NOVARTIS

Validation Expert

Job ID
REQ-10028115
Nov 07, 2024
Spain

About the Role

Major accountabilities:

- Support site validation planning by writing and maintaining master plans for processes, cleaning, packaging processes and ongoing verification for processes and cleaning.
- 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, packaging or cleaning validation protocols & reports, ongoing process and cleaning verification protocols & reports.
- Support execution of validation activities at the shop floor. Support validation lead 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.

Minimum Requirements:
Work Experience:

- Education: BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology.
- 2-3 years of experience in manufacturing/ manufacturing science and technology/technical development/quality.
- Thorough understanding of manufacturing processes and related process equipment.
- Strong working knowledge of quality systems and regulatory requirements across multiple health authorities.
- Experience in executing process validation and reviewing and writing technical reports.
- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions).
- Fundamental understanding of standard pharmaceutical analytical testing.
- Fluent in English and Spanish, written and spoken.

Why Novartis? Our purpose is to reimagine medicine to improve and extend people’s lives and our vision is to

become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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

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.

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

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

Division
Operations
Business Unit
Innovative Medicines
Location
Spain
Site
Zaragoza
Company / Legal Entity
ES45 (FCRS = ES045) AAA Ibérica S.L.U.
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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REQ-10028115

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