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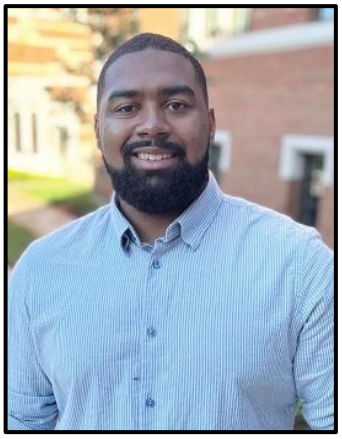

Practicum Site: Regeneron Pharmaceuticals

Practicum Site Supervisor: Juliana Badalucco

Understanding Health Canada And Post Approval Submissions

Introduction: The main goal of this practicum was to understand Health Canada's regulatory process and how Regeneron Pharmaceuticals can prepare an effective submissions package for new and existing pharmaceutical products. A submissions package is a complete list of changes, recommendations, and data in the form of documentation for a given pharmaceutical product. This package is made to ensure that the pharmaceutical product meets safety and quality standards with heal departments. The project culminated in a presentation to the Chemistry Manufacturing and Controls (CMC) Regulatory Sciences department, a poster detailing the experience, a comprehensive document, and served as a steppingstone to expanding Regeneron's reach to global regulatory agencies.

Methods: The process involved understanding Regeneron Pharmaceuticals' and CMC Regulatory Sciences' roles and purposes, meeting with Regulatory Sciences (RegSci) team members who either specialize in Canada or have extensive regulatory knowledge, and using these meetings to research critical documents, processes, and preparation methods. Weekly reviews by manager Juliana Badalucco were conducted to address gaps in knowledge and support collaborative decision-making.

Results: Key documents that further help regulatory specialists with understanding the regulatory process for a given regulatory agency, such as the Lot Release and Post Notice of Compliance Approvals, were crucial for preparing submission packages. Market Authorization Holders (MAH) like Regeneron must understand the types of submissions needed for different pharmaceutical drug changes, ranging from Supplemental (Level I) to Annual Notifications (Level III). CMC Regulatory Sciences creates approval timelines, utilizes the Electronic Table of Contents to track important updates and submission package details, and selects the right team to oversee approval processes.

Conclusions: The comprehensive document created for CMC Regulatory Sciences will be reviewed for future projects, enhancing understanding of Health Canada's regulatory process within Regeneron Pharmaceuticals. This understanding underscores the importance of regulatory sciences, public health policy, and epidemiological application. Effective collaboration between regulatory agencies and pharmaceutical companies is essential to ensure pharmaceutical products meet safety, efficiency, quality, and performance standards, thus protecting public health.