MEDPACE

REGULATORY PUBLISHING

Experts. Experience. Execution.

Discover the POWER OF X

Efficiency in Electronic Regulatory Publishing

A typical regulatory submission includes thousands of pieces of data that need to be compiled and managed for thoroughness, accuracy, and integrity against agency requirements.

At Medpace, our submissions utilize up-to-date knowledge on global formats and conventions to structure global submissions to tell the right story with the right data, and to expedite data exchange between Sponsor and Agency. Our Regulatory Publishing team has the ability to adapt to any sponsor's needs for any submission document, and, in collaboration with our Regulatory Affairs staff, support the application throughout the submission lifecycle.

Medpace Regulatory Publishers are highly skilled, with advanced publishing and document management experience. Our goal is not only to guide our sponsors through the process, but to involve them in every decision leading to agency approval. Our integrated experts in Regulatory Affairs and Regulatory Publishing form a highly collaborative team that provides the best in strategic and technical service for our Sponsors.

Electronic Submission Services (ESS)

- eCTD ready templates for authoring submission content
- Document formatting and PDF generation
- Bookmarking and hyperlinking documents, CRFs, and datasets
- Prepare eCTD submission-ready Clinical Study Reports (organize Appendix 16 documents and hyperlink to report body)
- eCTD compiled, validated, and ready for client review
- Submission planning and lifecycle management
- Organize PDF files containing metadata and lifecycle instructions to ensure the data is properly transferred to agency reviewers and can be easily navigated
- Well-organized submissions facilitate agency review and approval

Comprehensive Services – Submission Component Preparation

- Scanning services and legacy document conversion
- Document and report publishing
- Clinical Data Interchange Standards Consortium (CDISC) and U.S. Food and Drug Administration (FDA) submission data conversion services
- Regional regulatory expertise
- Defining eCTD granularity
- Submission readiness assessment, including eCTD readiness review and gap analysis

Global Submission Publishing

- Paper submission publishing
- Electronic common technical document (eCTD) submission planning and tracking
- Electronic submission publishing, including eCTD, non-eCTD, and hybrid formats
- Conversion of paper/legacy format to eCTD format applications
- Considerations for report and Case Report Form publishing
- Publishing clinical study reports for paper and electronic submissions

Medpace Regulatory Affairs and Publishing teams specialize in full global development, and can help plan, manage, and prepare for global, multi-country simultaneous, or sequential filings while meeting all product development milestones. Our experts are experienced in developing and submitting regulatory applications globally, with specialized expertise in electronic Common Technical Documents (eCTD) in specific regional formats.

Medpace regulatory experts employ proven software solutions to deliver compliant, timely submission component documents and valid electronic submissions. We offer secure electronic document file sharing and review, as well as timely secure electronic submissions through agency gateways.

Medpace Global Regulatory Affairs

Medpace Global Regulatory Affairs, led by Steven B. Johnson, Vice President, is a world-class, stage-setting, and professional regulatory affairs and medical writing organization that facilitates the rapid development of safe and effective therapeutics for our clients. Our team is comprised of more than 50 experts providing coverage across all areas of clinical development through marketing authorization.

About Medpace

Medpace is a scientifically-driven, global full-service clinical contract research organization (CRO) providing Phase I-IV clinical development services for drug, biologic, and device programs. Medpace's physician-led, high-science, and disciplined operating approach leverages regulatory and therapeutic expertise to accelerate the global development of safe and effective medical therapeutics across all major areas including oncology, cardiovascular, metabolic/diabetes, infectious disease, and neuroscience.