NOVARTIS

# Manager MS&T (Validation expert)

Job ID
REQ-10072815
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Индия

### Сводка

The Purpose of the Validation expert role is to support Site Manufacturing Science & Technology (MS&T) by providing expertise in process and cleaning validation for aseptic Drug product manufacturing. The role ensures that validation strategies and lifecycle activities are scientifically sound, compliant with cGMP, regulatory authority expectations and effectively integrated into technology transfer, PPQ Studies. Work closely with Site MS&T team, Quality, and Technical Operations for on time deliverable of activities.

### About the Role

**Key Responsibilities:**

- Responsible and supporting Drug product Aseptic validation activities i.e; filling & compounding processes, primary packaging activities (assembly & packaging) and cleaning validation.
- Hold time verifications, general verification studies.
- Demonstrate a strong understanding of process and cleaning validation principles, as well as technology transfer concepts.
- Prepare and maintain validation documentation, including process validation protocols and reports, risk assessments, and cleaning validation protocols and reports, in alignment with the Site MS&T team.
- Support revalidation strategies to meet cGMP and quality requirements within agreed timelines and budgets, ensuring compliance with regulatory authority expectations and applicable SOPs.
- Support the establishment of local procedures & templates for validation activities and contribute to continuous improvements and optimization of validation concepts/strategies etc.
- Provide senior level expertise on complex process validation topics.
- Support in health authority, internal, and customer inspections.
- Ensure all site validation activities comply with Novartis and GMP requirements and ensure timely availability of technical documentation in accordance with Novartis guidelines.
- Good understanding of quality management system (QMS) actions such as Change Controls, CAPA, effectiveness checks (EC), risk assessments, and OOXs management.

**Essential Requirements:**

- Bachelor's/Master's degree in Pharmacy, Biotechnology, Chemistry or equivalent science streams. Desirable MSc/MS. or equivalent experience.
- Strong understanding of Aseptic drug product filling and/or assembly and packaging operations, including associated validation activities.
- Minimum 10 years of experience in Aseptic Manufacturing science and technology (MS&T) with strong exposure to Process & Cleaning Validations/technology transfer /Site transfers/ technical development.
- Should be familiar with regulatory guidance on Validation, product filing and post approval changes (e.g; US FDA, EMA, ICH Guidelines).
- Proven project management experience in a cross-functional environment (e.g. multi-site, technical development, other functions).
- Good communication, presentation and Interpersonal skills.
- Proficient and excellent in English (oral and written) is a requirement.
- Expertise in document management system and writing technical reports·
- Experience in Health authority audits and Self inspections.

**Desirable Requirements:**

- Quality / Accuracy / Right First Time
- Accuracy and compliance of Validation documentation
- Adherence to regulatory requirements during audits and inspections
- Effectiveness of standardized documentation processes

**Skills:**

- Aseptic Drug Product Manufacturing science & technology (MS&T)
- Process and Cleaning Validation.
- Technology transfer (R&D to Site, Site to Site)
- Scale up (Pilot and Commercial)
- Manufacturing of Aseptic Drug Products (Production)
- Knowledge Of GMP (Good Manufacturing Practices)
- Drug Product Aseptic Manufacturing Technologies.
- Operational Excellence & Continuous improvement Principles/strategy
- Effective communicator
- Effective stakeholder engagement
- Project Management
- Good Documentation Practice
- Report writing.

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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.
Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

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Дивизион
Operations
Business Unit
Production / Manufacturing
Место
Индия
Сайт
Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No

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 individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@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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