



Improving Patient Health and Safety

Case Study: Regulatory Affairs Project Manager

The regulatory affairs department for a biotech company had several regulatory filings and needed help with their submissions to meet important company deadlines. The experienced regulatory consultant met with regulatory executives and team members to conduct a gap analysis to identify the regulatory documents in scope for the submission per the applicable regulations. The consultant then collected the regulatory information applicable to the dossier submissions and developed project plans for transparency to the related cross functional activities. The consultant also interfaced with the vendors on document redaction, review, approval, and overall project scope and the planning of activities leading to the submissions. In addition, the consultant managed the document review and approval workflows in the Electronic Document Management System (EDMS) for all documents in scope and ensured timely provisioning of publishing activities.

From a cross functional and project management perspective, the consultant provided strategic guidance to teams and project managers to lay the groundwork for program success. Working closely with the project teams, the consultant managed submission forecasts to ensure timely and quality regulatory submissions to health authorities within the required timelines.

As a result of the expert project management and regulatory services provided, the client was able to meet all regulatory filing dates for the year. The teams had transparency to weekly tasks that were not provided prior to the consultant's arrival. The executives had more confidence in the progression of the filings and more confidence in communicating the regulatory deadlines to the Board. The consultant was also able to embed these tools, processes, and communications within the teams to ensure future submissions would be delivered in a timely and quality manner.

