

Regulatory Support for Globally Marketed Product



Challenge

Develop Regulatory Documents for Globally Marketed MS Product

MMS was requested to provide a number of regulatory resources to step into a global, cross functional team to help support a marketed MS product. The MMS team was asked to provide writing support for a variety regulatory documents including Risk Management Plans (RMP), health authority questions, labeling updates, and common technical document (CTD) submission summary documents..

Solution

Provide Regulatory Writing Resources to Support Sponsor Team

MMS assigned regulatory resources to quickly review the existing data on the marketed compound and write the requested documents. The MMS resources were able to efficiently learn the sponsor's document management system and forge strong working relationships with sponsor team members across several functional areas. The sponsor was able to rely on MMS writers as the main regulatory writing contacts for the team, which allowed their internal writing resources to be used to meet other business needs.



Outcome

MMS Delivered High Quality Deliverables

The MMS resources are now seen as valuable, extended members of the sponsor team, and have received a number of accolades on the many documents they have authored. The sponsor decided to extend the contracts of these resources to leverage the value they have provided to their teams, and this team is now in their 4th year of support.



"I want to thank the MMS team for their extraordinary efforts on the compound RMPs. Your work on the documents was clear and organized, and I especially appreciate sharing of your experiences with prior RMPs. Thanks to your tremendous efforts. In this assignment, you demonstrated a great deal of flexibility, and not only the ability to work under tremendous pressure, but to build a great rapport with the team. Many thanks!"
- Sponsor Project Lead

