

# MS&T Technical Manager

Job ID REQ-10060492

8月 28, 2025

India

## 摘要

Lead and manage all Manufacturing Science & Technology activities for the assigned Contract Manufacturing Organizations (CMOs). This includes providing product stewardship by ensuring the performance of all NVS products are monitored and maintained in a validated state, supporting root cause investigations by providing MS&T intelligence to deviations, technical complaints, OOS & CAPAs, identifying and executing continuous improvement opportunities.

Acts as the ESO Project Team Lead (PTL) for new product launch at CMO's / technology transfer at CMO's. Assembles and leads a cross-functional team to ensure the successful transfers of manufacturing at CMOs. Ensures appropriate project management to achieve milestones in time, with required quality and in budget by leading the respective technical sub-team and liaising efficiently with related functions.

Supports the MS&T organization by leading ESO-wide initiatives and/or work-streams and representing ESO MS&T in various global networks.

General
Job Title
Technical Manager MS&T
Department
External Supply Operations - Manufacturing Science and Technology (MS&T)
Reports to (Job Title)
Functional Lead MS&T - ESO
Key Responsibilities:
Lead and manage all Manufacturing Science & Technology activities for the assigned
Contract Manufacturing Organizations (CMOs). This includes providing product stewardship by en suring the performance of all NVS products are monitored and maintained in a validated state, supporting root cause investigations by providing MS&T intelligence to deviations, technical complaints, OOS & CAPAs, identifying and executing continuous improvement
opportunities.
Acts as the ESO Project Team Lead (PTL) for new product launch at CMO 's / technology transfer at CMO 's. Assembles and leads a cross-functional team to ensure the successful transfers of manufacturing at CMOs. Ensures appropriate project management to achieve milestones in time, with required quality and in budget by leading the respective technical sub-team and liaising efficiently with related functions.
Supports the MS&T organization by leading ESO-wide initiatives and/or work-streams and representing ESO MS&T in various global networks.
Major Accountabilities
Product Stewardship

About the Role

- As Product Steward, ensure that the products stay in a validated state and their technical performance/capability is monitored.
- Major accountabilities include:
  - Assessing impact of manufacturing changes.
  - Providing MS&T intelligence to deviations, investigations, OOE's and OOS's technical complaints.
  - Defining and tracking technical CAPAs resulting from APR/PQR assessments or manufacturing variances.
  - Providing MS&T intelligence to APR/PQR and delivering the performance capability results, interpretations and recommended CAPAs;
  - Identifying process optimization opportunities and executing them when approved;
- Identifying and leading product manufacturing remediations.
- Establishing and executing product revalidation strategies including approval of QRAs, validation protocols and reports.
- Establishing and executing continued process verification strategies and annual verification.
- Ensuring maintenance of knowledge for the manufacturing of NVS products.

#### Product Transfers and New Product Launch

- Leads a cross functional team for product transfers/launches to 3rd parties (process, technology, analytics, capacity, resources).
- Ensures appropriate project management to achieve milestones in time, with required quality and in budget by leading the respective technical sub-team and liaising efficiently with related functions.
- Provides technical expertise together with manufacturing experts.
- Supports CMO site selection and ensure right technical fit for transfer/launch
- Defines and monitors technical project scope, timing and progress in collaboration with Giving Site or TRD
- Writes Manufacturing Process Transfer Documents (protocol, report).
- Coordinates feasibility, regulatory and validation batches at site.
- Initiates monitoring and Continued Process Verification CPV phase.
- Ensures that all activities are performed to current standards (current Good Manufacturing Practices cGMP, Health Safety Environment HSE, Regulatory etc.).
- Supports continuous process and quality improvements.
- Supports QA to ensure inspection readiness (Pre Approval Inspection PAI).

### **Essential Requirements:**

- Technical transfer milestones achieved on time and in full, including schedule for registration and launches.
- Robust manufacturing process at CMO, delivering critical quality attributes.
- Analytical methods in place, meeting cGMP standards.
- No critical observations during internal and external GMP inspections and Pre-Approval Inspections (PAI).
- Adheres to project / Capital Approval Request CAR costs.
- Recognized as an excellent collaborator and partner by the CMOs, SRTs, QA and others partner functions (R&D)
- When acting as Product Steward, meet related KPIs:
- Product is maintained in constant state of validation.
- Product history is documented and available and current since transfer from development/transfer to CMO to date.
- Recurring Deviations.
- Continuously improving CpK process capability.
- · Degree of standardization of product process
- OoS, OoE Out of Specification, Out of Expectation.

<ul> <li>Customer Complaints.</li> <li>Recalls.</li> <li>Success rate of Health Authorities' inspections.</li> <li>Completeness of Reg CMC dossier</li> <li>Effective CAPA.</li> <li>Continuously improving Yield.</li> <li>Technical reports executed on time and with the right expectations.</li> </ul>
Job Dimensions
Number of associates:
None (may have direct reports depending on Division)
Financial responsibility:
(Budget, Cost, Sales, etc.)
mpact on the organization:
Strengthen product/process manufacturing performance, reducing product quality complaints.

Improve Supply Chain performance by increasing process robustness, minimizing recalls, rejected batches and write- offs.

#### High

Ensures that Novartis products manufactured at CMOs meet stay in a validated state, are trended a nd optimization potential are implemented.

Ensures Transfers and launches are executed according to plan

Contribute to ESO Manufacturing financial /business/quality goals.

Minimize rejected batches and write-offs.

Maximize Yield improvements.

Desirable Requirements:

#### Education:

- BSc / MSc. / BTech or MTech (Chemistry / Chemical Technology) or equivalent scientific degree.
- Highly desirable: MSc. or equivalent experience.

#### Language:

• Fluent in English

#### Experience:

- 10 yrs of experience in a pharmaceutical manufacturing-API/technical environment/Technology transfer and project management.
- Strong leadership skills with a minimum of 5 years managerial experience
- Demonstrated technical expertise in manufacturing science and drug development.
- Project management skills
- Significant knowledge of industry practices and regulations (e.g. GxP, ISO, ICH / VICH, etc.) across multiple health authorities (e.g. FDA, EMEA, Health Canada, etc.)
- Statistical knowledge required, Lean/Six Sigma Certification preferred
- Demonstrated leadership and accomplishments in a global/matrix environment in the pharmaceutical industry
- Strong project management, interpersonal, cross-cultural, communication, negotiation and problem-solving skills

**Novartis Competencies** 

Leadership Standards

**Fundamental** 

Intermediate
Advanced
Thought Leader
Sets Clear Direction & Aligns Team & Others Around Common Objectives
Energizes The Team
Display Passion For The 3Cs
Exercises Good Judgement & Drives Change For Competitive Advantage
Exercises Good Judgement & Drives Change For Competitive Advantage
Drives For Superior Results & Has Passion To Win
Builds The Talent Pipeline
Inspires Continuous Improvement & Breakthrough Thinking
Displays Analytical & Conceptual Thinking

Functional Competencies
Functional Competencies
Fundamental
Intermediate
Advanced
Thought Leader
Manufacturing process science
Manufacturing process technologies
Quality Compliance
Problem Resolution
Project Management
Operations

• Finance	
• IT/Automation	
• HSE	
Lominger Competencies	
Fundamental	
Intermediate	
Advanced	
Thought Leader	
Decision Quality	
Problem Solving	
Functional/Technical Skills	
Technical Learning	

Integrity and Trust
• Intellectual horsepower
• Planning
Drive for Results
Total Work Systems
Action Oriented
Process Management
Strategic Agility
Why Novartis: Our purpose is to reimagine medicine to improve and extend people 's lives and our vision is to become the most valued and trusted medicines company in the world. How can we

achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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.

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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: <a href="https://www.novartis.com/careers/benefits-rewards">https://www.novartis.com/careers/benefits-rewards</a>

部门 Operations

Business Unit Universal Hierarchy Node

地点 India

站点

Mumbai (Head 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

## Accessibility and accommodation

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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 <a href="mailto:diversityandincl.india@novartis.com">diversityandincl.india@novartis.com</a> and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.



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