The difference is in the data.™

QC Support for FDA Approved NDA Submission for Rare Disease Therapeutic

CHALLENGE

A large biopharma client received queries from the FDA about their NDA submission of a therapeutic for a rare disease. The MMS team supported the QC of the Response to Questions (RTQ) document, which was highly complex. The timeline was incredible tight with short notice requests, and the team used a streamlined QC process to complete the completion of QC on complex documents within the timeframe without compromising quality.

MMS SOLUTION

Through close collaboration and open communication with the client, the MMS team was able to provide complex QC support for the client's request. The QC group was familiar with the pivotal studies, and draft responses were reviewed for compliance with regulatory requirements. The QC team worked on a 24-hour clock, across MMS' global operations from India to the US, and worked extended hours to meet the timelines. In addition, the team used a streamlined QC process to complete the completion of QC on complex documents within the timeframe without compromising quality.

"We did it! As a team, we all (you included) did it! All of our Day 90 Responses to Questions are complete, QC'd, and approved or in approval by the deadline. Your help, dedication to our requests, and hard work made it possible. I know you put in extra hours, long days, and probably the weekend too. It feels you acted as colleagues. From the bottom of my heart, thank you!"

-Associate Director of Medical Writing, Large Biopharma

OUTCOME

The MMS team completed the projects on time or ahead of time. The client was impressed with the team's dedicated work and extended hours to meet their requests. Overall, the rare disease therapeutic was approved by the FDA.