The difference is in the data.™

Regulatory Affairs Management Support for Large Pharma

CHALLENGE

A regulatory affairs manager at a well-established large pharmaceutical company was going on maternity leave during preparation for a supplemental new drug application (sNDA) submission. This change left the team in need of someone to provide regulatory leadership to ensure the sNDA would be submitted on time and would meet regulatory expectations and requirements. This was a challenge as it necessitated that the Sponsor team change their program's regulatory affairs lead to someone without a background with the team or product right before an important submission that was being supported cross-functionally, with multiple workstreams developing different components of the submission.

MMS SOLUTION

An MMS Global Regulatory Affairs Manager initially joined the company's regulatory affairs team as the US Regulatory Lead (USRL). The MMS resource worked directly in the company's Regulatory Information Management (RIM) system to create regulatory affairs deliverables and provide reviews while participating in regular quality control (QC) of the Trial Master File (TMF) and scheduling submissions as needed. As USRL for multiple development programs, the MMS manager provided support by:

- Leading the development of numerous periodic reports for several products to meet Investigational New Drug (IND) and New Drug Application (NDA) annual reporting requirements
- Serving as the agency point of contact and providing regulatory guidance and oversite to teams
- Providing regulatory oversight for a pediatric label expansion program (sNDA), including populating and maintaining the submission inventory, guiding a cross-functional team of employees, many of whom were new to the company, and helping the team to navigate challenges with the data
- Working with the teams to inactivate an existing Investigational New Drug (IND) application
- Corresponding with the FDA regarding post-marketing requirements (PMRs)

"The MMS Sr. Global Regulatory Affairs Manager was great to work with; **extremely knowledgeable, dependable and resourceful."**

OUTCOME

The overall health of the established products programs were maintained, and all required submissions were made on time and met FDA standards for content and quality. This included the pediatric sNDA, which was submitted with no validation errors and underwent filing review with no filing review issues. Due to the overall success as USRL, the company extended its contract and moved the MMS resource to a Global Regulatory Lead (GRL) position. As GRL, the MMS resource provides oversite and mentorship to the USRL on her project team, while at the same time, guiding a larger, global team for a product approved in over 30 countries.