NOVARTIS

Senior QC Specialist

Job ID
REQ-10058702

8月 11, 2025

Switzerland

摘要

BDSS QC Bioanalytics is responsible for bioanalytical testing of Biopharmaceuticals for late-phase development projects and commercial products. Applied analytical techniques are mainly cell-based potency assays for bioactivity determination and ELISA /qPCR for the determination of process-related impurities (e.g. host-cell proteins (HCP), residual Protein A, residual DNA).

About the Role

We are looking for a motivated Senior QC Specialist (Lab Head) to supervise the performance of bioanalytical experiments (i.e. cell-based bioassays, ELISA and qPCR) for quality control (release, stability, and in-process control (IPC) testing) of biotech drug substances (DS) and drug products (DP) in collaboration with members of the own and cross-functional teams in a cGMP environment. Analytical method validation and transfers will be part of the position.

Major Accountabilities of the role as Senior QC Specialist (Lab Head) include:

- Supervision of routine QC testing activities, including line unit approval of analytical records and raw data, investigations of deviations, OOE/OOS, and analytical changes
- Full compliance with regulatory and cGMP guidelines within the field of responsibility
- Support of technical project teams as analytical expert
- Performance of method validations (full ICH validation) and transfers, author of validation- and transfer protocols / -reports
- Trending and evaluation of analytical data
- Method lifecycle management for commercial products including method updates, post-approval changes, or troubleshooting
- Management and coordination of internal and external customer interfaces (e.g. testing/resource requirements, setup of service level agreements)
- Support in health authority inspections as subject matter expert (e.g. routine GMP inspections, pre-approval inspections)
- System owner of laboratory equipment and computerized systems including initial qualification and periodic maintenance/functional testing

Requirements:

- PhD or equivalent education in Biology, Biochemistry, Chemistry, or related discipline
- Several years of experience in analytics / quality control in a leadership role. Experience with Biopharmaceuticals desirable
- Thorough knowledge of cGMP requirements
- Results oriented, team player and able to work with all levels of the organization
- Strong leadership and problem solving skills. Able to identify issues and develop business-friendly solutions in line with the overall compliance
- Good knowledge of instrument qualification, quality metrics
- Experience in audits or inspections from health authorities
- Very good communication and presentation skills
- Fluent English required (oral & written); good skills in German and/or French as local site language (oral) desired

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部门
Operations

Business Unit
Innovative Medicines

地点
Switzerland

站点
Basel (City)

Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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