APCER LIFE SCIENCES
Together for better health

CASE STUDY

Successfully Enabled CTD Modules Preparation within Stringent Timelines

Therapeutic area: Immunology

Product type: Drugs

Geography: European Union

Product life cycle stage: Marketing Authorization Application Submission

About the Client

The client is among well-established pharmaceutical companies committed to contribute to the development and maintenance of quality medicines recognised as essential to patient health. The company has products in diverse therapeutic areas, such as cardiology, immunology and neurology.

Business Challenge

The pharmaceutical company partnered with APCER for the preparation of CTD modules for Marketing Authorization Application (MAA) submission of their innovative product in the European Union (EU). The client team had aggressive internal timelines for the submission and lacked expertise and resources to prepare a comprehensive dossier according to the stringent regulatory requirements. Several hurdles threatened to delay the process:

- **Time Constraints:** The client had ambitious internal deadline for submitting the MAA, which made the project challenging. Authoring summary documents before receiving all the finalised source documents from the client added another layer of complexity.
- **Data Interpretation:** A few non-clinical study reports required interpretation to create non-clinical summaries and overviews, thereby requiring additional time and expertise.
- **Improper Document Format:** The source documents for this project presented a unique challenge. Some reports were scanned documents, while some were non-GLP, non-editable study reports, which required additional efforts to compile and interpret the data effectively for inclusion within the CTD modules.

Overview - Clinical Trial Document (CTD)

The CTD is an internationally agreed format accepted by Europe, USA and Japan regulatory authorities and is organised into five modules:

- Administrative, regional or national information is provided in Module 1.
- Module 2 includes:
- 2.4 Non-clinical Overview
- 2.5 Clinical Overview
- 2.6 Non-clinical Summaries
  - » 2.6.1 Pharmacology Written Summary
  - » 2.6.2 Pharmacology Tabular Summary
  - » 2.6.3 Pharmacokinetics Written Summary
  - » 2.6.4 Pharmacokinetics Tabular Summary
  - » 2.6.5 Toxicology Written Summary
  - » 2.6.6 Toxicology Tabular Summary
- 2.7 Clinical Summaries
  - » 2.7.1 Biopharmaceutic Studies and Associated Analytical Methods
  - » 2.7.2 Clinical Pharmacology Studies
  - » 2.7.3 Summary of Clinical Efficacy (SCE)
  - » 2.7.4 Summary of Clinical Safety (SCS)
  - » 2.7.5 Literature References
  - » 2.7.6 Synopses of Individual
- Studies on Chemical, Pharmaceutical and Biological documentation are provided by Module 3.
- Non-clinical study reports and clinical study reports are included in Module 4 and Module 5, respectively.

Solution

APCER's experienced medical writing team handled this complex MAA submission with challenging data formats and stringent timelines by:

- **Strategic Resource Allocation:** To expedite timely completion and ensure efficiency, we implemented a parallel authoring strategy by assigning dedicated medical writers to concurrently develop the various sections for Modules 2, 4 and 5 of the CTD.
- **Efficient Teamwork:** Weekly meetings led by the project lead medical writer ensured consistency across sections and documents and ensured regulatory compliance throughout the CTD dossier.
- **Real-Time Reviews:** Staggered peer and quality reviews helped to maintain high standards and project timelines. For this, a SharePoint platform was utilised, which facilitated seamless document sharing, review and revision.
- **Proactive Summarisation:** Instead of waiting for the finalised reports, APCER initiated writing summaries from draft documents to meet the tight timelines of the project. Upon receiving finalised reports, APCER additionally cross-checked for any updates against draft versions.
- **Expert Data Interpretation:** APCER's medical writers, with their deep understanding of the non-clinical data, efficiently extracted and interpreted data from non-GLP reports to create accurate non-clinical summaries and overviews.
- **Skilled Formatting:** The medical writers identified relevant data from the non-GLP reports and APCER's skilled formatters quickly converted scanned documents into clear and concise tables, maintaining industry standards across the CTD modules.

Outcome

Timely Submission: APCER delivered a well-written and compliant CTD dossier within the client's strict timelines for the EU MAA submission.

Regulatory Compliance: The dossier adhered to all relevant EU regulatory guidance, ensuring a smooth submission process.

Positive Feedback: The client provided excellent feedback, highlighting the superior quality of the modules.

Our Medical Writing Capabilities

A team of experienced and specialised medical writers having strong educational background, which includes pharmacists, dentists, physicians and other healthcare professionals having rich experience across therapeutic areas and expertise in preparing regulatory documents and scientific communications.

A robust two-step review process to ensure 100% quality control.

High-quality deliverables consistently exceeding expectations.

A dedicated team of copyeditors and typesetters to perform a check on language, grammar and style and ensuring e-submission readiness.

Customised solutions fully compliant to the ever-changing regulatory landscape.

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APCER Life Sciences is committed to improving health in partnership with its clients. We bring together safety, medical, regulatory and technology resources to ensure that patients receive the safest, most effective therapies possible.

We are an ISO 9001:2015, ISO 27001:2022, and ISO 27701:2019 certified company.

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