

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 pharmaceutical 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

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$27.79 - \$51.58/hour; *however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities.* 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.

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

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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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