NOVARTIS

AS&T Expert (Micro)

Job ID
REQ-10022108
Oct 01, 2024
Singapore

About the Role

AS&T Expert

Location - Singapore

About the Role:

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

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

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network.

Role Requirements

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

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Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Operations
Business Unit
Innovative Medicines
Location
Singapore
Site
Tuas South Avenue
Company / Legal Entity
SG12 (FCRS = SG012) Novartis Singapore Pharmaceutical Manufacturing Pte Ltd
Functional Area
Quality
Job Type
Full time
Employment Type

Regular
Shift Work
No
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