AS&T Expert (Micro)

Job ID
REQ-10022108
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Singapore

Sommario

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About the Role

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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 validation / verification and to ensure full compliance of introduced Microbiological and EM 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 all EM topics, including disinfectant studies, EM trends, Contamination Control Strategy etc.
- 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:

- 8+ years of related experience. Related experience should be in GMP-regulated industries in Quality Control. Experience in Sterile Product Manufacturing is a plus.
- Must understand FDA/EMA/ICH/EU annex 1 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. inter-relationship of departments, business priorities), including significant experience working cross-functionally.

Desirable Requirements:

- Minimum: BS in Pharmacy, Biotechnology or Microbiology
- Desirable: PhD in Biotechnology

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