

# Associate Quality Control Microbiology

## Overview

Biogen is building a new, Next-Generation Biologics Manufacturing Facility in Luterbach (Canton Solothurn) with high throughput production capacity. Rapid microbiological methodologies, such as PTS and Growth Direct in combination with highly efficient testing strategy will be instrumental in reducing the time required onsite to complete microbiological analysis for in-process and Drug Substance testing. The facility will utilize new technologies pioneered by our experts in technical development and employ an innovative, world-class engineering design to deliver substantially increased productivity. To help us setting-up this project we are looking for an Associate Quality Control Microbiology.

## Job Purpose and Responsibilities

The Associate Quality Control Microbiology will execute all of the Microbiology-related testing activities during preparing the new Microbiology lab and Work-in Progress (WIP) labs for routine operations and support the execution of the analytical capability strategy, which includes:

- Support acquisition of the analytical instruments in the Microbiology lab and Work-in Progress (WIP) labs
- Support generation of equipment qualification and method validation documents
- Perform qualification of the analytical instruments according cGMP requirements
- Perform validation of traditional microbiological methods as well as automated and rapid state-of-the art methods, such as microbiological identification (PRC-based method), Bacterial Endotoxins Test (kinetic-turbidimetric and kinetic-chromogenic), detection of microorganisms (BacT/Alert) and microbial enumeration test
- Perform routine analysis of microbiological samples as well as Total Organic Carbon and Conductivity
- Provide support that the instrumentation in the WIP labs are prepared for each corresponding unit operation to be performed in manufacturing
- Support day to day operations within the Central and WIP labs
- Support training of the On-The Floor (OTF) Quality staff members that will perform routine test execution in the WIP labs
- Support trouble shooting and root cause analysis in order to prevent reoccurrence
- Support all start-up activities for the new lab, e.g. definition and implementation of workflows and issuing standard operation procedures
- Support the facility certification with respect to the environmental monitoring (EM), utility monitoring (UM) and compressed gas distribution validation.
- Author, review and approve complex GMP documentation (Plans, protocols, procedures, specifications, CAPAs, deviations, etc.) according cGMP and regulatory requirements.

## Qualifications/Skills

- Apprenticeship degree (Laborant EFZ) and/or Bachelor degree in Biology or related Life Science or Technical discipline
- Minimum of 4 years of experience in regulated (bio)pharmaceutical quality control environments
- Strong experience within Biological Quality Control, Microbiology and analytical function
- Profound knowledge with the Quality systems and business processes associated with Microbiology testing (drug substance) and good understanding of modern analytical microbiological modalities
- Must have strong technical skills and be proficient with typical productivity software (Word, Excel, Power Point, Visio, etc.)
- Strong problem solving skills, ability to multi-task operations, working autonomously and cross-functional
- Demonstrated ability to work autonomously
- Very good command of German and English

## We offer

- The opportunity to join a world-class company and participate in building up a next generation biopharmaceutical facility
- A permanent contract with superior compensation, sustainable learning and great development opportunities in a fast paced multicultural environment

## About Biogen

Biogen (NASDAQ: BIIB) is a biotechnology leader that discovers, develops and delivers innovative therapies to improve the lives of patients. As a company, Biogen recognizes that cutting-edge science and medicines can change the course of devastating diseases.

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Please note that only online-applications will be accepted. Biogen will not retain paper application submitted.

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