QA Operations Specialist

Job ID
REQ-10029370
Nov 14, 2024
USA

About the Role

Major accountabilities:

- 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.
- Assist functional areas with achieving timely and compliant final product disposition of the product.
- Review, approve and support procedures and production/testing records as required and assist in the training of site associates.
- Ensure compliance of site personnel and application of aseptic techniques and full compliance to sterile manufacturing regulations.
- Support FDA/Regulatory interactions for the Indianapolis site activities and products to ensure successful regulatory submissions and inspections.
- Support QA Operations as a valued business partner, with a culture of safety, quality, delivery to patients, cost, compliance and data integrity.
- Other related duties as assigned.

Shift: This role will be Wednesday - Sunday, 6:00am - 4PM. This position may involve mandatory overtime as needed.

Essential Requirements:

- Bachelor's Degree, preferably in Life Sciences, chemistry or related relevant degree.
- 2+ years of experience in a GxP Biopharmaceutical manufacturing operations
- 1+ years of experience in a quality assurance role
- Collaborating across boundaries
- Functional Breadth
- QA and QC experience in biotech pharmaceutical industry with environmental monitoring & cleanliness zones

Role Requirements

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Division
Operations
Business Unit
Innovative Medicines
Location
USA
Site
Indianapolis
Company / Legal Entity
U469 (FCRS = US469) AAA USA Inc.
Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
No
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