CellPoint

The future of cell therapy is at the point-of-care

Manager Quality Assurance

Oegstgeest, The Netherlands

About CellPoint

Engineering immune T cells from cancer patients using Chimeric Antigen Receptors (CARs) are a great invention from the last decade, eradicating tumors and providing durable remissions. However, first generation CAR-Ts require shipment of cryopreserved cells to large factories and labor-intensive manual processing, as designed in the '90s.

At CellPoint, we designed an unconventional CAR-T manufacturing and supply model using the best technology available to completely disrupt time-to-time treatment and costs. Selected clinical centres of excellence are provided with Lonza's Cocoon™ platform, a fully closed and automated manufacturing device, to manufacture cell therapies at the point-of-care within a week without any logistics. The centres receive full training and support, while the secure online xCellit platform is used to facilitate scheduling and monitoring of the CAR-T treatment workflow.

About the role

As Manager QA you will join our team located in the Leiden Bio Science Park. Your main responsibilities will be:

- Participating in designing, setting up and maintaining a point of care quality assurance model
- Manage and maintain quality documents
- Being QA representative in Technology Transfers to point of care manufacturing partner
- Acting as counterpart for our point-of-care QA responsible persons and QP's
- Setting up and developing a Product Review Committee
- Building product knowledge with our point-of-care GMP manufacturing partners
- Creating and maintaining product quality review documents (PQRs) (annually) for each product
- Management of central deviations and change controls
- Supplier qualification management
- Subcontractors management
- Participate in materials management in cooperation with Tech Ops Services
- Setting up and managing an internal audit system

We are a young and fast-growing company. New team members have the opportunity to actively shape their position and contribute to our mission, being part of a very motivated and multidisciplinary team.

Qualifications

- MSc in life sciences, biotechnology, or related discipline
- Previous experience in a pharmaceutical/biotech company in a Quality role is a plus
- Previous experience with phase appropriate GxP quality systems is a plus
- Good knowledge and understanding of EU and US cGMP guidelines, preferably with focus on ATMPs
- Experience in deviation handling, conducting root cause analysis and risk management principles.
- Experience in inspections by competent authorities
- Experience in Supplier Qualification
- Strong interpersonal, verbal and written communication skills
- Ability to be flexible with changing priorities
- Self-driven and can-do mindset, without compromising quality and compliance
- Fluent in English

CellPoint offers

- Competitive salary
- Dynamic environment using cutting edge technologies, aiming to surpass the leaders in the field
- Great culture with strong emphasis on team performance and personal development

Interested?

Get in touch or apply with a CV and short motivation to careers@cellpoint.bio