Pilot Plant QC Qualification Expert

Job ID
REQ-10040620

Apr 02, 2025

Italy

Summary

Role Purpose:
Responsible to ensure compliance to cGxP and Novartis standards for topic within area of responsibility (during development, transfer, release and stability), including safety testing, monitoring and trending. Participating to Pilot Plant build-up phase as qualification responsible person for GMP quality control labs, as well as support for development labs.
Provide guidance, support and leadership for implementation of analytical standards.

About the Role

Key responsibilities:

- 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.
- Management of external service providers and instrument vendors for what concern laboratory qualification processes.

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

Ideal Background

Education:

- Degree (Master is preferred) in Pharmacy, Chemistry or Engineering in chemistry, physics or similar scientific field

Languages:

- Italian: proficient or mother tongue
- English: fluent in professional language both verbally and in writing

Experience / Professional requirements:

- 2+ years ' experience in a similar role in GMP environment
- Experience with quality management systems.
- Analytical laboratory experience in GMP environment
- Knowledge of nuclear medicine industry is preferable
- Highly organized and detail-oriented with strong focus on accuracy
- Knowledge of Good Documentation Practices and Data Integrity principles
- Demonstrates strong personal ethics and responsibility to purpose
- Ability to work independently / self-starter
- Excellent communication skills (both written and verbal) - experience corresponding with external vendors or business partners in a professional setting.

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International

部門
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国

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

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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