NOVARTIS

Project QA Lead

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REQ-10068777
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Китай

Сводка

The Project QA lead is responsible for providing end-to-end Quality Assurance oversight for the design, construction, qualification, and start-up of all new strategic projects in site.

This role ensures that the new building, utilities, equipment and processes are designed and implemented in full compliance with Novartis global QMS, CGMP and local regulations, and that the facility is inspection-ready at start-up.

About the Role

Major accountabilities:

- Project Quality Oversight：Act as the QA lead and key quality contact (QA SPOC) for the project, 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:Lead or 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. Provide training and coaching on relevant GMP, aseptic processing requirements and project quality processes to project team members.

Key performance indicators:

- 1.Project Delivery

1.1 On-time Project Completion Rate

1.2 Right first time for Quality Deliverables

1.3 Validation / NPI Success Rate

- 2. Quality & Compliance Performance

2.1 Major Deviation Rate

2.2 On time Closure of Deviations & CAPA

2.3 Change Control Quality & Timeliness

2.4 Audit & Inspection Performance

2.5 Media Fill & Environmental Control Compliance

- 3. People & Capability

Training & Capability Development Achievement Rate

- 4. Collaboration & Business Impact

4.1 Internal Customer Satisfaction

4.2 Continuous Improvement & Cost/Time Impact

Minimum Requirements:

- Minimum 5 years of experience in the pharmaceutical industry in Quality-related roles (QA/QC/Validation/Production), with at least 3 years of experience in sterile/aseptic manufacturing.
- 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.
- Prior people management and/or project leadership experience (e.g. leading project teams or line management of 2+ direct reports) is an advantage.

Skills:

- Strong understanding of China GMP and Annex 1 (sterile medicinal products) requirements; familiarity with EU GMP, PIC/S, and ICH Q-series guidelines.
- Solid knowledge of sterile/aseptic manufacturing processes, cleanroom design and operation, environmental monitoring, sterilization and sterile filtration, media fill, water systems, and HVAC systems from a quality perspective.
- Familiarity with the validation lifecycle concept, including process validation, cleaning validation, sterilization validation, and computerised system validation.
- Proficiency in deviation investigation, root cause analysis, CAPA management, and quality risk management tools (e.g. FMEA, 5 Whys, fishbone diagrams).
- 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.

Languages :

- English (fluent)
- Chinese (fluent)

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Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
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Дивизион
Operations
Business Unit
Quality
Место
Китай
Сайт
Changping County (Beijing)
Company / Legal Entity
CN06 (FCRS = CN006) Beijing Novartis Pharma Co., Ltd
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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