



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

募集職種

人材紹介会社

ジェイエイシーリクルートメント マレーシア

求人ID

1580479

業種

医薬品

雇用形態

正社員

勤務地

マレーシア

給与

経験考慮の上、応相談

更新日

2026年03月17日 04:00

応募必要条件

職務経験

3年以上

キャリアレベル

中途経験者レベル

英語レベル

流暢

日本語レベル

無し

最終学歴

短大卒：準学士号

現在のビザ

日本での就労許可は必要ありません

募集要項

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

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会社説明