



PR/160196 | Specialist, Regulatory Affairs, Quality Assurance and Pharmacovigilance

Job Information

Recruiter

JAC Recruitment Malaysia

Job ID

1580479

Industry

Pharmaceutical

Job Type

Permanent Full-time

Location

Malaysia

Salary

Negotiable, based on experience

Refreshed

March 3rd, 2026 10:27

General Requirements

Minimum Experience Level

Over 3 years

Career Level

Mid Career

Minimum English Level

Fluent

Minimum Japanese Level

None

Minimum Education Level

Associate Degree/Diploma

Visa Status

No permission to work in Japan required

Job Description

Company and Job Overview

A global pharmaceutical company is seeking a Specialist, Regulatory Affairs, Quality Assurance, and Pharmacovigilance. In this role, you will serve as the primary point-of-contact for all Regulatory Affairs (RA), Pharmacovigilance (PV), and Quality Assurance (QA) activities in Malaysia.

Job Responsibilities

- Manage regulatory submissions, NPRA communications, labeling/artwork compliance, and maintenance of licenses (e.g., Import, Wholesaler)
- Lead QA activities such as product release, GDP/GMP compliance, audits (internal, external, NPRA, HQ), and handling product quality issues
- Maintain and oversee the Company's PV system, ensuring ICSRs reporting, compliance with Malaysian and global PV requirements, and leading PV audits
- Coordinate with Regional HQ, distributors, and manufacturers on RA/QA/PV matters, resolving regulatory issues or potential supply disruptions
- Draft, review, and manage all RA/QA/PV-related agreements, SOPs, PSMF, and process improvements

- Support broader organizational needs, including regional projects, CCM nominee director responsibilities (if required), and stakeholder management

Job Requirements

- Bachelor of Pharmacy (B.Pharm) degree
- Minimum 3–4 years of experience in regulatory affairs for pharmaceutical products in Malaysia
- Registered Pharmacist in Malaysia
- Experience in handling Quality Assurance (QA) and/or Pharmacovigilance (PV) activities
- Strong knowledge of Malaysia's pharmaceutical regulations, including RA, QA, and PV requirements
- Familiarity with regional (ASEAN) and global regulatory landscapes
- Good understanding of GMP, GDP, and GVP guidelines
- Ability to work effectively with cross-functional teams, with a sound understanding of commercial operations within the pharmaceutical industry
- Must be a Malaysian citizen or possess valid residency status

Interested applicants, feel free to click APPLY NOW

#LI-JACMY

#countrymalaysia

Notice: By submitting an application for this position, you acknowledge and consent to the disclosure of your personal information to the Privacy Policy and Terms and Conditions, for the purpose of recruitment and candidate evaluation.

Privacy Policy Link: <https://www.jac-recruitment.my/privacy-policy>

Terms and Conditions Link: <https://www.jac-recruitment.my/terms-of-use>

Company Description