R&D Quality Manager

Job ID
REQ-10053493
Jun 03, 2025
Italy

Summary

-Provide quality assurance expertise, guidance and support to operational activities in development and research organizations to ensure compliance with applicable regulatory requirements and Novartis procedures and quality standards. Manage projects, including Quality Plan initiatives, and processes that support quality objectives to assure their compliance with GxP regulations.

About the Role

Key responsibilities:

- Support discipline/service provision individually or within a team; provide functional expertise to QA/Line Units as needed.
- Review, approve, and release GMP-relevant deliverables and tools to ensure cGMP compliance.
- Manage project-related activities (e.g., process/quality initiatives, facility upgrades, IT validation) as per responsibility.
- Ensure compliance with internal/external quality and safety guidelines (e.g., GMP, SOPs, Quality Manual).
- Drive continuous quality improvements for manufacturing, collaborating with production, engineering, and supply chain.
- Oversee qualification/validation of processes, equipment, facilities, and software for GMP use.
- Review and approve GMP documents, including URS, IQ/OQ/PQ, Change Controls, CAPAs, and SOPs.
- Support inspection preparations and maintain oversight of external maintenance and qualification activities.

Essential requirements:

- Degree in Pharmacy, Biology, Chemistry, Engineering, or equivalent.
- Fluency in English (verbal and written).
- Strong awareness of quality issues and urgency in task completion.
- Open and clear collaboration and communication skills.
- Scientific, technical, and regulatory knowledge in the specific area, with basic understanding of drug development.
- Detailed knowledge of cGMP and familiarity with safety/environmental regulations.
- Minimum 5 years of experience in pharmaceutical companies in equivalent roles.
- Strong organizational skills.

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