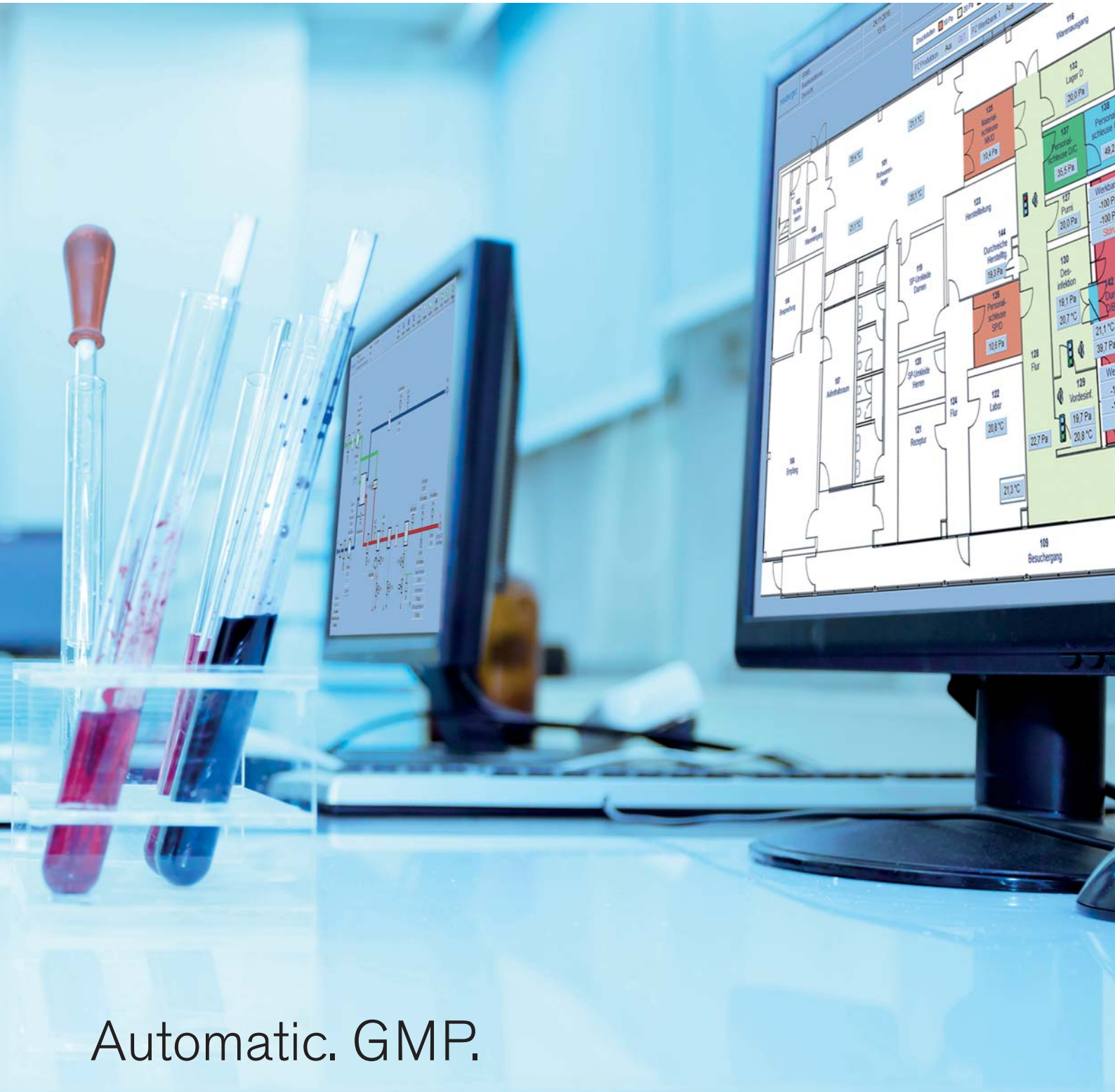


neuberger.

product

Information about GMP-Monitoring and Cleanroom solutions



Automatic. GMP.

GMP-Monitoring and qualification in accordance with the GMP directives

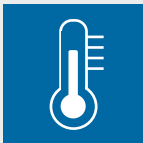
Solutions for clean rooms & health care

Monitoring



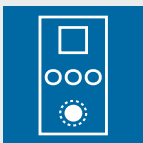
GMP-Monitoring

The systems are developed according to GMP and fulfill all necessary requirements in accordance to FDA 21 CFR Part 11. We postulate successful auditing.



Sensors

Sensor technology for each application and customized requirements.

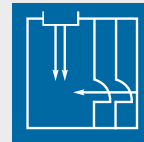


Clean Room Terminals

To control and visualize of clean rooms.



Air Lock control



Air Lock Control

Control of the personnel and material locks to secure employees, environment and products.



Building Control and Management System

Control of all building services systems and its clean room conditions.



Evaluation and Reports

Clear presentation of evaluated quality-relevant data.

One stop solution

Service



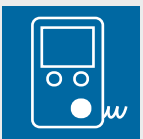
Mapping

By determining the temperature distribution, cold- and hot-spots the product quality in warehouses, refrigerators and freezers can be assured.



Qualification

Composing documents and performing the qualification.



Calibration

We calibrate for you on site or at the factory and always with the latest measurement technology.



After-Sales-Service



Hotline and Support

Reliable Service at any time – 24/7.
Our competent specialists take care of our customers.



Maintenance

As Neuberger we see a good service for our customers as a very important part of our extensive range of services we offer. This also applies to our maintenance.

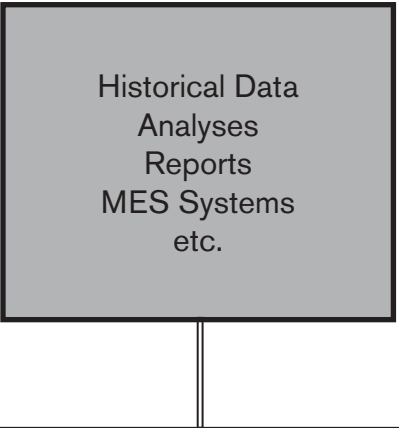


Training

By regular training of our customers, service engineers and employees we make sure that updated knowledge on products and technology is conveyed.

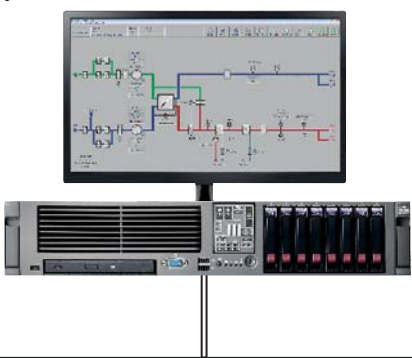
User-friendly, open, flexible. **Automatic. Clear.**

Higher-Level Systems



Monitoring Server / Building Management System (BMS)

Server Computer ProGraNT /
highly available / redundant / virtual (VM)



Operating and Monitoring / Web-access / Remote Maintenance / Reporting / Alarming

Clean Room
Touch-Terminal



Operating Station / Web-Client
Touch Panel/-PC



Smartphone /
Tablet



Internet/Intranet, Ethernet, TCP/IP, ISDN, Modem,
BACnet/IP, OPC, PROFIBUS, LON

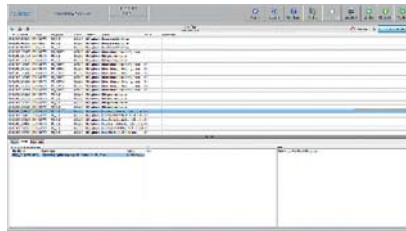


GMP-Monitoring according to 21 CFR Part 11

Neuberger develops, plans, programs, installs and qualifies in accordance with the GMP guidelines. Due to the very well-structured working method and the GMP-conformable documentation nothing stands in the way of the validation process. The monitoring software ProGraNT and the automation station PMC2 guarantees the highest operational security and lifelong spare parts supply. This is only possible since Neuberger uses products from its own development and manufacturing.

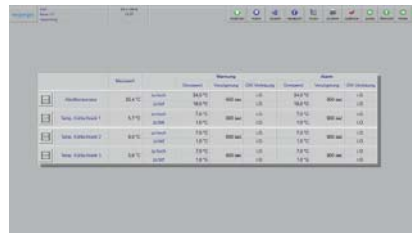
Audit Trail

Every single operator intervention is seamlessly traceable after several years. ProGraNT records permanently who, what, when and where changes have been made or entered. Every single status before and after is entered with its reason for change and saved. It hence can be assured that no data is lost. The manipulation of data is excluded. Furthermore, there is also the possibility to export data or to transfer it to other systems.



Electronic Records

All values, states and alarms as well as the audit trail are saved tamper-resistant in the data base and are presented by ProGraNT as freely configurable curves and tables. The data is always available for later evaluation.



Trending, Alarming

ProGraNT archives all measured values, status values, limit values, reports etc. in a SQL-database. Every single data is always available for visualization of evaluation, reports etc.



Plant Visualization

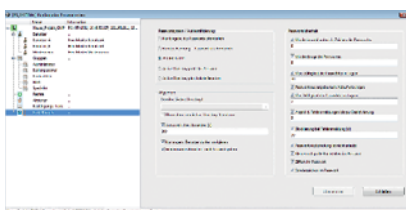
ProGraNT stands out due to its intuitive and convenient operation concept. The visualization is carried out in accordance with the customer requirements.

ProGraNT stands out due to its intuitive and convenient operation concept. The visualization is carried out in accordance with the customer requirements.



User Management

The convenient user management meets the GMP requirements in accordance with FDA 21 CFR Part 11. Password altering, locking when error message pops-up, entering the minimum length, password management also by active directory etc. are possible without restriction.



Data Security

Data can be saved securely in the SQL-database. Automatic backup can be saved directly on network storage or other storage media. It is possible to transfer the data to other superordinate systems (e.g. historical data).



Sensors

Temperature T
Humidity H
Pressure P
Germ number N
Air flow L



The pharmaceutical industry and especially clean room surroundings require to meet the night demands of data acquisition with regard to accuracy and stability.

Very important is the resistance of the sensor system to any chemicals, cleaning agents and dirt.

Therefore, Neuberger uses a high quality sensor system which is installed and qualified by special trained service engineers.

Intelligent combination of GMP monitoring and building automation

If the measured values of the clean room sensors are not only used for the GMP monitoring but also for the building automation system, you are able to avoid expensive double instrumentation as well as any errors of the recorded measured values.



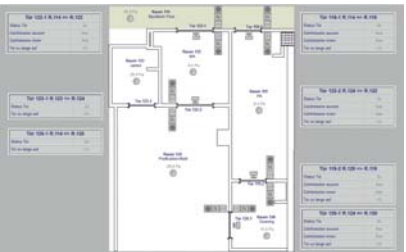
avoid expensive double instrumentation as well as any errors of the recorded measured values.

Neuberger makes sure that your project will be a success:

- Customized definition of the measuring areas (according to project requirements)
- Quality requirements according to project guidelines
- Delivery, installation and commissioning by trained and skilled personnel including producer certificates



We support you from the implementation planning until the project completion - always focused on solutions.



References



Aeropharm, Rudolstadt

Alexion, Athlone
Allergopharma, Reinbek
AMS, Graz
B. Braun, Melsungen
Boehringer, Ingelheim
Central Veterinary Research Laboratory (CVRL), Dubai
CeramTec, Marktreidwitz
Covance Laboratories, Münster
DKFZ, Heidelberg
EBEWE Pharma / Sandoz, Unterach
EVER Pharma, Jena, Oberburgau
First Sensor, Berlin
Forteq, Nidau

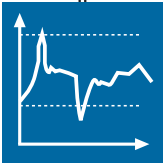
Genetic City, Kiew

Holopack, Sulzbach / Laufen
IDT Biologika, Dessau / Rossau
IHP, Frankfurt (Oder)
Intervet, Köln
JGL d.d., Rijeka
Kneipp Werke,
Ochsenfurt / Hohestadt
LEO Laboratories, Dublin
LIPOID, Ludwigshafen
Luzerner Kantonsspital, Luzern
Merck & Co., Singapur
Merck, Darmstadt, Gernsheim, Vevey
Merz Pharma, Dessau / Rossau
Novartis Stein

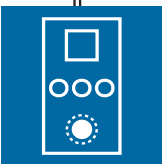
Octapharma, Heidelberg

Oncotec, Dessau / Rossau
Pharma Wernigerode
Ries-Apotheke, Nördlingen
Roche Diagnostics,
Mannheim, Penzberg
Roche, Rotkreuz
Siegfried Hameln, Hameln
TETEC, Reutlingen
Vetter Pharma, Ravensburg
Wala Heilmittel, Bad Boll
Wasserburger Arzneimittelwerk,
Wasserburg
Weleda, Schwäbisch Gmünd

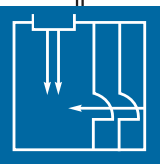
PMC2 - the flexible and reliable automation station



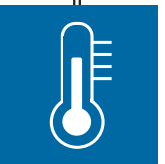
GMP-Monitoring



Clean room
terminals



Air lock control



Sensors

GMP-Monitoring. **Validated. Safe.**

At all levels user oriented. **Automatic. Efficient.**



Clean room terminals

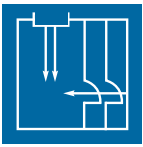
Simple use and clear visualization of the condition of clean rooms and laboratories

Several options of surveillance and control, e.g. air lock, doors, light and disinfection

Accurate recording, measurement and display of room conditions, e.g. temperature, humidity and particles

- Integrated temperature-, humidity- and differential pressure sensors
- Screw-free surface made of stainless steel or glass
- Integrated graphical color display with individual representation of colors, size and background - optionally with an interactive multi-touch display
- Flexible arrangement of all measuring and process values as well as the possibility to display alarming and status reports on the display screen
- Acoustic signal and/or special highlighted dynamic change on the display screen which is occurring when errors, alarms or limit violations take place
- Easy calibration of the measuring system in the mounted state
- Includes other functions such as the contactless access control, door control with emergency operation, disinfection with indicator lamp, light control for several light zones, etc.
- Communication with monitoring system, process and building automation
- Secure archiving of all states and reports
- Customized solutions in accordance with the project and the customers' requirements





Air lock control

door control
door monitoring
pressure monitoring
alarming
display
access control

Special environmental requirements and clean rooms ask for special security regulations. Neuberger's air lock control is characterized by the good integration into the central GMP-monitoring along with every advantage of the coherent networking.

The flexible automation station of the PMC-series, in conjunction with the powerful GMP-monitoring system ProGrafNT by Neuberger masters this challenging task.

- User-friendly handling
- Flexible configurable control
- Monitoring of the door states, pressure states, safety devices and holding times
- Panel display with user-definable TFT-color displays



Photo: K. Jaeger/C. Ludwig; B. Braun Melsungen AG



Photo: K. Jaeger/C. Ludwig; B. Braun Melsungen AG



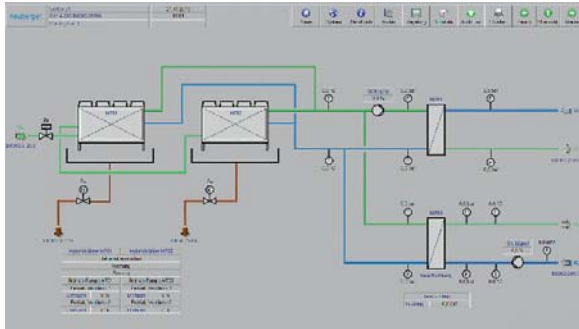
Control and room conditions

Copying/Adopting the measurement values from the monitor

Modular and communicative automation station with long-term event archivation

Open architecture and future proof interfaces

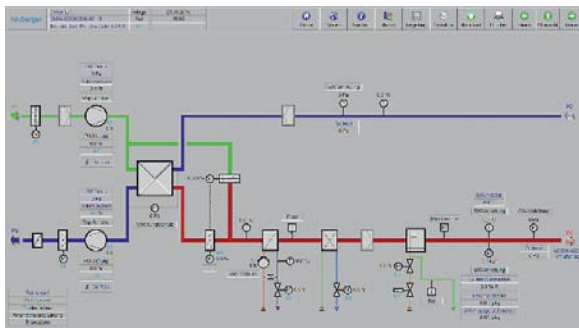
Intelligent peripheral modules



Strict regulations are mandatory in the field of Life Science – this also implies regulations and room conditioning.

Minor variations of the room conditions might have major consequences for clean rooms, research institutes and laboratories.

Air-conditioning, heating and cooling systems of the primer facilities belong to these important fields. The recording of the current facility states, such as temperature, humidity, pressure and air quality have to be considered as well in the control strategy to secure the reproducible room conditions.



For the highly precise regulations of room conditions the flexible automation system PMC together with the powerful building management system ProGrafNT of Neuberger is used. Neuberger enables its providers and users, to identify discrepancies early and take appropriate actions. A central observation and control as well as adjustment of limit values can be implemented online at any time in consideration of the GMP-requirements. Neuberger's products are developed and produced in accordance with FDA-requirements with 21 CFR Part 11. Lifelong spare part guarantee for facilities form the basis of a long-term cooperatively customer relationship.



The screenshot shows the AWS IAM console for the account '76AB25MZC'. The 'Groups' tab is selected, and the 'Groups' list is empty. The 'Users' tab is also visible, showing 10 users. The 'Users' list has columns for Name, Access type, and Permissions. All users have 'Programmatic access' and 'Full access to all resources' permissions.

Name	Access type	Permissions
aws_iam_user_1	Programmatic access	Full access to all resources
aws_iam_user_2	Programmatic access	Full access to all resources
aws_iam_user_3	Programmatic access	Full access to all resources
aws_iam_user_4	Programmatic access	Full access to all resources
aws_iam_user_5	Programmatic access	Full access to all resources
aws_iam_user_6	Programmatic access	Full access to all resources
aws_iam_user_7	Programmatic access	Full access to all resources
aws_iam_user_8	Programmatic access	Full access to all resources
aws_iam_user_9	Programmatic access	Full access to all resources
aws_iam_user_10	Programmatic access	Full access to all resources

Störungszeitpunkt: 26.09.2016 00:00:00

Störung: Feuchte R. 03-A-003.02 DC-Anlage

Verzögerungszeit: 60 Sek.

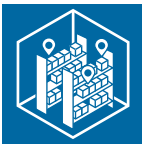
Grenzwert: 65,0 r.F.

1. Störung: Beginn: 26.09.2016 00:00:00 Ende: 26.09.2016 02:04:46

- Compilation and evaluation of all quality-relevant data
- Creation of reports with input and output forms for free text entering
- Analyze masks customizable and adaptable according to customer wish
- Reports producible with batch name, number, climate data, trends etc.

- Graphical monitoring of the limit values summarized in an archive image
- Customizable and adaptable according to customer wish
- Limit values for warning and alarm levels with error messages when it is exceeded
- Error messages are processed and transferred appropriate to its priority and responsibility

- Evaluation and preparation of the data with report function directly exported from the monitoring surface
- Listing of limit values, errors, actual values, target values etc., beginning and ending of the recording which is summarized in one document
- If asked for with comment boxes, remarks, notes, clues, explanations and control fields for signatures
- Freely configurable after joint vote



Mapping

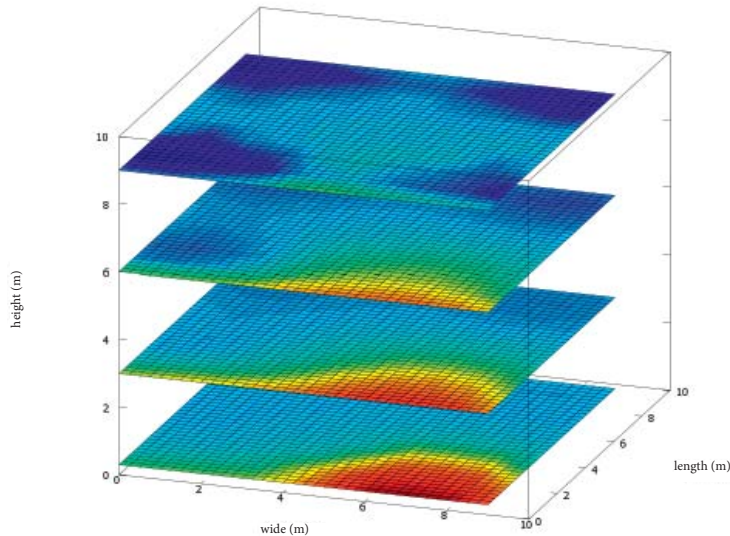
Determination of the humidity and temperature distribution and visualization using the latest 3D-graphics.

To secure the storage quality of pharmaceutical products we determine precisely the temperature profile and humidity profile in cooling- and freezing areas and warehouses.

We therefore perform precise measurements in accordance with special requirements in summer and winter both in a loaded and in an unloaded state. The implementation, calibration and documentation are carried out with regard to GMP-regulations.

We offer the following services:

- Expert advice and common understanding of requirements
- Service temperature range from -35°C to $+55^{\circ}\text{C}$
- Planning, testing and approval of the placement of the measurement stations
- Calibration of sensors
- Assembly of the measurement equipment on site and performance of measurements
- Door opening tests, power failure test and if necessary test of the defrosting function
- Recalibration of sensors
- Evaluation, creation of mapping report, analyses of measuring values and 3D-display showing its areal distribution
- Compilation of the documents in accordance with the GMP-regulation and handing it over to the customer
- Definition of actions to prevent cold- and hot-spots
- Compliance in accordance with the ISPE-regulation Good Practice Guide and the WHO Guideline No. 9661,2011



Temperature distribution



Qualification

- RA - Risk Analysis**
- DQ - Design Qualification**
- PS - Performance Specification**
- HDS - Hardware Design Specification**
- SDS - Software Design Specification**
- FAT - Factory Acceptance Test**
- IQ - Installation Qualification**
- OQ - Operational Qualification**
- SAT - Site Acceptance Test**
- CC - Change Control**

GMP compliance cannot be realized only with software and hardware. Through validation, handling and organization of the systems by using appropriate process instructions (SOPs) a correct solution can be created. Neuberger offers you proven systems that have also been audited successfully several times by pharmaceutical companies. In close collaboration and coordination with the customer successful documents will be created individually. In addition to the complete software and hardware solutions, Neuberger provides consultation, validation and training that as a result there's only one contact person needed for the entire GMP-Monitoring process.

Qualification

Neuberger supports you with all necessary qualification steps.

Competent employees

In order to provide our clients with extensive and competent advice our employees are trained to keep them abreast of the latest technological developments and the GMP-requirements.

Use of our measurement and test instruments

Our specialists are equipped with all necessary measurement and test instruments that are needed for the qualification and put them into practice in a professional way.

Qualification is a matter of trust

GMP-conform validation and qualification is a matter of trust. Work together with an experienced and skilled partner. Neuberger is a trustworthy partner that you can rely on.

This also implies the creation of qualified documentation in accordance with the GMP-requirements and meeting the needs of the customer.



Photo: K. Jaeger/C. Ludwig; B. Braun Melsungen AG



Calibration

Temperature
Relative humidity
Pressure
Laminar Flow

We calibrate for you on site or at our factory in Rothenburg.

Regardless of comparative measurements, 1 or 3 point calibration, first or recalibration, Neuberger calibrates with skilled employees according to your conditions using certified and proved measuring equipment. The entire loop is being calibrated.

Of course, the calibrations can be performed self-sufficient.

We perform the calibration with reference measurement equipment, that include DAkks certificate or similar

qualification.

This provides you, as our customer, the advantage of traceability.

Our service at a glance:

- Timely performing of the calibration
- Creating and keeping record of functional measurement descriptions
- Creation of calibration reports
- Clear marking of the sensor after the calibration process
- Preparation of a certificate with all important information
- Carrying out the work through qualified personnel
- Regular training and continuing education of our employees

tion of our employees

- Use of reference measurement equipment, that include DAkks certificate or similar qualification.

Types of calibration:

- Comparative measurement
- 1 point calibration
- 3 point calibration
- On request more than 3 point calibration





Hotline and Support

Reliable service at any time

Product and service quality are strictly interlinked at Neuberger. In our reliable specialists we have found skilled employees who take care of you personally. This is because we see individual contact as a matter of fact.



- 24-hour-Service - 7 days a week - 365 day a year
- Customer proximity through a comprehensive service network
- Personal support by qualified Neuberger experts
- Competent and steadily trained service personnel



Maintenance

Secure, fast, sustainable

Anyone who has selected a product from our company benefits from our scientifically substantiated maintenance at any time. Regular inspections and maintenance intervals by providing experienced plant technicians ensure the longevity of your automation and building management systems.



- Maintenance according to VDMA criteria
- Calibration
- Optimization of the control and regulation of incidents and of control engineering problems
- Unlimited spare parts supply for all Neuberger products



Training

Focused, detailed, effective

Being a proficient partner in the sector of building and clean room automation one of our goals is to educate and train our customers, partners and employees sustainably. Experienced subject specialists take over the transfer of profound technical knowledge in theory and practice.



- Regular seminars on the topics of the process and building management system ProGraNT as well as to automation stations
- Basic, advanced and professional courses
- In the Neuberger training centre or on request on your site/location

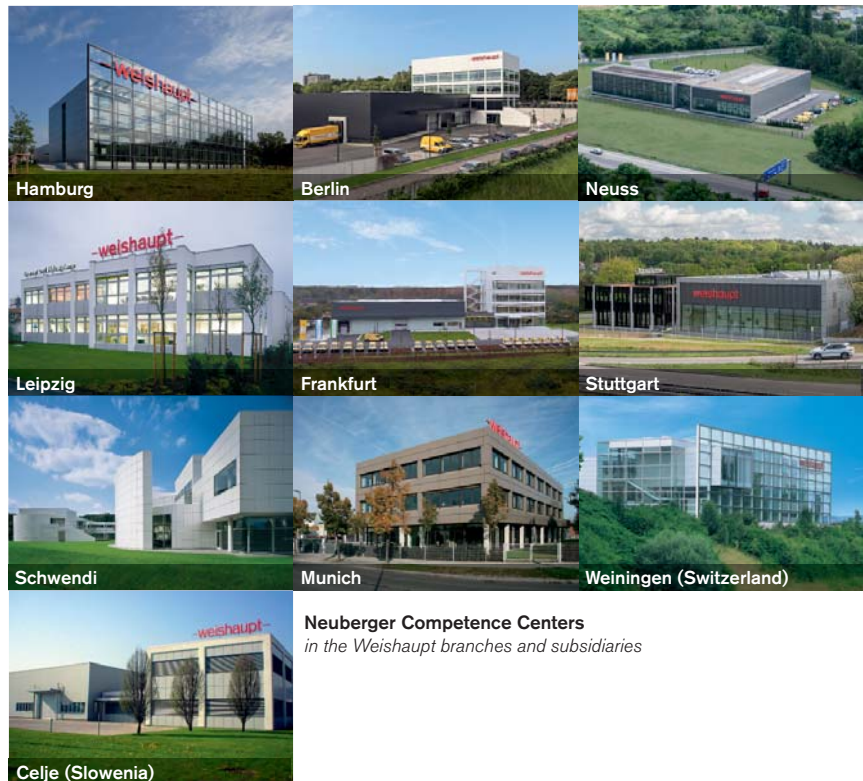
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Internet: www.neuberger.net

One stop solution

The Neuberger company, founded in 1968, is a highly qualified supplier of products and solutions in the building automation and pharmaceutical industry.

Since 1995 Neuberger is a part of the Weishaupt Group and delivers everything from one source: planning, products, software, installation, commissioning, maintenance and service support 24 hours / 7 days.

Neuberger Gebäudeautomation provides highest efficiency to enable connection of all technical systems.



Headquarters in Rothenburg ob der Tauber, Germany