Product Steward Senior (H/F) " >

Job ID
327778BR
Oct 01, 2021
France

Job Description

10 million doses is what the Huningue Biotechnology Center produces each year, which is a center of reference in the production of bio-drugs, clinical and commercial, by culturing mammalian cells.
"Quality and safety depend of course on our high-tech equipment, but they also and above all come from our teams, who bring innovation and improvement for the patient" explains Paula Rosa, Site Manager.
Come join a committed team of 700 people, in a motivating environment.

The Product Steward (Senior) has expertise in the manufacturing processes of commercial products, maintains visibility on the capabilities of these processes, through data analysis and statistical analysis of critical parameters, to ensure that the manufacturing process is solid, in a constant state of validation and constantly improving.
It supports and / or drives the post-approval product management program, in alignment with other manufacturing sites and Novartis Global operations.
It ensures that product knowledge and information flows seamlessly across functions and, where appropriate, to other locations.

You will be responsible but not limited to.

Your responsibilities include, but are not limited to:
• Maintain the oversight and knowledge for entire drug product manufacturing process performed on site and throughout the entire commercial lifecycle, since transfer from development to date, act as single point of contact (SPOC)
• Support an appropriate process control strategy based on critical quality attributes (CQA) and on critical process parameter (CPP), critical material attributes (CMA) and support improving the control strategy where applicable.
• Monitor and evaluate all critical and key variables as appropriate using statistical analysis and conduction regular product specific data trending (e.g. ongoing process verification OPV, APQR) and communicate at site level
• Present process performance and status of product improvement projects in site and global Manufacturing Robustness Review Board (MRRB)
• Assess impact of process and technical changes, assess their technical feasibility and determine scope of technical batches, challenge technical and process risk and business benefit of process/technical changes proposed

Minimum Requirements

What you'll bring to the role:
Essential:

• BSc. in Biotechnology, Chemistry, Pharmacy, Chemical Engineering or Pharmaceutical Technology. Desirable MSc in the above or equivalent
• Minimum 8 years' of experience in GMP manufacturing relevant and/or late stage development and/or QA/QC in Biotechnology
• Shown process understanding of biotechnology manufacturing technologies (DSP, USP)
• Detailed experience in computerized systems and fundamental understanding of applied statistics (MS-office, SAP, Minitab, etc.)
• Good understanding and oversight of relevant regulatory requirements, e.g. GMPs, ICH Q-guidelines.
• Fluent in English, French beneficial
• Ability to act in a sophisticated and rapidly changing business environment
• Consistent record in leading interdisciplinary teams, project management
skills as well as communication skills Desirable requirements:
• Great teammate with ability to foster stakeholder engagement
• Strong negotiator, influencing and persuading

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!

Our recruitment decisions are based on selecting the best person for the job, regardless of gender, religion, age, colour, race, sexual orientation, nationality or disability.
Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here:

https://talentnetwork.novartis.com/network
Division
Novartis Technical Operations
Business Unit
NTO LARGE MOLECULES
Location
France
Site
Huningue
Company / Legal Entity
Novartis Pharma France SAS
Functional Area
Technical Operations
Job Type
Temps plein

Employment Type
Permanent
Shift Work
Non
Apply to Job Access Job Account

Job ID
327778BR

Product Steward Senior (H/F)

Apply to Job Access Job Account

Source URL: *https://www.novartis.com/careers/career-search/job-details/327778br/product-steward-senior-hf*

List of links present in page

- https://www.novartis.com/careers/career-search/job-details/327778br/product-steward-senior-hf
- https://sjobs.brassring.com/TGnewUI/Search/home/HomeWithPreLoad?PageType=JobDetails&partnerid=13617&siteid=5260&jobid=2745993&AL=1