

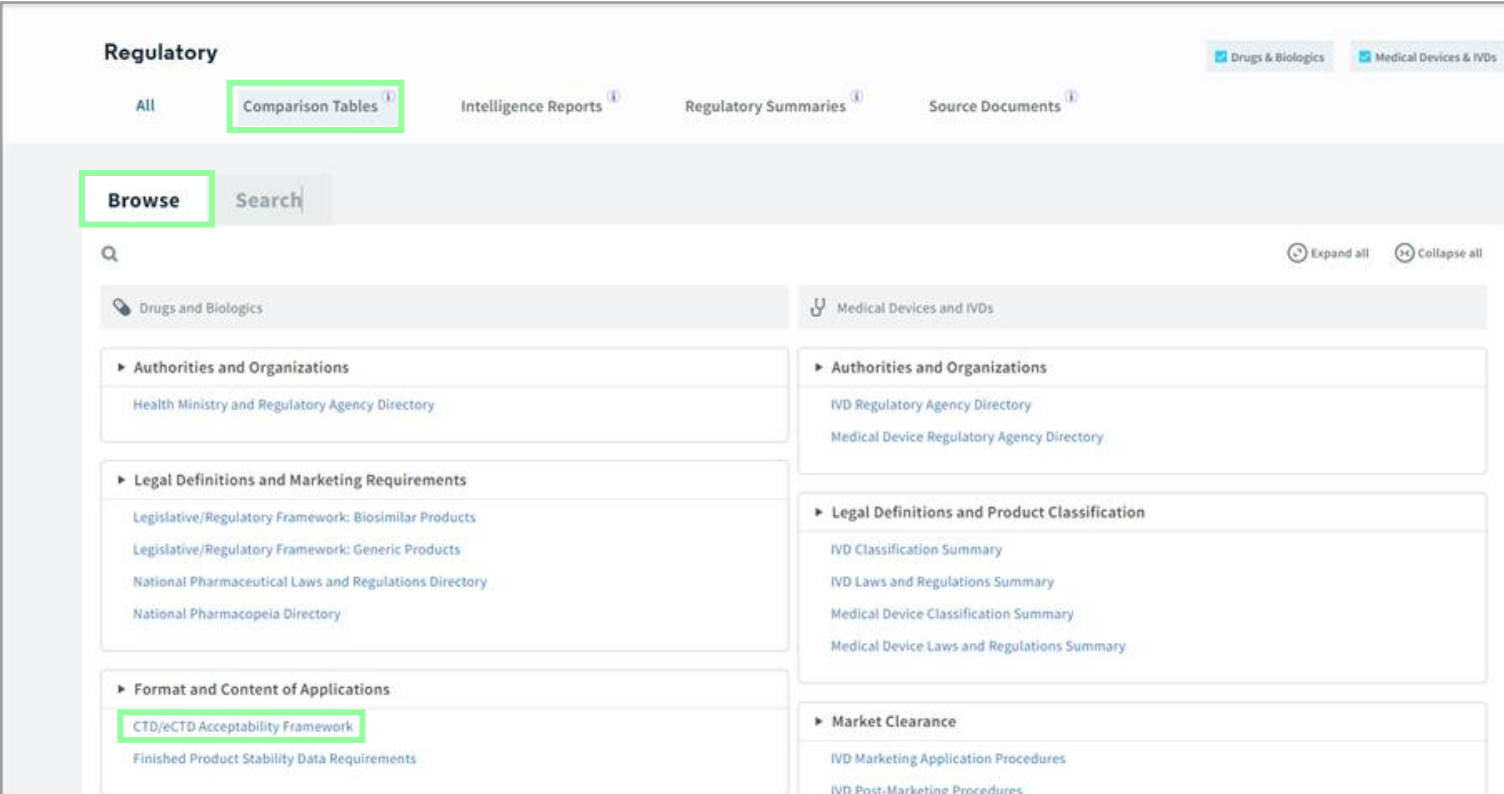
Comparison Tables*

The Comparison Tables help you quickly understand and compare key information from guidelines and regulations on topics across your countries or regions of interest. You can also link to the most important source documents and Regulatory Summaries directly from the tables and benefit from additional regulatory expertise from Cortellis editors and consultants.

*Available for Drugs & Biologics and Medical Devices & IVDs.

Example: Find which countries accept the CTD versus eCTD.

1. Click **Comparison Tables**.
2. To scan the tables, ensure Browse is selected and scroll down the page and click on **CTD/eCTD Acceptability Framework**. You may also use Search to find tables that contain specific terms.





The screenshot displays the Cortellis Regulatory Intelligence web application. At the top, the 'Regulatory' section is active, with tabs for 'All', 'Comparison Tables' (highlighted with a green box), 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. Below this, the 'Browse' tab is selected (also highlighted with a green box), and the 'Search' bar is visible. The main content area is divided into two columns: 'Drugs and Biologics' on the left and 'Medical Devices and IVDs' on the right. Each column contains a list of regulatory topics. In the 'Drugs and Biologics' column, under the 'Format and Content of Applications' section, the 'CTD/eCTD Acceptability Framework' is highlighted with a green box. Other topics listed include 'Authorities and Organizations', 'Legal Definitions and Marketing Requirements', and 'Finished Product Stability Data Requirements'. The 'Medical Devices and IVDs' column lists similar topics, including 'Authorities and Organizations', 'Legal Definitions and Product Classification', and 'Market Clearance'.

1. The Title, indexing terms, Abstract and Last Updated Date appear first with the **Global Comparison table** underneath.
2. Use the **filters** to narrow down to your countries of interest and other data.
3. Turn on the **My Regions Filter** to narrow down to the countries you previously set in My Regions. Edit the My Regions filter by clicking the pencil icon.

CTD/eCTD Acceptability Framework

97441
Drugs and Biologics
Format and Content of Applications

Set email alerts and download to Excel by clicking these icons.

Abstract

The Common Technical Document (CTD) and electronic Common Technical Document (eCTD) formats provide standard documents with common elements to support drug marketing applications in the three ICH regions (US, Japan and European Union). Non-ICH countries may accept regulatory information in the CTD/eCTD format, but there are usually country-specific requirements that should be followed.


This framework provides information on:

- Acceptability status for both CTD and eCTD submissions.
- Regulatory authorities accepting online submissions via the internet or specific web portals, those requiring CD/DVDs and those asking for paper documentation as a supplement or a replacement to an electronic submission.
- Links to related Regulatory Summaries and reference documents, with a focus on validation criteria requirements for eCTD or NeeS submissions.
- Note that for EU member states, the requirements shown in this table are restricted to national.


Last Updated Date

08-Sep-2023

Global Comparison



Click the links to view the Source Documents or Regulatory Summaries

☐ My Regions


Country/Region	Electronic Submission D/DVD, etc.)	Paper Requirements supplementing (or replacing) Electronic Submission	Electronic and/or Paper Delivery Address	Regulatory Summary on CTD/eCTD	Reference Document(s) on CTD	Reference Document(s) on eCTD	Reference Document(s) on Validation Criteria
Algeria	CD, DVD (2 sets)	One copy of Module 1 only	Delivery by hand by an authorized person (usually Regulatory Affairs ...)	Application Format, Content and Submission	Executive Decree n° 20-325 Related to Pharmaceutical Products ...	N/A	N/A
Argentina	Paper submissions: Documents are transformed to electronic ...	Only for full paper based submission. Electronic submissions do not r ...	Electronic Submission at: http://portal.anmat.gov.ar ...	Application Format, Content and Submission	Circular 11: Registration procedure for Biological and Radiopharmaceutical ...	Disposition 0680/2013: Adopts the "Electronic Management System with ...	N/A

For more information contact Customer Service at **LS Product Support**.