CUTISS AG, a biotech company spin-off of the University of Zurich (UZH), focuses on the development of personalized bioengineered skin graft products for the treatment of skin defects in Switzerland and Europe.

For our Quality Assurance department in Schlieren, Switzerland, we are currently seeking an experienced

Quality Assurance (senior) specialist (f/m/d) 100%

The qualified candidate is a highly motivated, interactive individual that possesses the ability to work individually and collectively. He/she will demonstrate clear and professional verbal, written communication and reporting.

Your main duties

- Ensuring the proactive, phase-appropriate management of a complete and independent Quality Management System (QMS), as well as supporting and preparing for QA compliance readiness during inspections and audits.
- Ensuring compliance to codes, standards, regulations, and QMS requirements, including creation/revision of appropriate SOPs.
- Managing, preparing and maintaining key QA compliance systems (Deviations, CAPAs, Change Control, Risk analysis, Audits).
- Preparing metrics and measures to drive assessment and continuous improvement.
- Optimizing compliance processes to reduce lead times.
- Managing the development and implementation of the Quality Management System (QMS) for planning, fabrication, inspection, documentation, and operations activities (f. e. planning duties and providing leadership to the QA personnel).
- Ensuring efficient Batch record review, writing and reviewing QA related SOPs
- Implementing and executing the activities related to the supplier management process as outlined in the SOPs (including supplier audits).
- Maintaining QA activities in compliance with Swissmedic, EU, and FDA (if applicable) regulations across therapeutic areas.
- Participating in the collaboration and negotiations of Quality Agreements with third parties and material suppliers.

Your background

You hold a M.Sc./PhD in a natural science field field (e.g., pharmacy, biology, tissue engineering, biotechnologies, and biomedicine) or a comparable education. Knowledge of medical device regulation is a plus. You gained 3 years working experience in QA related role in pharmaceutical companies in a wide spectrum of QA activities. You have been involved in batch record review and you are experienced in inspections.

Desired Skills and Experience

- Must have work permit in Switzerland
- At least 3 years of experience in QA related role in biopharmaceutical companies (ideally ATMPs) in wide spectrum of QA activities, including active inspection experience

- Ideally experience in transferring QMS from paper-based to electronic QMS
- Involvement in batch record review and release process of biopharmaceutical/ATMP product
- auditor ISO/GMP experience (outsourced activities, critical material suppliers, internal audits)
  Fluent in English both oral and written, German is a plus.

We offer the unique chance to be part of a young and motivated project team with the vision to change the patients' quality of life. This interesting and challenging job will give you the opportunity to further develop your working skills in a biotech start-up environment and to get in touch with international partners and clinical trial centers. In summary you can expect:

- A high pace start-up environment
- Flexible working hours in arrangement with the team leader
- Competitive benefit package
- A young and dynamic team
- 26 days of holidays/year

Are you curious to find out more?
If you are interested in applying for this position, please send your complete application, which should include the following documents in **English**

- One-page motivation letter
- Curriculum vitae
- Copies of degrees and references

by using the following link:

Apply Online

For further information regarding the recruiting process, please contact our HR partner HC Solutions, Annika Danielsson or Alessia Cesari.

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