

It's so much more than Electronic Batch Recording!



Ferring introduces electronic Batch Recording at their site in Kiel, Germany.

Ferring Pharmaceuticals went for a change in their way of working at their site in Kiel, Germany. Due to good experiences from other Ferring locations, the decision was made to introduce a manufacturing execution system for electronic Batch Recording (eBR). First, Ferring started in the visual inspection area as one out of eight production areas. With the experienced Körber Pharma Consulting experts on board, the Ferring team opted to review workflows and processes first in order to prepare them for the digital transformation.

The new to-be processes were summarized and shown the Körber Process Landscape® tool, a tool that helps to obtain a clear view on the processes. This was done for each section of the visual inspection area, namely manual, semi-automatic and automatic inspections. The process steps were analyzed by directly walking the shop floor and clarifying open points with the operators. This helped to identify misinterpretations that had resulted from the master batch records' (mBRs) data take-over and helped to clarify the processes.

Final clarifications and decisions were made in meetings that included all process stakeholders. By doing so, the team was able to identify process simplifications and process optimization opportunities. As a result of this harmonization exercise, the number of process steps was tremendously reduced and optimized.

With the optimal-designed recipes in place, the MES-eBR supports the operator when entering the data. Immediate feedback is provided in order to guide him through the complex production processes. A desired side effect: all calculations and most of the test steps are executed automatically. Thereby human errors are massively reduced and the review of the batch documentation is simplified compared to the previous paper based efforts. The described savings are valid for the visual inspection area – as the production processes in other areas are far more complex, even more benefits are expected with the planned roll-outs.



Simplifying

A clear asset in the project was the modular approach. Following the ISA 88 recommendations, directives, the project team used a clustering process, combining the different process steps to a set of building blocks. These building blocks were combined to make up the recipe.

The modular approach of the prevalidated building blocks was utilized. Therefore, when re-using the building blocks it is only necessary to validate the new characteristics. Therefore the overall validation effort decreases drastically. The project team was able to reuse approximately 70–80% of the blocks in different recipes by applying this modular approach.

Through automatic checks and calculations in the eBR, the review effort for the electronic records was significantly reduced compared to the paper-based documentation. The quality of the batch reports increased concurrently. Now, all recipes are managed and executed in the manufacturing execution system for the visual inspection. The roll-out of the MES for the other areas are planned and ongoing for the next years and will be supported by Körber.

“For the colleagues it is a tremendous change to introduce electronic Batch Recording. With the support from Körber, we were able to identify and realize process optimizations. If you put your trust in Körber’s experts, you can draw on twenty plus years of MES and process know-how. We are looking forward to continue working together on the introduction in the other areas.”

Hartwig Hönerloh
Project Owner, Ferring in Kiel

“It was and is a pleasure to work with such a dedicated team, which drove the project to a quick completion. In addition, we were able to clearly demonstrate the benefits to the customer which lead to an overall success”, complemented Tim Meyer, Team Lead Consulting at Körber.

Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven specialty biopharmaceutical group committed to helping people around the world build families and live better lives. Ferring is a leader in reproductive medicine and maternal health, and in specialty areas within gastroenterology and urology. Ferring, which is headquartered in Saint-Prex, Switzerland, has been developing treatments for mothers and babies for over 50 years.

Key Benefits

Situation

- Project on the path to digital manufacturing – Pharma 4.0 – paperless production
- eBR introduction & local implementation of the Ferring core system

Customer benefits

- Reduction of batch deviations up to 25 %
- 100 % of typical batch documentation errors eliminated
- Reduced required documentation time during production between 25% and 40%
- Reduced time for Batch Record Review by 60% on average
- Right first time: minus 15 minutes per visual inspection Batch



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