



# Siegfried | User Report

**Siegfried Hameln**

# Content



## Production Optimization With FASTEC 4 PRO at Siegfried Hameln

Siegfried, the world's leading CDMO (Custom Development and Manufacturing Organization), produces active pharmaceutical ingredients, intermediates and finished products from a single source. The core competence lies in the integration of complementary chemical and pharmaceutical competencies in a single business model.

This user report focuses on the Hameln location, where production has been optimized with FASTEC 4 PRO for over ten years. Siegfried Hameln mainly produces parenterals; that is, liquid drugs that bypass the digestive tract and are administered intravenously or intramuscularly.


Siegfried Hameln is also active as a contract manufacturer and produces pharmaceutical products (including anesthetics, painkillers and medication for intensive care) for other companies. The majority of the manufactured products are used internationally.

### Topics:

- **Challenge**
- **Solution**
- **Benefit**
- **Conclusion**
- **Contact**

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# Challenges



At Siegfried Hameln, data acquisition was previously carried out exclusively via manual entries and evaluations. In order to tackle the path to digital production, electronic data acquisition for production optimization was therefore the obvious choice.

## **Vision: Paperless Production in the Clean Room Area**

When a new building for the sterile filling of parenterals was built in Hameln, Siegfried Hameln's vision was clear: Paperless production in the clean room area of the new building. In addition, the company continuously strives for optimization in order to produce even more efficiently at the highest quality level. The manual processing of key figures in Excel had to be replaced by electronic data acquisition in order to obtain precise evaluations of machine reliability and effectiveness. From the beginning, the goal was to derive optimization projects from this data.

## **GMP Validation**

An important requirement when introducing digital data acquisition at Siegfried Hameln was the possibility of validation according to GAMP 5. The company wanted to use resource logbooks to record data such as cleaning steps on the machines.

Furthermore, not only machine-relevant downtimes should be recorded, but also the status of the machine should be available in real time. This recording in the resource logbook is a GMP-critical process step, which is why the system requires GMP validation based on the user requirement specification.

Siegfried Hameln performed a risk analysis from its own requirements for production optimization software. From this, concrete measures and projects were developed, which were then transferred into a validation matrix and defined as test points for the GMP validation.

When changes are made to FASTEC 4 PRO, all test points are checked again based on the specifications (URS) and a new risk analysis is performed.

The GMP validation is then extended or shortened and then carried out. In order to avoid interruptions or errors in ongoing production, revalidation is usually carried out first in the test system and then transferred to the production system after testing.

## Validation According to GAMP 5

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# Solution

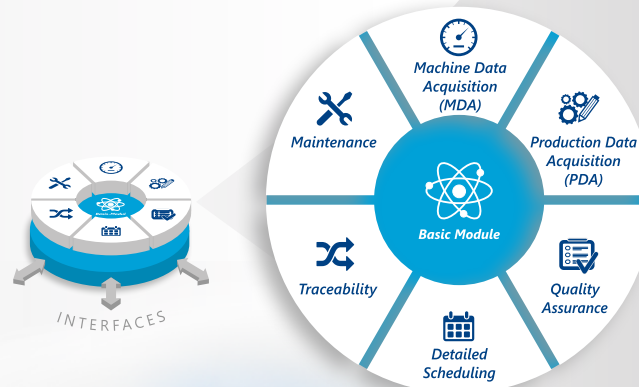
## Our Software:

### Flexible, Modular, Individually Adaptable

The modular software solution FASTEC 4 PRO supports the optimization of your entire production.

It improves production planning, creates more transparency and regulated processes, provides KPIs, analyses and reports – regardless of industry and flexibly adaptable even to special production processes.

Building on the basic module, the six main modules can be combined with one another according to individual requirements and supplemented by various additional functions. The individual modules access a common and uniform database. This means that consistent data is available at all times – there are no additional interfaces between the modules and no duplicate data storage.



## Individual Implementation:

At Siegfried Hameln, FASTEC 4 PRO was initially only connected to prototype machines in order to test the system's functionality and to be convinced of its reliability. This test phase lasted six months. The company then decided to continue on the path with FASTEC and to connect more and more machines and lines to FASTEC 4 PRO. The software has now been implemented on all machines and workstations and all employees are grateful for using it in production.

Since there is no area-wide network available in production, WLAN is used. The machine connection for recording the number of pieces and states is carried out with newer machines via direct PLC communication, with older machines via I/O modules. FASTEC 4 PRO is very flexible and can be easily connected to numerous machines. It is often not possible to draw conclusions about the entire line from individual machine components, so connection via PLC control does not always make sense.

In production lines, a sensor often records the line's performance. This measuring point can be used to draw conclusions about the productivity of the entire line. In the case of more complex lines that consist of a network of machines and buffer lines, direct PLC communication is ideal for precise recording.

# Gradual Rollout Throughout the Plant

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# Benefit

- **Use Far Beyond the Production Level**

FASTEC fulfills all of Siegfried Hameln's individual requirements for a software solution for digital production optimization. The data is recorded in real time on the machines and lines and the connection of FASTEC 4 PRO was implemented very quickly. All team leaders and managers can access the FASTEC 4 PRO Office Client on their end devices. Large screens have been placed in the production area where the current overview of the production status is visible at all times.

The software is also used intensively outside of production. Departments such as controlling or quality analysis have access to the machine's resource logbooks and can thus carry out a wide range of data evaluations.

The software also serves as an indicator for quality control. FASTEC 4 PRO visualizes the current production process step, which provides the signal for the necessary environment monitoring as part of quality assurance on the respective line.

- **Individual Evaluations – At Any Time**

Data evaluations are immediately available and can be traced back over a history of ten years without gaps and without data loss. This reliability is crucial for Siegfried Hameln as a producer of pharmaceutical products. The resource logbook is used to create a wide range of evaluations, diagrams and timelines. Especially in the OpEx area, FASTEC 4 PRO is used intensively to base optimizations on well-founded data. The evaluations are discussed in the weekly GMP update. Current production status, changes or disruptions in production as well as current problems and other questions from employees are analyzed here based on the data from FASTEC 4 PRO in the department meeting. In addition, the significantly highest downtimes are evaluated and documented as a key figure for the management on a daily basis. "FASTEC's support is always available and reliably handles all requests. Our IT department has also been very positive about the cooperation with FASTEC. We have often received help through fast channels – FASTEC rightly positions itself as a customer partner."

*"We get key figure evaluations at the push of a button and can put together overviews in the system individually – the functionality and performance of FASTEC 4 PRO convinces us again and again."*

*"The greatest benefit for us is the electronic acquisition of data. Thanks to FASTEC, we have mastered a step towards paperless production – both production employees and management appreciate this reduction in workload."*

**Katrin Straßer**

Senior Specialist Operational Excellence, Siegfried Hameln

**All Data Available in Real Time**

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# Conclusion

Katrin Straßer (Senior Specialist Operational Excellence) from Siegfried Hameln has summarized the most important tips for introducing software for electronic data acquisition and production optimization in a few key points:

## Recommendations

- At the beginning, the system requirements must be clearly defined and the effects on GMP-relevant processes must be analyzed.
- Building on this, a partner with modular software should be selected and the individual modules and additional functions should be combined with one another depending on the requirements – this ensures that no unnecessary purchases increase the project costs.
- Transparency and open communication with all employees and works councils are critical success factors for the introduction of production software and should therefore be practiced right from the start.

# Transparency as the Key to Success

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## Why Not Get to Know Us Personally?

Production companies must produce on time, in a traceable, flexible and customer-specific manner, while ensuring consistently high quality. Achieving these goals requires transparency through real-time information, good planning and quick and adequate reactions to deviations. Our Manufacturing Execution System (MES) FASTEC 4 PRO is the right tool for this purpose. With great success since 1995.

### We would also like to give you a good advice personally!

Our sales department will be happy to provide you with further user reports and information material! Or else, make an appointment with our sales department for a presentation at your location, in our company or via web. Of course, you can also experience FASTEC 4 PRO live and on site with our customers.

[vertrieb@fastec.de](mailto:vertrieb@fastec.de) or by phone at: **+49 5251 1647-0**

Additionally, we offer videos of our software and customer solutions in our YouTube channel:

[www.youtube.com/FASTECGmbH](http://www.youtube.com/FASTECGmbH)

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Gold  
**Microsoft Partner**  


**SAP**  
Silver  
Partner

With FASTEC 4 PRO, you gain the necessary level of transparency in all areas of production in real time, enabling you to discover previously unused potential for increasing productivity and optimizing processes. Thanks to targeted planning, you can also respond to short-term requirements from sales and efficiently design production processes – traceable and documented.



### FASTEC 4 PRO

- Get transparent data in real time
- Reduce production costs
- Detect and eliminate weak points
- Develop high productivity potentials
- Benefit from the continuous flow of information
- Use available resources efficiently

▶ **As a data hub, FASTEC 4 PRO is essential on the way to the Smart Factory.**