valicare

competent, reliable & efficient

Our Services:

Good Manufacturing Practice (GMP) Compliance Services:

- GMP project management
- Pharmaceutical procurement & design review
- Preparation of technical risk analysis (e. g. FMEA, HACCP) according to international regulations like ICH Q9, EU-GMP guide part III, PIC/S, FDA and GAMP5
- Risk-based qualification of equipment and clean rooms
- Cycle development and validation of isolators
- Qualification of inspection systems
- Qualification documentation (DQ, IQ, OQ & PQ)
- Development of validation master plans & validation of processes
- Review or creation of documents for pharmaceutical quality assurance
- Preparation of concept and process SOPs
- Method and process transfer
- Implementation of quality assurance tools
- Layouts of personnel and material flows
- GMP basic training courses & training concepts

Audits and Inspection Service:

- Preparation, support and execution of audits (qualification, routine und for-cause audits)
- Third party audits, e. g. as part of the supplier qualification
- Follow-up audits
- Gap analysis for compliance check of existing GMP systems
- Preparation and support of authority inspections
- Execution of mock inspections

GMP for Advanced Therapy Medicinal Products (ATMPs):

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

Analytical Method Validation (AMV):

- Implementation of a validation concept for analytical methods
- Preparation or review of validation plans and reports
- Interpretation of guideline ICH Q2
- Transfer of analytical methods
- Support on verification of pharmacopoeia methods
- Qualification of analytical equipment
- Computer system validation
- Basic training on validation of analytical methods

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Our Company:

Valicare GmbH is an ISO 9001 certified GMP service company with headquarter in Frankfurt am Main and offers for 17 years a comprehensive spectrum of services for GMP-regulated industry.

We work across industries for customers in the field of Pharmaceutical and Medical Device Industry, in Biotechnology and for manufacturer of Advanced Therapy Medicinal Products (ATMPs).

Based on international required regulations, we advice and support you in multidisciplinary teams, always according to the current state-of-the-art.

Rely on our competence, reliability and efficiency and contact our experts:

Contact persons:

Dr. Hans Georg Eckert

Senior GMP Consultant, ATMP, Pharma & Medical Devices/GMP & ISO Compliance Consulting, Audit & Inspection Support

Dr. Claudia Papewalis

Senior GMP Consultant, ATMP/GMP & ISO Compliance Consulting, Process Analyses & Validation, Audit & Inspection Support

Mohsen Masoumi

Senior GMP Consultant, GMP Compliance Consulting, Active Ingredients/Qualification & Validation, Audit & Inspection Support

Lutz Wagner

Team Leader, Recalibration and Requalification after Plant Modification & Automation Upgrades

Alena Wagner

Team Leader, Qualification of Sterile Filling Systems (new) for Liquid Pharmaceuticals, Cycle Design & Cycle Validation of Isolators

Andreas Harzer

Team Leader, Qualification of new Plants for Solid Pharmaceuticals, Inspection Technology, Track & Trace

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