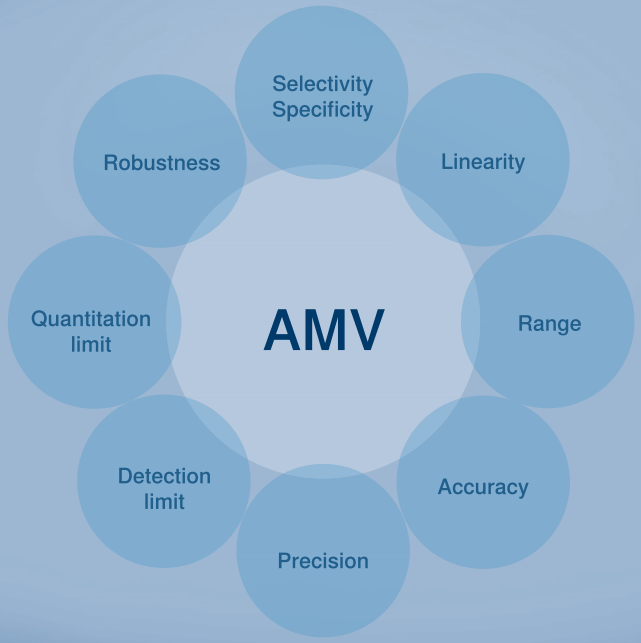
Valicare's services for AMV includes:

- Implementation of concepts for the validation of analytical methods
- Preparation or review of your validation plans and reports
- Interpretation of the ICH Q2 Guideline
- Transfer of analytical methods
- Support on verification of EU pharmacopoeia methods
- Qualification of analytical equipment
- Computer System Validation
- Basic training on validation of analytical method validation

Our PhD natural scientists know many (bio-)analytical methods from their own application and can therefore provide you with comprehensive advice and efficient support.
We will help you to ensure that the analytical methods used during drug product manufacturing and quality control generate valid data on which your company can make regulatory decisions.

Valicare experts support you on validation of your analytical methods used in quality control based on the validation characteristics from ICH Q2.



competence is our business

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

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

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

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Analytical Method Validation (AMV)

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 (ATMP).
As a special part of our service, we support you on regulatory compliant validation of analytical methods.

Benefit from our experience and competence to achieve your goals.

Validation of analytical methods is a regulatory requirement in the pharmaceutical industry. The ICH Q2 guideline “Validation of Analytical Procedures” identifies and discusses the validation parameters and characteristics needed during the validation of the analytical procedures, which are included as part of registration applications.

Our experts support you to implement analytical methods, in compliance to this guideline in your company. Depending on the type of analytical method as well as the planed usage, we will guide you through required validation parameter, characteristics and acceptance criteria.

Your benefit of choosing Valicare

Substantial knowledge of validation characteristics and their applicability

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 (FMEA), “Hazard Analysis and Critical Control Points” (HACCP).
- 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
- 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 project together, generate a time schedule and define the responsibilities.

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60489 Frankfurt / Main

Phone: +49 (0) 69 153 293 700
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