectives was to deploy a flexible system that could enable rapid change of the production schedule according to new priorities from the market or incidents of raw material shortage internally. 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.

▪ Accelerate 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. These inefficient review methods needed to be eliminated.

"XFP-MES has been selected as the global solution for all European production sites. The pilot site was in Ireland and Baxter has decided to set up a center of excellence in Belgium to manage the various roll outs. The user-friendliness and flexibility of the XFP-MES solution has resulted in fast and easy knowledge transfer between teams. Each rollout is fully optimized, leveraging previous site experience."

Tony Mannion, IT Director Europe, Baxter

The Solution

The European division of Baxter MD & Renal selected the XFP-MES suite from Elan Software in 2003 to manage all production operations, from the entry of raw materials into the workshop to the transfer of finished goods to the warehouse. The implementation of 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, 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 XFP, the ERP and LIMS systems.

At the time of writing, the XFP-MES Suite is deployed at the following Baxter manufacturing facilities: Ireland, Belgium and Italy. The next site to be deployed is located in Spain. Ireland served as a pilot site and Belgium has become the MES excellence

center, which all upcoming roll-outs now rely on for testing, validation and deployment.

The decision factors associated with the selection of the XFP-MES Suite were numerous and included Elan Software's reputable industry-expertise and the proven excellence in weighing and mixing - the first and highly critical part of any pharma process. Baxter were also interested in the high product configurability which enables easy updating and fast maintenance as well as the powerful yet easy to use workflow capabilities.



The Benefits

The implementation of a full electronic batch record solution has more than exceeded Baxter's expectations. The e-batch system, as it is known internally, 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.



"As batch records are now completed electronically, this has resulted in the elimination of omissions and reduction of GDP errors. This has removed the requirement of primary and secondary reviews. This in turn has led to increased compliance and cost reduction improvements."

John Walsh, QA Manager, Baxter Castlebar