Validation Expert

Job ID
REQ-10067568

11月 25, 2025

Italy

摘要

The Validation Expert is responsible for executing and managing process, primary packaging and cleaning validation activities and change
management activities to meet cGMP requirements on time and quality to ensure that site validation programs are compliant with global regulatory exceptions.

About the Role

Major accountabilities:

- Support site validation planning by writing and maintaining master plans for processes, cleaning, packaging.
- Support process validation lifecycle activities by ensuring a state of control is maintained through ongoing.
- Author and review process, packaging or cleaning validation protocols & reports, ongoing

process and cleaning verification protocols & reports.
- Support execution of validation activities at the shop floor.
- Reviews Master Batch Records and associated change controls. Confirm revalidation need based on technical changes.
- 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 newproduct 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.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).

Essential requirements:

- Scientific Degree (CTF/Pharmacy/Biotechnology/Chemical Engineering or related field).
- Previous experience in a similar role within a sterile GMP environment.
- Knowledge of Quality and IT tools.
- Fluent in Italian and English.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we ' ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

部门

Operations

Business Unit
Production / Manufacturing

地点
Italy

站点
Ivrea

Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Alternative Location 1
Saluggia, Italy

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

Apply to Job

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

Job ID
REQ-10067568

Validation Expert

Apply to Job

Source URL:
https://www.novartis.com.cn/careers/career-search/job/details/req-10067568-validation-expert

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ivrea/Validation-ExpertREQ-10067568-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Ivrea/Validation-ExpertREQ-10067568-1