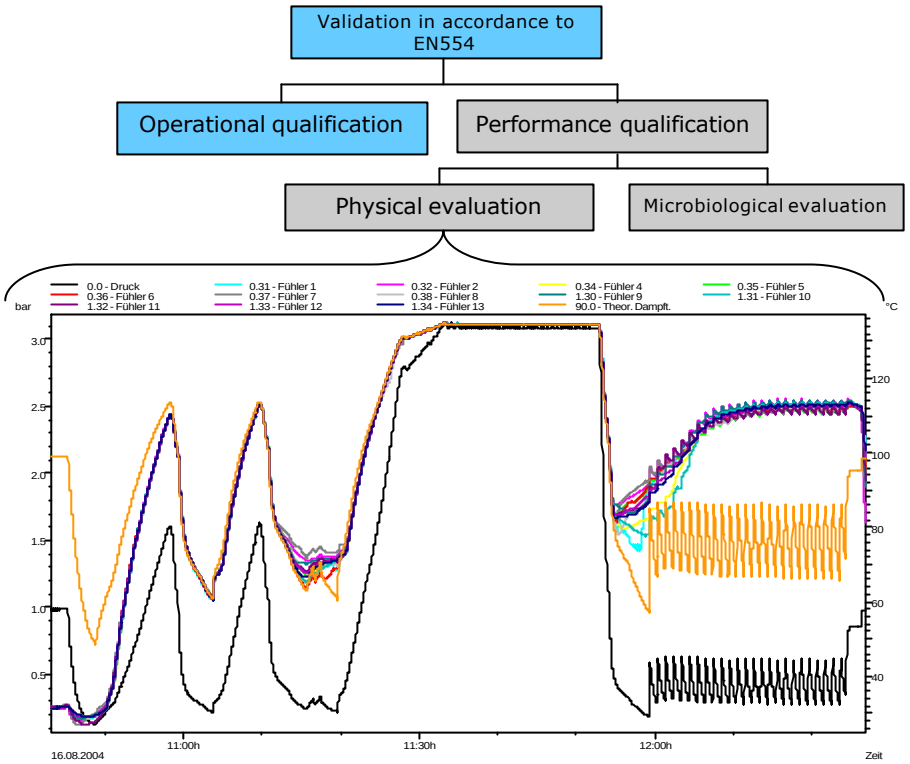
Qualification and Validation

- DQ- Design qualification
- IQ- Installation qualification
- OQ– Operational qualification
  - Calibration of displays
- PQ– Performance qualification



Proof of performance for your processes

- Validation of sterilization by moist heat in accordance to EN554
- Qualification of laboratory instruments used for thermal processes
- Autoclaves
  Climatic cabinets
  Freezers and ULT freezers
  Incubators
  Sterilizers
  Others on request

Qualification studies establish confidence that the process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.

Validation studies provide a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

A lot of administrations, regulations and laws (e.g. AMG, MPG) demand for qualification and validation, every time when a reproduceable product is required.

The operator is responsible to meet all requirements.

Definition:

Design Qualification - DQ
Design qualification defines the functional and operational specifications of the instrument and details the conscious decisions in the selection of the supplier.

Installation Qualification - IQ
Documented verification that all key aspects of hardware installation adhere to appropriate codes and approved design intentions and that the recommendations of the manufacturer have been suitable considered.

Operational Qualification - OQ
Documented verification that the equipment related system or subsystem performs as intended throughout representative or anticipated operating ranges.

Performance Qualification - PQ
Documented verification that the process and/or the total process related system performs as intended throughout all anticipated operating ranges.

Benefits:

To clarify all activities and to define the responsibilities is the basis for individual qualification or validation studies. It is most important to meet the requirements of the operator, following the motto „as much as necessary" but not „as much as possible".

Many factors have affect on a process or its results. To take into account all factors it makes often sense to rate them by means of a risk analysis. By a risk analysis critical factors can be discovered in time, which allows to consider necessary actions in the planning.

Sometimes the amount of inspection has been defined by standards or manufacturer recommendations. In this case it is common just to add individual or process oriented requirements.

You should always count qualification and validation as quality assurance elements, independent on regulatory affairs. Correctly planned and performed pragmatically all studies give proof of process parameters, which are essential to rate the quality of a product.

Re-qualifications, if performed periodically, give you information about the long-term behaviour of an instrument or a process and may contribute to identify creeping changes in time.

Range of services:

- We clarify the amount of inspection together with the contractor. To simplify the pre-clarification, check lists are available.
- Issuing of a master plan for control and release by the contractor.
- On-site performance of all planned tests.
- Documentation
  The style and the amount of the documentation are depending on the contractors requirements and/or regulatory affairs. On request an individual customized documentation can be issued.
- For planning, realisation and evaluation of microbiological tests we cooperate with an accredited microbiological laboratory.
- As an accredited testing laboratory in accordance to DIN EN ISO/IEC 17025 biomedis has the competence to perform pressure measurements and temperature measurements on autoclaves, sterilizers and incubators. For details of the scope of accreditation please have a look onto our accreditation certificate.

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