

Qualification Expert (m/f/d)

Job ID
REQ-10016040
Oct 24, 2024
Italy

Summary

Location: Colletterto Giacosa

Role Purpose:

Responsible to ensure compliance to cGxP standards for topic within area of responsibility (during development, transfer, release and stability), including safety testing, monitoring and trending.
Provide guidance, support and leadership for implementation of analytical standards.

About the Role

Main Responsibilities:

Operational

- Project leader for initial qualification of laboratories, associated analytical instruments and systems; Approves qualification documents, if applicable
- In charge of planning the qualification activities according to the business need. Ensure Readiness and release of Instruments according to the business need
- Ensure qualification/calibration status of analytical equipment and associated utilities and facilities (Alarm management, Pest control...)
- Change Control: Initiator and Owner of Change requests associated with laboratories implementation; Initiator, Owner and Approver of CAPA and Task Loop
- Author and Reviewer of SOPs within area of responsibility.
- Ensure laboratories are maintained according to cGxP standards. Ensure compliance of analytical laboratories and development according to applicable regulatory requirements and guidelines
- Ensure overall inspection readiness for area of responsibility and Contribute to GxP audits/inspections. Ensure methods and procedures are up-to-date
- Management of documentation and methods according to cGxP.

Leadership & Culture

- Support the organization by identifying and reviewing the appropriate list of training for all in-scope associates
- Ensure that associates are qualified for a GMP task prior to independent performance
- Monitor overall training compliance for in-scope associates
- Identify and maintain a list of subject matter experts for in-scope areas of expertise
- Create a work environment that enables high employee engagement

- Role model the culture aspiration of being Curious, Inspired and Unbossed and ensure leaders and associates are aware and aligned on expectations and hold them accountable for success of culture journey

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Division

International

Business Unit

Innovative Medicines

Location

Italy

Site

Ivrea

Company / Legal Entity

IT58 (FCRS = IT058) AAA Italy Srl.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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