NOVARTIS

Manufacturing Quality Assurance Specialist (1st Shift)

Job ID
REQ-10089005
Nov 11, 2026
LOC_US

About the Role

Location:

- This position will be located in Durham, NC and will be an onsite role.
- Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

Shift:

- This will be a first shift role working 8:00 am - 4:30 pm, Monday - Friday

Key Responsibilities:

- Provide proactive quality oversight through shop floor presence, walkthroughs, and real-time manufacturing support.
- Review and approve master and executed batch records to ensure compliant clinical and commercial production.
- Partner with manufacturing teams to ensure consistent, compliant processes aligned with GMP requirements.
- Support media, buffer, cell expansion, upstream, downstream, and aseptic filling manufacturing operations.
- Lead deviation and corrective action investigations, ensuring thorough root cause analysis and effective remediation.
- Review alarms, data integrity, and electronic records to confirm accuracy and regulatory compliance.
- Support internal and external audits, inspections, and regulatory readiness activities.
- Provide quality expertise in manufacturing batch record design, review, and continuous improvement.
- Analyze quality metrics, identify trends, and communicate actionable insights to management.
- Lead or contribute to continuous improvement and quality system enhancement projects.

Essential Requirements:

- Bachelor of Science degree in microbiology, chemistry, biochemistry, or a related scientific discipline.
- Minimum of five years of experience working in a regulated GMP manufacturing environment.
- Strong working knowledge and application of CFR, FDA, and EU regulatory requirements.
- Proven experience supporting or participating in FDA and EU regulatory inspections and audits.
- Hands-on experience reviewing, authoring, and approving quality procedures and standard operating documents.
- Demonstrated ability to manage deviations, investigations, and corrective and preventive actions to closure.
- Strong analytical skills with the ability to interpret data, identify trends, and recommend compliant paths forward.
- Excellent written and verbal communication skills with the ability to collaborate effectively across functions.

Desirable Requirements:

- Experience supporting viral gene therapies or orphan disease manufacturing programs.
- Experience leading or coordinating internal quality audits and inspection readiness activities.

Novartis Compensation and Benefit Summary:

The salary for this position is expected to range between $43.08 and $80.00 per hour.

The final salary offered is determined based on factors like, but not limited to, relevant skills and experience, and upon joining Novartis will be reviewed periodically. Novartis may change the published salary range based on company and market factors.

Your compensation will include a performance-based cash incentive and, depending on the level of the role, eligibility to be considered for annual equity awards.

US-based eligible employees will receive a comprehensive benefits package that includes health, life and disability benefits, a 401(k) with company contribution and match, and a variety of other benefits. In addition, employees are eligible for a generous time off package including vacation, personal days, holidays and other leaves.

#LI-Onsite

Role Requirements

Division
DIV_TO
Business Unit
Quality
Location
LOC_US
Site
Durham
Company / Legal Entity
U473 (FCRS = US473) Novartis Innovative Technologies Inc
Functional Area
FCT_QA
Job Type
Full time
Employment Type
Regular
Shift Work
No
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