

Validation Lead

Job ID
REQ-10083757
июл 27, 2026
Сингапур
Available in: English

Сводка

#LI-Hybrid
Location: Tuas South Avenue, Singapore

This role will be responsible for executing and managing process, shipping, and cleaning validation activities (and ongoing/continuous in the aforementioned areas) and associated change management activities to meet cGMP requirements on time without compromise to quality ensuring site validation programs are compliant with global regulatory expectations.

About the Role

Major accountabilities:

- Support site validation planning by writing and maintaining master plans for process, cleaning, shipping processes and ongoing verification activities (as applicable).
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing process verification (OPV). Ensure that appropriate variables are identified for on-going monitoring as a contributor to quality risk management activities.
- Author and review process, process, shipping and or cleaning validation protocols & reports, and subsequent ongoing / continuous verification protocols & reports.
- Support execution of validation activities at the shop floor and for KPI reporting.
- Reviews Master Batch Records and associated change controls. Confirm revalidation need based on technical changes.
- Maintain all activities and projects under own responsibility in an inspection ready status.
- Provides technical expertise (and may facilitate) pre-validation risk assessments using risk management tools. Work collaboratively and cross functionally to help ensure that process risks are analyzed, appropriately controlled and appropriately documented.
- Ensure that all Site validation activities are performed and are in line with the current Novartis requirements and cGMP, manage deviations associated with process validation and makes recommendations for deviation resolution as well as prevention of reoccurrence.
- Work in close collaboration with development organization (or sending site) for technical transfers and new product launches to ensure that knowledge is transferred, control strategies are appropriate, risks are analyzed and controlled and to ensure that commercial processes are validation ready.
- Participate in pre-validation activities and risk assessments to ensure the success of commercial process validation.

Essential requirements:

- University degree (BSc, MSc) in Chemistry, Biologics, Pharma / Chemical Engineering or equivalent.
- Strong working knowledge of quality systems and regulatory requirements across multiple health authorities.
- 2-4 years of experience in biopharmaceutical environment within a manufacturing site.
- Experience in executing process and/or cleaning validation and in reviewing and writing technical reports.
- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions).

Commitment to Diversity and Inclusion

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

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
Сингапур
Сайт
Tuas South Avenue
Company / Legal Entity
SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work

No

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