

Strategic Support for a CTMP: Navigating EU Regulatory Filings



The Situation

DLRC collaborated with a US-biotechnology company that was in the mid-development phase of a Cell Therapy Medicinal Product (CTMP). The client required DLRC's expertise in EU regulatory requirements to advance their product to marketing authorisation (MA) filing. They could therefore leverage from the EU's fast-to-market regulatory pathways for products addressing unmet medical needs in an oncology indication.

Therefore, DLRC provided comprehensive support for:

- The client's conditional MA strategy
- Agency interactions and meetings
- Helped the client navigate through the EU Accelerated Assessment pathway
- Supported the compliance check for their Paediatric Investigational Plan
- MA filing process.

Additionally, DLRC's CMC subject matter experts needed to conduct a Quality (CMC) GAP analysis. This analysis assessed the available quality data. This included the product supply chain against EU requirements to ensure the quality sections of the dossier met the EU criteria.

DLRC assisted the client with key Agency interactions prior to filing. We ensured compliance with EU guidance and regulations as applicable for CTMPs and oncology medicinal products. As the client was US-based, it was crucial for DLRC's subject matter experts in EU clinical development to also offer guidance on clinical product development through to MA filing.

The MA was based on a single-arm pivotal study, an approach that requires strong scientific and clinical justifications in support an indication. DLRC was able to collaborate with the client to navigate potential (and retrospective) risks as well as develop timely mitigation strategies for this MA approach. DLRC supported the preparation of key clinical documents, and the overall dossier preparation for filing.

DLRC's Solution

We prioritised collaboration, flexibility, and innovation. Therefore, DLRC successfully guided and assisted the client from their mid-clinical development phase up to the MA filing.

The filing was successfully published and submitted by DLRC's Regulatory Operations team. The tireless effort from the team ensured the submission was also made ahead of the scheduled submission date.

The Outcome

DLRC helped the client achieve a key corporate milestone for their innovative product, therefore expanding their product development to the EU region.

The successful collaboration resulted in the client wanting to move forward with DLRC for the filing of the MA for the same product in another region. This will allow more patients to have access to a medicinal product aimed at addressing an unmet medical need.

If you are seeking support and expertise of DLRC in your regulatory endeavours, we invite you to reach out to us at hello@dlrcgroup.com. Together we can turn your regulatory challenges into success.

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