



Moni.NET Class C: Digitalisation for discontinuous particle monitoring

Optimisation of work flows in the paperless cleanroom Class B, C and D

Discontinuous particle monitoring for GMP cleanroom classes B, C and D is usually performed sporadically and is a very time-consuming activity. The operational processes have been carried out in the same way by many cleanroom operators for decades: Measurements are taken, data is transferred to Access databases, for example, and visualised using Excel. The required data integrity is achieved by the particle counter-integrated printing function of the measurement results on thermal paper. Since the readability of information on thermal paper has a limited shelf life, all measurement protocols must be glued on, labelled with abbreviations, copied and archived. In some cases, numerical values are transferred manually in order to obtain a higher significance or for the creation of protocols. Here, possible transmission and calculation errors represent a risk. If mobile particle counters from different manufacturers are used, the overall situation becomes even more complicated and the workload and risk potential increase.

With the **Moni.NET Class C** tool, **eurogard** offers its customers a solution with which the outlined processes can be optimised in terms of time, quality, costs and sustainability. For this purpose, process times in operational data handling are accelerated, data integrity is increased and resource-saving approaches are implemented to reduce the flood of paper. The tool can be used to automatically configure particle counters from different manufacturers (e.g.: clean-up time, sampling volume, number of measurement cycles). There is a comprehensive user administration and a complete audit trail. At the same time, Moni.NET Class C simplifies the ongoing administrative tasks many times over: the recorded measurement data is imported automatically from the particle counters (online or offline) and stored in a tamper-proof database. In addition, diagrams can be created using this stored data. For evaluation, extensive standardised print functions and reports are available, including convenient selection of the print scope. In addition, there are functions for displaying limit violations, as well as long-term trending of measured values for any measuring points.

Moni.NET Class C stands for the future-oriented automatic generation of measurement reports. This not only results in very convenient measurements, but also an enormous increase in the quality of the documentation, as well as a very high economic benefit.

Moni.NET Class C takes into account the following standards and guidelines:

- Discontinuous particle monitoring of cleanroom classes B, C and D according to
 - EU-GMP-Guideline Annex 1 and
 - ISO 14644
- Regulatory compliance with the requirements for computer systems according to
 - EU-GMP-Guideline Annex 11
- GMP-qualified software:
 - Validated software according to GAMP5® category 3 (IQ, no OQ)
 - Development in accordance with GAMP5® Category 5



- Integrated user administration with audit trail function (CFR 21 Part 11)

- Optimised work flow in the clean room
- Error resistant process
- GMP compliant
- Multiple reports
- Tamper-proof
- Data security
- Historical data
- Audit trail
- Digital signature
- Automated filing and dispatch of protocols
- Easy installation and integration

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