

Validation Expert

Job ID
REQ-10010209

7月 22, 2024

T ü rkiye

摘要

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 accessible 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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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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部门
Operations

Business Unit
Innovative Medicines

地点
T ü rkiye

站点
istanbul Kurtköy

Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.

Alternative Location 1
Mengeš, Slovenia

Alternative Location 2
Warsaw, Poland

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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