

Senior Technical Manager (MS&T), ESO

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Индия

Сводка

As a product technology expert, responsible within the External Supplier Relationship team for the management of products throughout their lifecycle, oversight of processes by data trending and statistical analysis of critical parameters, and for ensuring product robustness, proper validation status, and continuous process improvement.

About the Role

Key Responsibilities:

- Maintains oversight of processes for the assigned product in a specific contract manufacturing organization (e.g. from raw materials to packaging).
- Maintains the knowledge and the history of the products throughout the commercial lifecycle, since transfer from development to the present moment.
- Liaises with the global/X-CMO product steward at the global level, acting as a representative of MS&T within the relevant supplier relationship teams. Closely cooperates with ESO functions (Quality Assurance, Site Change Coordinator, SCM, etc.), and establishes relations with CMOs with special focus to ensure and improve product process capability, to keep up to date the knowledge of the process and to maintain the product in a constant state of validation.
- Controls and ensures the maintenance of technical documentation, e.g. process transfer protocols/reports, comparability protocol/reports.
- Authoring/reviewing relative source documents for dossier, HA query and other RA tasks.
- Participate in deviation investigation, lead complex investigations.
- Ensure that product and process-related issues identified in the OPV / APQR process with CAPA assigned are remediated with clear interfaces with Quality, AS&T, Operations, Engineering and Technical Development (as needed).
- Science and risk-based approaches, to ensure that product quality can be sustainably reproduced once transferred into the CMO site.
- Decision
- to transfer to CMO based on technical evaluation at transferring and receiving organization and aligned with strategy.
- Actively participates in and represents their products in the relevant committee (e.g. Product Stewardship Committee) when improvements of non-conformable products are planned, priorities are set, and improvements are monitored.
- Ensures that technical batches provide sufficient process knowledge by thoroughly testing critical variables; uses the data obtained to verify critical process parameters.
- Provides all the information needed for validation documentation.
- Supports the validation lead and experts in assessing the need and planning validations / re-validations / verifications / annual batch monitoring, consulting, approving and reviewing the process validation master plan in cooperation with the above.

Essential Requirement:

- **15+ years of experience** in biotechnology or pharmaceutical industry, worked extensively in large molecule and/or cell and gene therapy, and small molecules (oligonucleotides/radioligand therapy) domains.
- Demonstrated experience in process and/or product technical roles (e.g. MS&T, process development, manufacturing science, product stewardship).
- Good understanding of regulated environments, validation concepts and applicable guidelines.
- Technically astute with the ability to understand complex processes and translate technical topics into clear messages for stakeholders.
- Experience with troubleshooting of systems and processes, and familiarity with deviation, incident and problem management processes.
- Proven ability to work effectively in a global, matrix team organization and to collaborate with both technical and non technical professionals.
- Ability to work independently under time and pressure constraints, while managing multiple priorities.
- Strong communication and interpersonal skills with acute attention to detail.
- Ability to support and manage change effectively, with awareness of business processes and system implications.

Skills:

- Demonstrated skills in trouble shooting of systems, with working knowledge of incident and problem management processes Data Analytics
- Strong team player in global matrix team organization with an ability to confidently manage both pharma and non-pharma professionals.
- Ability to work independently under time and pressure constraints.
- Demonstrated ability to be proactive and flexible.
- Strong communication and interpersonal skills.
- Ability to manage change effectively always mindful of business processes, and system implications Quick learner with the ability to develop an in-depth knowledge of healthcare provider regulation requirements

Desirable Requirement:

- **Education:** Bachelor's degree in science or pharma or equivalent
- **Languages:** English (Fluent)

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

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