

Head of Quality Assurance & Qualified Person (m/f)*

Reference-number: 1001203

Company Information

Our client is an innovative biotechnology company that develops personalized cell therapies for treatment of incontinence. The company is running multinational clinical trials for its two 'tissue-engineered' products in development. Using their innovative 'ultrasound-guided' injector, patients benefit from a minimally invasive surgery. More than 500 patients have been treated since 2002.

Position

- Preparation and validation of quality assurance procedures for the entire life cycle of their products
 - Generation of operational sequences with in-process and end controlling
 - Implementation and maintenance of GMP compliance
 - Preparation of audit plans for validation of methods and processes
 - Evaluations of production materials concerning suitability, biosafety and documentations
 - Preparation of stability studies within the transport logistics
 - Product release (in the function of a „Qualified Person“ (directive 2001/83/EC for medicinal products for human use)
- Maintenance / Expansion of the manufacturing plant
 - Controlling and documentation of the physical and microbiological monitoring within the manufacturing plant
 - Controlling and validation of the manufacturing plant as well as initiation of requalification processes
- Regulatory tasks
 - Preparations of risk analyses and regulatory documents
 - Support the licensing teams concerning scientific advice
- Research / Development CMC / Biosafety
 - Integration of new production processes and materials via RA-investigation - validation
 - Completion of the CMC part (CTD - modul 3) with focus on characteristics, impurities, tumorigenicity / genetic stability
 - Investigations for biosafety and analytical methods
- Research / Development pre-clinical
 - Completion of the CMC part (CTD - modul 4)
 - Obtaining offers / commissioning of external laboratories
- Leading a small team of a biologist and a pharmacist

Candidate Profile

- Scientific background, industrial experience - ideally in the field of tissue engineering
- Knowledge of regulation terms for medical devices
- Experience and admittance as a "Qualified Person" (possibility/willingness to get this qualification)
- Hands-on mentality
- Excellent verbal and written command of English and knowledge in German
- First leadership experience - leading a small team
- Excellent communication and people skills
- Diligent with reporting and keeping systems up to date
- Works well in a team environment, leads and follows well, and encourages others within the team

Direct Reporting Line: Chief Scientific Officer

Place of Work: West-Austria

Salary Range: Annual gross salary from € 80.000,- according to skills and experience

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If you are interested in this position please email your CV to Mrs. Doris Gardavsky/Research Consultant doris.gardavsky@mediatum.com

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