

Efficient Navigation of UK MAA Regulatory Pathways



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The Situation

A small biotech company approached DLRC on the basis of a recommendation.

The company had FDA approval for their medicinal product (an advanced therapy medicinal product (ATMP)), and an EMA review of the MAA had started.

Our team were asked to look at the most efficient way to obtain approval in the UK, specifically whether there would be benefit in leveraging the MHRA's International Recognition Procedure (IRP).

DLRC's Solution

DLRC evaluated submission options for the product, taking the product's properties, i.e. ATMP, into account, as well as its international regulatory status, previous intelligence from the MHRA and MAA review timelines across the different pathways.

Once a pathway had been agreed, DLRC led the preparation of the UK MAA dossier, integrating seamlessly as project team members, driving the preparation of the required documents, and collaborating with the client subject matter experts where appropriate. We adapted to the client's ways of working, ensuring a fast, well-integrated team striving together to achieve the end goal, which ultimately was to enable patient access to this orphan medicine in an efficient and timely manner.

The DLRC team was able to leverage the many years of experience working with the MHRA and provide guidance on nuances and MHRA preferences, which are often not clearly specified in the official guidance, to help ensure a smooth validation and subsequent assessment of the MAA.

During the procedure, on receipt of questions from the regulators, the DLRC team led the project team, managing response authoring and reviewing, whilst working to tight timelines with a highly stretched client team. Relying on the DLRC team to handle the UK submission allowed the client to work across other multiple ongoing procedures and ensured complete, comprehensive responses to MHRA of high quality, mitigating the likelihood of further rounds of questions.

The Outcome

The MAA was submitted within a very short timeline, and subsequently approved ahead of client expectations. DLRC provided advice and hands-on support that resulted in a fully prepared, high-quality UK MAA dossier, gave strategic guidance on the optimal submission pathway, and delivered flexible, end-to-end project leadership throughout the review and Q&A process.

As a result of this support, the client achieved rapid entry to the UK market, ensuring that patients had access to this treatment in a timely manner. DLRC's expertise in the MHRA's preferences and ways of working reduced the likelihood of delays, ensured smooth procedure validation, and kept the assessment on track.

This was the start of a long-standing relationship with this innovative biotech company. We have continued working with them beyond the initial MAA, supporting follow-on regulatory activities and as trusted advisors providing ongoing strategic advice.

This project created regulatory success, long-term efficiencies, and strategic advantages for the client, while ultimately helping bring a much needed treatment to patients as quickly as possible.