ATMP Service Packages

Support & services along the entire ATMP life cycle

Manufacturing of Advanced Therapy Medicinal Products (ATMP) are mainly manually, complex and always a challenge. Contrary to classical drugs, alternative manufacturing and quality control are allowed if modifications are risk-based, traceable and guarantee quality and safety of the ATMP. But for both the national and the European approval a manufacturing license is obligate and for the latter also clinical trials.

The transfer from R&D into GMP needs regulatory expertise. Our **ATMP experts** support you at every single step of the process.

Our Competence

- Profound GMP and regulatory expertise
- Extensive experience with risk assessment in ATMP (Cell Therapy, Gene Therapy) manufacturing
- Manufacturing and quality control managers in our consulting team
- Vast experience with requirements for supplier qualification

Our Services & Support

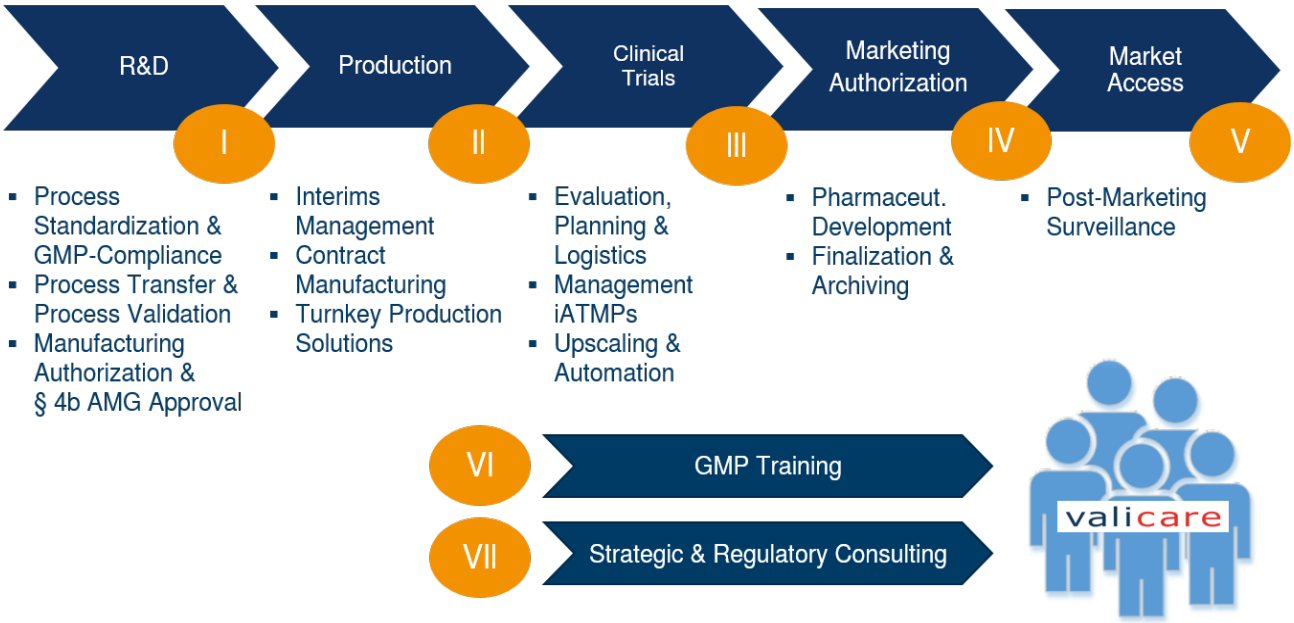
- GMP for ATMP/iATMP
- Risk- and quality management
- Audits, mock inspections and supplier qualification
- Process analysis and standardization
- Definition of specifications
- Validation (process, systems, methods)
- Manufacturing authorization
- Preclinical support
- GMP training

Your Benefits

- Reduced time to market
- Regulatory compliance safety
- Reliable personal resources
- External objective GMP view
- Risk reduction through competence
- Still time for routine business

valicare
GMP Compliance Services & Solutions

The Valicare-Team supports you along the entire value-added chain!



Contact us if you are planning an ATMP manufacturing project or already started one. We will support you!

Dr. Ellen Sons-Brinkmann
Business Development & Marketing
Phone +49 69 153 293 709
Mobile +49 172 413 0603
Ellen.Sons-Brinkmann@valicare.com

Dr. C. Papewalis
Lead ATMP Team
Phone +49 69 153 293 710
Mobile +49 162 295 5876
Claudia.Papewalis@valicare.com

Valicare GmbH
Eschborner Landstr. 130-132
60489 Frankfurt, Germany

Phone +49 69 153 293 700
info@valicare.com
www.valicare.com