APCER LIFE SCIENCES
Together for better health

CASE STUDY

Streamlining lifecycle management through proficient eCTD submission roadmap

Therapeutic area: Cardiovascular

Product type: Drugs and devices

Geography: US

Product life cycle stage: Clinical Development through Post-approval Lifecycle

About the Client

The client is a global pharmaceutical company focused on the development of cardiovascular drugs for unmet needs in the indications of thrombosis and cardiac rhythm control.

Business Challenge

The company sought support to maintain LCM activities for its ongoing clinical trials and registered products in order to comply with the regulatory expectations. The company faced challenges due to:

- limited resources and expertise related to eCTD publishing and gateway submission activities for regulatory authorities, and
- delayed submissions leading to delayed approvals, which were adversely impacting budgets.

Overview - eCTD Submission

Electronic Common Technical Document (eCTD) is an electronic format that supports the submission of applications, amendments, supplements, and reports to the United States Food and Drug Administration (USFDA), European Medicines Agency (EMA), and other health authorities (HAs) worldwide.

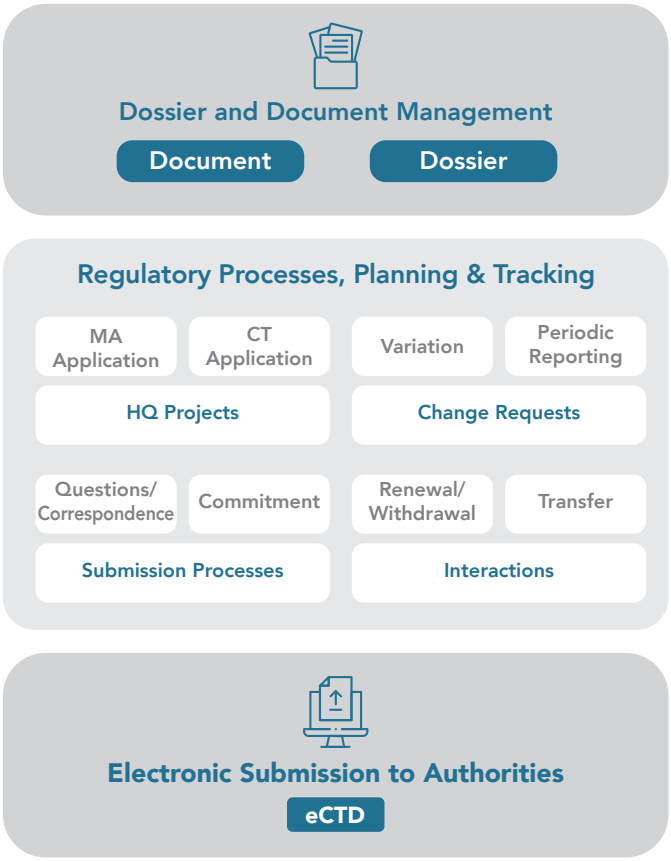
eCTD facilitates the quick creation and review of electronic data with a flexibility to integrate metatags, hyperlinks, and bookmarks to the data.

It enables efficient assessment and effective lifecycle management (LCM) of submissions for quicker market approvals and authorizations.

Solution

APCER Life Sciences was chosen as a partner for our in-house expertise on regulatory publishing and submission services. We helped the client address their challenges by:

- gathering all the desired information and creating a comprehensive plan to manage the submission of the products,
- effectively performing activities such as filing, data compilation, data publishing, and dossier dispatches driven by our comprehensive knowledge of global regulatory publishing trends and submission formats, and
- supporting the publishing and submission activities of Investigational New Drugs (INDs) and New Drug Applications (NDAs) within the specified timeline.



Outcome

- Formalized the submission process for protracted LCM.
- Achieved regulatory compliance by harmonizing the product lifecycle to meet agency requirements.
- Paved the way for LCM from IND to post-approval maintenance of a reformulation, the company was convinced that such a step was necessary to preserve their time, expense, and reputation in the longer term.

Our Regulatory Affairs Capabilities

Regulatory consulting and execution services with an experienced team of CMC writers and reviewers.

Regulatory and scientific team with **extensive experience** in preparing regulatory documents throughout the product life cycle.

Publication and submission of electronic dossiers in different countries, such as the US, the European Union, the United Kingdom, and Canada.

High-quality deliverables consistently meeting or exceeding client and regulatory expectations.

Custom and fully compliant solutions to meet ever-changing regulatory requirements.

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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.

Learn more at www.apcerls.com or contact us at one of our global offices: Americas: (+1) 609 455 1600 • Europe: (+49) 2409 725 6120 • UK: (+44) 208 326 3220 • Asia: (+91) 79 6677 8600

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