System Overview

Facility monitoring system

1 Guidelines

In terms of GMP requirements, the Neuberger Monitoring System (ProGrafNT) is developed in compliance with the following Guidelines:

- Code of Federal Regulations, Title 21, 21CFR Part 11 (FDA)
- The rules governing medicinal products in the European Union, Volume 4
- The rules governing medicinal products in the European Union, Volume 4, Annex 1
- The rules governing medicinal products in the European Union, Volume 4, Annex 11 (Computerized Systems)
- The rules governing medicinal products in the European Union, Volume 4, Annex 15
- ISPE GAMP5 (Compliant GxP Computerized Systems)
- ISPE Guideline, Commissioning and Qualification, Vol.5
- ISPE Good Practice Guide on HVAC
- Quality Management System, ISO 9001:2015

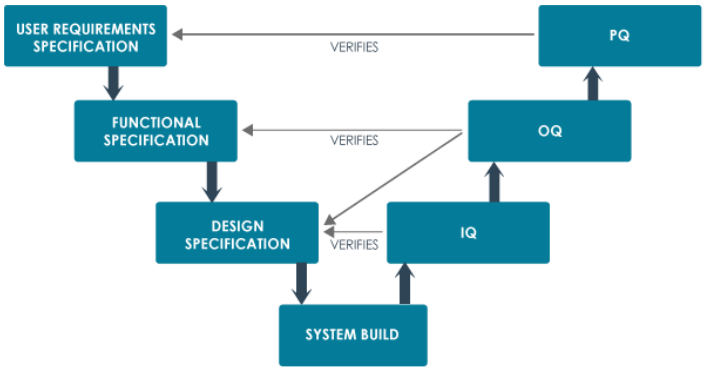
2 Qualification

The qualification follows the GMP Standard Procedures: DQ -> IQ -> OQ -> PQ

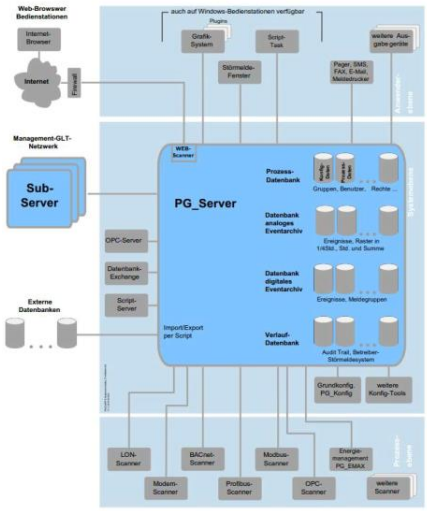
Based on the V-Model all requirements are part of qualification tests and will be checked.

To guarantee the highest level of measuring accuracy all transmitters become a 3-point calibration on site. The total measuring loop is part of the calibration.

Experts for qualification, calibration, commissioning and installation are permanently trained.



3 Technology



The ProGrafNT Monitoring System (SCADA) is a databased System running on Windows. All requirement for usage under GMP Conditions are implemented and qualified. Audit trail, User Management, data storage, visualisation and trending are state of the art.

The local data collectors (PLC) has special additional functions like local data storage for emergency situations (e.g. network breakdown).

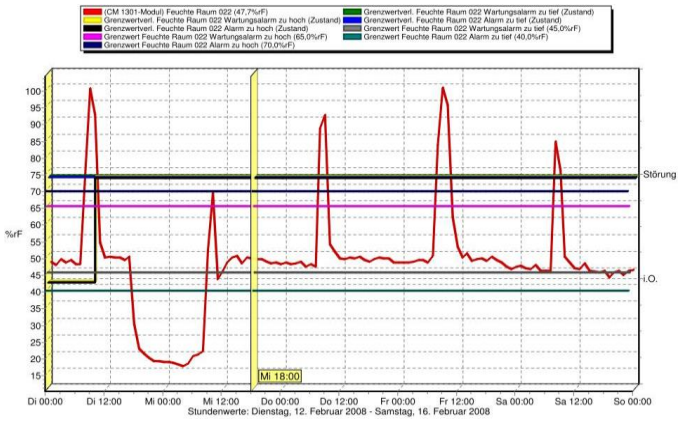
To ensure a safe communication e.g. to the SD System, the FMS software includes different under GMP conditions qualified interface protocols.

The User interface (HMI) is complete in Norwegian language.

Operation Clients (Client Software) ensures an easy handling from any PC. Inside the Cleanroom a Touch PC can be used to check all actual information's

Inside all rooms red/green lights give information's about the room conditions and status of the monitored Laboratory equipment.

4 Measuring



All measured Parameters are shown in the attached Layout (see Annex 1).
Room relevant Parameters like pressure, humidity, temperature and (in Class B rooms) room airborne particles are connected, as well as relevant parameters from freezers, incubators, and bio safety cabinets (BSCs).

- Room Pressure
- Room Temperature
- Room Humidity
- Airborne Particle
- Laminar Flow (Air Velocity)
- Temperature Freezer`s
- Temperature CO2 Incubator`s
- CO2 Incubator`s

All components and materials are select for installation in aseptic clean room environments.

5 Selected references:

The following clients from pharmaceutical industry and health care rely on our solutions for secure, GMP compliance and high-quality state of the art monitoring systems:

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Ebewe PHARMA

EVER PHARMA JENA

HELIOS

MERCK

NOVARTIS

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For the safe and optimal use of human proteins

Uniklinikum Würzburg