AS&T Expert (Analytical)

Job ID
REQ-10043437

Apr 13, 2025

Singapore

Summary

This position is responsible for the direction and oversight of the analytical projects. He/she supports analytical investigations, validation, remediation, transfer and implementation of analytical methods. He/she works cross-functionally with QC, MS&T (Manufacturing Sciences and Technology), Manufacturing, Supply Chain and the Novartis networks to ensure the success of assigned projects.

About the Role

Key Responsibilities

- Own & Lead projects, often complex in nature; including direct responsibility for leading various teams to successful completion of various projects. Strong ability to manage multiple priorities.
- Own & Lead analytical method transfer / validation / verification and to ensure full compliance of introduced analytical methods to current standards. Responsible for implementation of

projects into QC laboratories.
- Work with tech transfer teams to prepare new processes; point of contact for QC/lab operations for external customers. Set-up and coordinate detailed planning and document deliverables as per Master Plan and agreed timelines by working collaboratively within QC and cross-functional teams.
- Direct customer and regulatory agency interaction as required. Involve in regulatory audits in an independent manner. Responsible for analytical validation/transfer topics.
- Lead and approve validation documents (Example: Method Qualification / Validation / Investigation).
- Superior ability to troubleshoot all applicable methods.
- Provide trending and statistical support for periodic reporting, and or decision making
- Support investigations for major and critical discrepancies (OOS, complaints, deviations). Make recommendation for product quality impact assessments and propose CAPA actions.

Essential requirements:

- Minimum: BS in Pharmacy, Biotechnology, Chemistry, Microbiology or Chemical Engineering
- Desirable: PhD in Biotechnology, Chemistry, or Chemical Engineering
- 8+ years of related experience. Related experience should be in GMP-regulated industries in Quality Control. Experience in analytical validation/transfer is a plus.
- Must understand FDA/EMA/ICH requirements as well as industry quality systems
- Knowledge and understanding of manufacturing and quality control. Experience in bio-technology/bioprocess/bio manufacturing is highly desirable.
- Strong analytical, planning, execution, interpersonal, communication, negotiation and problem-solving skills
- Strong project management skills
- Considerable organization awareness (e.g. interrelationship of departments, business priorities), including significant experience working cross-functionally

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部門
Operations

部門
Innovative Medicines

国
Singapore

勤務地
Tuas South Avenue

Company / Legal Entity
SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

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