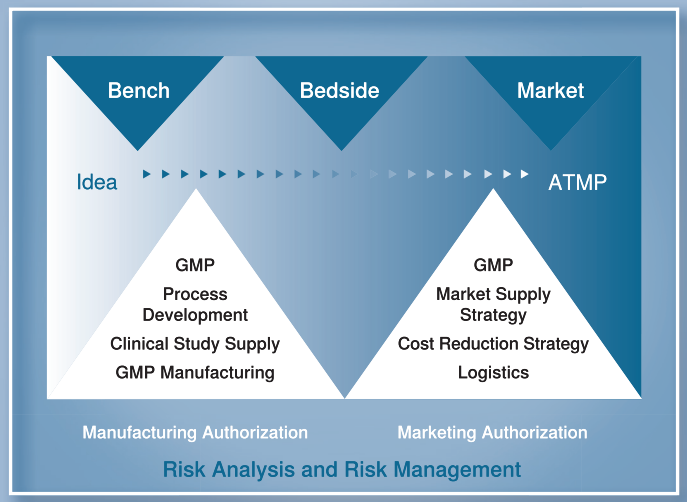
Valicare's service for ATMPs includes:

- GMP compliance analysis
- GMP process design
- Development of a general ATMP manufacturing concept
- Turnkey ATMP manufacturing solutions
- Risk analysis and quality risk management
- Securing the sterility requirements including virus safety
- Preparation or review of SOPs and batch records
- Preparation or review of the ATMP development report
- Support for supplier qualification
- Process transfer and transfer validation
- Validation of (bio-) analytical methods
- Basic training GMP for ATMPs
- Strategies to minimize costs and concepts for market supply

Valicare experts support ATMP manufacturers during the complete life cycle of their product.



competence is our business

We are DIN EN ISO 9001:2015 certified and support the GMP-regulated industry since 2002.

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GMP for ATMPs

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 "Good Manufacturing Practice" (GMP).

Our multidisciplinary teams work for the Pharmaceutical and Medical Device Industry, in Biotechnology and, in particular, for manufacturers of Advanced Therapy Medicinal Products (ATMPs).

Benefit from our experience and competence to achieve your goals.

On the basis of international requirements (e.g. EU-GMP (EMA), 21 CFR (FDA), PIC/S, ICH, GAMP® 5) we provide advice and support for Quality Assurance (QA), Quality Control (QC), production and the technical service to achieve GMP compliance. Our highly efficient support in the development and implementation of the GMP concept of your GMP- compliant concept will help you to achieve compliance with the official requirements in shorter time.

Your benefit of choosing Valicare:

Efficient implementation of your »time to market« and »bench to bedside« goals

Reliable planning of resources with our experienced experts

Increased productivity by saving time and personnel

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
- Method and process transfer to establish your projects from research and development in a fast and GMP-compliant manner
- 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)
- Layouts of personal and material flows
- Conception of quality control laboratories
- Execution of qualification and validation including reports

- 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

We offer a gap analysis to check your existing QM system for GMP compliance. Based on this, we define the topics to be addressed togehter, draw up a time schedule and define the responsibilities.

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