TRD Quality Manager

Job ID
REQ-10058443

7月 22, 2025

Italy

摘要

1. Support a discipline and/or provide a service individually or within a team of associates. May provide functional expertise to Line Unit and other QA Units in area of responsibility
2. Write review, decide on approval and/or release of GMP-relevant deliverables, as applicable, and/or related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.
3. Manage project related activities (e.g. TRD product portfolio, development of new tools, processes, Quality initiatives, Quality Manual implementation, Quality Plans, Quality Risk Assessments, training activities, qualification and facility upgrade activities, IT validation projects) as per area of responsibility.
4. Support Project management functions as a project team member.
5. Provide support to TRD line functions in GMP related topics as per area of responsibility.
6. Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).

About the Role

Key responsibilities:

- Support the TRD QA function within a team, providing expertise to Line Units and other QA units in areas of responsibility.
- Write, review, and ensure compliance of GMP-relevant deliverables and tools with cGMP standards and project quality requirements.
- Oversee quality assurance for technical activities during development stages, including technical transfers and release requirements.
- Support project-related activities such as process development, quality initiatives, risk assessments, facility upgrades, and IT validation.
- Ensure alignment and consistency of regulatory submissions (IMPD/IND, NDA/MAA) and address health authority queries.
- Assist clinical trial teams with QA activity timelines and supply chain oversight.
- Perform QMS-related activities, including training, KPI oversight, SOP maintenance, and audit/inspection support.
- Act as QA point-of-contact for assigned CMO, including audits, CAPAs, documentation reviews, and compliance monitoring.

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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部门
Development

Business Unit
Innovative Medicines

地点
Italy

站点
Ivrea

Company / Legal Entity
IT58 (FCRS = IT058) Advanced Accelerator Applications Italy Srl

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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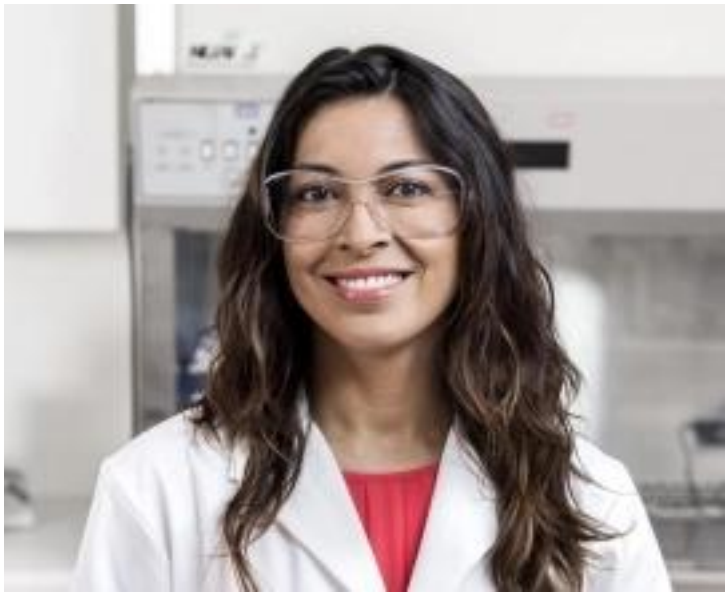

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