

Validation lead

Job ID
REQ-10007048
07 June 2024
Turkey

Summary

In this role you will be executing and managing process validation activities for aseptic products (fill&finish) and support preparation of various technical documentation packages (protocols, reports, technical assessments) in highest quality and given timelines.

About the Role

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

Key Responsibilities:

- Support 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).
- 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.
- Support site validation planning by writing and maintaining plans for processes, cleaning, packaging processes and ongoing verification for processes and cleaning (as applicable).
- Author and review process validation protocols & reports, ongoing process protocols & reports.
- 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.

Essential Requirements:

- University degree in Chemistry, Pharmacy, Biotechnology, Pharmaceutical Technology or equivalent
- 5 years of experience with validations in the aseptics manufacturing in the pharmaceutical industry
- Fluent in English, German is a plus
- Great communication skills as well as experience in writing technical reports
- Proven understanding of quality systems and regulatory requirements across multiple health authorities.
- Collaborative mindset and problem solving skills with a high degree of flexibility

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Division

Operations

Business Unit

Innovative Medicines

Location

Turkey

Site

İstanbul 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

Regulär

Shift Work

No

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