NOVARTIS

MS&T Engineer

Job ID
REQ-10040296
Mar 03, 2025
México

Resumen

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.

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? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

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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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Accessibility and accommodation

Novartis is committed to work with and provide 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 tas.mexico@novartis.com 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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