NOVARTIS

Project QA Expert

Job ID
REQ-10081346
Jul 13, 2026
LOC_CN

About the Role

Project Quality Oversight

- Act as the QA expert and key quality contact for the project, providing quality support from concept design through qualification and handover to operations.
- Ensure appropriate application of GMP, data integrity and contamination control principles across all project phases.

Design & Engineering Phase

- Review and challenge URS, design concepts, layouts and technical specifications for facility, equipment and utilities.
- Ensure that flows of personnel, materials, waste, and equipment support contamination control, segregation and cross-contamination prevention.
- Contribute to contamination control strategy (CCS) development for the new sterile facility.

Construction, Commissioning & Vendor Management

- Provide QA oversight during construction, installation and commissioning activities to ensure alignment with approved design and GMP requirements.
- Participate in or review FAT/SAT activities for critical equipment and systems (e.g. filling lines, isolators/RABS, autoclaves, lyophilizers, HVAC, water systems, clean utilities).
- Review quality aspects of vendor documentation, and support supplier qualification where relevant.

Qualification & Validation

- Review and approve qualification/validation master plans related to the sterile project (facility, HVAC, utilities, equipment, cleaning, sterilization, aseptic processes).Review and approve IQ/OQ/PQ protocols and reports for critical equipment and systems to ensure compliance with internal standards and regulatory expectations.Ensure data integrity controls are built into computerized systems and automation relevant to the sterile area.

Quality Systems & Documentation

- Ensure appropriate change control, deviation management, CAPA and risk management processes are applied within the project.
- Support creation and review of SOPs, master batch records, forms, and other GMP documents necessary for sterile operations.
- Ensure project documentation is complete, traceable, and inspection-ready.

GMP Readiness & Inspection Preparation

- Support GMP readiness assessments and self inspections for the new sterile facility and associated systems.
- Prepare and support the site for regulatory inspections and internal audits related to the sterile project, including participation in facility tours, document review and responses.
- Coordinate with Operations QA to ensure a smooth transition from project to routine quality oversight.

Cross Functional Collaboration

- Work closely with Engineering, Project Management, Validation, Production, QC, HSE, Procurement, and external contractors/vendors to ensure quality requirements are understood and implemented.
- Share relevant GMP, aseptic processing requirements and project quality processes with project team members as needed.

Background:

- University degree in Pharmacy, Pharmaceutical Science, Biotechnology, Chemistry, Engineering or related scientific/technical discipline.
- Strong written and verbal communication skills in Chinese and English; able to read, interpret, and apply English regulations and guidelines. Experience in supporting inspections/audits in English is a plus.
- Minimum 5 years of experience in the pharmaceutical industry in Quality-related roles (QA/QC/Validation/Production), with a3 years of experience in sterile/aseptic manufacturing is preferable.Proven experience playing a leading or core role in projects such as new/modified sterile production lines, new product introduction, technology transfer, or large-scale validation programs is preferable.Experience in multinational pharmaceutical companies or at sites that have undergone inspections by multiple health authorities (e.g. NMPA / FDA / EMA / PIC/S) is strongly preferred.Experience as a core contributor in cross-functional projects is an advantage.
- Strong professional judgment and problem-solving skills, with the ability to provide sound quality input in complex situations.Good interpersonal and cross-functional communication skills, with the ability to work effectively with different stakeholders.
- Solid project management skills; able to manage multiple priorities and deliver under time pressure.
- Strong sense of accountability, attention to detail, and continuous improvement mindset.

Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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DIV_TO
Business Unit
Quality
Location
LOC_CN
Site
Changping County (Beijing)
Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work

No

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