

# eCTD ARTICLE SERVICE

For Regulatory Submissions & Records

## Reprints Desk Turns eCTD into easyCTD

eCTD Article Service is the mission-critical service from Reprints Desk® that expedites the bulk aggregation and preparation of scientific journal articles for inclusion in the reference sections of electronic Common Technical Document (eCTD) submissions made to the FDA and other regulatory agencies.

With eCTD article service from Reprints Desk®, companies like yours can produce submissions in the most efficient way possible to **minimize submission delays & achieve faster approvals.**



- Federal Drug Administration
- European Medicines Agency (EMA)
- Health Canada
- and Others

## How It Works

With eCTD Article Service, professionals like you who are involved in preparing or supporting regulatory submission work benefit from an easy, cost-effective article preparation alternative to insourcing. Reprints Desk receives requests for a single or batch of articles, then retrieves and processes articles according to both regulatory agency and supplemental client specifications.

The service saves valuable time for higher impact activities and can be managed directly within regulatory affairs or by supporting entities such as corporate libraries and providers of submission software and services. To save time, all potential articles can be ordered in advance so they are ready as needed. Alternatively, eCTD articles can also be ordered individually as needed.



**REPRINTS DESK**

The Content Workflow Company

### KEY BENEFITS

- Minimize submission delays
- Achieve faster approvals
- Establish standardized processes
- Gain global visibility into eCTD article ordering

### FEATURE HIGHLIGHTS

- Batch or single article ordering
- Digitally formatted to internal & local regulatory specifications
- Quality control and assurance processing
- Detailed usage reporting
- Assignment of a dedicated Reprints Desk project manager

## Benefits to Submission Managers

eCTD Article Service provides regulatory submission managers – with responsibilities ranging from dossier management to project management – with an easy, full-service alternative to the labor-intensive sourcing and preparation of scientific literature in PDF format. Reprints Desk can work directly with Regulatory Affairs or through the corporate library to enable integrated ordering with primary literature retrieval services.

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## Benefits to Corporate Libraries

With eCTD Article Service from Reprints Desk, information professionals within corporate settings are able to leverage their information management expertise to provide an indispensable service in support of the eCTD regulatory submission process. The service complements traditional document delivery offerings and represents one of the many intersections for regulatory and copyright compliance.

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## Benefits to eCTD Service Providers

eCTD Article Service is also a value-added service that enables submission software and service providers to differentiate themselves, while ensuring that pharmaceutical client submissions are produced most efficiently and in compliance with international copyright law.

### ABOUT eCTD

eCTD is a specification designed by the International Conference on Harmonization (ICH) that represents a common organization structure for the submission of regulatory information – marketing applications, renewals, variations, drug safety reports, and more – to worldwide health authorities.

In the U.S., the Food and Drug Administration (FDA) has mandated that submission requests be in eCTD format since 2008.

Similar to the FDA, the European Medicines Agency (EMA) has outlined an implementation strategy that requires the use of the eCTD format for all electronic submissions beginning in 2010.

## Get Started Today

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