

Quality Manager Digital Solutions TRD QA

Job ID
REQ-10062290

9月 25, 2025

India

摘要

Support global Data & Digital Initiatives (DDI) within Technical Research and Development (TRD) Quality Assurance by implementing digital solutions, in compliance with related quality systems ensuring regulatory compliance. This role reports to Quality Lead Data & Digital TRD QA and drives operational excellence by deploying and continuously improving GMP-compliant digital tools and processes. The position strengthens quality oversight, aligns with regulatory expectations, and enables cross-functional collaboration to support business transformation of TRD in data and digital space.

About the Role

Key Responsibilities:

- Implement and manage digital solutions for CMC (Chemistry Manufacturing Control) quality processes as directed by Quality Lead. Support the deployment and optimization of digital

tools and systems that enhance quality processes and data integrity.

- Deploy AI/ML-based tools for process monitoring, deviation detection, and predictive analytics within CMC. Integrate manufacturing, laboratory, and quality data for comprehensive oversight and real-time decision-making.
- Lead validation, change control, and lifecycle management of digital GMP CMC systems to ensure GMP compliance. Oversee digitalization of CMC data management, documentation, and analytics (e.g., eBMR, eQMS, data lakes).
- Collaborate with IT, data science, manufacturing, regulatory, and global QA teams to align digital initiatives.
- Drive continuous improvement and automation in CMC quality processes. Contribute to GenAI and digital innovation initiatives by representing TRD QA in relevant forums and networks.
- Train and support end-users, fostering adoption and best practices in digital solutions.
- Monitor and report on quality metrics, identifying areas for improvement and driving corrective actions.
- Ensure documentation, audits, and inspections are managed effectively and in compliance with internal and external standards.

Minimum Requirements:

- 10 years in pharmaceutical quality, with at least 2-5 years in digital solutions implementation or management within CMC or related areas.
- Hands-on experience with validation, deployment, and lifecycle management of digital tools in a regulated (GMP) environment.
- Proven track record leading digital projects, supporting global and cross-functional teams.
- Experience with audits, inspections, and maintaining compliance of digital CMC systems. Technical expertise in digital CMC platforms, data science, and AI/ML applications in pharma.
- Strong project management and digital tool deployment capability. Strong understanding of Software development Life Cycle (SDLC)
- Understanding of chemical manufacturing processes, Laboratory practices etc. Deep knowledge of GxP, QMS, CSV, and regulatory compliance for CMC systems.

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部门

Development

Business Unit

Universal Hierarchy Node

地点

India

站点

Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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