

QA Operations Supervisor

Job ID
REQ-10069097
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CLIA

Сводка

Help reimagine cancer care by shaping how our Radioligand Therapies (RLT) reach more patients—safely, reliably, and faster. At Novartis, we're pioneering the future of treatment through the fusion of nuclear medicine and precision oncology.

The QA Operations Supervisor provides hands on support for shop floor quality oversight and batch release activities while acting as supervisor to the QA Operations and Batch Release Specialists of their shift.

Location: Indianapolis, IN #LI-Onsite

Shift: Night Shift. weekend nights included

About the Role

Key Responsibilities:

- Provide direct supervision of QA Operations Specialists and QA Batch Release Specialists, ensuring alignment with site quality objectives.
- Coordinate daily activities, prioritize workload, and ensure timely completion of QA tasks across both functions.
- Serve as the primary point of contact for quality-related issues during assigned shifts, ensuring timely escalation and resolution.
- Ensure shopfloor quality oversight of production, QC, and supply chain activities, verifying adherence to cGMP, aseptic techniques, and data integrity standards.
- Oversee live review of manufacturing batch records and documentation to support timely and compliant batch release.
- Confirm compliance of site personnel with sterile manufacturing regulations and internal procedures.
- Support the release of all manufactured, packaged and tested.
- Support the Controlled issuance of batch records in preparation for manufacturing.
- Perform review of manufacturing batch records in preparation for batch release and escalate any discrepancies immediately.
- Support metric tracking of documentation and release data to ensure continuous improvement.
- Support all QA operations as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance, and data integrity.
- Provide Quality Oversight on Deviation, Change Control, and CAPA management
- Maintain batch documentation library (record check-in, check-out, follow-up, and distribution)
- Provide shopfloor quality oversight of all production, quality control and supply chain departments to ensure their practice fully adheres to cGMP, including data integrity. Ensure timely escalation to management of all applicable incidents.
- Perform live review of manufacturing batch records in preparation for batch release and escalate any discrepancies immediately

Essential qualifications:

- Bachelors' Degree, preferably in Life Sciences, chemistry, or related relevant degree. In lieu of degree, 5 years in a role within pharma industry that includes quality assurance and batch release experience will be considered
- 3+ years of experience in GxP Biopharmaceutical manufacturing operations
- 2+ years of experience in a quality assurance role
- Cross functional collaboration QA and QC experience in biotech pharmaceutical biotechnology industry with environmental monitoring & cleanliness zones is desired
- Proven track record and practical experience with cGMP requirements
- Knowledge of FDA and EU regulations and experience in US and international regulatory agency inspections.

The salary for this position is expected to range between \$89,600 and \$166,400 per year. 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.

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>

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
[Read our handbook \(PDF 30 MB\)](#)

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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.

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Состояние
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Job Type
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