



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. Its lead product denovoSkin™ has successfully completed Phase I in burns patients. Clinical Phase II studies are underway in Europe and Switzerland.

CUTISS AG aims at designing an intelligent, automated platform to accelerate the manufacturing of its bioengineered skin product. Therefore, we are seeking a highly dedicated

## **Head of Quality Assurance (30-50%)**

who can manage the development of next-generation skin grafts and start **as of now or per arrangement**.

### **Your main duties**

As Head of Quality Assurance, you are responsible for ensuring and fostering a pro-active, phase appropriate approach to the establishment of a complete and independent Quality Management System (QMS).

- Ensure compliance to codes, standards, regulations and QMS requirements, including creation/revision of appropriate SOPs
- Act as the company Qualified Person (QP/ FvP)
- Implement metrics and measures to drive assessment and continuous improvement.
- Management and review of trends and report significant investigation/deviation issues and system deficiencies
- Manage inspection readiness activities and contribute to regulatory health authority inspections
- Establishing service standards for end users (i.e., internal department or external customer);
- Identifying and developing Quality Assurance personnel certification requirements and continuing education/training needs
- Providing leadership, mentorship, and direction to our Quality Assurance personnel

### **Your background**

You hold a minimum M.Sc. in a biological field (e.g., Biology, Pharmacy/ Biotechnology/ Chemistry) or a comparable education with a minimum of 12 years working experience in regulated industry in similar position. Pharmaceutical industry is preferred.

### **Desired Skills and Experience**

- Expert knowledge of Process Validation, particularly Swissmedic, EMA, FDA and ICH requirements
- Experience in developing and monitoring of project QA budgets.
- Experience working within local jurisdictional and regulatory authorities

- Advanced ability to communicate effectively, both verbal and written, with internal organization departments, suppliers, subcontractors, and regulatory authorities
- Strong coordination and organization skills, with strict emphasis on accuracy and attention to detail
- Exercise sound and balanced judgment in ensuring that written procedures are followed and in evaluating quality systems, processes, procedures, plans and protocols for compliance
- Must have the ability to work within strict deadlines and under pressure while maintaining a professional demeanor
- Proven experience in relevant roles, particularly as Qualified Person in Switzerland
- Thorough knowledge of methodologies of quality assurance and standards
- Excellent understanding of data analysis/statistical methods
- Fluent in English and German, both oral and written. Italian/French is a plus

### **Place of work**

Grabenstrasse 11, 8952 Schlieren

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:

- High pace start-up environment
- Flexible working hours in arrangement with the Direct Supervisor
- Competitive benefit package
- A dynamic team
- 5 weeks holidays

### **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 Simona Lieber.

HC Solutions AG | Zollikerstrasse 153 | 8008 Zürich | 044 915 12 12 | [www.hcsolutions.ch](http://www.hcsolutions.ch)