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Regulatory Manager - CMC biologics (various European locations)

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Company: Parexel

Location: Zaventem

Category: other-general

When our values align, there's no limit to what we can achieve.

Are you an experienced regulatory professional looking for a new opportunity? We are currently seeking a talented**CMC Regulatory Manager**(Regulatory Affairs Consultant) to join our dynamic team! This is a client dedicated project, and the role can be office or home based in various European locations.

As the CMC Regulatory Manager, you will play a vital role in our company's worldwide post-approval regulatory activities, specifically focused on Chemistry, Manufacturing, and Controls (CMC) for biological products.

Primary Tasks & Responsibilities:

Develop submission strategies and plans for post-approval CMC activities such as variations, renewals, market expansions, and annual reports.

Assess change controls and provide regulatory assessments of quality changes in production and quality control.

Review study reports from the quality control and production departments to ensure compliance with regulatory requirements.

Coordinate submission preparation with various departments including manufacturing, supply chain, quality control and quality assurance, and other regulatory departments and local companies.

Write and/or review submission content to ensure alignment with regulatory requirements, specifically related to variations and questions from health authorities.

Manage projects within all Regulatory Information Management systems, ensuring the maintenance of worldwide submissions.

Identify, escalate, and mitigate risks associated with regulatory procedures and activities.

Experience and Knowledge Requirements:
University-level education, preferably in Life Sciences, or equivalent by experience.

Previous experience in regulatory affairs, particularly related to technical/CMC/quality, within the pharmaceutical industry.

Strong understanding of CMC and post-approval regulatory requirements.

Experience in writing CMC (technical) sections of regulatory documents such as registration files or variations.

Knowledge of biological processes.

Background in validation/Quality Assurance/production in the pharmaceutical industry, with experience in preparing regulatory documentation. Understanding of qualification/validation principles.

Proficiency in Word, PowerPoint, Excel, and experience with Veeva Vault is valued.

Team spirit, flexibility, accountability, and organizational skills.

Fluent in English (written and spoken). French, Italian and German would be a strong plus.

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