VERISTAT

Expert Regulatory Publishing to Support Successful eCTD Submissions

Publishing Through FDA Electronic Submissions Gateway (ESG)

Our regulatory publishing team will support the publishing of your applications, amendments, supplements and reports to the United States Food and Drug Administration (FDA) through the Electronic Submissions Gateway (ESG). As noted below, the FDA requires most regulatory submissions to be submitted in eCTD format, which improves the efficiency of delivery, formatting, and review of the submission files.

As of May 5, 2017, the following submission types must be submitted electronically:

- New Drug Application (NDA)
- Biologics License Application (BLA)
- Abbreviated New Drug Application (ANDA)

As of May 5, 2018, the requirement for electronic submission also included:

- Commercial Investigational New Drug Application (IND)[1]
- Master Files (DMF; Except Type III)

Type III DMFs must be submitted through the ESG by May 5, 2019.

Veristat teams have worked on

>75 original marketing applications

>45 with approvals to date

12% of New Molecular Entities (NMEs) approved by the FDA in 2018 were supported by Veristat

[1] Noncommercial INDs and certain medical device INDs reviewed by CBER are exempt from electronic submission. Noncommercial INDs will be accepted electronically, but it is not a requirement.

Providing Oversight, Expertise, and Ability to Successfully Publish eSubmissions to the FDA

Due to these FDA requirements and growing demand, Veristat now delivers regulatory publishing support as part of our regulatory submission solution. Our clients benefit from having end-to-end services – the same team works on your program from a regulatory, CMC, and clinical perspective, writes your regulatory documents, and then submits them through the ESG to the FDA. Our publishing experts provide:

- Project and timeline management for the publishing process
- Conversion from paper submissions to eCTD format
- Use of standardized templates
- Document level publishing
  - *Word formatting: styles, captions, cross-references, tables, etc.*
  - *Report level publishing of E3 and legacy CSRs*
  - *Validated and QC'd hyperlinks, bookmarks and technical specifications with the support of TRS Toolbox*
- Submission level publishing: eCTD placement, cross-document links, study tagging files (STF), submission metadata
- Submission quality control (QC) and validation
- Transmission of submissions to FDA via Electronic Submissions Gateway
- Archive and document transfer: archival of final Word docs and submission sequence
- eCTD viewer seats available

Types of Regulatory Submissions Published

- Pre-IND, IND, NDA, and BLA – inclusive of all supporting submissions (i.e., protocol amendments, investigator documents, expedited pathway submissions, annual reports, etc.)
- DMFs

The Publishing Technology

eCTD manager

Veristat publishing experts manage electronic submissions to the regulatory agencies using EXTEDO eCTDmanager – an eCTD management software solution – designed to ensure compliance with ICH and regional regulatory requirements. The technology solution allows us to build, view, validate and publish eSubmissions.

Veristat has an extraordinary record of success, helping biopharmaceutical clients prepare over 75 marketing applications to date. By utilizing our regulatory publishing services, we can shorten and better manage the submission timelines, or we can make up for existing delays.

Consult Our Regulatory Experts

We offer you the benefit of working with a single regulatory group for consultation from a regulatory, CMC, and clinical perspective – as well as the writing and submission of your regulatory documents.

Reach out to us today to learn more about how Veristat can assist you with your regulatory submission's planning, writing, data conversion, finalization, and publishing.

www.veristat.com