NOVARTIS

Validation Lead 工艺验证经理

Job ID
REQ-10072787
Feb 25, 2026
LOC_CN

About the Role

Major accountabilities:

Stewardship

- Maintain the oversight and knowledge for entire manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as SPOC.
- Create and maintain a product specific Quality Risk Analysis (QRAs).
- Monitor all critical variables and key variables as appropriate using statistical analysis and conducting regular product specific data trending.
- Review APQR and decide on state of control.
- Lead / support root cause investigation of process failures, initiate and lead product improvement projects, involving cross functionalteams.
- Ensure inspection readiness for all process related aspects of assigned products.
- Present product performance and status of product improvement projects in site Manufacturing Robustness Review Board(MRRB).
- Owns the knowledge of specific pharmaceutical manufacturing process technologies, locally, including any pilot scale, scale up or down, and Design of Experiments (DoE).
- Harmonize and optimize technical processes across the site.
- Maintaining the process control strategy.
- Define and implement validation strategy (process, cleaning, ongoing verification) and defend to authorities.
- Overall responsibility for establishment, prioritization, execution and tracking of Validation Master Plan for process, cleaning, packaging validation and ongoing process verification (OPV), ongoing cleaning verification.

Qualification & Validation

- Maintain the oversight and knowledge for entire manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as SPOC.
- Define and implement validation strategy (process, cleaning, ongoing verification) and defend to authorities.
- Overall responsibility for establishment, prioritization, execution and tracking of Validation Master Plan for process, cleaning,packaging validation and ongoing process verification (OPV), ongoing cleaning verification.
- Maintain all validation activities in an inspection ready status. Product is maintained in constant state of validation
- Author complex validation protocols.• Establish local procedures & templates for respective validation documentation.Ensure that all Site validation activities are performed and are in line with the current Novartis requirements and cGMP.
- Handling any deviations associated to these activities including oversight of pre-validation and validation resulting fromtechnical changes.
- Provide technical expertise (and may facilitate) pre-validation risk assessments using risk management tools.
- Support Site MS&T Head in ensuring that responsible departments execute and maintain the VMP activities.
- Prepare Qualification documents of equipment with leverage to Global standard Qualification approach/practice.Engage cross functions including 3rd party to ensure that all PQ activities are performed and are in line with the currentNovartis requirements and cGMP, handling any deviations associated
- Ensure PQ activities and Documents along within project schedule and budget
- Facilitate execution of integrated line PQ, provide insight to finalize process design.
- Execute smoke study, VHP PQ and all PQ activities allocated

Key performance indicators:

- Cost, C-Sat and productivity targets
- Achievement of project plans & milestones
- Internal customer satisfaction with quality of services provided
- Validation Master Plan (VMP) completed and up to date.
- Product maintained in a constant state of validation.
- Transfers/launches implemented on schedule and on targeted Quaility.
- Validation approach meets Novartis QM requirements, health authority and industry standards
- OOS, OOE, Deviation, CAPA, compliant, recall – process-related.• Completeness of Regulatory CMC dossier.
- All related SOPs are updated on time.
- Success rate of Health Authorities' inspections.

Minimum Requirements:
Work Experience:

- Cross-functional experience
- Functional Breadth
- In-depth Technical Expertise
- Operations Management and Execution
- Working knowledge of applied statistics, quality systems and regulatory requirements across multiple health authorities.
- Proven project management experience in a cross-functional environment
- Proven process understanding (Pharma, GMP, Regulatory aspects).
- Willing to work in workshop for validation activities in related

Languages:

- English.
- Chinese

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.
Read our handbook (PDF 30 MB)

Division
DIV_TO
Business Unit
Production / Manufacturing
Location
LOC_CN
Site
Haiyan (Zhejiang Province)
Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.
Functional Area
FCT_TO
Job Type
Full time
Employment Type
Regular

Shift Work
No
Apply to Job

Job ID
REQ-10072787

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