CERTARA

Synchrogenix Helps Sponsor Achieve Document Quality to Support Regulatory Filings

Background

This specialty pharmaceutical company is focused on the development and commercialization of an immunosuppressant for the prevention of organ rejection in kidney transplant patients. Currently a Marketing Authorization Application has been submitted to the European Medicines Agency (EMA) and a New Drug Application with Orphan Drug Status is under review with the US Food and Drug Administration (FDA).

Challenge

Since 2011, Synchrogenix has provided various services to this specialty pharmaceutical company in support of their recent filings to the EMA and FDA, including authoring, technical editing, document conversion, and Quality Control. With simultaneous submissions, this company needed additional support to align their documents with EMA and FDA guidelines. Documents were coming at various time points from multiple authors, and the exact workload could not be defined. An ad hoc, single-source solution was needed to provide organization, ensure consistency, and adhere to regulatory requirements.

Solution

Synchrogenix outlined three types of activities: Style Guide, Document Management, and Document Review as follows:

- **Style Guide:** Customization based on sponsor specifications and conventions
- **Document Management:** Coordination and maintenance of file structure, upholding responsibility for the versioning of the official documents, and making all updates to those official versions on sponsor's document management site
- **Document Review:** Review all documents for consistency from an editorial perspective and from Subject Matter Expert perspective on specific documents

Synchrogenix created a granular tracking sheet that was maintained on the sponsor's document management site.

Benefit

The process was organized and efficient, allowing the client to focus on other submission-related activities.

Challenge

With simultaneous submissions, the sponsor required additional support to align their documents with EMA and FDA guidelines. Documents were coming at various time points from multiple authors, and the exact workload could not be defined.

Solution

Clearly communicate all required activities to the sponsor for alignment with EMA and FDA guidelines. Create a shared document tracking sheet to organize activities and maintain on a real-time basis.

Benefit

Synchrogenix created an organized and efficient process and managed the work stream allowing the client to focus on other submission-related activities.

About Certara

Certara is a leading provider of decision support technology and consulting services for optimizing drug development and improving health outcomes. Certara's solutions, which span the drug development and patient care lifecycle, help increase the probability of regulatory and commercial success by using the most scientifically advanced modeling and simulation technologies and regulatory strategies. Its clients include hundreds of global biopharmaceutical companies, leading academic institutions and key regulatory agencies.

For more information visit www.certara.com or email sales@certara.com.

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