Validation Expert (f/m/d)

Job ID
REQ-10022745
Sep 27, 2024
Switzerland

Summary

As a Validation Expert you will be executing 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 expectations.

About the Role

Key Responsibilities:

- 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).
- Support site validation planning by writing and maintaining master plans for processes, cleaning, packaging processes and ongoing verification for processes and cleaning.
- Author and review process, packaging or cleaning validation protocols & reports, ongoing process and cleaning verification protocols & reports.
- 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.
- Ensure that all production documents are systematically up to date and that the production documents necessary for the validation / revalidation of processes are available.
- Review Master Batch Records and associated change controls.
- Confirm revalidation need based on technical changes.
- 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.

We are offering a temporary position limited to max. 2 years.

Minimum Requirements:

- Experience in manufacturing/ manufacturing science and technology/technical development/quality.
- Advanced English is a must. German language skills are desirable.
- BSc. in Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology.
- 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.

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change patients' lives. Ready to create a brighter future together?
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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 all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to diversity.inclusion_ch@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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Business Unit
Innovative Medicines
Location
Switzerland
Site
Stein Aargau

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Functional Area
Technical Operations
Job Type
Full time
Employment Type
Temporary (Fixed Term)
Shift Work
No
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