

# Paperless Manufacturing: FabEagle®LC Line Controller for Pharmaceutical Primary Packaging Production



"The high level of customer acceptance after four completed lines makes our line controller solution the standard for all future lines and locations."

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Senior Sales Manager  
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**FabEagle®LC**

Leading supplier of primary packaging for the pharmaceutical industry

## Platform:

FabEagle®LC – Line Controller with standardised communication interfaces

## Kontron AIS services:

Consulting and creating a concept, programming, commissioning, validation process according to GAMP



### Goals

- Paperless manufacturing
- Traceability and error analysis
- Increase transparency for downtimes and reasons for downtimes
- Save costs with digitization and automation



### Challenge

- Clarify all requirements for a fully integrated system
- Project management to support many stakeholders and suppliers
- Qualification and standardization of the interfaces to the line components



### Results

- Electronic batch recording in accordance with pharmaceutical requirements
- Digitization of the pre- and post-processing of the batches
- Track and trace from individual product to the packaging unit
- Automated reports for process support

They are an essential part of everyday medical life: pharmaceutical primary packaging such as syringes, vials and ampoules. The packaging has to fulfill high quality standards and their manufacture is subject to the strict GAMP regulations. At the same time, pharmaceutical manufacturers have to maintain a very high level of documentation, including the recording of batch-related data. The higher the degree of digitization in production, the easier this step is, and the less paper is required.

With this in mind, and with the goal of organizing its production completely without paper, the customer decided to use the robust and customizable FabEagle®LC line controller solution from Kontron AIS. In accordance with GAMP, the pilot line consisting of four large modules with a total of 50 stations, 7 robots and four optical inspections was made ready for fully automated series production. Meantime, there are now four fully automatic production lines at the manufacturer's site.

### **Objective: paperless manufacturing and complete digital batch recording**

In the specifications for the system, the classic functions of a line controller such as order and recipe management, product tracking and recording of machine data were taken as given. The machine and operating data recorded digitally during production optimize line availability and enable a rapid response in the event of process deviations.

The main objective of the line controller was to introduce digital batch reporting and replace paper on the production line, while avoiding sources of error in data entry. The task for Kontron AIS was therefore to gather all the data required for electronic batch recording from the individual production line components using appropriate interfaces, while at the same time ensuring their correct and complete transmission. EUROMAP as well as connections to PLC controls, SCADA systems and databases were used as interfaces.

The operator is then provided with a line controller that supports and automatically summarizes batch reporting with an Electronic Batch Record (EBR). Any interventions in the process are automatically recorded and saved in the audit trail. The system is also designed to support the operator with check lists for batch preparation and post-processing. This includes checking the recipes and parameters set on the line components. If necessary, any incorrect settings are indicated to the operator before production can be started. Automated workflows support the operator during production with cyclical tasks.

At the operational level, the biggest challenge was project management. A multitude of specifications and on-going development of the process had to be brought together on the pilot line during the project. In addition, a large number of different people and decision-makers from the customer's company as well as from the suppliers needed to be involved in the process. However, close cooperation between Kontron AIS and all project teams enabled a well-coordinated process and smooth implementation of the project.



## Result: End-to-end highly automated production

Following an intensive concept and development phase, the line controller systems were successfully put into operation. The FabEagle®LC line controller communicates with the machine controls, the MES and a PIMS, enabling end-to-end highly automated production.

### Advantages for the customer:

- ✓ Electronic Batch Recording (EBR) and automated operator support for batch preparation and post-processing prevents errors and saves time
- ✓ Digital signature using RFID badge linked to the customer's incoming goods control system
- ✓ Track and trace is carried out digitally on the production line for each product right up to final packaging and allows a high level of detail in terms of evaluation and traceability
- ✓ Process data monitoring of GMP-related measured values
- ✓ Time savings as a result of automated reports for KPIs on line availability, error frequencies, reasons for downtime and output
- ✓ Web-based Andon boards provide a quick overview of the most important data during production
- ✓ Costs are saved and OEE is increased thanks to digitization and automation

During the projects, the preparation of the qualification processes from DQ (Design Qualification) to PQ (Performance Qualification) was also digitized to a large extent by Kontron AIS with the system-supported creation of FMEA (Failure Mode and Effects Analysis), traceability matrix and test plans. Test results and the status of any deviations are documented in digital form. In the context of the follow-up lines, digitization and thus easier reusability enabled the qualification effort to be halved.

## About Kontron AIS GmbH

We set the benchmark in industrial software – for more than 30 years and with an experienced team of over 200 employees. Our proven software products and customized digitalization solutions enable machine and equipment builders as well as factory operators to break new ground in automation and secure long-term competitive advantages. Together with our customers we implement worldwide cross-industry, intelligent digitalization strategies and solutions for the smart manufacturing of tomorrow.

As a subsidiary of the Kontron AG, we offer integrated, end-to-end IoT concepts consisting of hardware and software as well as worldwide project management, service, and support thanks to a global network.

For more information please visit: [www.kontron-ais.com](http://www.kontron-ais.com)