NOVARTIS

Validation Lead 工艺验证经理

Job ID
REQ-10072787
фев 25, 2026
Китай

Сводка

Technical Transfer Lead
Responsible for technology transfer activities at site level (within, inbound and outbound), including any scale-up or other process adaptations. Leads technical transfer project team at site and liaises efficiently with involved functions (e.g. Technical Development, Supply Chain, Production Unit, Quality Control, HSE, other sites.).
Product Steward
Owns the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving.Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s). Provides second line technical/scientific process support.
Technical Steward
Provides to the Site the specialist knowledge and expertise, as Subject Matter Expert (SME), of specific pharmaceutical processes or process technologies (e.g. Technical Steward for galenics, for film coating, biologics – upstream or downstream, etc.).Oversees processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.
Validation Lead
Responsible for developing, implementing and managing the site process validation, primary packaging validation, cleaning validation and revalidation strategies to meet cGMP and quality requirements on time and on budget to ensure that programs are compliant with Regulatory Authorities' expectations and related SOPs.
Senior Scientist MS&T
Design, plan, perform, interpret and report scientific experiments under the lead of the department head to contribute to overall MS&T strategies and objectives.

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

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)

Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Китай
Сайт
Haiyan (Zhejiang Province)
Company / Legal Entity
CN27 (FCRS = CN027) Novartis Pharmaceutical Technology Zhejiang Co., Ltd.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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.

Job ID
REQ-10072787

Validation Lead 工艺验证经理

Apply to Job
Job ID
REQ-10072787

Validation Lead 工艺验证经理

Apply to Job

Source URL: *https://novartis.ru/ru-ru/careers/career-search/job/details/req-10072787-validation-lead-gongyiyanzhengjingli*

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://www.novartis.com/sites/novartis_com/files/novartis-life-handbook.pdf
3. mailto:diversityandincl.china@novartis.com
4. https://platform.moseeker.com/m/customize/page/novartis?job_number=REQ-10072787
5. https://platform.moseeker.com/m/customize/page/novartis?job_number=REQ-10072787