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GMP COMPLIANCE SERVICE

Valicare GmbH / 2025

A member of the **Syntegon Group**
enables the pharmaceutical and biotechnological
industry in GMP projects worldwide

ABOUT US

GMP and ISO compliance services for the fields:

- **Daughter company of Syntegon Technology GmbH** *a leading supplier of process and packaging technology*
- **Support for pharmaceutical and biotechnology industry and for manufacturer of medical devices**
- Over **100 employees** work on **national and international GMP projects**
- **Permanent senior consultants** with **many years of GMP expertise** *offer high quality compliance services*
- **Multidisciplinary engineers and scientists** *provide planning and execution of risk-based qualification and validation projects*

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THE COMPANY

Valicare & Syntegon

OUR LEAD CONSULTANTS

Competence Profile

Our permanent lead consultants with over 120 years of GMP experience:

Dr. Hans-Georg Eckert

Managing Director / Senior GMP Consultant

- Consulting and project management of GMP and quality projects
- Former head of production sites (GMP; ATMP)
- Experienced GMP auditor

Dr. Carsten Boerger

Senior GMP Consultant / Senior GMP Project Manager

- Qualification and validation projects of API production, quality control and GMP systems
- Former head of production site (API)
- GMP certified auditor

Dr. Mario Ramos

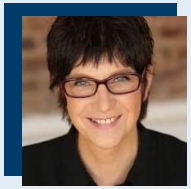
Senior GMP Consultant/ Senior GMP Project Manager

- Planning and execution of qualification and validation projects
- Quality control and GMP projects
- Former head of quality control (ATMPs)

Dr. Berthold Düthorn

Senior GMP Consultant / Senior GMP Project Manager

- Vice President at Syntegon
- Consulting and project management of GMP and quality projects
- Qualified Person (EC GMP) & ISO 9001 certified auditor



Dr. Claudia Papewalis

Senior GMP Consultant / Senior GMP Project Manager

- Planning and execution of qualification, validation and GMP projects
- Former head of production site (ATMP)
- ISO 9001 & GMP certified auditor

Dr. Katherina Pfister

Senior GMP Consultant / Senior GMP Project Manager

- Planning and execution of qualification, validation and GMP projects
- Quality management support
- Quality management representative (DEKRA)

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OUR EXPERTS

The Valicare **multi-disciplinary team** (~ 100 associates) comprises natural scientists, engineers of different disciplines and **skilled technicians** with **profound expertise** and **experience** in the regulated pharmaceutical, biotechnology and medical device industries.

Our **GMP consulting, qualification and validation experts** act in Europe, Asia and America. Annually, **400 GMP projects** are carried out. Mainly in **qualification and validation** but also in different **GMP consulting projects**, including gap analyses, risk management, GMP compliance, upgrades and concepts, trainings, audit and inspection support.

Since **2016** a strategic focus has been placed on **Advanced Therapy Medicinal Products** (ATMPs). Our experts accompany customer throughout the **entire life cycle** from development to marketing authorization and manufacturing of ATMPs.

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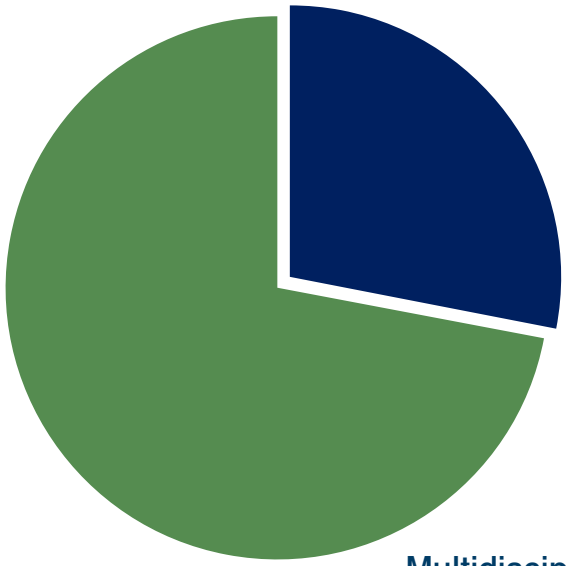
OUR EXPERTS

Competence Profile



28 %
Natural scientists

72 %
Engineers

> 100 employees in EU

Multidisciplinary teams of **engineers** and **natural scientists** with PhD in pharmacy, biology and (bio)chemistry

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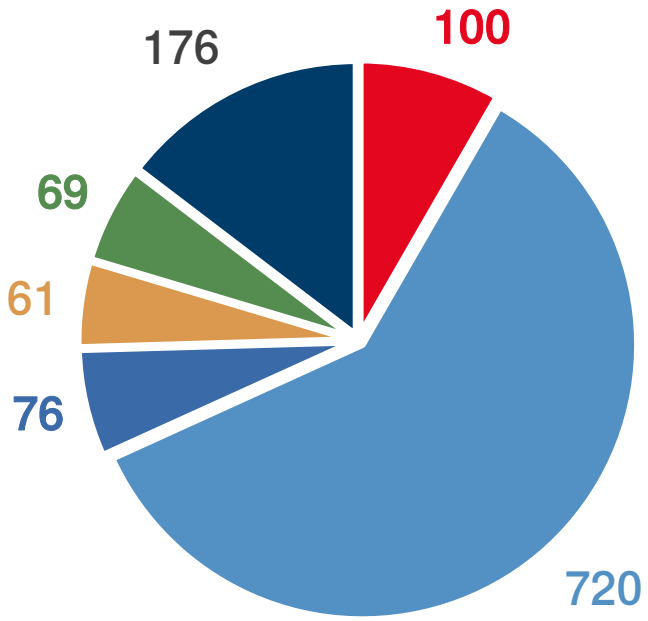
WE ACCOMPLISHED IN THE LAST YEARS

Competence Profile

More than 1.202 GMP projects have been carried out by Valicare within 3 years



- **Qualification & Validation:** (Re)-Qual. & Re-Val.; (Re)-Calibration; AFTs
- **Risk Analysis:** Technical Risk Analysis
- **Site & Factory Acceptance Tests**
- **Isolator Process Development & Validation:** Workshops, Documentation & Execution
- **Computer system Validation:** AFTs of HMI and PLC
- **GMP-Consulting:** Concept, Implementation, Audit, Training…

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GMP/GxP COMPLIANCE SERVICES

Service Portfolio

Consultancy Service Portfolio:

- GMP Expert Discussion
- GMP Concept and Implementation
- GMP Compliance Analysis
- GMP Audit
- GDP & GLP Concepts & System Upgrades
- GMP/GxP Topic Related Training
- Risk Assessment & Risk Management
- Contamination Control
- Pharmaceutical Quality Management System
- CAPA Project Management and Execution

General GxP Service Portfolio:

- GMP Project Management
- GMP / GxP Basic Training
- GMP Documentation / GMP System SOPs
- Risk Analysis
- Qualification (Rooms, Equipment & Supply Systems
- Qualification Management
- Process Validation (Manufacturing Processes)
- Computerized System Validation
- Analytical Method Validation
- Cleaning Validation

Quality Management:

- EN ISO 13485 & 9001 Compliance Support
- Assessment, Update & Implementation of QMS
- Preparation of QMH & SOPs

Interims Management:

- Head of Production / Head of QC
- Head of QA / External QM Department
- DIN EN ISO 9001:2015 / 27001

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GMP/GxP BUSINESS AREAS

Service Portfolio

ATMP & Biotech:

- GMP Process Development
- ATMP-GMP and PQ-System Introduction
- Definition of Specifications
- Validation (Transfer, Processes, Systems & Methods)
- Manufacturing Authorization Support
- GMP Layouts & Turnkey Production Solutions

Pharma:

- Design Review
- URS, FS & Q-Plan
- DQ, IQ, OQ & PQ (Rooms, Equipment & Supply Systems)
- FAT, SAT, Alarm & Function Tests
- Requalification & Recalibration
- Bio-Decontamination Process Development & Validation

Medical Devices:

- Regulatory Compliance and Strategy (EU MDR, IVDR)
- EN ISO 13485 Compliance Support
- Risk Management (ISO 14971)
- Product Development and Design Control
- Qualification & Validation
- Lifecycle Management

CSV Services:

- Computerized System Validation Preparation & Execution
- CSV Documentation Creation and Maintenance
- Coverage of the Complete SDLC
- CSV & IT Interims Management
- CSV / GAMP® Training
- CSV Audits (GxP, GAMP®, QMS, ISMS)

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MEDICAL DEVICE CONSULTING

Service Portfolio

Valicare experts are your trusted partner for medical device compliance and the market success of your products:

- **Strategic guidance for market access:** Navigating MDR ((EU) 2017/745), FDA (21 CFRs), and other global regulations
- **Ensuring regulatory compliance:** Expertise in EN ISO 13485, EN ISO 14971, ISO 10993, and IEC 62366
- **Supporting the entire product lifecycle:** From concept to market approval and post-market surveillance
- **Process optimization & innovation:** Enhancing efficiency, safety, and usability for long-term success
- **Customer-oriented solutions:** Tailored services designed to meet your specific needs, ensuring seamless compliance, product safety, and market success

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MEDICAL DEVICE CONSULTING

Service Portfolio

Regulatory Compliance
Expertise in MDR ((EU) 2017/745), FDA (21 CFRs), and global standards

Quality Management Systems (QMS)
Implementation & optimization of EN ISO 13485 compliant systems

Risk Management (EN ISO 14971)
Comprehensive risk assessment throughout the product lifecycle

Usability Engineering (IEC 62366)
Human factors analysis, usability testing & compliance strategies

Biocompatibility Assessment (ISO 10993)
Ensuring product safety & regulatory acceptance

Process Validation & Qualification
Ensuring consistent high-quality manufacturing

Supplier Management
Evaluating & maintaining a compliant supply chain

Training & Education
Practical seminars on GMP, quality management & regulatory updates

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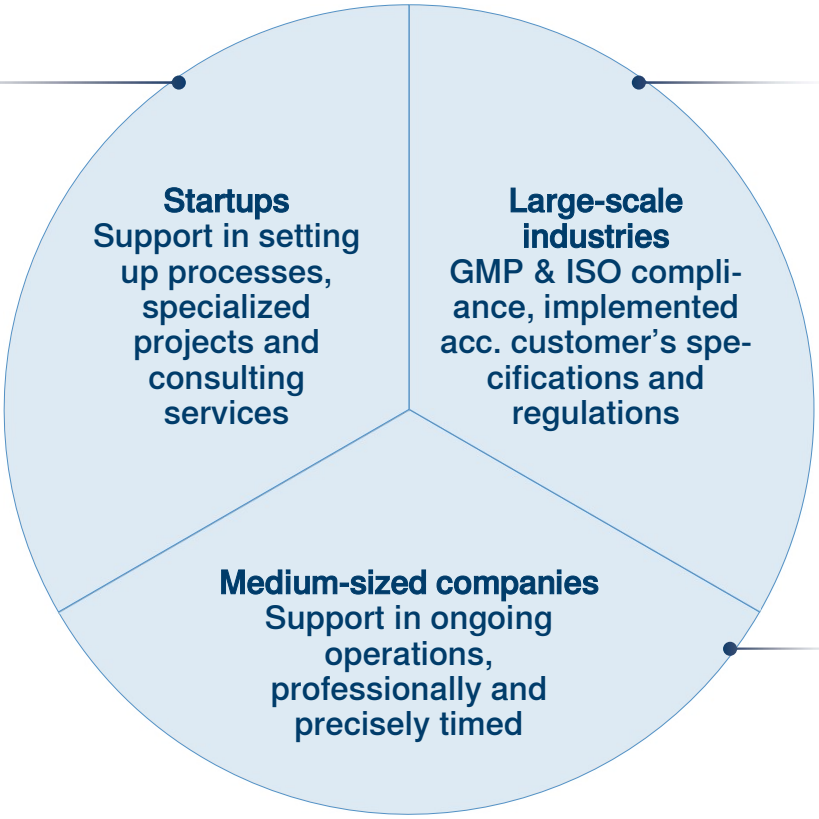
PHARMA, BIOTECH & MEDICINAL TECHNOLOGY

Customer Portfolio

- Development of **GMP concepts** and **processes** & **method transfer**
- **Security profiles** for your products
- Definition of **specifications**
- **Manufacturing** authorization according to **§ 13 AMG**
- **Qualification** and Validation of exceptional equipment & **novel processes**
- Creation of QM **systems, SOPs** & **master batch records**



- **Risk analysis**, calibration, qualification & validation and **design reviews**
- **Process technology**, primary packaging, sterile filling & isolators, inspection technology, pharma & biotech production facilities

- **Gap analysis & GMP upgrade projects**
- Risk **assessment** & **analysis**
- **Qualification** & **Validation**

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PHARMA, BIOTECH & MEDICINAL TECHNOLOGY

Our Customers

8/10 of the top players are **our customers**

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BENEFITS & ADVANTAGES

Contact the Experts

- Assurance of GMP compliance
- Confidence for upcoming inspections
- Effective set-up of manufacturing and quality control concepts
- Reliable personnel resources with compliance expertise to free your personnel for day-to-day activities
- Short project time through efficient planning and execution by experts leads to reduced time to market

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WHY CHOOSING VALICARE AS A PARTNER?

Contact the Experts

Because Valicare convinces through:

- **Lead consultants** working more than **20 years** successfully in the GMP area always **up to date** about the European and international compliance standards for the regulated industry.
- **Multidisciplinary expert teams for** qualification and validation with deep technical background in manufacturing and packaging.
- **Natural scientists** expertised with **GMP transfer and validation** of biological and biotechnological processes.
- **Long-term experience through management and execution** of **> 5,000 GMP-projects worldwide** since founding.

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valicare
competent, reliable & efficient

CONTACT OUR EXPERT

WE ALWAYS FIND SOLUTIONS!

Dr. Ellen Sons-Brinkmann

+ 49 69 153 293 709/700

www.valicare.com

Eschborner Landstr. 130–132, 60489 Frankfurt

info@valicare.com