CUTISS AG is a biotech company spin-off of the University of Zurich (UZH) and focuses on the development of personalized bioengineered skin graft products for the treatment of skin defects. Its lead product denovoSkin™ has successfully completed Phase I in pediatric patients. Clinical Phase II studies are underway in Europe and Switzerland.

For our expanding Quality department in Schlieren, Switzerland, we are currently seeking a highly motivated and experienced

QC Manager (f/m/d) 60-100%

The Quality Control Manager is responsible for ensuring and fostering a pro-active, appropriate approach to the establishment of a complete management of activities related to the testing, monitoring and release of denovoSkin™ intermediates and product. This position will be also be responsible for ensuring that technology transfer activities are conducted in accordance with applicable regulatory requirements, guidelines, laws and internally established standards and practices, process and product validation.

Your main duties

- Responsible for supervising the implementation, validation, and maintenance of the Quality Control Unit (QC) about the control of the manufacturing of autologous skin substitutes for clinical and commercial phases according to GMP guidelines
- Ensure compliance to codes, standards, regulations, equipment specific specifications, and QMS requirements, including creation/revision of appropriate SOPs
- Implement metrics and measures to drive assessment and continuous improvement
- Review of trends and report significant investigation/deviation issues and system deficiencies
- Manage inspection readiness activities and contribute to regulatory health authority inspections
- Identify and develop QC personnel certification requirements and continuing education/training needs
- Provide leadership, mentorship, and direction to QC personnel

Your background

Ideal candidates hold a B.Sc. (M.Sc. preferred) in a biological field (e.g. biology, tissue engineering, biotechnologies, and biomedicine) or a comparable education with a minimum of 8+ years working experience in regulated industry, pharmaceutical industry preferred

Desired Skills and Experience

- Proven experience as a Quality Control manager or relevant role
- Experience in shutdown planning and execution
- Experience is installing new facilities/new programs
- Excellent knowledge of Process Validation, particularly EU, FDA and ICH requirements
- Ability to develop and manage non-conformance, deficiencies, including root cause analysis

- Experience working within local jurisdictional and regulatory authorities
- Exercise sound and balanced judgment in ensuring that written procedures are followed and in evaluating quality systems, processes, procedures, plans and protocols for compliance
- Good knowledge of safety programs
- Supervision of safe storage and verification of all project related documentation, both paper documents and electronic files
- Excellent numerical skills and understanding of data analysis/statistical methods
- Excellent organizational and leadership abilities
- great sense of quality and responsibility, high level of accuracy
- communicative, team-oriented
- Reliable and Trustworthy
- Solid IT user skills e.g. Microsoft Office and databases
- Proficient in German and English (any other languages, particularly Italian, are a plus)

We offer

- High pace start-up environment
- flexible working hours in arrangement with the head of department
- competitive benefit package
- a young and dynamic team
- 5 weeks holidays

Are you interested?

We look forward to receiving your complete application including the following documents:

- Motivation letter
- Curriculum vitae
- Copies of degrees and references

to hr@cutiss.swiss.

For further information about this role, please contact Mrs. Kathi Mujynya (kathi.mujynya@cutiss.swiss).