

Cortellis Regulatory Intelligence

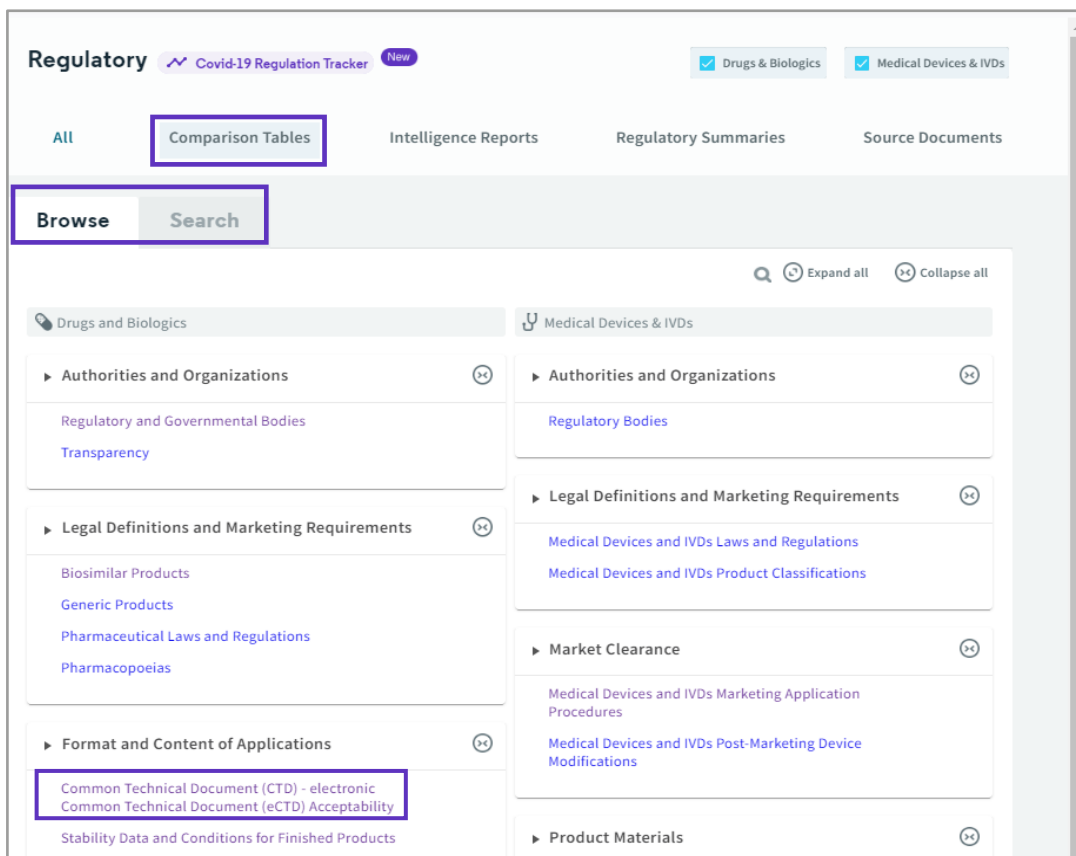
Global Regulatory Comparisons*

The Global Regulatory Comparisons 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.

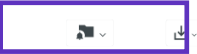
1. Click **Comparison Tables**.
2. To scan the tables, ensure Browse is selected and scroll down the page and click on **Common Technical Document (CTD) – electronic Common Technical Document (eCTD) Acceptability**. You may also use Search to find tables that contain specific terms.



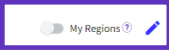
The screenshot displays the Cortellis Regulatory Intelligence interface. At the top, there is a navigation bar with the 'Regulatory' title, a 'Covid-19 Regulation Tracker' badge, and filters for 'Drugs & Biologics' and 'Medical Devices & IVDs'. Below this is a menu with 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Comparison Tables' section is active, showing a 'Browse' tab and a 'Search' input field. The main content area is divided into two columns: 'Drugs and Biologics' and 'Medical Devices & IVDs'. Each column lists various regulatory topics with expand/collapse icons. In the 'Drugs and Biologics' column, the 'Common Technical Document (CTD) - electronic Common Technical Document (eCTD) Acceptability' table is highlighted with a red box. Other tables include 'Authorities and Organizations', 'Legal Definitions and Marketing Requirements', and 'Format and Content of Applications'. The 'Medical Devices & IVDs' column includes 'Authorities and Organizations', 'Legal Definitions and Marketing Requirements', 'Market Clearance', and 'Product Materials'.

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.

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



Click the links to view the Source Documents or Regulatory Summaries



Common Technical Document (CTD) - electronic Common Technical Document (eCTD) Acceptability

97441 Drugs and Biologics Format and Content of Applications

Abstract

The CTD and eCTD formats provide standard documents with common elements to support drug marketing applications in the three ICH regions. Although countries beyond the US, Japan and European Union are accepting regulatory information in the CTD/eCTD format there are usually country-specific requirements that should be followed.

This subject provides information on acceptability status for both CTD and eCTD submissions.

It highlights regulatory authorities accepting online submissions via the internet or specific web portals, those requiring CD/DVDs and those still asking for paper documentation as a supplement or a replacement to an electronic submission.

Links to related Regulatory Summaries and reference documents are included, 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 procedures.

Abbreviations: ACTD: ASEAN

Last Updated Date

19-Nov-2020

Global Comparison

Apply Filters

Country/Region	CTD Acceptability by Regulatory Agency	Notes for CTD Acceptability by Regulatory Agency	Regulatory Summary on CTD	Reference Text(s) on CTD	eCTD Acceptability by Regulatory Agency	Notes for eCTD Acceptability by Regulatory Agency	Online Electronic Submission (Agency portals, email addresses, etc)
Algeria	Yes	Although it isn't officially required in any law or guideline in Algeria, the CT...	Format and Content of Applications	N/A	Yes	Although not officially stated in the regulations, electronic submission is mandatory if...	N/A
Argentina	Yes	The format and content of a Marketing Authorization	Format and Content of Applications	Circular 11: Registration procedure for Biological and	No	N/A	Yes, for Article 3 and 4 products, and for biologics and vaccines, via http://portal.anmat.gov.ar/

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