CUTISS AG is a biotech spin-off company of the University of Zurich (UZH) that was awarded the winner of the Top100 Startups 2020 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

Quality Assurance Specialist (f/m/d) 80-100%

who can support the development of next-generation skin grafts and start **as soon as possible or as agreed**.

Your main duties
Support of Quality assurance, Quality Systems, Quality Compliance in the production, revision and management of project-specific documentation, such as:

- Writing and reviewing QMS documentation (QMS processes)
- Standard Operating Procedures (SOP's)
- Working Instructions (WI) and related documents (e.g. forms, templates, annexes)
- Incident management, change controls, deviations, CAPAs, OOS,
- Record and perform trainings
- Risk analysis
- Documentation for the clean room certification package (Swissmedic, EMA and FDA)
- Product review
- Development and maintenance of the local site procedures and risk assessments
- Corrective actions/preventive actions
- Follow-up on contractual documents with suppliers
- Supplier qualification
- Internal audits
- Purchasing
- Management of project specific raw materials and consumables
- Continuous education

Your background
You hold a B.Sc. or M.Sc. health sciences, pharmacy, biotechnology or related and have 2-3 years of experience within the Quality department of a GMP manufacturing company, preferably in the pharmaceutical or biotech industry.

Required Skills and Experience:
- Must have work permit in Switzerland
- Excellent knowledge of quality assurance: quality systems and compliance
- Excellent knowledge in handling of documentation, change control, deviations, CAPAS
- Excellent knowledge of GMP operations, ideally in manufacturing of biologics.
- Experienced in risk analysis and writing of SOPs

- Demonstrate interpersonal, oral and written communication, and organizational skills
- Attention to detail with excellent organizational and record keeping
- Excellent interpersonal skills
- Fluent in English both oral and written

Desired Skills and Experience

- Demonstrate ability to work independently
- Self-reliant in determining priorities
- Goal oriented
- Accurate and precise
- Quality auditing expertise
- Good understanding of pharmaceutical industry trends and practices.
- Good working knowledge of EU and U.S GMP regulations, as well as pharmaceutical industry quality systems.
- Good computer skills e.g. Microsoft Office, Excel, Sharepoint

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
- 5 weeks of holidays

Are you curious to find out more?

If you are interested in applying for this position, you may send your complete application, which should include the following documents:

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

by using the following link:

Apply Online

For further information, 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