FabEagle®LC

PAPERLESS MANUFACTURING

Line controller for the production of
pharmaceutical primary packaging

They are an essential part of everyday medical life: pharmaceutical primary packaging such as syringes, vials and ampoules. They have to fulfil high quality standards and their manufacture is subject to the strict GAMP specifications. At the same time, pharmaceutical manufacturers have to maintain a very high level of documentation, including the recording of batches. The higher the degree of digitalization 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 specifications, the pilot line consisting of four large modules with a total of 50 stations, seven robots and four optical inspections was made ready for fully automated series production. There are currently four fully automatic production lines at the manufacturer's site.

GOALS

▶ Paperless manufacture

▶ Traceability and fault analysis

▶ Increase transparency for downtimes and reasons for downtimes

▶ Save costs with digitalization and automation

CHALLENGE

▶ Clarify all requirements for a fully integrated system

▶ Project management due to the large number of people involved and suppliers

▶ Qualification and standardization of the interfaces to the line components

RESULT

▶ Electronic batch reporting in line with the requirements of the pharmaceuticals industry

▶ Digitalisation of the pre- and post-processing of the batches

▶ Track & Trace for single product up to packaging unit

▶ Automated reports for process support

POSSIBILITIES START HERE

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OBJECTIVE: PAPERLESS MANUFACTURE AND COMPREHENSIVE DIGITAL BATCH REPORTING

When defining the requirements expected of the system, the classic functions of a line controller such as order and recipe management, product tracking and machine data acquisition were taken for granted. The machine and operating data recorded digitally during production optimizes line availability and enables 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. Kontron AIS therefore had the task of recording all the data necessary for electronic batch reporting from the individual machine parts via suitable interfaces and simultaneously ensuring their correct and complete transfer. 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 also had to provide the operator with checklists as additional support during 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 with cyclical tasks during production.

At the operational level, the biggest challenge was project management. A multitude of specifications and ongoing 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 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 reporting (EBR) and automated operator support for batch preparation and post-processing prevent errors and save time

- ✓ Digital signature using RFID badge linked to the customer's incoming goods control system

- ✓ Track & 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 digitalization and automation

During the projects, the preparation of the qualification processes from DQ to PQ was also digitalised to a large extent by Kontron AIS with the system-supported creation of FMEA, traceability matrix and test schedules.

Test results and the status of any deviations are documented in digital form. Consequently, the time taken for the qualification of follow-up systems was halved thanks to digitalisation because the data could easily be reused.

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About Kontron – Member of the S&T Group

Kontron is a global leader in IoT/Embedded Computing Technology (ECT). As part of the S&T technology group, Kontron offers individual solutions in the areas of Internet of Things (IoT) and Industry 4.0 through a combined portfolio of hardware, software and services. With its standard and customized products based on highly reliable state-of-the-art technologies, Kontron provides secure and innovative applications for a wide variety of industries. As a result, customers benefit from accelerated time-to-market, lower total cost of ownership, extended product lifecycles and the best fully integrated applications.

For more information, please visit: **www.kontron.com**

About Kontron AIS GmbH – Member of the S&T Group

We set the benchmark in industrial software. For more than 30 years and with a growing team of 160 employees, we have been providing solutions for equipment manufacturers as well as factories to break new ground in automation and thereby substantially reduce costs. Together with our customers, we develop concepts for smart manufacturing and Industry 4.0, helping to implement intelligent digitization strategies successfully.

For more information, please visit: **www.kontron-ais.com**

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