cecava

Job Advertisement

CeCaVa, a biopharmaceutical immuno-oncology company was founded as a spin-off of CeGaT GmbH with the mission to develop personalized neoantigen-based cancer vaccines derived from tumor-specific mutations. To strengthen the team in Tübingen (Germany) and to support the preparation of first clinical trials CeCaVa **is searching for an experienced**

QM Expert Supplier & Process Qualification (f/m/d)

in full time. The candidate will support the management in all quality-related aspects, including the completion and maintenance of the Quality Management System (QMS) as well as the qualification and management of Contract Manufacturing Organizations (CMO) and Contract Analytical Testing Labs. The candidate ensures that the processes for manufacturing and analytical testing of investigational medicinal products (IMPs) are qualified and conducted by contractors in accordance with GxP requirements.

Your field of responsibility

- Contribute to the qualification and contracting of suppliers (negotiate quality agreements)
- Prepare, conduct, and document audits of contractors in accordance with relevant regulations (GMP, etc.)
- Together with contractors define and establish manufacturing and control strategies for drug substances (DS) and drug products (DP) to comply with cGMP/GMP guidelines
- Together with contractors define and conduct qualification studies for analytical assays to be applied in clinical trials (incl. NGS, T cell activation assays)
- Establish excellent working relationships, communication and quality oversight of contractors to ensure manufacturing, control and timely supply of IMPs for clinical trials
- Compile and revise SOPs to finalize and maintain the QMS of CeCaVa
- Perform Product Quality Reviews and manage Deviations, Lab Investigations, OOS, CAPA and Change Control processes
- Liaise with internal stakeholders and report quality related occurrences to the management (Quality Management Review)
- Support discussions with regulators and IND/CTA filings (e.g. support writing and review of CMC/IMPD sections)

Our expectations

- University degree in life sciences (e.g. Biology, Biochemistry, Chemistry, Pharmacy)
- Several years of professional experience in a QM/QA function in a pharmaceutical/GMP-regulated environment
- Practical experience in managing and qualifying contractors, among others through virtual and onsite audits, to ensure vendor compliance oversight within a GxP discipline
- Proven experience in supporting the qualification of GMP manufacturing processes and analytical methods
- Preferably first experiences with the oversight of QC and release of IMPs for clinical trials
- Quality mindset and good knowledge of regulations and guidelines of health authorities (FDA/EMA/ICH), including cGMP/GMP/GLP/ GCP principles and USP/EP compendia
- Experience in the preparation of CMC chapters (IND/IMPD/IB) is a plus
- Solid understanding of Quality Systems, including preferably the management of Deviations, Lab Investigations, OOS, CAPA and Change Control procedures
- Ideally basic knowledge of molecular and cell biology methods and their qualification (i.e. NGS, ELISpot, intra-cellular cytokine staining)
- Excellent organizational, interpersonal and communication skills in both German and English (oral, written) as well as good negotiation skills
- Self-motivated, detail-oriented team player with critical thinking, and problem-solving skills
- Willingness to travel for audits

Our offer

- An exciting opportunity to contribute to the development of a disruptive technology for the benefit of cancer patients
- Work within a dedicated team in an entrepreneurial, innovative, and open-minded working atmosphere
- Flat hierarchies and easy access to all company functions
- Use your expertise to help shape the company
- Free drinks and fresh fruits
- Job bike and Job ticket (*Deutschlandticket*)

Your Application

Please send your complete application (including cover letter, CV, certificates, expected availability date, salary expectations, a complete list of publications and 2 - 3 references) by email and in one PDF document to jobs@cecava.de.

We look forward to receiving your application!

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