Submitting Marketing Applications

Marketing applications in a nutshell

Submitting your marketing authorization application (MAA) or new drug/biologics license application (NDA/BLA) is a significant undertaking, involving a team of 20–30 people over a period of 18–24 months.

Navigating the regulatory processes in the lead-up to the submission can be extremely challenging. Submission timelines are vital and planning your MAA or NDA/BLA submission should start 2–3 years before you submit. This is to ensure that you have time to assemble all the dossier components and bring the required resource onto the project.

We have filed numerous MAA and NDA/BLA submissions across different therapeutic areas and can guide you through the best practices for submission planning.

How we can help

We can support every aspect of the filing, including the following:

- Developing a Common Technical Document (CTD) table of contents for the submission and conducting a gap analysis to ensure that all submission components have been identified and planned.
- Preparing key messaging and the company core data sheet.
- Preparing regional labelling such as the Summary of Product Characteristics and US Prescribing Information.
- Planning the data presentation, analysis and discussion in the dossier.
- Conducting detailed reviews of the data (tables, figures and listings) shells to ensure the required analysis and outputs are planned.
- Writing Modules 1–5 of the electronic CTD.
- Publishing and submitting the completed submission.
- Responding to questions from the agency during the evaluation.

We frequently, work as part of the global filing team for parallel submission to the US, EU and additional authorities. If possible, it is worthwhile writing a submission with common US and EU Module 2–5 components, especially the Module 2 summaries, so that multiple consistent submissions can be made to streamline regulatory agency interactions.

We can also provide peer review of existing projects, to stress-test the work that has been done and recommend solutions to address any gaps. Peer review may be especially useful to prepare for the MAA submission, where an additional perspective may help to highlight any potential risks.

Your roadmap to working with Somerville Development Partner

Initial conversation

It is always a good idea to start with an open-ended discussion about your needs and challenges, and we can give you some preliminary advice on how to approach your regulatory interactions in Europe and the US.

Project scoping

To provide a specific proposal for how we would approach your project, we require access to some of your project details. Therefore, we always recommend signing a confidentiality agreement before discussing the scope of your project.

Next, we will provide a scope of work for you to review. Once this is agreed, we will start work on the project.

Kick-off

We will assign an experienced consultant to act as your Regulatory Lead from the very beginning—your expert will take overall responsibility and accountability for your project from start to finish.

Your Regulatory Lead will always be someone who has:

- 10–15 years of experience
- tenure in established pharmaceutical and biotechnology companies, and
- been the regulatory lead on a global project team.

Your Regulatory Lead will be your primary point of contact and will also draw on support and expertise from additional consultants, as needed.

We ask that you securely share all product-related documents so that we can conduct a detailed evaluation of the data. This will enable us to provide informed recommendations for how we will deliver the project.

The most common documents we request include:

- study protocols,
- the investigator brochure,
- clinical study reports,
- briefing books from prior regulatory interactions, and
- meeting minutes from prior regulatory interactions.

This also means that we can repurpose as much content as possible to reduce costs.

We will agree the timelines, overall project delivery and desired outcomes with you. We will also identify the relevant stakeholders who will need to review and provide input into the project.

Delivery

During the project, we look out for your best interests and work to help you achieve your corporate objectives. We work as a partner and proactively identify issues, solutions and opportunities, rather than acting as a passive or transactional vendor.

Our consulting team will produce the agreed deliverables to the required timetable.

We will meet with you as often as needed to discuss the progress of the project and request any additional information. We will also meet—as necessary—to discuss review cycles, final signoff and submission.

Every project we work on undergoes peer review, as well as quality control of the final submission. That way we effectively draw on all additional experience from among our team of life sciences experts.

Feedback

Feedback is very important to us, so most of all we want to hear your thoughts on how the project went.

Getting in touch

We always welcome the opportunity to discuss a potential project with you!

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