CASE STUDY

Compressing Timelines Toward Regulatory Submissions Without Sacrificing Quality

SCENARIO

A pharmaceutical company was about to submit a New Drug Application (NDA) and a Marketing Authorisation Application (MAA), and sought guidance in submission preparation.

THE CHALLENGE

Our client was faced with extremely tight timelines in submitting their New Drug Application (NDA) and a Marketing Authorisation Application (MAA). Senior leadership had promised a highly aggressive date for product approval and launch.

THE STRATEGY

Expert advice to the company's cross-functional team charged with improving the complex submission preparation, decision making, and communication process led to a high-quality content NDA/MAA submission within compressed timelines.

A close interface with the project planning team provided insights during the submission process on how to address questions and comments from the competent authorities (FDA and EMA) during the NDA and MAA review.

The cross-functional team, comprised of global SMEs, delineated clear roles and responsibilities in preparing the submission, while Bracken and the client interfaced with them on an ongoing basis throughout the preparation leading to the submissions, and during FDA and EMA review.

Review and refinement of each team member's role and responsibilities avoided overlaps or gaps and clarified activities for all team members. Taking the time to refine this aspect in the beginning and building in periodic checks and balances saved time in the end.

Creating clear communication channels within the cross-functional team and between the team and senior leadership allowed the team to remain nimble and focused on decision-driven outcomes.

THE RESULTS

This type of communication path and process contributed to the creation of a high-quality dossier within a highly compressed timeline.

The best part? Using this method significantly reduced the standard review time from 12 months to 9.5 months.

Regulatory Expertise

Our team of expert consultants are here to help you, leveraging our knowledge for your solutions.

Our tailored services range from ad hoc consulting, to providing a virtual C suite (CEO, CFO, CMO, CSO) clinical and regulatory team ready and able to integrate with yours.

By employing a comprehensive and customizable multidisciplinary, problem-solving methodology, we are able to reduce risks and streamline development plans.

The regulatory landscape is tough to navigate---don't go it alone.

BRACKEN

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