

Job description for Production/QA-QC technician



Swiss Bioscience GmbH is a rapidly developing GMP manufacturing biotechnology company focusing on the production of human mesenchymal stem cells and their banking, located in the Zurich Area, Switzerland.

As a support, we are seeking a **Production/QA-QC technician (M/F/D, 100%)** to join our collaborative culture and our growing team.

His/her main tasks will include:

- Ensure compliance of QC Laboratory and support QA Compliance activities (e.g., environmental monitoring, equipment, and utility qualification, SOPs, cleaning validation, validation protocols/reports creation and review),
- Verify GMP compliance within internal facilities, utilities, systems, equipment,
- Manage, create, and review change controls, deviations, and CAPAs related to the internal Bio-pharmaceutical operations facilities (not project specific),
- Perform investigations and risk assessments to support deviations and change controls,
- Manage, create, and review qualification & validation documents of GMP equipment (facilities and utilities),
- Write, review, and manage internal quality system SOPs and other GMP regulatory-related documentation,
- Promptly report critical self-inspection findings to the Responsible Person and management,
- Support the preparation and conduct of Regulatory Authority Inspections, external and internal GMP audits, and internal self-inspection programs,
- Monitor changes in quality regulations and initiate required activities to maintain compliance with the quality system,
- Promote and participate actively in continuous quality improvements program,
- Maintenance of aseptic work environment and support regular maintenance of laboratory equipment,
- Orders, distribution, and management of raw materials for GMP production,
- Preparation and cryopreserving of stem cell products according to defined protocols,
- Conducting necessary cleaning activities,
- Provide the highest quality analytical support for manufacturing while ensuring compliance with protocols, cGMP, and safety regulations,
- Review and approve or rejects, as seen fit, starting materials, packaging materials, intermediate, bulk, and finished products,
- Approve specifications sampling instructions, test methods, and other quality control procedures,
- Establishes a system to release or reject starting materials, raw materials, intermediates, packaging, and labeling materials,
- Ensure that all necessary testing is conducted, and the associated records evaluated,
- inspection, investigation, and taking of samples to monitor factors that may affect product quality.
- Promote high standards of good laboratory practices as well as good manufacturing practices

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The candidate profile should include:

- BSc/MSc in the following field, cell biology, microbiology, chemistry, and Pharmacy, or Education as a laboratory technician,
- Basic knowledge of microbiology,
- Proven aseptic work experience,
- Previous experience with adherent cells cultures in a highly regulated industry is desired,
- Hands-on experience with an automated microbial detection system and flow cytometry will be a plus,
- Very Good MS Office and documentation skills,
- Excellent written and verbal communication in English, as well as German, will be a strong asset,
- Resolute, flexible, and resilient team player with the ability to work under pressure and within a challenging environment,
- Careful and accurate working style, quality awareness; with a dedication to high quality and diligence paired with organizational skills

If you are an enthusiastic collaborator with high diligence, excellent communication, and good organization skills; you are solution-oriented and autonomous, and you possess an initiative-taking working style, apply for this position. Please, send your complete application (CV, short cover letter, references, and certificates/diplomas) to the following email address: info@swissbioscience.ch and zeinaldeen.anas@swissbioscience.ch