Validation Expert

Job ID
REQ-10010209
Juil 22, 2024
Turquie

Résumé

Manufacturing Science and Technology Validation Expert in Cell & Gene represents a unique opportunity to learn and be part of a growing business that has a tremendous impact on patient life.

In this role you will execute and manage 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

Location: Istanbul Kurtköy, Turkey; Warsaw, Poland; Mengeš, Slovenia #Hybrid

Novartis is unable to offer relocation support for this role: please only apply if this location is accesible for you.

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 (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, 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.

Essential Requirements:

- University degree in Chemistry, Pharmacy, Chemical Engineering, Pharmaceutical Technology or equivalent
- 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; Expert in reviewing and writing technical reports
- Fluent in English, German is a plus

Desirable Requirements:

- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions)
- Fundamental understanding of standard pharmaceutical analytical testing

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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Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.
Hiring decisions are only based on the qualification for the position, regardless of gender, ethnicity, religion, sexual orientation, age and disability.

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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

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Company / Legal Entity
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Alternative Location 1
Mengeš, République de Slovénie
Alternative Location 2
Warsaw, Pologne
Functional Area
Opérations techniques
Job Type
Full time
Employment Type
Regular
Shift Work
No
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