Sequential NDA and MAA Submissions: Regulatory Strategy

The Situation

DLRC partnered with a pharmaceutical company who were planning to file a new drug application (NDA) to the FDA and a marketing authorisation application (MAA) to the EMA sequentially. This project was a follow-up project, based on a previous history of working together.

The client was looking for regulatory strategy and support to guide them through the filings, from "pre" pre-submission meetings, through to validation and subsequent approval.

DLRC provided regulatory consulting, medical writing, labelling, project management, publishing and submission support.
This project was a large development programme, with a large volume of documents and tight timelines.

There were numerous documents for the filings to be authored, many in parallel. Whilst taking account of efficiencies in preparing the two submissions, it was equally important to understand, acknowledge and address regional nuances, whilst at the same time, being aware of project deliverables and timelines.

DLRC's Solution

DLRC's team worked collaboratively with the client throughout this project, including organising and leading meetings, as well as driving consensus and completion of critical documents. The team placed a strong emphasis on clear, consistent, and responsive communication, which helped build trust and maintain momentum. This collaborative and communicative approach enabled the development of a well-coordinated regulatory submission strategy, executed efficiently.

The Outcome

Regular communication between DLRC and the client, continually found solutions to problems, making sure timelines were met, and both NDA and MAA applications were submitted within the projected timelines. DLRC's commitment to strategic coordination and communication played a key role in the overall success of the regulatory process.

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