Senior Expert, Drug Supply " >

Job ID
329131BR
Nov 17, 2021
USA

Job Description

350+ trials, about 25,000+ patients per year! This is your chance to reimagine medicine in 2021.

Ensure the continues improvement of our aseptic clinical manufacturing processes to deliver on time in full the clinical supplies to our patients. Support manufacturing of clinical supplies by creating, updating, maintaining and archiving as appropriate documentation required for regulatory compliance. Ensure timely operational excellence and responsible for developing processes and capabilities to implement continuous quality and productivity improvements.

• Create, update, review, maintain and archive records and other key documents to provide track and trace evidence for every aspect of the production and distribution of investigational product in a cGMP state. This accountability may be inclusive of one or more of the following: batch records, assembly line and shipping directions. Work cross functionally with Manufacturing Experts, Manufacturing, Quality, Supply Chain, Engineering and Validation to ensure first time right batch record documentation and on time closure.
• Interact and collaborate with other line units in Development to facilitate transfer of technical knowledge, documentation and deliverables with the production of clinical supplies to assure all critical and non-critical process parameters are captured and transferred from the Manufacturing Instruction to the Master Batch Record.
• Support quality of clinical supply products through authoring MBR and review of the eBR documentation to assure compliance with Novartis, QM, QD and global regulations using GDP and ALCOA+ principles.
• Understands and is able to play a lead role in investigations to identify root causes and appropriate sustainable solutions to optimize the manufacturing processes. Continuous improvement should be linked with root cause investigation, reduction of deviations, reduction of variability and exchange of best practices within NVS network by sharing lessons learned across Pilot Plant Aseptics Team.
• Drive continuous improvement to enable Pilot Plant performance and remain batch right first time manufacturing as well as on time in full delivery. Support internal and external audits.
• Ensure Compliance with Quality Manual / Quality Modules / GOPs / NMM etc.

Diversity & Inclusion / EEO

The Novartis Group of Companies are Equal Opportunity Employers and take pride in maintaining a diverse environment. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, gender, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to building diverse teams, representative of the patients and communities we serve, and we strive to create an inclusive workplace that cultivates bold innovation through collaboration and empowers our people to unleash their full potential.

Minimum Requirements

• Bachelor’s Degree (chemistry, pharmaceutics, engineering or related science) or equivalent experience is required.
• Advanced degree (chemistry, pharmaceutics, engineering or related science) is preferred.
• 5+ years of relevant experience is required.
• Experience in the area of biologics drug product manufacturing or biologics process development is required.
• GMP and HSE experience is required.
• Sterile operation experience (process, equipment, quality management and operational excellence) is required
• Working knowledge of process improvement tools is required.
• Excellent communication skills, ability to effective present complex ideas and solutions to management, technical experts and global project Team’s is required.

Why Novartis?

769 million lives were touched by Novartis medicines in 2020, and while we’re proud of this, we know there is so much more we could do to help improve and extend people’s lives.

We believe new insights, perspectives and ground-breaking solutions can be found at the intersection of medical science and digital innovation. That a diverse, equitable and inclusive environment inspires new ways of working.

We believe our potential can thrive and grow in an unbossed culture underpinned by integrity, curiosity and flexibility. And we can reinvent what's possible, when we collaborate with courage to aggressively and ambitiously tackle the world’s toughest medical challenges. Because the greatest risk in life, is the risk of never trying!

Imagine what you could do here at Novartis!
Division
Global Drug Development
Business Unit
TECHNICAL R & D GDD
Location
USA
Site
Fort Worth, TX
Company / Legal Entity
Novartis Pharmaceuticals
Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No

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