TRD Quality Process & Engineering Manager

Job ID
394643BR

9月 09, 2024

Italy

摘要

TRD Quality Process & Engineering Manager will collaborate with RLT Engineering organization for RLT TRD, to establish, maintain and improve the engineering processes with respect to buildings, equipment, utilities and energy. This role includes oversight of operational and validation activities and continuous process improvements.

About the Role

Key responsibilities:

- 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.
- Write review, decide on approval and release of GMP-relevant deliverables and/or related tools as per area of responsibility in order to ensure compliance with cGMP and project quality deliverables.

- 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.
- Support Project management functions as a project team member
- Provide support to TRD line functions in GMP related topics as per area of responsibility
- Comply with internal and external guidelines regarding quality and safety (Quality Manual, regulatory cGMP guidelines, Health Authority guidance, SOPs etc.).
- Ensures manufacturing processes, facility, equipment and software are properly qualified and validated for GMP use.
- Generate and maintain VMP to ensure all facility, equipment, process, utilities, analytical methods, cleaning and computerized systems are qualified in compliance with regulations, standards, and specifically with GMP.
- Oversight of external parties responsible for maintenance and qualification/ re-qualification of pilot plant areas and equipment.
- Review and approve URS, DQ, IQ, OQ and PQ documentation.
- Drive continuous quality improvement program for aseptic manufacturing operations and partner with production, engineering and supply chain teams to implement/optimizes to improve efficiency (right the first time) and monitor/escalate as needed.
- Ensure review, decision and approval of all GMP deliverables.
- Approval of the whole set of documents in the area of analytical instruments and production equipment qualification and operation.
- Approval of equipment periodic reviews.
- Approval of Change Controls (CCP)
- Review/Approval of Deviations, Actions, CAPAs and Quality Events.
- Support for inspections preparation.
- Approval in document management systems
- Review of SOPs in ESOPS D2

Essential Requirements

- Bachelor Degree
- Fluent in Italian and English
- Communication skills to sufficiently address GMP and logistic related questions with line unit experts. Scientific, technical and regulatory knowledge in a specific area.
- Basic knowledge of drug development.
- Detailed knowledge of cGMP, working knowledge of safety and environmental regulations and guidelines. Good 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) AAA Italy Srl.

Functional Area
Quality

Job Type
Full time

Employment Type
Regular

Shift Work
No

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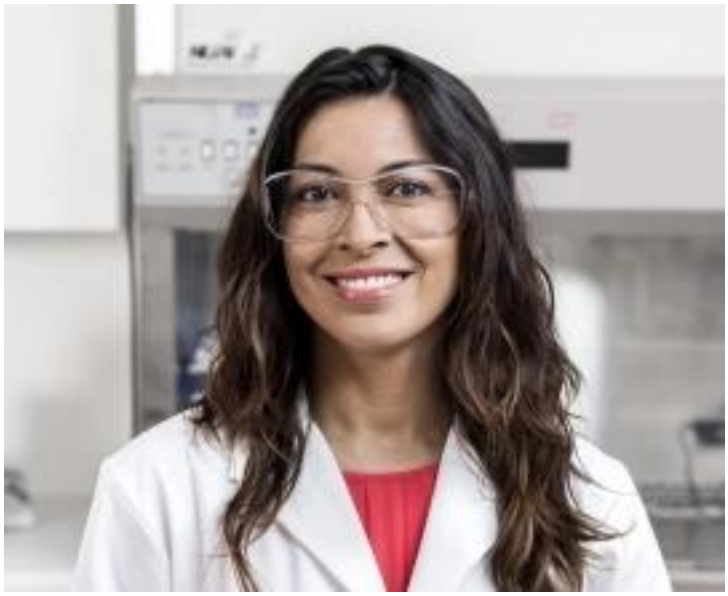

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