BUSINESS CASE

Case Study: Preparation of an IMPD for an ATMP product

CHALLENGE

A biopharmaceutical company engaged in developing an advanced therapy medicinal product (ATMP) planning to start Phase I of a clinical trial in the United Kingdom.

- **Key gaps identification** in the source documentation to facilitate a smooth UK health authority assessment.
- Strict **time constraints** limited the ability to perform a comprehensive gap analysis and complete the CMC IMPD document writing.
- **Resource allocation planning** to schedule and assign resources for CMC IMPD document writing.
- **Clinical Trial Application support** for IRAS portal submission.
- Ongoing **clinical phase support** to identify critical CMC data.
- **Milestone management** and planning for key regulatory interactions.

SOLUTION

- Detailed **gap analysis** of existing source documentation and **strategic mitigation plan** proposal to address identified deficiencies.
- Comprehensive **CMC strategy** to ensure alignment with the defined calendar and project goals.
- Acted as **primary contact point** with relevant stakeholders to streamline coordination and facilitate efficient data gathering.
- Preparation of **CMC IMPD documents** ensuring alignment with the clinical trial application requirements and adherence to timeline.
- Provided **ongoing support** for further clinical phases, including evaluation of CMC changes throughout the clinical trial and the need for quality amendments.

Additional non-CMC specific activities performed:

- Oversaw **all regulatory activities** concerning the **clinical trial**, including **CTA submission** and **follow-up** with **authorities**.
- Authored the **Investigator's Brochure (IB)**, along with the **pre-clinical** and **clinical** sections of the **IMPD**.
- Well-planned and meticulous **project management** to ensure **successful application** within the proposed timeline.

OUTCOME

The project culminated in the successful authorization of the clinical trial, achieved through:

- **Timely Authorization**: the clinical trial authorization was granted within the planned starting date, ensuring no delays in project execution.
- **Optimized Strategy:** implemented an optimized writing strategy for anticipated changes during the clinical trial course.
- **Budget Adherence**: all activities were completed within the agreed budget, demonstrating effective cost management.

This comprehensive approach ensured that the client could proceed with confidence in initiating their clinical trial, supported by a robust CMC strategy.

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