Regulatory Affairs: Chemistry, Manufacturing, and Controls (CMC)

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Overview

Regulatory affairs chemistry, manufacturing, and controls (CMC) is a subset under the broader regulatory affairs umbrella. Pharmacists in this role share many of the same responsibilities as the general regulatory affairs functional area, such as liaising with regulatory authorities, supporting clinical trials, and developing drug/biologic submissions. However, in this department pharmacists have distinctly more interaction with the technical content, which resides in Module 3 Quality of the eCTD. Examples of projects that you may be involved in include amendments to update drug substance manufacturing process and manufacturing site changes, providing regulatory advice for CMC issues in various countries, and preparing meeting packages for regulatory body meetings regarding CMC questions. Opportunities within the industry exist in a variety of areas such as small molecules, biopharmaceuticals, consumer products, vaccines, and cell and gene therapy, as well as in both the pre-approval and post-approval space. Soft skills of pharmacists, such as project management, cross-functional collaboration, and verbal and written communication are highly valued in this type of position. Ideal candidates will have some technical background or research experience in order to understand the content within drug substance and drug product sections.

Roles and Responsibilities of PharmDs in Regulatory Affairs CMC

- Manage CMC-related submissions (IND, IMPD, BLA, etc) and amendments, including coordinating internal review, approval, and publishing
- Guide resolution of technical issues with authoring scientists
- Respond to questions from and liaise with regulatory authorities regarding CMC issues
- Manage country-specific requirements for supporting CMC documentation
- Participate as part of regulatory matrix teams

Top 5 skills for PharmDs working in Regulatory Affairs CMC

- Ability to manage multiple project timelines simultaneously)
- Ability to work collaboratively with variety of functional areas
- Understanding of how CMC outcomes or changes may impact other business functions, such as clinical supply
- Understanding of CMC regulations in different international markets
- Technical experience in fields such as analytical chemistry, manufacturing, engineering, medical devices, formulation, cell banking, microbiology, or quality