valicare
GMP Compliance Services & Solutions

Valicare – Your GMP Service Supplier

Planning, implementation & execution from one source

Valicare, a member of the Syntegon Group, offers Good Manufacturing Practice (GMP) compliance services for the pharmaceutical, biotechnology and medical device manufacturing and processing industry.

Headquartered in Frankfurt on the Main since 2002 and ISO 9001 certified since 2011.

Together with the Valicare in Trenčianska Turná, in Slovakia, more than 100 engineers and natural scientists work as GMP consultants and validation specialists in projects worldwide.

With over 2.000 GMP projects since founding, Valicare is experienced with management and execution of a wide scope of GMP tasks.

Our Competence:

- 20 successful years in the GMP compliance business
- Lead consultants always up to date with European and international guidelines such as EU-GMP, PIC/S, WHO
- Engineers from various fields with technical expertise
- Natural scientists with process expertise
- High quality and efficiency in project planning, management, and execution

Our experts support you with:

- GMP compliance check (gap analysis), audit & mock inspection
- Basic and advanced GMP trainings
- Classical GMP consultancy and problem solving
  Risk-based qualification (IQ,OQ,PQ)
- Risk-based validation (process, cleaning, methods, IT-systems)
- GMP documentation on all levels

Your Benefits:

- In theory and praxis experienced senior GMP consultants
- Certified auditors who know what is important during inspections
- Assurance for GMP compliance
- Efficient project plans und execution
- Reduced time to market

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Our services at a glance

- GMP Compliance Analyses
- Concepts & Implementation
- GMP Upgrade
- Audits & Inspections (Mock)
- Interims Management
- Training & Workshops
- GDP & GLP
- GMP Documentation

- EN ISO 13485 & 9001 Compliance Support
- Assessment, Update & Implementation of QMS
- Preparation of QMH, SOPs
- Risk Assessment & Risk Management
- Risk Analyses
- Qualification & Validation

ATMP & Biotech:

- GMP Process Analysis & Standardization
- Development of Specifications
- Validation (Process, Systems, Methods)
- Manufacturing Authorization
- Preclinical Support
- Turnkey Production Solutions

Pharma:

- Design Review
- URS, FS, Q-Plan
- DQ, IQ, OQ, PQ
- FAT, SAT, Alarm & Function Tests
- Requal. & Recal.
- Bio-decontamination Process Dev. & Val.
- CSV & CV

Please call us for support!

We are glad to advise you.

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