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Associate Regulatory Site Officer

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Company: STAR GROUP

Location: Belgium

Category: other-general

Responsibilities

As a Associate Regulatory Site Officer you are responsible for managing and reviewing of CMC (Chemistry, Manufacturing and Controls) dossiers, variations, renewals, annual reports, site registrations and territory extensions as part of regulatory product lifecycle management responsibility

You are responsible for implementing change control updates from our partnered sites into the existing regulatory dossiers and prepare associated regulatory CMC documentation for submission to the authorities, in collaboration with Sanofi experts and external partners

You are analyzing impact of proposed change controls on the existing regulatory submissions

You are responsible for reviewing operational documentation/reports in order to ensure compliance with the dossiers

Requirements

Bachelor or master with scientific background

CMC background/experience required

Regulatory background/experience required + experience with major market submissions such as US, EU, Japan, China,…

Regulatory database (Veeva Vault RIM) experience required

Previous experience with working at Sanofi is considered highly beneficial

Good organizational skills

Attention to details

Good communicator and project manager

Proven ability to work across functions and cultures

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