

PTR Regional Hub Sr. Regulatory Associate / Regulatory Manager

Job ID: 00412746

Job Function

Technical Regulatory Affairs

Schedule

Full-time

Location

Singapore-Singapore
Singapore

Job type

Regular Employee

Company/Division

Pharmaceutical

Job Level

Experienced

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 Regional Hub Sr. Regulatory Associate (E3) /

PTR Regional Hub Regulatory Manager (E4)¹

Department: Pharma Technical Regulatory (PTR)

Job Family / Category: PTR Regional Hubs

Purpose

This position will be responsible for execution and management of regional 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:

- * The incumbent will be the primary technical regulatory (CMC) point of contact for the Affiliate DRAs and as such he/she will work closely with them and the regional Supply Chain teams as well as with the PTR product managers and the PTR network.
- * In coordination with global PTR Technical Regulatory Leaders (TRL), execute regulatory strategy for 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.
- * Coordinate strategic planning with Regional Supply Chain and Affiliates DRA for change management alignment and early visibility/communication/planning of changes impacting markets in the region.
- * Assemble lifecycle submissions for markets under responsibility to guarantee right first time submissions and coordinate/manage 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 maintain the regulatory intelligence repository for regional markets under responsibility.
- * Ensure timely update of the CMC change management electronic systems with the regulatory information submitted/approved externally by a Health Authority or internally by the appropriate functional area.
- * Upon request, support Affiliate DRA with interactions 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.
- * 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 5 to 10 years of experience in the pharmaceutical industry.

- * The successful candidate will be a leader in the Regulatory Affairs / CMC field with significant experience in the Asia Pacific region.
- * The ideal candidate will have a strong experience in Regulatory Affairs for the 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, detail oriented 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.

- * Ability to influence and work both independently and collaboratively in a team structure.

- * Proven ability to work well under pressure.

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.

1 Position title and level will be commensurate with experience.

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