PRECISION IN
PHARMACEUTICAL MONITORING

COMPREHENSIVE GMP CLEANROOM MONITORING BY NIOTRONIC

niotronic gmbh

MONITORING FOR THE PHARMACEUTICAL INDUSTRY

COMPREHENSIVE CLEANROOM MONITORING

Telemon Monitoring was developed taking into consideration the requirements of pharmaceutical production and ensures compliance with all strict GMP guidelines.

Due to continuous recording, monitoring and alerting of quality-relevant parameters in pharmaceutical production plants, deviations are uncovered immediately. With Telemon GMP Monitoring, you ensure the quality standard of your products and have a comprehensive overview of your facility at all times. The Telemon Monitoring System has been continuously developed further over the past 10 years and has adjusted to the growing requirements of pharmaceutical production.

TAILORED TO YOUR REQUIREMENTS

The Telemon Monitoring System is perfectly adjustable to your individual requirements due to its flexible, modular setup. We develope special solutions for each unique facility promptly and cost effectively in our in-house research and development department. The Niotronic hard- and software components thereby set many new standards in the pharmaceutical industry. Telemon has been developed and validated entirely with the use of GAMP 5 and is in accordance with the FDA - 21 CFR Part11 guideline. It is thus perfectly suited for being used for validated and tamper-proof documentation of your production environment in the pharmaceutical field.

PERFECT DOCUMENTATION AND RELEASE OF EACH BATCH

The critical aspect of manufacturing, before your product begins its journey to your customers, is made particularly easy by Telemon Monitoring. The manufacturing process is fully replicable and appraisable in conclusion. Telemon Monitoring perfectly supports the generation of the required documentation. The batch report generator shows that all critical production parameters are being met and lie within the tolerance values. The comprehensive Telemon Reporting is an all-encompassing tool to support your quality management.

THE BENEFITS AT A LOOK

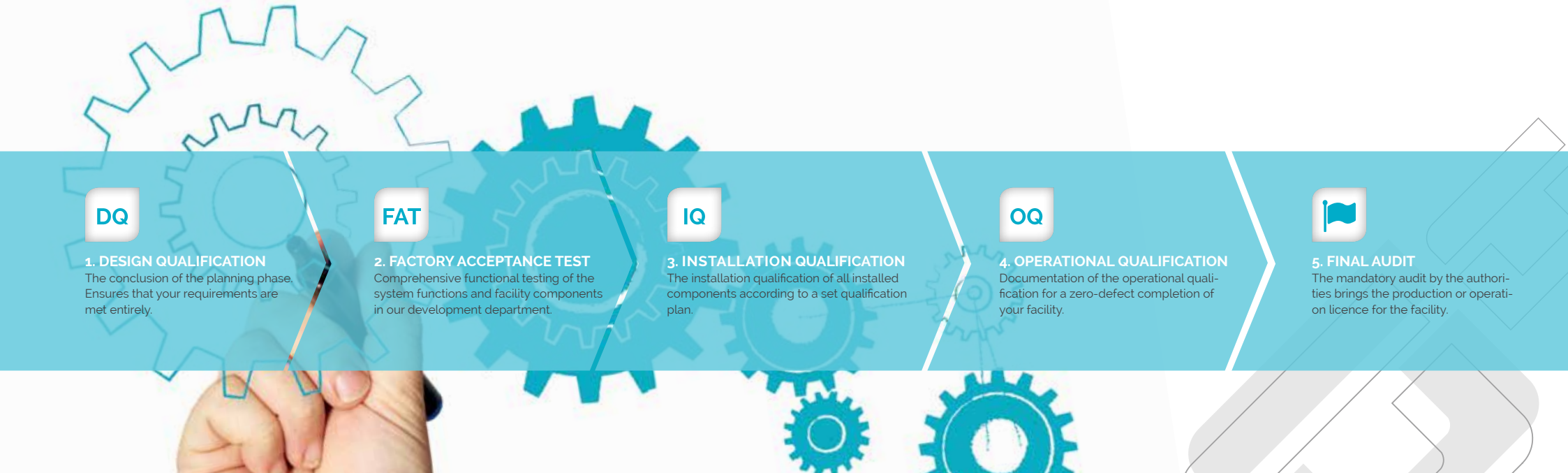
- Excellent usability
- Digitally connected sensors & measurement indicators
- On site voice alerting (text-to-speech engine)
- Optical and acoustical alerting
- Visualisation of unreceipted alarms
- Multiple assessment and annotation of alarms
- Alerting via text message, e-mail and voice call
- Generation of signed accounts and reports
- Multi-user system due to client-server architecture
- FDA 21 CFR part11 compliant
- GAMP5 / APV validated
- Reduced qualification effort of the category 4 software
- Modular hardware setup for future extensions
- Matched to Niotronic sensors and particle counters

FROM A SINGLE SOURCE:
PLANNING & IMPLEMENTATION

THE IDEAL SOLUTION FOR ALL AREAS

Telemon GMP Monitoring provides an optimal overview of all measuring points of your facility and thus enables a safe and regulations-compliant operation.

The complete digitalisation thanks to Telemon Monitoring guarantees a validated and tamper-proof documentation of your production process. With the aid of the Telemon Monitoring Centre, the entire facility can be easily monitored. The GMP condition of the measuring points is clearly marked with coloured symbols. Deviations from the defined limit values trigger an acoustical and optical signal. The measurements of the individual measuring points can be visualised directly in the cleanroom, if requested.



DQ

1. DESIGN QUALIFICATION
The conclusion of the planning phase. Ensures that your requirements are met entirely.

FAT

2. FACTORY ACCEPTANCE TEST
Comprehensive functional testing of the system functions and facility components in our development department.

IQ

3. INSTALLATION QUALIFICATION
The installation qualification of all installed components according to a set qualification plan.

OQ

4. OPERATIONAL QUALIFICATION
Documentation of the operational qualification for a zero-defect completion of your facility.

5. FINAL AUDIT
The mandatory audit by the authorities brings the production or operation licence for the facility.

COLD STORAGE CELL AND CLIMATE CABINETS UNDER CONTROL

Critical products must be permanently stored in a strictly limited temperature range. A permanent monitoring of refrigerators, cold storage cells and climate cabinets is essential. Breakdown of cooling devices or air handling units is generally attached to high costs. The integrated temperature sensors are usually incorporated into the Telemon system without any problems or can be augmented with the specially developed DDS cleanroom climate sensors. In case of deviations from the defined temperature ranges, the system immediately gives an alarm and informs you via text message, voice call or e-mail.

A PARTNER FROM THE PLANNING PHASE TO THE PRODUCTION LICENCE

Based on your requirements, we develop a customised implementation proposal for each of your pharmaceutical production processes. On request, we will deliver your turn-key ready facility including final qualification. After planning, implementation and activation, we will compile all necessary records and documents for the official acceptance test, so your facility can go into operation as agreed upon.

FOR EACH REQUIREMENT THE PERFECT SOLUTION

We develop unusual special solutions for each unique facility promptly and cost effectively in our in-house research and development department. Fault-prone and delaying interfaces due to subcontractors are thus avoided. Our dependable hard- & software components work together smoothly and trouble-free in any case. You will have a reliable contact person for all your requirements.

HIGHEST
MEASUREMENT ACCURACY IN ALL AREAS

DIGITAL TRANSMISSION FOR HIGHEST PRECISION

The sensors of the DDS series that we currently use make the digitalisation directly at the measuring point and eliminate the inadequacies of analogue signalling.

The particle counters of the Aeromon series are also connected to the monitoring system via digital and interference-free interfaces, thus transmitting encrypted, tamper-proof and fail-safe data. All perfectly matched standard components work smoothly together. Of course we can, on request, also incorporate customised expansions.

MONITORING OF PRESSURE, TEMPERATURE AND AIR HUMIDITY

Monitoring of the room pressure is obligatory for proving the compliance with the defined pressure stages. Permanent measuring ensures that the cleanrooms remain free from contaminations. Recording of temperature and humidity must only take place if these parameters are relevant to the product quality. An optimisation of the sensors is hereby of essential significance. The sensors of the DDS series are permanently resistant to cleaning and disinfecting agents (alcohol, H_2O_2 etc.), which are being used in pharmaceutical production. Furthermore, the installed DDS sensors significantly reduce the yearly recurring calibration costs. The sensor calibration takes place outside of the cleanrooms or laboratories, contaminations are avoided and significant time saving is achieved.

AVAILABLE SENSORS

- Digital DDS Differential Pressure Sensor
- Digital DDS Cleanroom Climate Sensor
- Digital DDS Cooling Capacity Sensor
- Digital DDS Flow Rate Sensor
- Digital DDS Radiation Detector

DETECTION OF SMALLEST PARTICLES

According to the GMP guidelines, the determination of the air purity category as per DIN EN ISO 14644 in cleanrooms of classes A and B requires the measuring of particles. The particle counters of the Aeromon series were optimised for the use in the pharmaceutical area and can be directly connected to the Monitoring system bus. On request, the measuring of particles can also be started and stopped in synchronisation with the operating condition of biological safety cabinets or LF units.

AIR LOCK MANAGEMENT
DOORMATE

THE AIR LOCK SOLUTION FOR TROUBLE-FREE TRANSITIONS

The Doormate Air lock Management solution ensures the compliance of cleanroom classes for the transition between different pressure areas.

To eliminate cross contamination, multiple Air lock doors must never be open at the same time. Additionally, after opening an Air lock gate, adequate relaxation times must be allowed before opening another door.

SECURITY FOR ALL AREAS

If the room parameters lie outside of the acceptable limit values, the Air lock doors must not open. The release of each Air lock gate is effected by the monitoring system, which monitors the GMP condition of the individual rooms. Doormate Air lock Management was developed specifically for the requirements of cleanroom technology and far exceeds the necessary minimum requirements with its functionality. The integration of large area buttons, access control system and external operator control modules is easily possible.

EXPANDABLE FOR ALL REQUIREMENTS

The modular system consists of a central unit, door control unit, displays and control elements. This setup can be easily adapted to all requirements. From simple pass-through Air locks to multiple Air locks with direction priorisation and presence detection, everything is possible. Elegant stainless steel panels, multi-coloured LED displays and control elements, as well as optional LED digital displays for countdowns or Air lock condition, integrate seamlessy into every modern cleanroom design.

USER-FRIENDLY CONTROLS

Setup and configuration of the Air lock management is performed with a comfortable Windows software. It
visualises the I/O conditions of all connected door control units, displays and control elements. All logical connections and processes are freely configurable and can be defined according to the respective
requirements.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SECURITY IN PHARMACEUTICAL PRODUCTION

NIOTRONIC HARD- & SOFTWARE GMBH

As reliable expert in customer-specific planning and realisation of GMP compliant pharmaceutical plants, Niotronic maintains customers all over the world.

The high-tech company has a series of high-quality references in the area of pharmaceutical production. Development, planning, production and implementation of industrial hard- and software components all come from a single source with Niotronic. These consistent system solutions from one system supplier make all-encompassing monitoring possible.

SUPPORT WITH PLANNING SECURITY

Even after a successful start-up of operations, Niotronic remains a reliable partner. Optimisations of the facility via remote maintenance as well as planned extensions are implemented promptly and in accordance with your production process. We thus ensure a maximum of quality and security for your product at all times. Vital maintenance and repair works or requalifications are carefully arranged and implemented in order to guarantee unaffected operations. Planned downtimes of your facility can, on request, be arranged to take place during your company holiday or repairs and extensions can be implemented on weekends or holidays. With Niotronic you will always get a consistent solution for optimal cleanroom conditions for all your production processes.

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