

MS&T Engineer

Job ID
REQ-10040296

3月 03, 2025

Mexico

摘要

The MS&T Engineer(Manufacturing Science and Technology), is responsible for conducting process maintenance and data analysis activities associated with the drug substance (expansion, upstream and downstream) and/or drug product manufacturing processes used to manufacture gene therapy products. These activities are associated only with responsibilities which can be executed from a fully remote location.

About the Role

Responsibilities:

- Performs all maintenance and regulatory oversight activities associated with the Master and Working Cell Banks, Bulk Plasmids, and Plasmid Cell Banks
- Serving a primary interface with 3rd party contract manufacturers for cell banks and plasmids

- Tracking inventory and managing orders and manufacturing oversight of each batch
- Maintaining specifications for cell banks and plasmids
- Ensuring compliance with all regulatory filing requirements associated with cell banks and plasmids
- Participation in audit defense and risk management activities for cell banks and plasmids
- Ensuring appropriate stability program execution and annual filings of re-test dates as required
- Partnering with the Upstream MSAT Manager and Strategic Product lead on long term strategies for management of cell bank and plasmids
- Ensuring deviation oversight and providing guidance to CMOs during manufacture
- Maintaining appropriate documentation for the management of banks such as high level plans, protocols, specs, and certificates of analysis
- Perform marketing and post-marketing commitments related to banks and plasmids
- Participate in any technical transfer activities required to produce or test banks and plasmids
- Execute on assessments of Supplier Change Notifications and implement change requests as needed
- Perform trending and data analysis of parameters and attributes associated with the production of these materials as well as the potential output parameters in the process
- May support the reporting outputs for the Continued Process Verification (CPV) program in collaboration with other MSAT functions
- Execute periodic review of documentation and gap assessments of global SOPs
- Assist with the update and routing of lifecycle documentation as needed such as Leachable extractable assessment and coordination of studies (as needed), control strategy and process description documents, etc.
- Looks for opportunities to implement operational excellence and continuous improvement
- Partners with Quality to ensure a compliant manufacturing environment
- Participates in GTx pipeline technical transfer activities where new banks or plasmids are needed to transition to commercial
- Completes requisite training, as well as applicable policies and procedures, related to the job function
- May work on special projects related to development and improvement of business and/or manufacturing processes
- Other related duties as assigned

Requirements:

- Bachelor ' s degree in biochemistry, chemical engineering, bioengineering, or related technical field at least 4 years of experience in biopharmaceutical based GMP manufacturing operations including direct experience in cell culture, cell banking, and/or management of 3rd party CMOs in biopharmaceutical or cell and gene therapy operations.
- Bachelor ' s degree in biochemistry, chemical engineering, bioengineering, or related technical field at least 3 years of direct Novartis GTx experience.
- Master of Science degree in biochemistry, chemical engineering, bioengineering, or related technical field and at least 2 years of experience in support of biopharmaceutical manufacturing, or related engineering field.
- Familiar with global regulations on cGMP manufacturing of drug substance, drug products devices, validation/qualification requirements.
- Strong technical writing ability in English.

- Proven ability to effectively participate on teams.
- Excellent oral and written communication skills.
- Up to 15% travel.

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部门

Operations

Business Unit

Innovative Medicines

地点

Mexico

站点

INSURGENTES

Company / Legal Entity

MX06 (FCRS = MX006) Novartis Farmacéutica S.A. de C.V.

Functional Area

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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