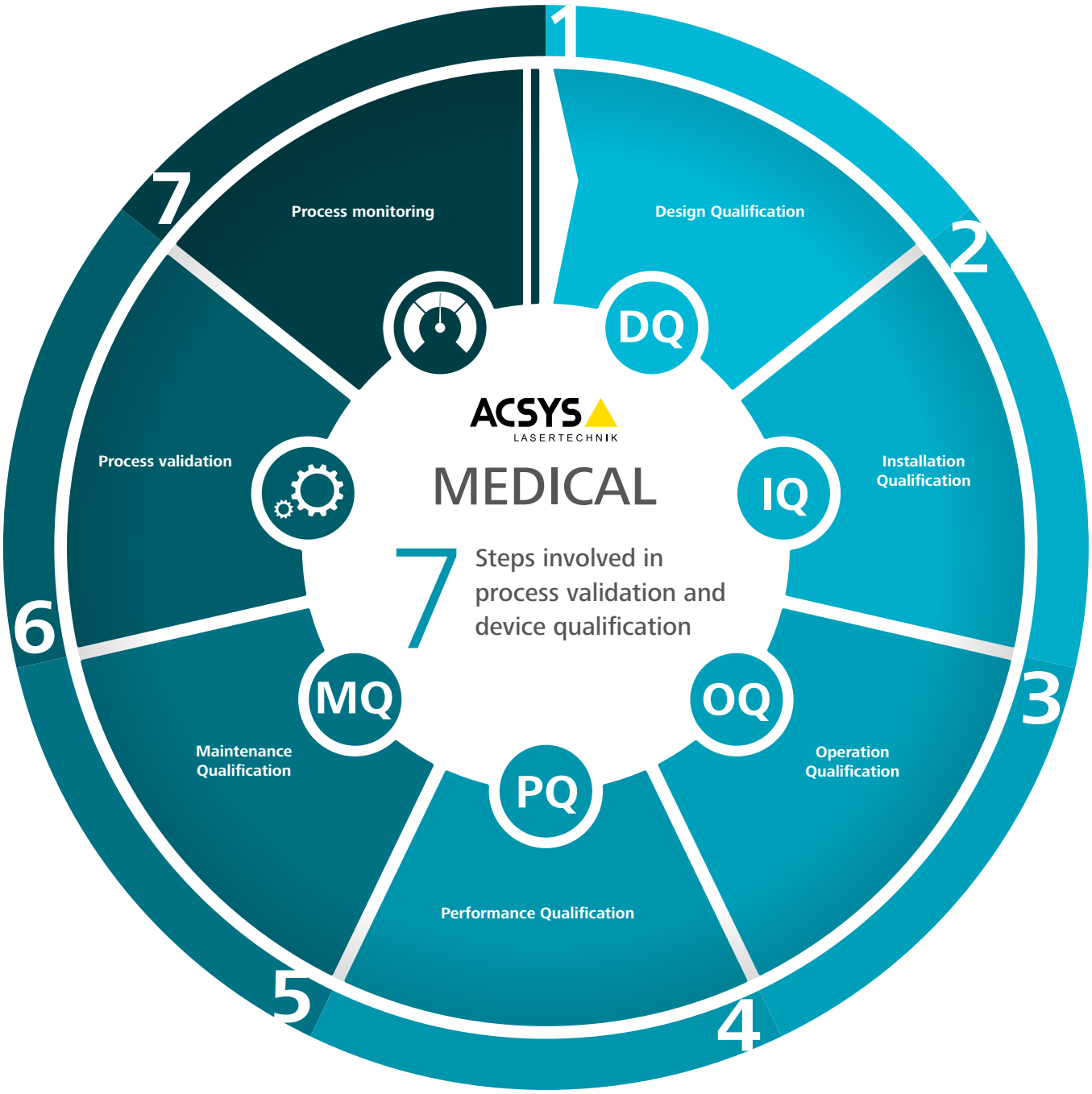
ACSYS LASERTECHNIK

Process validation and qualification of laser system solutions



Laser marking · Laser engraving · Laser cutting · Laser welding · Laser digitizing

Know-how is Passion.

Process validation

and qualification of laser system solutions

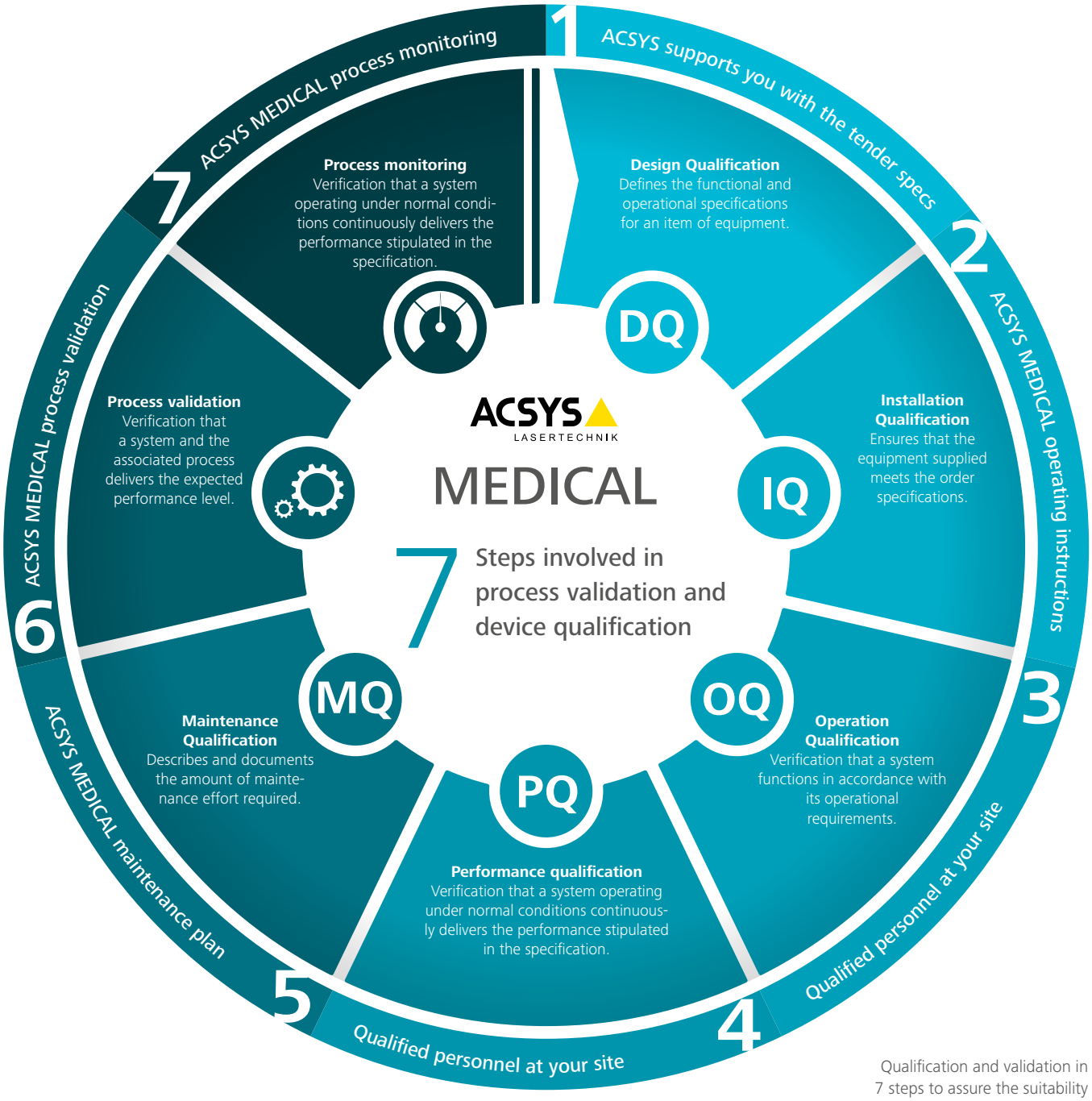
The basic concept underlying process validation is that quality requirements for the product must be satisfied reliably and to one hundred percent in the production process. To this end, every step in the manufacturing process is viewed and tested in advance.

Process validation therefore is a form of documented verification to show that a product can be manufactured within the context of a defined process sequence, and that it possesses the required characteristics, provided that certain parameters are observed during production.

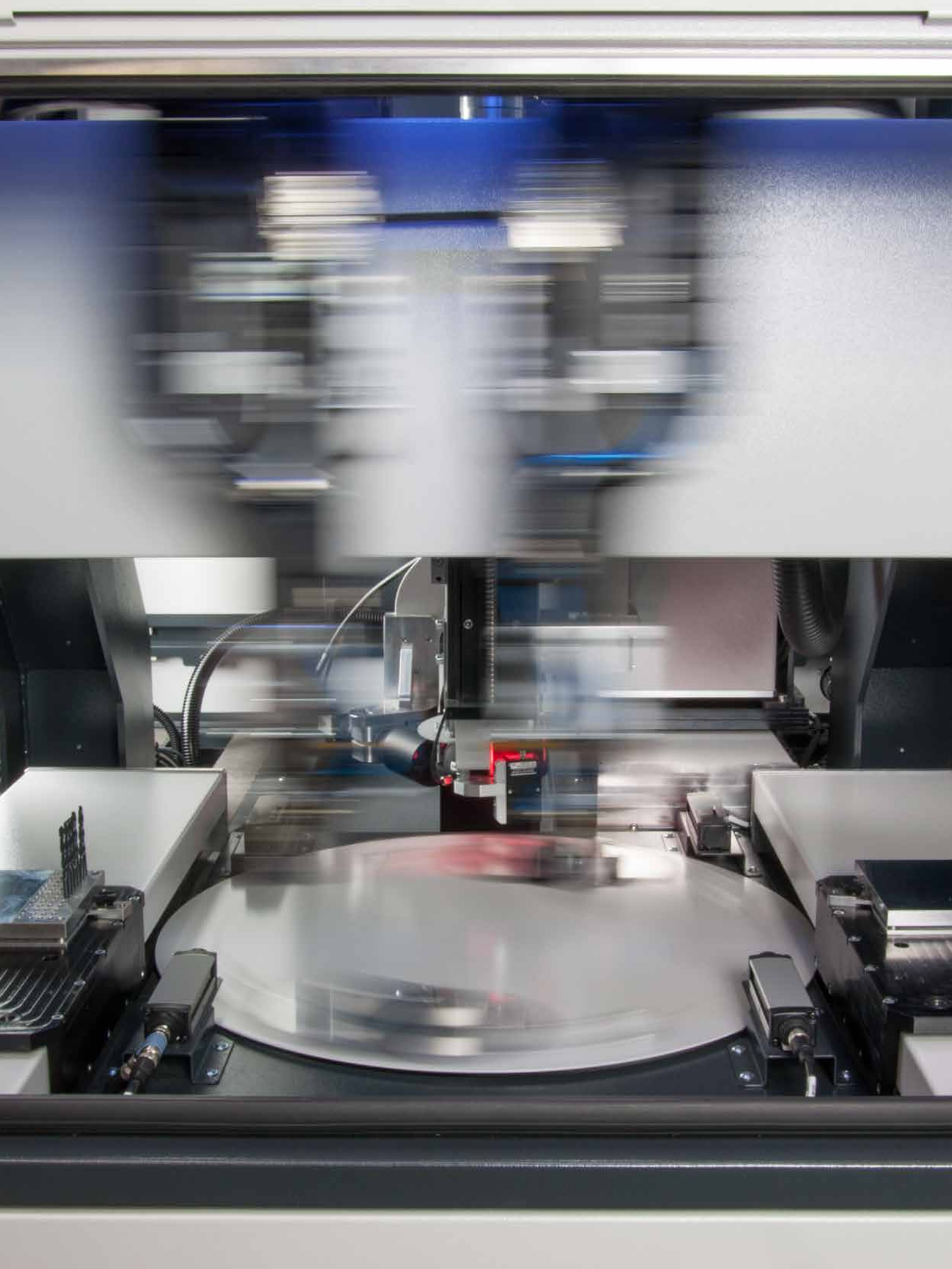
The qualification of laser machining systems for the manufacture of medical products is a clearly defined requirement from the “Rules of Good Manufacturing Practice - GMP”, and is therefore an indispensable element of the quality assurance process. This guide provides an overview of the specifics governing how we should proceed with the qualification process – in particular with respect to the inclusion of individual activities in the planning and building of complex laser systems.

Right from the outset, ACSYS is there to provide you with detailed technical knowledge in relation to the FDA-compliant qualification (US Food and Drug Administration) of laser units in the medical industry.

Solutions for you from a single source.



Qualification and validation in 7 steps to assure the suitability of a laser machining system in the medical industry for an intended application.



1. Design Qualification

Design Qualification is a form of documented verification to show that due account has been taken of quality-relevant, GMP-related requirements for the design of a laser machining system and its optional accessories, including buildings, premises and auxiliary equipment items. ACSYS actively supports you in the production of the tender specifications.
DQ is an examination of the **requirements** relating to:

Hardware specifications
- Materials
- Condition
- Dimensioning

Software specifications
- Functional characteristics
- Performance characteristics

System documentation
- Completeness
- Thoroughness

2. Installation Qualification

Installation Qualification (IQ) is a form of documented verification to show that critical items of equipment and systems have been supplied and installed in accordance with the requirements stipulated, and with legislative requirements. The operating instructions are part of the ACSYS MEDICAL package, specifically designed to meet the requirements of the medical industry.
IQ is an examination of **execution** relating to:

- Documentation
- Scope of delivery / completeness
- Specifications / marking
- Installation
- Supply and disposal connections
- Safety devices
- Overall condition
- Accessibility for maintenance and cleaning

3. Operation Qualification

Operation Qualification is a form of documented verification to show that critical items of equipment and systems operate in the intended manner, in compliance with the requirements stipulated throughout their operational range and within specified limits. ACSYS accompanies you with qualified personnel on site, i.e., on your premises.
The OQ checks **Operation** in relation to:

- Tightness
- Mechanically moved parts
- Manually moved parts
- Switching and control circuits
- Step sequence and program sequence controls
- Safety devices
- Measurement, display and recording equipment
- Working conditions

4. Performance Qualification

Performance Qualification (PQ) is a documented form of verification to show that critical equipment items and systems operate in accordance with stipulated requirements across the entire working area under prevailing workplace conditions (with product) and deliver the required levels of performance. ACSYS accompanies you with qualified personnel on site, i.e., on your premises.
PQ checks **performance** in relation to:

- Measurement of critical performance criteria
- Definition of requirements (working conditions)
- Definition of the test method
- Definition of the test aids
- Definition of the acceptance criteria (limits)

5. Maintenance Qualification

Maintenance Qualification (MQ) describes and documents the required maintenance and servicing work, including the documentation of repairs. A maintenance program is an essential requirement to ensure that a system - including premises and auxiliary items - remains in its qualified condition and is therefore also an FDA requirement. ACSYS supports you with an ACSYS MEDICAL maintenance schedule.
MQ is a **definition** of:

- Maintenance and inspection points
- Maintenance cycles
- Responsibilities
- Procedure
- Documentation and evaluation of the execution process

6. Process validation:

Process validation is a documented form of verification to show that a product can be manufactured within the context of a defined process sequence, and that it possesses the required properties, provided that defined parameters are observed during production. The FDA Quality System Regulations, specifically in 21 CFR 820.75, describe the requirements for process validation: Process validation involves the collection and assessment of data, starting with the design phase and extending through to production, delivering scientific evidence that a process delivers quality products on a continuous basis.

The basic concept underlying process validation is that quality requirements for a product must be satisfied reliably and in full, i.e., to 100%, in a production process. To this end, every step in the manufacturing process is viewed and tested in advance.

7. Process monitoring:

Process monitoring is a documented form of verification to show that critical items of measuring equipment operate reliably under prevailing operating conditions within the intended range of values and that they comply with specified tolerances.

The ACSYS MEDICAL program supports you in the selection of measuring methods, the testing, aptitude inspection of measuring equipment and the corresponding validation of that measuring equipment.

Calibration checks the **definition** of:

- Value ranges
- Operating conditions
- Error limits
- Tolerances
- Calibration values
- Calibration cycles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