# Specialist, Clinical Manufacturing

Job ID
REQ-10059122

8月 01, 2025

USA

## 摘要

The Specialist, Clinical Manufacturing, is responsible for providing project support and direct Manufacturing execution support for new product introductions. This includes technical writing skills to author new documents and translate from existing tech transfer documents. This role will work cross functionally with the Manufacturing, MSAT, Engineering and TRD groups in order to bring clinical manufacturing programs into the facility.

## About the Role

This position will be located in Durham, NC. This person is required to be onsite the majority of the time and must be on-site during production runs.

*Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.*

**Responsibilities:**

- Authors and manages master manufacturing documents of assigned products (e.g. Master Batch Record, Standard Operating Procedure, Bill of Material (BOM), and Recipe, Quality Risk Assessment, Hazard Analysis).
- Implementation and delivery of new Clinical products into the facility.
- Provide direct hands-on front-line support to manufacturing.
- Executes batch activities with the shift teams, focusing on manufacturing each batch safely, on time, in compliance with the batch instructions and quality requirements.
- Supports technology transfer projects, to include new product change controls for the introduction of clinical production at the site.
- Manages projects to implement significant changes to Clinical manufacturing processes.
- Supports the PMO group for any technology transfer activities.
- Maintains quality standards to meet GMP requirements, CFR's and internal company policies with respect to the manufacturing process.
- Supports Deviation/CAPA team.
- Support internal and external audits for group owned processes.
- Other related duties as assigned.

**Requirements:**

- B.S. degree in Engineering or the life sciences and 5 years of work experience in biopharmaceutical based GMP manufacturing operations.
- Strong technical writing ability required, specifically experience writing SOPs and Batch Records.
- Experience in technology transfer of biotechnology candidate clinical products and/or technology transfer of commercial products from site to site. Cell and/or Gene therapy, large molecule or biologics is a plus.
- In-depth knowledge of FDA regulations and GMP systems and experience providing process support in a highly regulated or pharmaceutical / biotech facility.
- Applied knowledge of Quality by Design, six-sigma, and operational excellence tools in creating efficient and high-quality processes and end products are preferred.
- Excellent oral and written communication skills.
- Travel as required to other internal sites, vendors, and CMOs as required (<5%).

**Novartis Compensation and Benefit Summary:**

The pay range for this position at commencement of employment is expected to be between $81,200 and $150,800/year; **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.

Company will not sponsor visas for this position.

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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.

部门
Operations

Business Unit
Innovative Medicines

地点
USA

状态
North Carolina

站点
Durham

Company / Legal Entity
U473 (FCRS = US473) Novartis Gene Therapies

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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