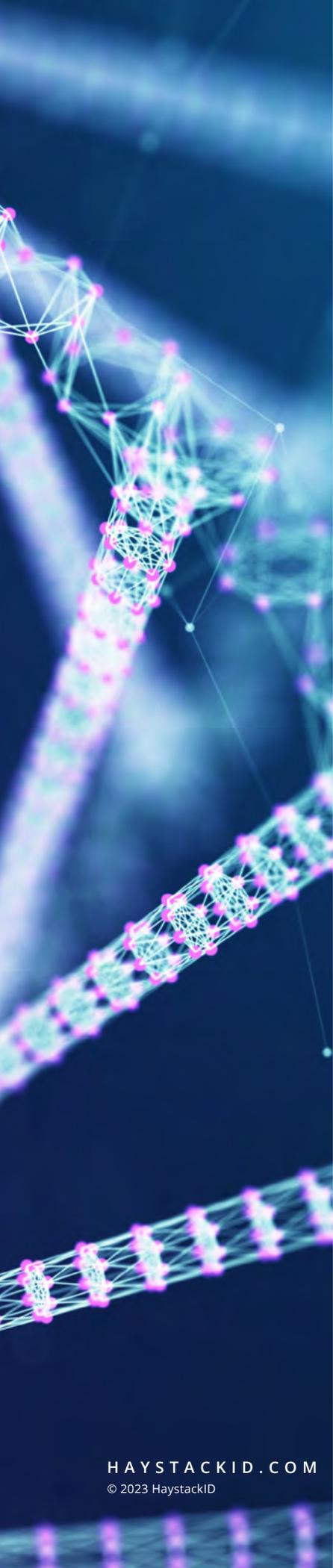


FACT SHEET

eCTD Compliance Review Module

An Overview of HaystackID's Electronic Common Technical Document (eCTD)
Review Capability within Relativity®

HAYSTACK®



Tackle Complicated eCTD Filings Effectively with HaystackID®

HaystackID has developed a cutting-edge solution, the Electronic Common Technical Document (eCTD) Compliance Review Module, designed to empower legal professionals in effectively managing the complexities of eCTD filings. This module seamlessly integrates with Relativity®, providing a range of advanced features to simplify and streamline the eCTD review process.

eCTD is the standard format for submitting applications, amendments, supplements, and reports to the U.S. Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), and Center for Biologics Evaluation and Research (CBER).

Submissions Requiring eCTD Format:

- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs)
- Biologic License Applications (BLAs)
- Commercial Investigational New Drug Applications (IND)
- Drug Master Files (DMFs)
- All Subsequent Submissions

These eCTD file formats contain years worth of cumulative work product, all of which are critical not only to the application process but also to any subjective challenge to the application and submission to a regulatory body, as well as within litigation.

Regulatory Requirements and Proactive Preparation for eDiscovery

These FDA-driven regulatory requirements have caused a shift in the way Pharmaceutical Manufacturing, Drug Marketing, Biotechnology, and Research and Development (R&D) companies handle their applications and submissions. However, these companies are not the only ones who are impacted by these requirements. Attorneys, litigators, corporate counsel, patent specialists, and regulatory proceeding experts are now seeing these files regularly in the course of legal discovery.

An eDiscovery Solution

HaystackID has solved the challenge of eCTD review for legal professionals with our proprietary eCTD Compliance Review Module. This review module is designed to help legal experts tackle the complicated formats of eCTD filings.

Key features of the eCTD Compliance Review Module include:

- Direct integration with Relativity for dynamic review, search, culling, tagging, redaction, and production.
- Viewing of historical sequence timelines of submission lifecycles.
- Full preservation of complex folder structure, metadata, and revision history within Relativity.
- Automated parsing and Relativity field mapping of embedded XML-based metadata content.
- Push button review of family-level, linked document associations.
- Customizable relational pane in Relativity for eCTD submission display.
- Streamlined production process of all associated metadata and file content to industry-standard electronic discovery load-file formats.

A Powerful Approach to a Specific Challenge

Traditionally, specific software designed to create, edit, modify, and review eCTD submission files and the documents contained within those submissions while also preserving a history of changes is not designed for electronic discovery purposes, nor do they allow for collaboration and tagging of documents by multiple users utilizing typical document review workflows. HaystackID's proprietary design decodes complex eCTD data structure and supporting files, all while preserving important folder structure, metadata, and revision history within Relativity, providing a powerful approach to a specific review challenge.

HaystackID's eCTD Compliance Review Module also provides context and structure around documents contained in an eCTD submission immediately upon upload into Relativity, during document review, and through productions to others, standing alone as the only comprehensive solution on the market for eCTD review challenges.

Additionally, when it is time for production, folders, revision history, documents, and custom metadata related to files and folders can all be easily produced in typical electronic discovery load-file formats. This approach ensures that critical context regarding the structure and content of an eCTD submission is preserved as evidence that can be acted on throughout investigation and litigation lifecycles.

Learn More. Today.

[Contact us today](#) to learn more about our specialized eDiscovery services and how our eCTD Compliance Review Module can help streamline and accelerate investigations, legal review, and document productions from data submitted to meet CDER regulatory requirements.

About HaystackID®

HaystackID is a specialized eDiscovery services firm that supports law firms and corporate legal departments and has increased its offerings and expanded with five acquisitions since 2018. Its core offerings now include Global Advisory, Discovery Intelligence, HaystackID Core™, and artificial intelligence-enhanced Global Managed Review services powered by ReviewRight®. The company has achieved ISO 27001 compliance and completed a SOC 2 Type 2 audit for all five trust principles for the second year in a row. Repeatedly recognized as a trusted service provider by prestigious publishers such as Chambers, Gartner, IDC, and The National Law Journal, HaystackID implements innovative cyber discovery services, enterprise solutions, and legal discovery offerings to leading companies across North America and Europe, all while providing best-in-class customer service and prioritizing security, privacy, and integrity. For more information about its suite of services, including programs and solutions for unique legal enterprise needs, please visit HaystackID.com.