

Quality Control (QC) Manager / Lead (m/f/d)

Full-time | Fixed-term: Sept/Oct 2026 – Dec 2028

Location: This position is based in Radeberg, Saxony, and requires regular on-site presence.

About Viacure Therapeutics GmbH

Viacure Therapeutics GmbH is a biotechnology startup and spin-off from Helmholtz Munich, developing a first-in-class antibody therapy for type 2 diabetes. The company's approach is based on targeting the "Inceptor" receptor to enable regeneration of insulin-producing beta cells.

Role Overview

The QC Manager/Lead will be responsible for defining and overseeing the analytical control strategy for Viacure's antibody program, ensuring generation of robust, reliable, and regulatory-compliant data across all stages of development.

Key Responsibilities

- Oversee analytical method development, qualification, validation, and transfer
- Manage and coordinate outsourced analytical activities (CROs/CDMOs)
- Support product and process characterization (identity, purity, potency, impurities, comparability), setup of QTPP and CQA assessment
- Define and implement analytical control strategy for antibody based drug substance (DS) and drug product (DP) in cooperation with external, GMP compliant supplier
- Establish specifications for raw materials, intermediates, DS, and DP
- Review and approve analytical data, reports, and certificates of analysis
- Ensure data integrity, traceability, and compliance of analytical data
- Design and oversee ICH compliant stability studies to support CTA submission
- Provide analytical input to regulatory documentation (IMPD/CTA)

Qualifications

- Degree in Analytical Chemistry, Biochemistry, or a related field
- Several years of experience in QC or analytical development in biotech/pharma, preferably with antibodies / biologicals.
- Strong knowledge of relevant EU guidelines
- Strong knowledge of analytical techniques (e.g., chromatography, bioassays)

- Experience managing external laboratories (CRO/CDMO model)
- Detail-oriented with strong analytical thinking
- Fluency in English and German is required

What We Offer

- Key role in building the analytical foundation for a first-in-class therapy
- Direct contribution to CTA-enabling activities
- Collaborative and fast-paced startup environment
- Fixed-term full-time position

How to apply

We'd love to hear from you! Please send your CV to **c.ballester-lopez@viacure.de** and tell us a little about your experience and interest in the role.