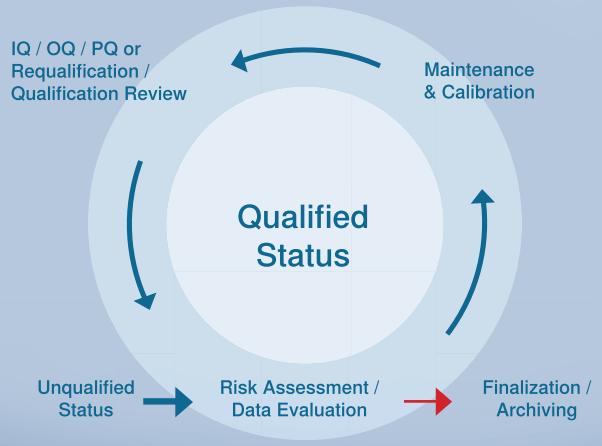
Our service for qualification and validation:

- Risk-based qualification approaches
- Preparation of a qualification strategy (creation of master plans, determination of qualification steps, requalification plans according to industrial starnd v-model and life cycle approaches)
- Initial qualifications (from establishment of URS to completion of the last preparation phase)
- Generation of qualification and validation plans, protocolls and reports
- Comprehensive support and full implementation of qualification and validation projects
- Qualification of equipment and facilities including clean rooms
- Quality-relevant tests (particle count, microbial count, temperature mappings…)
- Requalifications (in compliance with periodic intervals, after modifications/component exchange, with risk-based approaches…)
- Process and cleaning validation
- Computer system validation (CSV)
- Change management

Qualification and validation are cornerstones in the world of GMP for implementation of mandatory quality standards, long-term conservation and guarantee of a consistent quality level of production.

Qualification according to the Lifecycle Management



Our goal is to support you in the best possible way and professionally with the implementation of your qualification and validation projects, to comply entirely with authority requirements. To ensure maximum customer satisfaction, we operate competent, on schedule and cost-effective.

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Qualification & Validation

competence is our business

Valicare, founded in 2002 in Frankfurt/Main, Germany, is a subsidiary of Syntegon Technology GmbH and offers competent consultancy and support in the area of GMP-compliant **(re)qualification** and **(re)validation**, but also full realization of those project plans.

We work across sectors in the fields of pharmaceutical industry, medical technology and biotechnology.

Benefit from our experience and competence to achieve your goals.

The working basis of Valicare GmbH are worldwide obligatory regulatory requirements (i.a. FDA-cGMP, EU GMP guideline, ICH, WHO, PIC/S regulations) and their supplements of specific guidelines at national level.

Your benefit of choosing Valicare

Focused project planning and management of qualification or validation projects

Increase in productivity and creation of open spaces for your personnel capacity by the engagement of Valicare personnel

Implementation of contract modalities in time and in cost

Our GMP compliance services

Preparation of:

- Specifications for facilities and equipment, such as your user requirements (URS), functional specifications (FS) and hardware/software design specifications.
- Risk analysis by using industrial standards e.g. Failure Mode and Effect Analysis, “Hazard Analysis and Critical Control Points”.
- Qualification planning, execution and documentation with plans, test protocols and reports for design, installation, operational and performance qualification (DQ/IQ/OQPQ).
- Validation master plans i.a. for planning and determination of validation activities, responsibilities as well as time and resource planning of your validation processes.
- Quality management handbook (QMH), site master file (SMF), hygiene master file, pharmacovigilance master file, standard operating procedures (SOPs) and form sheets for development and implementation of pharmaceutical QM systems.

Practical and comprehensive

- GMP concepts and upgrades
- GMP project management
- Gap analysis assessing established compliance status
- Handling of findings and deviations after audits & inspections
- Supplier qualification through questionnaires or GMP audits
- GMP review on computerized systems and critical electronic records

- Technical (design) review of your facilities for GMP compliance and validability
- Design- and detail planning of production sites (sterile/non-sterile)
- Layout of personal and material flows
- Conception of quality control laboratories

- SOPs and master batch records for definition and execution of your GMP processes
- QM elements like e.g. preparation of change and deviation documentation
- GMP training and preparation for inspections

Upon request, we offer an initial analysis. Based on the results, we determine together with you issues to work on, develop a timetable and define responsibilities.

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Contact our office and ask for our experts:

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