

## › Productionspecific line controller in the pharmaceutical industry

# Use Case



## Production-specific line controller for traceability and product control in the pharmaceutical industry

Automation and digitalization of production, including the necessary quality assurance, is key to becoming the modern pharmaceutical company of tomorrow. Topics such as product liability and the certification and validation of production processes play a major role.

As a result, all data relating to the production of pharmaceutical products has to be saved and securely archived. This includes not only data relating to the process, quality and production, but also data on manual random checks, access to machine control systems and recipe changes, which have so far been recorded mainly on paper and double-checked by a second person.

susietec® offers a comprehensive solution for digitizing data collection and work processes along the production lines. In addition to the certified hardware infrastructure consisting of KISS servers, HYG hygiene displays and IoT components for the local integration of field devices, the susietec® toolkit also includes the line controller software based on the FabEagle® series.

All the services needed such as consulting, implementation, commissioning and validation are offered from a single source. In short: When implementing an efficient and reliable line controller for automated production sectors, pharmaceutical companies benefit from our know-how and many years of experience thanks to comprehensive consultation as well as a matched portfolio of hardware and software.

## The project

- › Line controller for production clusters in the pharmaceutical industry including integrated interfaces and input terminals

## susietec® products

- › FabEagle®LC
- › FabEagle®Connect
- › KISS Server
- › FlatView HYG Touch Panel

## The service

- › Creating GMP-related specifications and documentation
- › Defining and implementing machine interfaces
- › Installing and configuring/customizing the line controller
- › Commissioning and supporting GMP validation

## The challenge

- › Creating GMP-certifiable interfaces and integrating production line machines
- › Digital mapping all quality-relevant workflows in the line controller
- › Collecting and storing all product data for individual parts at a production cycle rate of < 1 second
- › Implementing GMP project process and the necessary certification

## The solution

- › Creating all GMP-relevant documents
- › Selecting and implementing suitable software and hardware components
- › Mapping the product and line details
- › Discussing and implementing machine interfaces with machine manufacturers
- › Commissioning, documenting, testing and validating the overall solution

## The result

- › Comprehensive line controller concept from a single source
- › Pre-qualification of hardware such as KISS servers and HYG hygiene displays in accordance with the required standards
- › Fast adaptation of quality assurance concepts to line details based on data that is automatically collected or manually entered
- › Simplification and acceleration of commissioning and GMP validation due to integrated approach

# ” Production-specific line controller for traceability and product control in the pharmaceutical industry ”

## Technical details of the project

Line controller for fully automated production sectors within the pharmaceutical industry based on the combination of software, hardware, services and expert knowledge. The FabEagle®LC software used contains functions that are designed especially for the pharmaceutical industry, such as product configuration and data collection to enhance traceability, recipe management, quality data acquisition, and the mapping of dynamic user workflows such as sampling, changes being confirmed by a second person, and cyclical maintenance/ tests that are adapted to the respective setup of the line.

The open integration platform FabEagle®Connect offers a large number of additional standard protocols for machine integration. Individual configuration based on the interfaces provided by each machine manufacturer enables secure and processor-oriented communication.

The rollout of the matched software packages is generally virtualized on reliable KISS servers. If required, a distributed IoT infrastructure can be integrated using a K-BOX, which distributes the data load of the machine interfaces.

The entire implementation of the project, from defining the requirements to final commissioning and process qualification, is backed up and validated with qualifications and documents in accordance with GMP.

## Advantages for the customer

The integrated approach, consisting of tried and tested hardware and service components, not only significantly reduces the amount of work required for certification and qualification, but also relieves the customer of the task of selecting and integrating individual components.

Instead of organizing and communicating with a large number of suppliers, the customer has a central contact person who provides advice and support while implementing the solution and all GMP environment processes. Project progress and time to market are accelerated while significantly reducing project risks at the same time. The result is a modern line controller solution that enables 100% paperless production even in the strictly regulated pharmaceutical environment.

## Customer key figures

- › Reduce project time by 50 percent
- › Completely do away with manual documentation in paper form
- › Comprehensive product configuration and product data collection with fully integrated/fully automated production

## About susietec®

We see digital transformation as a holistic approach. With the susietec® Toolset, we support companies in recognizing the potential of IoT and digitization: The combination of software, hardware and know-how enables functional and smart solutions for equipment suppliers, providers and manufacturers. That is how we succeed in implementing purposedriven changes effectively – with the aim of driving forward digitization in the long term. susietec® solutions can be used in an existing environment and also provide a basis for the new development of machines, components and production plants.

As part of the Kontron Group, we help you take the decisive steps towards digital transformation using our experience from numerous digitalization projects.

For more information, please visit:  
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