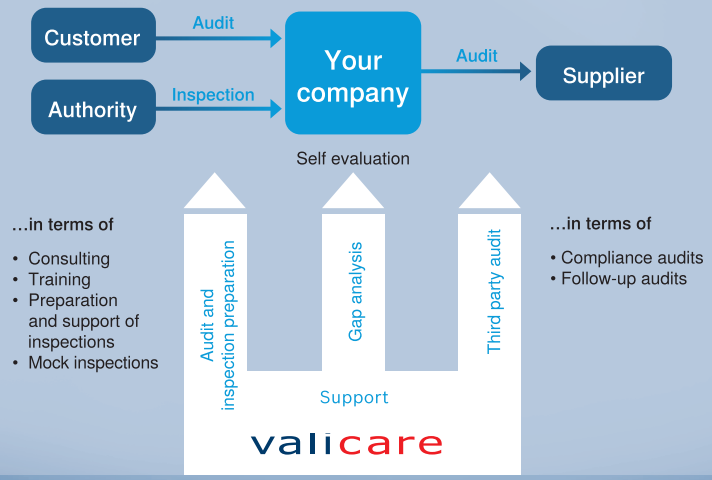
Main focus of Valicare's audit services:

- Preparation, support and execution of internal and external compliance audits, routine and for-cause audits
- Third party audits, for example as part of the supplier qualification for raw materials, intermediate products, and/or active pharmaceutical ingredients and excipients, as well as for equipment supplier, contract manufacturer, contract laboratories, and service providers
- Follow-up audits
- Gap analysis for compliance check of existing GMP systems
- Preparation and support for authority inspections
- Execution of mock inspections

The results are carefully and objectively documented in an audit or analysis report, whereby verification and traceability are important aspects for us. This maximizes the benefit you will get from our service. CAPAs are defined if required, and suggested corrective measures are checked with professional expertise. Their implementation is ensured through follow-up audits.

Whether you are in preparation for an internal, external or third party audit or an authority inspection, our certified and experienced auditors will support you with full commitment and professional expertise.



Our experts support you to handle GMP compliance issues professionally and to feel more comfortable in the execution of audits & inspections.

Valicare GmbH
Eschborner Landstraße 130-132
60489 Frankfurt / Main
Germany

Phone: +49 (0) 69 153 293 700
info@valicare.com
www.valicare.com

valicare

audit & inspection

competence is our business

Valicare, founded in 2002 in Frankfurt/Main, Germany, is a subsidiary of Syntegon Technology GmbH and offers competent consultancy and **audit & inspection service** in the area of **Good Manufacturing Practice** (GMP).

Our professional audit team supports you with the preparation and execution of third party audits, gap analysis and authority inspections.

Our multi-disciplinary team works for the Pharmaceutical and Medical Device Industry, Biotechnology and especially for manufacturer of Advanced Therapy Medicinal Products (ATMP).

Benefit from our experience and competence to achieve your goals.

Valicare's experienced and certified auditor team will support you with knowledge and high motivation regardless whether you are in preparation for internal, external or supplier audits or authority inspections.
GMP and ISO quality compliance of systems, products, processes and documentation systems of customers or supplier are checked through gap analysis and audits. International requirements, guidelines and harmonized standards (AMWHV, EU-GMP, FDA, ICH, PIC/S, EN ISO 9001, EN ISO 13485) are well known and followed.

Your benefit of choosing Valicare

Reliable resource planning with our experienced experts

Deeper understanding of GMP compliance requirements

More composure and sovereignty in handling of audits & inspections

Our GMP compliance services

Preparation of:

- Establishing specifications for your equipment, such as user requirement (URS) and hardware design (HDS) or functional specifications (FS) for equipment suppliers.
- Risk analysis e.g. by using Failure Mode and Effect Analysis (FMEA) as defined in international regulations as ICH Q9, EU-GMP guide part III, PIC/S, FDA Process Validation Guide and GAMP 5.
- Qualification documentation including design (DQ), installation (IQ), operational (OQ) and performance qualification (PQ).
- Validation master plans (VMP) for time and resource planning of the validation project for your processes and preparation of the corresponding validation and test protocols.
- Quality management handbook (QMH), site master files (SMF), hygiene master files (HFM), pharmacovigilance master files (PMF), standard operating procedures(SOPs) etc. for development and implementation of pharmaceutical and ISO 13485-compliant 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
- 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 system on GMP compliance. Based on the results, we define the corrective measures together, generate a time schedule and define the responsibilities.

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www.valicare.com

Contact our office and ask for our experts:

Dr. Hans Georg Eckert, Senior GMP Consultant:
ATMP/audit & inspection preparation
Dr. Claudia Papewalis, Senior GMP Consultant:
ATMP/audit & inspection preparation
Mohsen Masoumi, Senior GMP Consultant:
API/audit & inspection preparation