

Associate Director, Regulatory (PTR) APAC Regional Hub - Singapore

Job ID: 00412692

Job Function

Technical Regulatory Affairs

Schedule

Full-time

Location

Singapore-Singapore
Singapore

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Executive (Director/VP/SVP)

Who We Are

At the Roche Group, about 80,000 people across 150 countries are pushing back the frontiers of healthcare. Working together, we've become one of the world's leading research-focused healthcare groups. A member of the Roche Group, Genentech has been at the forefront of the biotechnology industry for more than 30 years, using human genetic information to develop novel medicines for serious and life-threatening diseases. The headquarters for Roche pharmaceutical operations in the United States, Genentech has multiple therapies on the market for cancer and other serious illnesses. Please take this opportunity to learn about Genentech, where we believe that our employees are our most important asset and are dedicated to remaining a great place to work.

The Position

PTR APAC Regional Hub Associate Director

Purpose

This position will lead a PTR team regionally located in Singapore responsible for Asia Pacific regional management of life-cycle submissions for all Roche products as well as new product registrations by focusing on local needs of Affiliate Drug Regulatory Affairs (DRA) teams to ensure right first-time submissions to Health Authorities.

Responsibilities:

* Lead team of professionals responsible for regional/local management of lifecycle

submissions in Asia Pacific markets, including: market applications (NDA/BLA), post-approval submissions/ variations, renewals and annual reports, for pharmaceutical small molecules and biological products.

- * In coordination with global PTR Technical Regulatory Leaders, lead submission strategy for execution of lifecycle submissions in Asia Pacific markets associated to management of CMC changes originating at manufacturing sites or affiliates toward maximizing efficiency, quality and rate of submission approvals by Health Authorities.

- * Liaise with Regional Supply Chain management team and Affiliates DRA for strategic planning and influencing change management alignment and early visibility/communication/ planning of changes impacting markets in the region.

- * Lead assembly of lifecycle submissions for markets under responsibility to guarantee right first time submissions and coordinate with affiliates for timely and effective submission of changes to the Health Authorities.

- * Act as subject matter expert in regulatory requirements for post approval submissions and assure maintenance of regulatory intelligence repository for regional markets under responsibility.

- * Ensure that the CMC change management electronic systems are timely updated and maintained in alignment with the regulatory information submitted/approved externally by a Health Authority or internally by the appropriate functional area.

- * In coordination with Affiliates DRA, act as direct liaison with regulatory authorities to facilitate the prompt review and approval of submissions (CMC content Subject Matter Expert).

Manage timely responses to Health Authority questions resulting from lifecycle submissions in regional markets under responsibility.

- * Manage tracking of commitments with a Health Authority as result of license/dossier approval and ensure commitments due dates are met.

- * Manage work activities for team members supporting the Asia Pacific region.

- * The candidate may be required to travel to other Roche sites on a periodic basis.

Who You Are

The candidate must possess a degree in science (advanced degree preferred) with at least 10 years of experience in the pharmaceutical industry, and at least 5 years of supervising experience.

- * The successful candidate will be an industry recognized leader in the Regulatory Affairs / CMC field with significant experience in the Asia Pacific region.

- * The ideal candidate will have strong proven experience in Regulatory Affairs for Asia Pacific markets, CMC requirements for small molecule/biologic products, development, manufacturing and/or quality assurance experience.

- * He/she will demonstrate effective problem solving, strong understanding of regulatory

strategies, excellent interpersonal skills and the ability to prioritize multiple tasks.

* Must have a proven ability to communicate effectively in both a written and verbal format. The ideal candidate will be fluent in 1-2 languages spoken in the region of responsibility, in addition to English.

* Proven ability to influence and work collaboratively in a team structure.

* Have a proven ability to work well under pressure.

* He/she must be detail oriented with strong leadership/people management skills.

Appointment to this position will be on local Singapore salary and benefits package. All internal candidates are reminded to inform your immediate manager/supervisor upon submission of your application.

Genentech is an Equal Opportunity Employer.