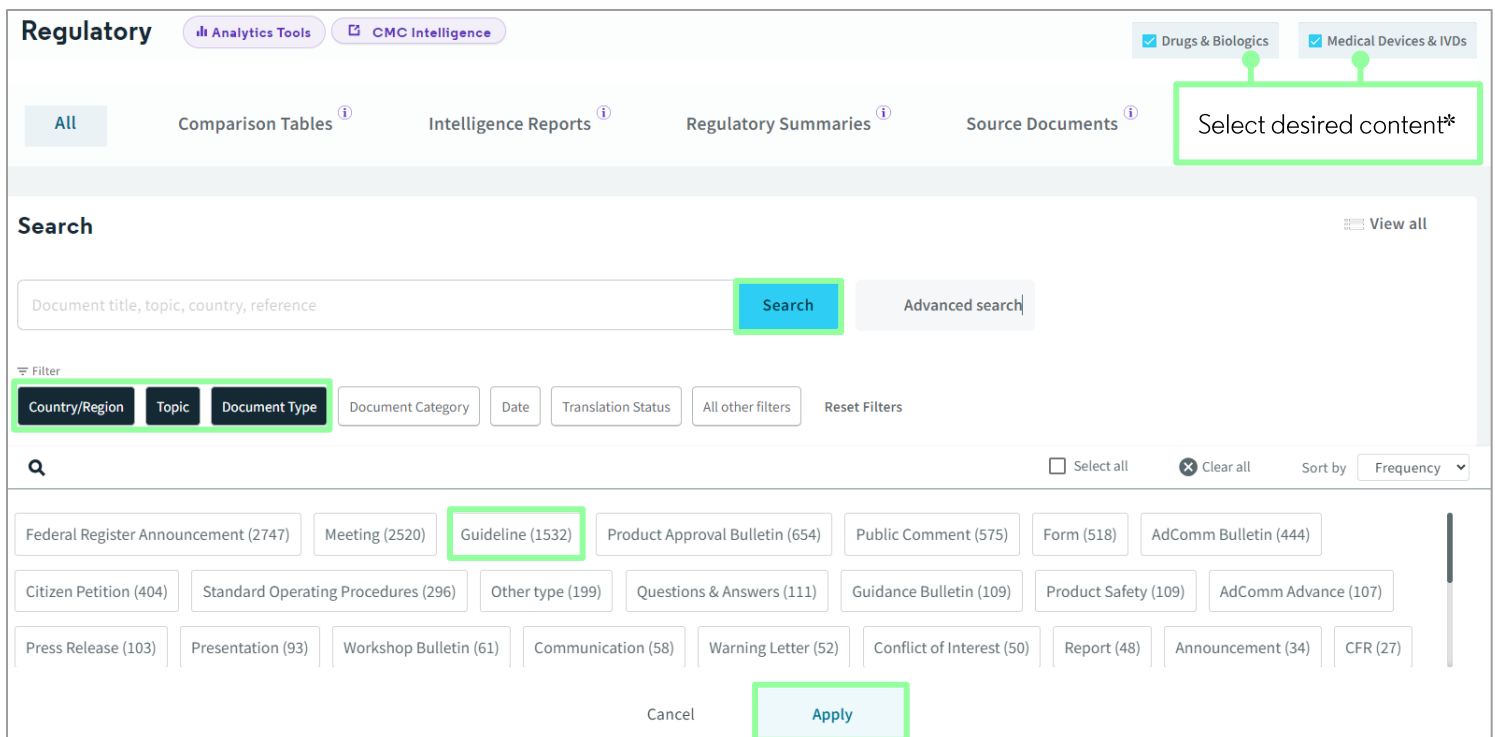


Searching for Guidelines in Cortellis

Guidelines are critical documents that need to be monitored regularly. With Cortellis, you can find and monitor guidelines on over 80 countries and regions for Drugs and Biologics, and over 70 countries and regions for Medical Devices and IVDs, all from one source.

Example: What are the most relevant guidelines for a topic, like Dossier format and submission, in the US and EU?

1. Using Regulatory Home Page Search select the **Country/Region filter**, select “USA” and “European Union”.
2. Open the **Topic Filter** and select “Dossier Format and Submission” and click “Apply”.
3. Open the **Document Type filter** and select “Guideline” and click “Apply”.
4. Click “Search”.



Regulatory Analytics Tools CMC Intelligence Drugs & Biologics Medical Devices & IVDs

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents Select desired content*

Search View all

Document title, topic, country, reference Search Advanced search

Filter

Country/Region **Topic** **Document Type** Document Category Date Translation Status All other filters Reset Filters

Q Select all Clear all Sort by Frequency

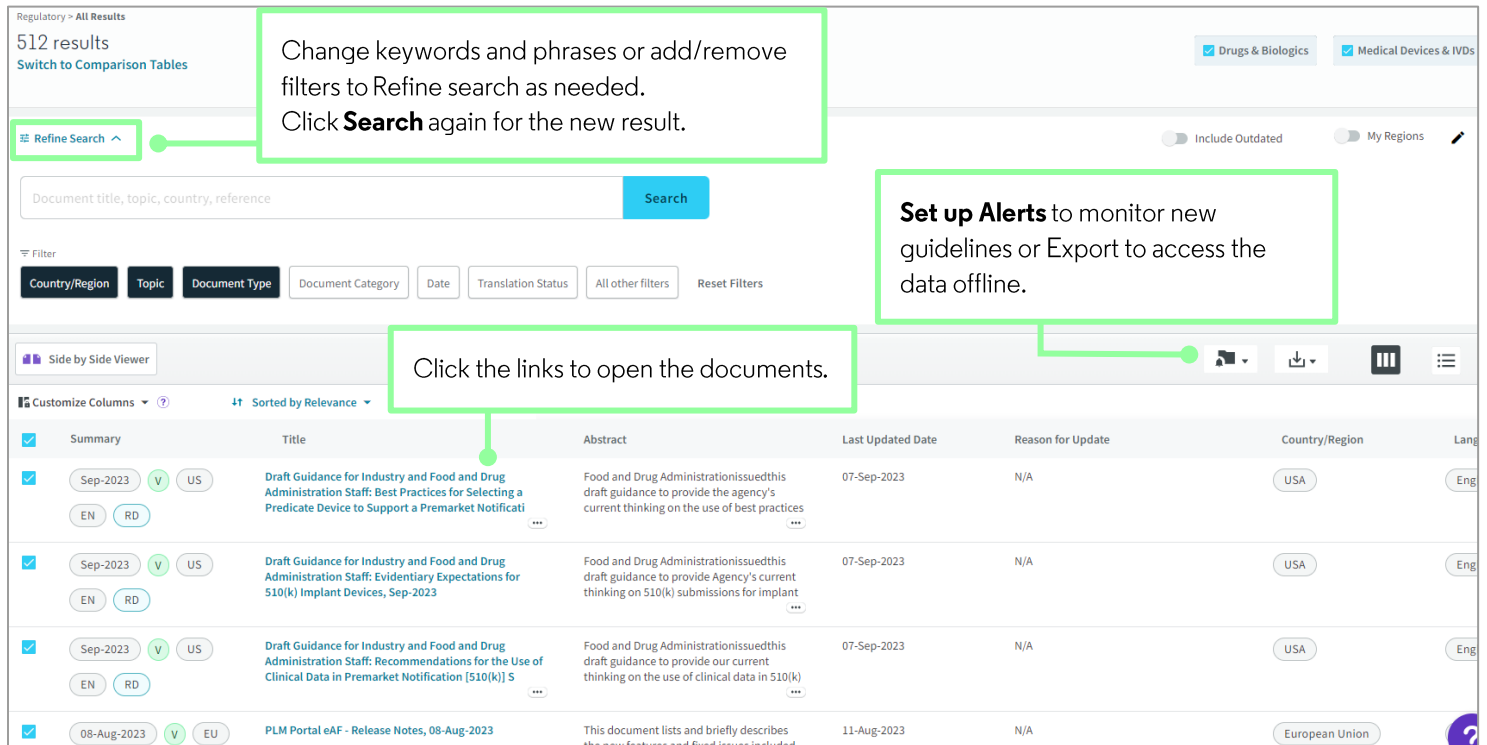
Federal Register Announcement (2747) Meeting (2520) **Guideline (1532)** Product Approval Bulletin (654) Public Comment (575) Form (518) AdComm Bulletin (444)

Citizen Petition (404) Standard Operating Procedures (296) Other type (199) Questions & Answers (111) Guidance Bulletin (109) Product Safety (109) AdComm Advance (107)


Press Release (103) Presentation (93) Workshop Bulletin (61) Communication (58) Warning Letter (52) Conflict of Interest (50) Report (48) Announcement (34) CFR (27)

Cancel Apply

*Users may have access to Drugs and Biologics and or Medical Devices and IVDs. Check subscription details with your Clarivate Account manager or [LS Product Support](#).



Regulatory > All Results
512 results
[Switch to Comparison Tables](#)

Refine Search 

Change keywords and phrases or add/remove filters to Refine search as needed. Click **Search** again for the new result.

Document title, topic, country, reference **Search**





Set up Alerts to monitor new guidelines or Export to access the data offline.

Click the links to open the documents.

Country/Region Topic Document Type Document Category Date Translation Status All other filters Reset Filters

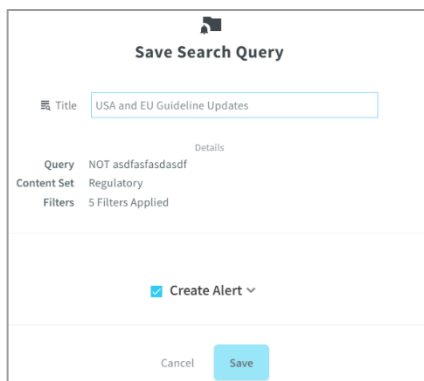
Side by Side Viewer

Customize Columns Sorted by Relevance

Summary	Title	Abstract	Last Updated Date	Reason for Update	Country/Region	Lang
<input checked="" type="checkbox"/> Sep-2023  US EN RD	Draft Guidance for Industry and Food and Drug Administration Staff: Best Practices for Selecting a Predicate Device to Support a Premarket Notificati	Food and Drug Administration issued this draft guidance to provide the agency's current thinking on the use of best practices	07-Sep-2023	N/A	USA	Eng
<input checked="" type="checkbox"/> Sep-2023  US EN RD	Draft Guidance for Industry and Food and Drug Administration Staff: Evidentiary Expectations for 510(k) Implant Devices, Sep-2023	Food and Drug Administration issued this draft guidance to provide Agency's current thinking on 510(k) submissions for implant	07-Sep-2023	N/A	USA	Eng
<input checked="" type="checkbox"/> Sep-2023  US EN RD	Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] S	Food and Drug Administration issued this draft guidance to provide our current thinking on the use of clinical data in 510(k)	07-Sep-2023	N/A	USA	Eng
<input checked="" type="checkbox"/> 08-Aug-2023  EU	PLM Portal eAF - Release Notes, 08-Aug-2023	This document lists and briefly describes the new features and fixed issues included	11-Aug-2023	N/A	European Union	?

To set up an alert

1. Click the icon  in the upper right-hand corner of the search result screen.
2. Select **Save and Alert on Query**.
3. Fill in the **Alert pop-up** and click **Save**.



Save Search Query

Title:

Details

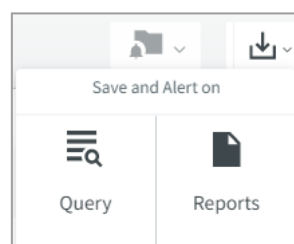
Query: NOT asdfasfasdasdf

Content Set: Regulatory

Filters: 5 Filters Applied

☒ Create Alert

Cancel Save



Save and Alert on

Query Reports

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