Quality Operations Specialist (Temporary)

Job ID
REQ-10040371
Feb 12, 2025
Türkei

Summary

Manages Quality aspects and projects within area of responsibility. Ensures and supports overall GxP conformity and Compliance with the Novartis Quality Management Systems.

About the Role

Major accountabilities:

- The Quality Operations Specialist is responsible for first level, hands on, day-to-day cGMP facilitator role for all site related GMP activities even shifts. Quality Operations Specialist with site staff, who are performing the daily operational functions in support of their effort to produce quality products. This role ensures that the quality strategy is implemented and that there is a continuous drive to improve product and process quality within the PU, QC labs, and other support areas.

Key performance indicators:

- Shopfloor Activities: Conduct routine Quality Operations related activities at shopfloor including, but not limited to, observations and walkthroughs
- Perform training of events on shopfloor for PU and QC laboratories as well as other support areas, ensuring that deviations records are initiated adequately in deviation management system
- Review Activities: Review and approve production electronic batch records (EBRs), and/or QC related documentation, to ensure adherence to Novartis policies, SOPs, and cGMP requirements
- Interface closely with PU and QC to assist with batch record/QC data review, release, and compliance issue resolution
- Actively participate in process improvement initiatives aiming for Right First Time (RFT) on documentation and deviation reduction
- Ensures levels of documentation are adequate and compliant to existing procedures
- Write, review and approve Standard Operating Procedures (SOPs), Work Procedures (WPs), and Forms (FRMs), as needed

Essential Requirements:

- Min. 2 years of experience in pharmaceuticals is preferred
- Knowledge and understanding of cGMPs, keeping up to date with current industry issues and changing regulations
- Excellent oral and written communication skills are required
- Demonstrate leadership ability and excellent interpersonal skills
- Ability to work as part of a team

- Strives for simplicity and clarity
- SAP, 1QEM, MES, LIMS knowledge is preferred
- English

Why Novartis?

Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

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Commitment to Diversity & Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse team's representative of the patients and communities we serve.

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Division
Operations
Business Unit
Innovative Medicines
Standort
Türkei
Site
İstanbul Kurtköy
Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.
Functional Area
Quality
Job Type
Full time
Employment Type

Temporary (Fixed Term)
Shift Work
No
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