Senior Technical Manager - API (DS)

Job ID
REQ-10030200
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India

Sommario

-Technical Transfer LeadResponsible for technology transfer activities at site level (within, inbound and outbound), including any scale-up or other process adaptations.Leads technical transfer project team at site and liaises efficiently with involved functions (e.g. Technical Development, Supply Chain, Production Unit, Quality Control, HSE, other sites.).Product StewardOwns the process knowledge of the product(s) assigned throughout the commercial lifecycle, maintains the oversight on process capability, through data trending and statistical analysis of critical variables, ensuring process(es) are robust, in continued state of validation and continuously improving.Ensures seamless flow of knowledge and information across functions, and with other Sites when applicable, with focus on the assigned product(s). Provides second line technical/scientific process support.Technical StewardProvides to the Site the specialist knowledge and expertise, as Subject Matter Expert (SME), of specific pharmaceutical processes or process technologies (e.g. Technical Steward for galenics, for film coating, biologics – upstream or downstream, etc.).Oversees processes and standards to maintain and improve existing and to implement new innovative manufacturing technologies.Validation LeadResponsible for developing, implementing and managing the site process validation, primary packaging validation, cleaning validation and revalidation strategies to meet cGMP and quality requirements on time and on budget to ensure that programs are compliant with Regulatory Authorities' expectations and related SOPs.Senior Scientist MSAndTDesign, plan, perform, interpret and report scientific experiments under the lead of the department head to contribute to overall MSAndT strategies and objectives.

About the Role

Job Purpose

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.

Major Accountabilities

Product Stewardship

• 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.

• Supportd QA to ensure inspection readiness (Pre Approval Inspection PAI).

Key Performance Indicators

- 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.
- Customer Complaints.
- Recalls.
- Success rate of Health Authorities' inspections.
- Completeness of Reg CMC dossier
- Effective CAPA.
- Continuously improving Yield.
- Technical reports executed on time and with the right expectations.

Number of associates:

None (may have direct reports depending on Division)

Financial responsibility:

(Budget, Cost, Sales, etc.)

Impact 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 and 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.

Ideal Background

Education :

Language:

- BSc. in Pharmacy, Pharmaceutical Technology, Chemistry or equivalent scientific degree.
- Highly desirable: Ph.D., MSc. or equivalent experience.
- Fluent in English

Experience:

- 10 yrs of experience in a Pharmaceutical manufacturing/technical environment.
- Strong leadership skills with a minimum of 5 years managerial experience
- Demonstrated technical expertise in manufacturing science and drug development.
- 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

Drives For Superior Results & Has Passion To Win

Builds The Talent Pipeline

Inspires Continuous Improvement & Breakthrough Thinking

Displays Analytical & Conceptual Thinking

Functional Competencies

Fundamental

Intermediate

Advanced

Thought Leader

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Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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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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