Process & Validation Expert

Job ID
REQ-10030822
Nov 22, 2024
USA

About the Role

Key responsibilities:

Stewardship:

- Support Product Steward in maintaining the process control strategy. Translate applicable process parameters and the process control strategy into a focused validation plan for process validation.
- Provide technical expertise and facilitate establishment of Quality Risk Assessment (as needed).

Validation:

- 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 Product Stewart for KPI reporting.
- Review Master Batch Records and associated change controls. Confirm revalidation need based on technical changes
- Provide 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.

Launch & Transfer:

- 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:

- BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology and 2 years of

experience in manufacturing, manufacturing science and technology, technical development or quality; including prior experience in executing process validation.
- Thorough understanding of manufacturing processes and related process equipment. Fundamental understanding of standard pharmaceutical analytical testing.
- Strong working knowledge of quality systems and regulatory requirements across multiple health authorities.
- Expert in reviewing and writing technical reports.
- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions).

#LI-Onsite

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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.

The pay range for this position at commencement of employment is expected to be between $97,600 and $146,400 per year; however, while salary ranges are effective from 1/1/24 through 12/31/24 fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

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Business Unit
Innovative Medicines
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USA
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Company / Legal Entity
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Technical Operations
Job Type
Full time
Employment Type
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Shift Work
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