AS&T Expert

Job ID
REQ-10045316

Apr 01, 2025

Malaysia

Summary

The AS &T Expert is responsible for leading the analytical method transfer, method validation, and verification activities, ensuring compliance with cGxP standards for products. Provide technical support to quality control team related to analytics and specifications. Individual contributor role, ensuring the timely implementation of assigned activities.

About the Role

Key Responsibilities:

- Lead analytical method transfer, method validation/verification activities, ensuring full compliance of introduced analytical methods to current standards.
- Act as subject matter expert for analytical and bio-analytical methods for testing of biopharmaceutical molecules (HPLC, UPLC, CIEF, Capillary Electrophoresis, PCR, ELISA, etc)

- Support onsite investigations related to OOX and deviations.
- Customer management and new product introduction to the site.
- Improvements in Analytical Methods and life cycle management.
- Introduction of new technologies for analytical testing.
- APQR, OPV analytics section authoring, and perform assessments.
- Stability Study Design, Protocol, and report preparation. Awareness of ICH requirements.
- Basic knowledge of Statistical data evaluation and trend assessment.
- Regulatory dossier reviews for analytical methods, method validation, stability, and control of materials.
- Third-party testing lab management- Track deliverables and provide technical guidance as per company policy.
- Raw material assessment for new product introduction and pharmacopeia compliance evaluation.

Essential Requirement

- BS degree with 8+ years of pharmaceutical/biotechnology analytics industry experience
- MS degree with 4+ years of pharmaceutical/biotechnology analytics industry experience
- Working experience in Laboratory environment in the biopharmaceutical analytics/QC/ equivalent industry.
- Familiar with major pharmacopeia standards such as USP, EP, JP/JPE, ChP etc
- Broad cGMP experience is required with knowledge and understanding of manufacturing, quality control, and validation requirements and activities
- Must have a working knowledge of health authority and regulatory requirements as well as industry quality management tools, standards, and quality systems.
- Working experience in GMP-regulated industries in the Quality Control analytics department is an advantage.
- Willing to travel from time to time from Malaysia to Singapore.

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

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

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

部門
Operations

部門
Universal Hierarchy Node

国
Malaysia

勤務地
Selangor

Company / Legal Entity
MY01 (FCRS = MY001) Novartis Corporation (Malaysia) Sdn. Bhd. (19710100054)

Functional Area
Quality

職種
Full time

雇用形態
Regular

Shift Work
No

Apply to Job.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Job ID
REQ-10045316

AS&T Expert

Apply to Job.

Source URL:
https://prod1.novartis.com/jp-ja/careers/career-search/job/details/req-10045316-ast-expert

List of links present in page

1. https://www.novartis.com/about/strategy/people-and-culture
2. https://talentnetwork.novartis.com/network
3. https://www.novartis.com/careers/benefits-rewards
4. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Selangor/AS-T-Expert_REQ-10045316-1
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Selangor/AS-T-