Auditing of blood banks

Ensure the quality of your ATMP starting materials.

Advanced therapy medicinal products (ATMPs) are produced from a wide range of biological starting materials. These are **substantially modified** to perform gene therapeutics (manipulated nucleic acids), genetically modified cell therapeutics or customized and/or stimulated, expanded cells.

Blood products represent a large proportion of the starting materials required. An important supplier of these starting materials are **blood banks**.

In order to identify ideal suppliers and starting materials for your ATMP and to ensure high quality, Valicare offers the auditing of blood banks in the form of third-party audits. During these audits, we check whether the blood banks meet the high regulatory standards and your specific requirements. The focus is on:

- Existing accreditations and certificates
- The organizational structure and the quality management system (QMS) of the blood bank
- The documentation and processes carried out within the QMS (purchasing, management of changes, complaints and deviations, as well as the management of corrective and preventive actions – CAPAs)
- The performance of audits and self-inspections
- The personnel working at the blood bank and their qualifications
- The equipment used, with regard to its identification and the status of qualification, validation, calibration and maintenance
- The layout and quality of the premises for blood collection, laboratory and storage (including monitoring)
- The sequence of the processes carried out (including safety measures)
- Patient management for the selection of donors and their pre- and post-donation care
- Sample management (collection, transport, labeling, quality control)

Valicare will provide you the GMP-compliant documentation of the audit results in the form of an audit report. We can use both your company's internal templates and Valicare's internal templates specially designed for your audit. This way, we ensure that the audit is conducted according to your expectations and requirements.

valicare
GMP Compliance Services & Solutions

Our Competence

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

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

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

Would you like to shape the future with your ATMP? Our experienced auditors will be glad to support you. Get in touch with us now. Together we will take your therapy to patients!

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