INDUSTRY: PHARMACEUTICAL

# Rottendorf Pharma GmbH

www.onoff-group.de

*"Individual GMP-compliant automated systems bring benefits especially in situations where consistently high product quality and flawless monitoring of manufacturing conditions are required".*

*Gero Stüve, Supply Chain Management, Head of Procurement*

## Efficient cleanroom and process monitoring in the pharmaceutical industry and life sciences

**Goals**

- Monitoring of production, laboratory and storage conditions throughout the enterprise
- Proper collection and long-term preservation of monitoring and process data
- Visualization and distribution of alarms and notifications
- Flexible data analysis and standard reporting
- FDA-compliant storage of GMP-relevant parameters

**Challenges**

- Monitor environmental conditions through a multi-stage alarm system
- Compliance with legal requirements and regulations
- Qualified system environment/application
- GMP-compliant user administration
- High product safety combined with maximum production flexibility

**Solutions and Products**

- ArchestrA System Platform
- Wonderware InTouch® HMI for Terminal Services
- Wonderware Historian (part of ArchestrA System Platform)

**Results**

- Collection, analysis and storage of GMP-critical parameters - including differential pressure, temperature e relative humidity - in production, laboratory and storage areas.
- System-generated users alarms in case of specification violation, including escalation mechanisms

For over 80 years, Rottendorf Pharma GmbH has been an independent service company with worldwide operations for the development, production and packaging of pharmaceutical products in a solid form. The company develops and produces solid oral medicines for approximately 200 customers, including many global corporations. With 700 employees, Rottendorf Pharma GmbH is one of the biggest subcontractors in the pharmaceutical industry. As service supplier, they are a synonym for development, production and packaging of highly valued products worldwide.

## Requirements

The production of pharmaceuticals requires to comply with several legal regulations and standards, including the principles of GMP (Good Manufacturing Practice) and GAMP (Good Automated Manufacturing Practice). To be able to respond quickly and cost-effectively to ever changing legal requirements and manufacturing technology conditions, while ensuring high product safety, an integrated quality management system is mandatory. Furthermore, in the production, analysis and storage of pharmaceuticals, specific environmental conditions must be guaranteed. At Rottendorf Pharma GmbH, a building control system takes care of this aspect. However, the lack of a control room revealed the necessity of a GMP-compliant room monitoring system.

A specific project was launched to define a system that monitors environmental conditions with a multi-level alarm concept. The pharmaceutical process parameters must be constantly measured and presented in standard reports.

## Implementation

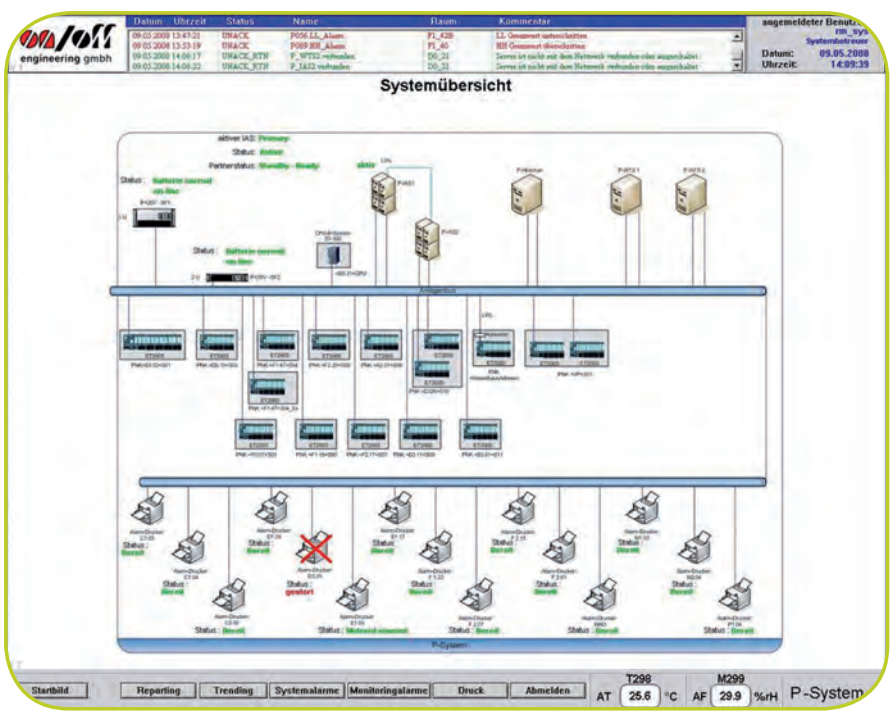
To cover the whole spectrum of requirements, among other things, an alarm concept was created to act as a foundation for the design of alarm levels and possible actions and/or operating sequences. With this concept, when alarms are triggered, a room- or user-specific notification of the alarm-triggering parameters is sent automatically to department printers, for instance. In addition, standard reports with monitoring and production data were defined and are now generated automatically.

This means that sensor signals are captured via decentralized peripheral devices by a PLC. Here, threshold values are monitored, alarms and escalations are generated. Room signal lamps are activated to signal an alarm in the corresponding room. This is where ArchestrA System Platform comes in and processes data coming from the PLC and a SNMP OPC Server for the monitoring of system components, finally generating the alarms.

Pharmaceutical process parameters for long-term analysis are then recorded in Wonderware Historian and reports are generated accordingly. To visualize the system, the Wonderware InTouch visualization software is used.

To ensure error-free operation and to have a test environment for expansions, the monitoring system in production was complemented by a quality system with identical functionality.

All system modifications are executed in the quality system and only after successful testing they are transferred to the production system. In this way, all new functions can be developed and tested thoroughly with no impact on the stability of the production system.



## Results

With the monitoring system developed by on/off based on Wonderware Software, GMP-critical values such as differential pressure, temperature and relative humidity are measured, analyzed and filed continuously. In case of alarm generation due to specification violations, users are notified and provided with smart escalation management instructions. All system alarms related to failed or defective system components are displayed at a central location, for instance, so that risk reduction and failure removal actions can be performed immediately.

Based on this system and process solution, it was possible to harmonize legal requirements, state-of-the-art science and technology, and individual requirements. GMP-compliant as well as automated systems bring benefits especially in situations where consistently high product quality and flawless monitoring of manufacturing conditions are required.

The adoption of Wonderware Software protects investments in the long term as a result of the creation of a standard system with low operating costs. Additionally, the ArchestrA technology provides the foundation for a scalable system – from a single room to an entire factory – using powerful, reusable and template-based objects. Ultimately, this solution led to the quick and easy qualification of a FDA- and GMP-compliant system.

## Benefits of a monitoring system

**Individual data acquisition**: Sampling intervals can be configured flexibly and they can also be event-driven; process data can therefore be acquired not just at fixed intervals, but also at any specified time when data acquisition is required for a charge.

**Flexible operation**: Users, according to individual authorization levels, can work at operating and monitoring stations or via network to monitor and operate specific plant sections, input and adjust parameters, administer and configure the system, attach and store protocols and reports.

**Traceability**; A tamper-proof audit trail ensures full traceability of all parameter modifications and system actions.

**Measurement diagrams**: All measurement values are detected and displayed in trend charts. The history functionality allows to record and store data for subsequent analysis for any length of time according to individual requirements.

**Alarming**: When threshold values are exceeded, alarms are triggered immediately and critical conditions/statuses are detailed in a list. Alarms can be notified by phone, SMS, pager, fax, e-mail etc.

**Efficient use of resources**: When monitoring systems have a modular concept, requirements can be adapted in the best way, from a single-workplace solution for few cleanrooms to client-server systems for an entire factory, leveraging the existing infrastructure (network, client and backup systems).

**Time saving**: Data acquisition and documentation is much more extensive and accurate than with a manual plant and process monitoring approach; this saves time and allows to react faster, as trends can be identified earlier.

**Standard components for custom solutions**: By using standard components with a modular approach, scalable monitoring solutions with any number of measuring points can be developed. This translates into cost reduction, investment protection and risk minimization in customer-specific implementations.

*This document was realized thanks to the support of:*
*Rottendorf Pharma GmbH*