valicare
GMP Compliance Services & Solutions

Valicare GmbH
GMP Consultancy and Qualification & Validation

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Valicare has many years of experience and looks back on more than 2,000 successful GMP projects worldwide. We offer you customized consulting and short project lead times – which result in faster time to market.
Get to know us better!

Valicare GmbH is an ISO 9001-certified international service provider with a focus on GMP compliance.
Valicare, founded in 2002 in Frankfurt/Main, Germany, is a subsidiary of the current Syntegon Group. In 2006, Valicare s.r.o. was established in Trenčín in Slovakia as a joint venture with Heitec AG.
Today, more than 100 qualified and highly motivated consulting and validation experts support companies all over the world in their GMP projects.

GMP Consulting

Valicare provides services and consulting for the assurance of Good Manufacturing Practice (GMP). Our GMP consultants have many years of practical expertise and regulatory competence – especially in manufacturing, quality control, storage, distribution, but also with the trade of pharmaceuticals and active pharmaceutical ingredients.
We advise you on all classic GMP topics. We carry out GMP compliance analyses (gap analyses) to clarify your GMP status. In addition, you can also book basic and advanced GMP training courses. But above all, we see ourselves as your problem solvers.
Valicare supports manufacturing, processing, and service companies in the pharmaceutical, biotechnology, and medical device industries worldwide.

Thanks to the extensive experience of our scientists and GMP consultants, we also offer services for ATMP (Advanced Therapy Medicinal Products). We successfully advise and support you from the development to the approval of your product. If required, we and the engineering and project management department of our parent company create flexible and turnkey cleanroom modular buildings for the development and production of starting materials through to clinical ATMP test materials (iATMPs).

Qualification and Validation

Valicare provides capacity-based services in risk-based qualification, validation (processes, cleaning, analytical methods, computer systems) and GMP documentation. Our risk-based, integrated qualification and validation approach complies with the global GMP requirements, described among others in Annex 15 of the EU GMP guide. If desired, we also follow the ECA's integrated qualification and validation guideline.
As a first step of the customer collaboration, we analyze the GMP-relevant risks of processes and equipment, based on risk analysis methods such as FMEA. We then define the necessary scope of qualification and validation – to ensure a time-efficient and cost-effective approach. Our qualification procedure provides optimal conditions for successful performance qualification (PQ) as well as subsequent process and cleaning validation.
Our validation and qualification plans and protocols are GMP-compliant; our approach is SOP-based. We use our own calibrated and qualified testing instruments for the qualification of your equipment.

Inside view of an isolator

Cleanroom modules for ATMP production

Services for Medical Devices

Valicare also offers comprehensive consulting for medical devices. We support the implementation of GMP requirements and DIN EN ISO 13485. When it comes to risk management for manufacturers of medical devices, we follow DIN EN ISO 14971.

Our Core Capabilities

Many years of experience in more than 2,000 successfully completed GMP projects worldwide and multidisciplinary teams enable us to offer you efficient and competent management and implementation of comprehensive GMP projects.
Our senior consultants have been working in the GMP-regulated environment for more than 20 years. By attending congresses and receiving ongoing training, they are always up to date regarding European and international regulations (FDA, EMA, PIC/S, WHO, ICH, GAMP).
Our experienced validation experts have a comprehensive technical understanding of process and packaging technology. A special focus is on filling technologies, which we know in detail thanks to the close cooperation with our parent company Syntegon. Specially complemented by our decades of expertise and experience in aseptic filling and isolator technology.

Our scientists successfully carry out validation and GMP transfers of methods and processes, with a focus on gene and cell therapy projects. Valicare' s in-depth GMP experience with various ATMP manufacturing processes and the design and construction of production facilities makes it a full-service provider for ATMP manufacturers.

Your Benefits

Save time and resources in your daily business by entrusting us with your qualification and validation projects. Leverage the experience and expertise of our senior consultants to ensure GMP compliance.
Approach upcoming inspections with confidence. Our certified and experienced auditors will prepare you in the best possible way.
What's more, you can look forward to short project lead times thanks to efficient planning and execution, resulting in faster time to market of your product.

Get in touch with us. We look forward to working with you!