NOVARTIS

Manufacturing Batch Record Coordinator

Job ID
REQ-10034851
Jan 03, 2025
USA

Summary

The Manufacturing Batch Record Coordinator is responsible for life cycle management of issued labels and documentation as well as the timely and effective GMP review of production records.
This role is located on-site in Morris Plains, NJ. Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Location: Morris Plains, NJ, LI-#Onsite

About the Role

Key Responsibilities:

- MES/SAP/LIMS Super User to include floor support and training, and within MES, is responsible for TECO all Manufacturing orders.
- SPOC for Batch Record Process includes creating reports; production terminating and approving records; issue resolution.
- Reviews all batch documentation for accuracy and completeness according to cGMP's to ensure timely release.
- Ensures deviations are initiated for any batch record review related events Find/communicate deviations to QA /help with investigation
- Adheres to internal/external guidelines, specifications and regulatory requirements while reviewing batch documentation, and ensures all GMP's, Work Procedures and SOP's are followed.
- Positively interacts with internal associates to quickly and effectively resolve batch record documentation related issues, and maintains strong collaborative relations with the Quality Group
- Addresses deficiencies and ensures completion of all follow-up actions, specifically those that target process fixes to maintain consistent resolutions to all batch review issues according to GMP standards and Novartis objectives.
- Provide periodic updates at Manufacturing Team meetings to review current batch record errors to improve performance.
- Maintain and follow CGTDM procedures for MBR creation, issuance, receipt, reconciliation, filing and archiving
- Print and issue batch records, in-process labels, and final product labels to support operations, and issue labeling/tags for Apheresis through packaging of final product labelling to QA/Operations.

Essential Requirements:

- BS degree preferred with at least 1 year of experience in a regulated cGMP Environment. In lieu of degree, at least 4 years of equivalent experience in pharma manufacturing operations considered and

strong background in Good Documentation Practices (GDP)
- Strong aseptic manufacturing knowledge preferred
- Strong interpersonal, written and communication skills along with problem solving and follow-up skills are required
- Must be well organized, flexible and work with minimal supervision
- Alternate shifts, weekends and overtime will be required

The pay range for this position at commencement of employment is expected to be between $57,800 and $107,300 per year; however, base pay offered may vary depending on multiple individualized factors, including market location, job-related knowledge, skills, and experience. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us

know the nature of your request and your contact information. Please include the job requisition number in your message.

Division
Operations
Business Unit
Innovative Medicines
Location
USA
State
New Jersey
Site
Morris Plains
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
Technical Operations
Job Type
Full time
Employment Type
Regular
Shift Work
No
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Manufacturing Batch Record Coordinator

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