



Track Guideline Changes with Cortellis More Efficiently

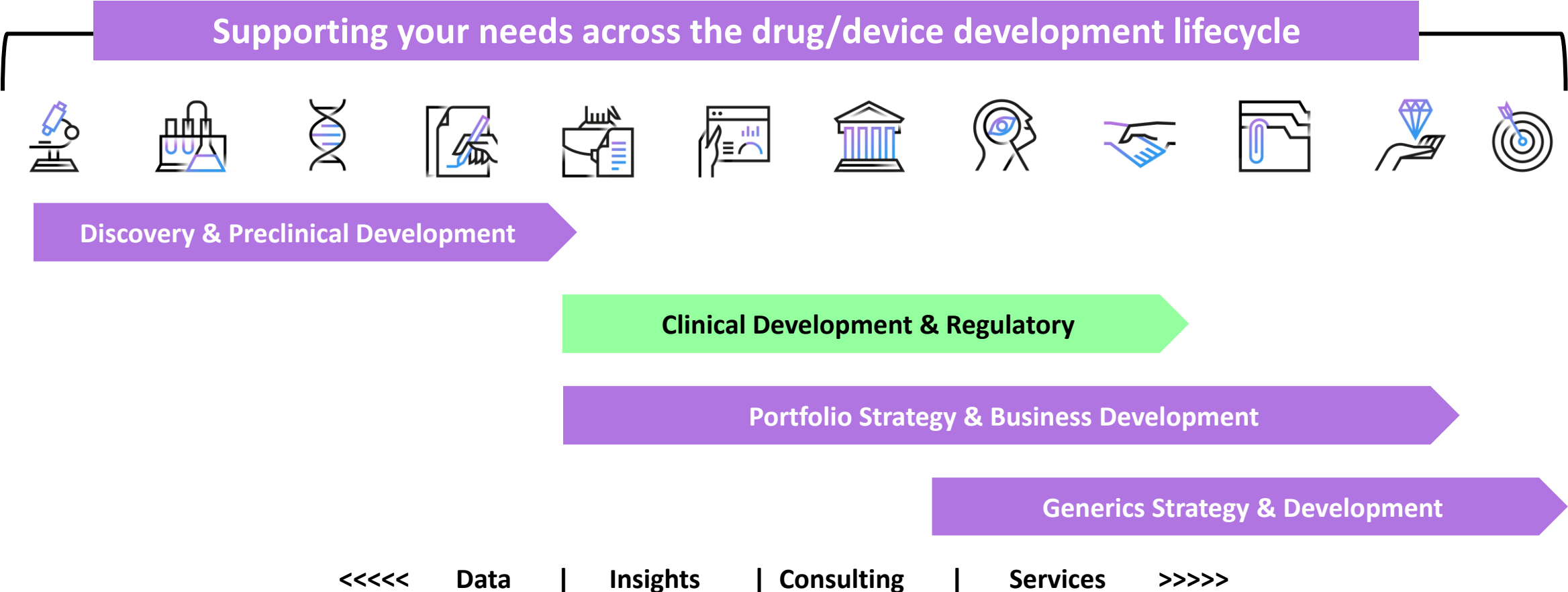
Claudia Haas, Beth Wise, Emma Jourdan | Customer Training Team | July 2026

Agenda

- What is Cortellis Regulatory Intelligence?
- Live demo
- Feedback, recap, Q&A

Cortellis: Unlock hidden insights and bring life to science

Make data-driven decisions with speed and certainty



What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities:



330K+ official documents supported by Cortellis AI-powered Assistant



8K+ Cortellis Value-add regulatory reports, analyses and global comparisons



English translations for all native language documents



**Drugs & Biologics: 81 countries & regions;
Medical Devices & IVDs: 75 countries & regions**



Updated daily



Regulatory experts & local consultants

Source Documents: Guideline example

330K+ documents updated daily from up to 80+ countries/regions all in one searchable platform

More than 41K are Guidance documents

NMPA Soliciting Public Comments on the Appendix to the Good Supply Practice for Pharmaceutical Products: Quality Management of Pharmaceutical Retail Chain Operations (Draft), 16-Apr-2026

Valid 427951 China Reference Document Guideline Translation: Machine Translation

Drugs and Biologics Distribution GDP

Side by side Save & alert Download

1. Summary	Summary
2. Document	Abstract
3. Reason For Update	To further regulate pharmaceutical retail chain operations for the public, and in accordance with the Drug Administration of the Quality of Drug Distribution and Use, the Good Supply Practice for Pharmaceutical Products is soliciting public comments.
4. Mentioned Documents	
5. Mentioned By	This Appendix applies to the pharmaceutical quality management of enterprises (hereinafter referred to as "chain enterprises") in several topics, such as: • Scope and applicability • Definition and structure of retail chain enterprises • Quality management system • Organizational structure and responsibility • Computerized management systems • Procurement and distribution

国家药监局综合司公开征求《药品经营质量管理规范附录：药品零售连锁质量管理（征求意见稿）》意见

发布时间：2026-04-20

为进一步规范药品零售连锁经营活动，切实保障人民群众用药安全、有效、可及，依据《中华人民共和国药品管理法》《药品经营和使用质量监督管理办法》《药品经营质量管理规范》，国家药监局起草了《药品经营质量管理规范附录：药品零售连锁质量管理（征求意见稿）》（见附件1），现再次向社会公开征求意见。

公开征求意见时间为2026年4月20日至5月19日。请有关单位和个人将意见建议反馈表电子版（见附件2）发送至指定邮箱：ypjgs@nmpa.gov.cn，并在邮件主题注明“药品GSP附录零售连锁意见建议反馈”。

附件：1. 药品经营质量管理规范附录：药品零售连锁质量管理（征求意见稿）
2. 意见建议反馈表

国家药监局综合司
2026年4月16日

Machine Translated by Google

The General Office of the National Medical Products Administration is publicly soliciting opinions on the "Appendix to Good Supply Practice for Pharmaceutical Products: Quality Management of Pharmaceutical Retail Chains (Draft for Comment)".

Release date: 2026-04-20

To further regulate the chain operation of pharmaceutical retail and effectively ensure the safety, effectiveness, and accessibility of medicines for the public, Based on the "Drug Administration Law of the People's Republic of China", the "Measures for the Supervision and Administration of the Quality of Drug Distribution and Use", and the "Regulations on Drug Distribution and Use"

The National Medical Products Administration has drafted the "Good Supply Practice for Pharmaceutical Products" Appendix: Pharmaceutical Retail Chains. The "Quality Management (Draft for Comments)" (see Appendix 1) is now open for public comment again.

The public consultation period is from April 20th to May 19th, 2026. Relevant organizations and individuals are requested to submit their opinions. Please send the electronic version of the feedback form (see Attachment 2) to the designated email address: ypjgs@nmpa.gov.cn, and include it in the email subject line. The title indicates "Retail Chain Feedback and Suggestions for Drug GSP Appendix".

Attachment: 1. Good Manufacturing Practices for Pharmaceuticals Appendix: Quality Management of Pharmaceutical Retail Chains (Draft for Comments)
2. Feedback Form

Access the native language versions and English translations without having to leave Cortellis

Use cases

Use Case 1 (Slides 10-13):

Identify a specific guideline quickly with the Cortellis Regulatory Assistant

Use Case 2 (Slide 14):

See how many and which guidelines were published for a country in the last 12 or 24 months

Use Case 3 (Slides 15-17):

Find the latest guidelines relevant to your topic or indication in the EU, US, and beyond

Use Case 4 (Slides 18-20):

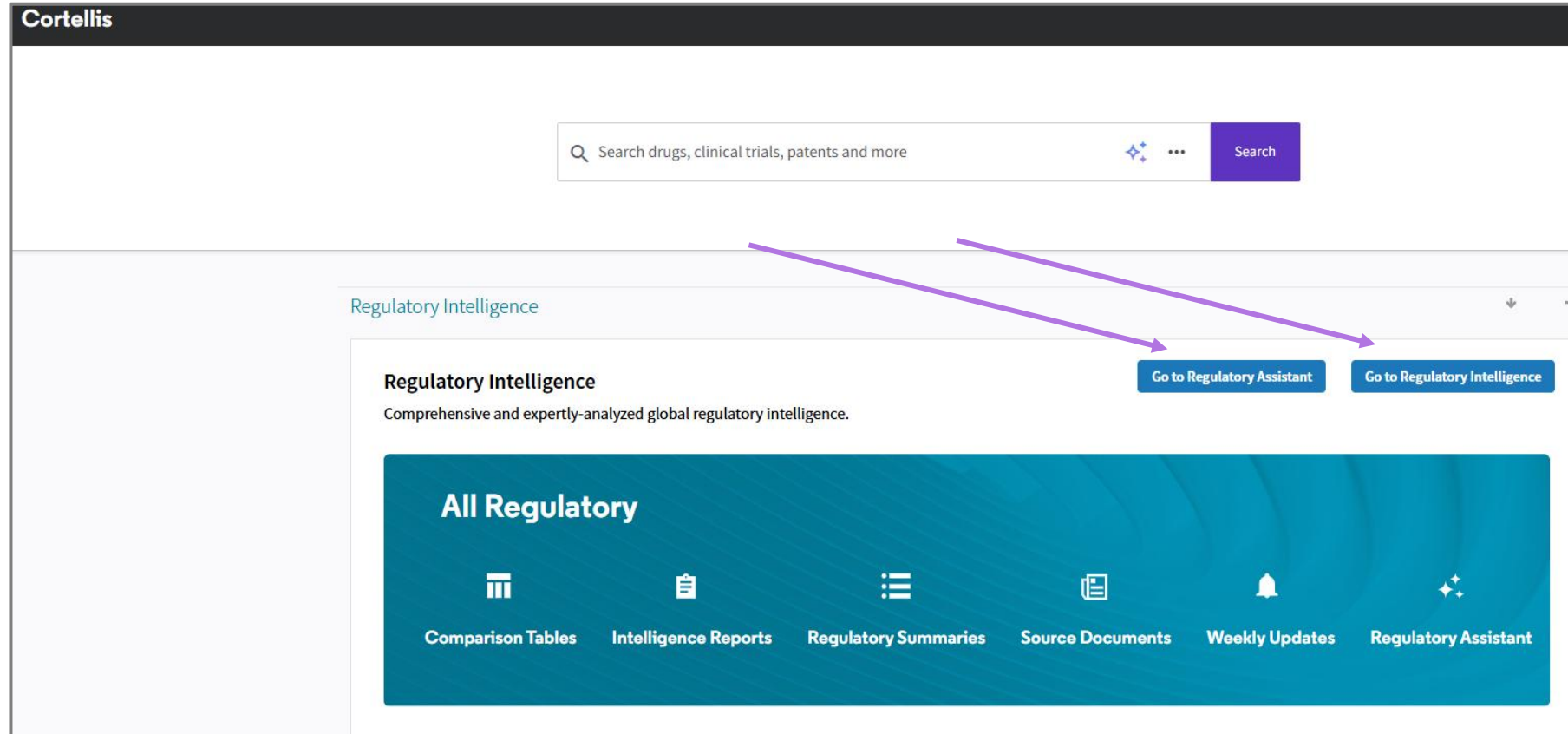
Set up alerts so you never miss new guidelines or important updates



Handout

Cortellis Landing Page

Click the “**Go to...**” button to access the Cortellis Regulatory Intelligence homepage or the Cortellis Regulatory Assistant.



Cortellis Regulatory Homepage

Click the tabs to browse value-add reports (Comparison tables, Intelligence Reports, Regulatory Summaries) or start searching with Quick Search, Source Documents Search or the Assistant*.

Regulatory **Analytics Tools** **CMC Intelligence**

All **Comparison Tables** **Intelligence Reports** **Regulatory Summaries** **Source Documents**

Quick Search

Quick search English keywords **Search** **Advanced search**

Filter

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

Try our NEW Regulatory Assistant

Last Updates

Ask the Expert

Local Consultants

Support

Category	Count
Comparison Tables	41
Regulatory Intelligence Report	19
Regulatory Summary	566
Reference Document	2511

Regulatory Assistant

How do I identify a specific guideline?

Cortellis

← Back

New chat

History

Alerts

Hi Beth, what is your regulatory question?

Let me find answers from our high-quality, comprehensive, and verified regulatory data

Find me a guidance on applicants seeking scientific advice for the EMA

→

You can currently ask me to...

Question tips

Understand a requirement

For example: "What is the requirement for retaining records in clinical trials in the US?"

Find a document

For example: "Find me a document about the distribution of drug samples in Canada"

Summarize a document

For example: "Briefly summarize the FDA's press release announcing completion of the first AI-assisted scientific review"

Compare versions

For example: "What changed between the latest EU Guideline on the Chemistry of Active Substances and the previous version?"

Support

AI-generated content: check for accuracy

About Regulatory Assistant

Legal

1. Go to the **Regulatory Assistant**

2. **Type into the search field as shown.**

Be sure to add as much detail as you can regarding the document and the authority/country

Regulatory Assistant

How do I identify a specific guideline?

The screenshot displays the Regulatory Assistant interface. At the top, a search bar contains the text "Find me a guidance on applicants seeking scientific advice for the EMA". Below this, the "Answer" section states: "I have found the following documents that matches with your description:". It lists three documents:

- EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025
- EMA Press Release: EMA to Encourage Use of Scientific Advice for Post-Authorisation Safety Studies, 28-Jul-2015
- EMA/736615/2013 Rev. 2: Involvement of Patient Representatives in Scientific Advice Procedures at the EMA, 10-Jan-2017

Below the list, it says: "If you'd like a brief summary of the document(s) please click on the Summarize button(s) below".

The "Source documents" section lists the same three documents with additional details and action buttons:

- 1** EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025
Guideline • EMA • European Union • Last updated 15-Apr-2025 • More info • **Summarize** • **Version comparison**
- 2** EMA Press Release: EMA to Encourage Use of Scientific Advice for Post-Authorisation Safety Studies, 28-Jul-2015
Press Release • EMA • European Union • Last updated 22-Aug-2019 • More info • **Summarize**
- 3** EMA/736615/2013 Rev. 2: Involvement of Patient Representatives in Scientific Advice Procedures at the EMA, 10-Jan-2017
Other type • EMA • European Union • Last updated 15-Aug-2025 • More info • **Summarize** • **Version comparison**

At the bottom, there is a "Frequently Asked Questions" dropdown menu with "Training Guide" selected. Below this is a text input field "Type your follow-up message" and a "Send" button (upward arrow). At the very bottom, there is a footer with "AI-generated content: check for accuracy", a link to "About Regulatory Assistant", and a "Legal" link.

1. **Access the documents** by clicking the links
2. **Click Summarize** to receive a summary of the document
3. **Click Version Comparison** and select the versions to compare on the pop-up screen
4. **Open the FAQ document or the Training Guide** by clicking on About Regulatory Assistant

Cortellis Regulatory Assistant: Summarize a document

How do I identify a specific guideline?

Briefly summarize document IDRAC 405183

Answer

Here is a brief summary of the "European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance (EMA/4260/2001 Rev. 16, 26 March 2025)":

- **Main Subject:** This guidance outlines the procedures for obtaining scientific advice and protocol assistance from the EMA, including for orphan medicinal products, and provides instructions for preparing and submitting requests.
- **Actionable Items:** Applicants must submit requests via the IRIS platform, using the required briefing document template. Fee payment is mandatory before advice is provided, with various reductions available for SMEs, orphan products, paediatric use, pandemic vaccines, and public health emergencies.
- **Impact on Stakeholders:** The guidance is relevant to pharmaceutical companies, sponsors of orphan drugs, SMEs, academic entities, and those developing advanced therapies or paediatric medicines. It also addresses parallel advice with FDA, HTA bodies, and WHO involvement.
- **Key Dates/Deadlines:** Submission deadlines are typically 4–8 weeks before the intended procedure start date, depending on whether a preparatory meeting is requested. The procedural timetable includes 40-day or 70-day evaluation phases.
- **Relationships:** This is a regularly updated document reflecting new regulatory developments and experience. It is linked to EU regulations and other EMA guidance documents.

Would you like a more detailed version of this summary?

Source documents

1 EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025

Guideline • EMA • European Union • Last updated 15-Apr-2025 • More info • Summarize • Version comparison

Would you like a more detailed version of this summary?

Source documents

1 EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025

Guideline • EMA • European Union • Last updated 15-Apr-2025 • More info • Summarize • Version comparison

Answer

Here is the detailed summary of the "European Medicines Agency Guidance for Applicants seeking scientific advice and protocol assistance (EMA/4260/2001 Rev. 16, 26 March 2025)":

Main Subject and Purpose

- The document provides comprehensive guidance for applicants seeking scientific advice and protocol assistance from the European Medicines Agency (EMA), including for orphan medicinal products.
- It outlines the legal basis, scope, procedures, and requirements for obtaining scientific advice and protocol assistance, aiming to facilitate efficient, high-quality submissions and evaluations.

Scope of Scientific Advice and Protocol Assistance

- Scientific advice covers quality, non-clinical, and clinical aspects of medicinal product development, including study

Cortellis Regulatory Assistant: Version comparison

How do I identify a specific guideline?

Source documents ▾

1 [EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025](#)

Guideline • EMA • European Union • Last updated 15-Apr-2025 • More info • Summarize • **Version comparison**

👍 🗨️ 📄

Compare IDRAC 405183 to IDRAC 398054

Answer

Here's a summary of the key updates in the 2025 version of the **EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025**, compared with the 2024 version of the **EMA/4260/2001 Rev. 15: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 13-Dec-2024**.

Key Updates in the **EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeking Scientific Advice and Protocol Assistance, 26-Mar-2025**

- 1. Clarification on Follow-up vs. New Requests** The guidance now emphasizes that applicants are recommended to request a new scientific advice or protocol assistance rather than a follow-up, and clarifies that amending previous advice typically requires a new procedure, not a follow-up. **(Modified)**
- 2. Removal of IRIS Process Reference** The specific reference to the IRIS system for initial requests and follow-up advice assignment has been removed. **(Deleted)**
- 3. Update to Publication Details** The description of how requests are published in the CHMP monthly highlights has been

How many and which guidelines have been published for a country of interest in the last 12 or 24 months?*

Quick Search

Search

Advanced search

Filter

Country/Region

Topic

Document Type

Document Category

Date

Translation Status

All other filters

Reset Filters

Brazil

Source Publication Date

7/1/2024

→

7/31/2026

Clear

+ add date

Cancel

Apply

- 1. Add your country in **Country/Region** filter (e.g. Brazil)
- 2. Select **Guideline** in Document Type Filter
- 3. Enter dates using the **Date** filter
- 4. Be sure to click **Apply** after adding each filter
- 5. Click **Search**

Side by Side Viewer

Showing 1-10 of 46 results

Customize Columns

Sorted by Relevance

	Summary	Title	Medical Device Specialty	Document Type	Regulatory Version	Authority Acceptance
☒	29-Jul-2026 PT RD	Guideline: ANVISA 'Solicita' System User Guide (Version 5.3), 29-Jul-2026	No specific Specialty	Guideline	Revision	29-Jul-2026
☒	Jul-2026 PT RD	Handbook: Import of Medicinal Products and Related Products (Version 3.1), Jul-2026	No specific Specialty	Guideline	Revision	Jul-2026

What are the latest guidelines relevant to your topic or indication in the EU, US, and beyond?

The screenshot shows the 'Quick Search' interface. At the top, there is a search bar with the placeholder 'Quick search English keywords' and a blue 'Search' button. Below the search bar, a 'Filter' section contains several buttons: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', 'All other filters', and 'Reset Filters'. The 'Document Type' button is highlighted with a purple box, and a dropdown menu is open showing 'Guideline'. Below the filter section, there is a grid of topic filters, each with a count in parentheses. The 'Clinical Research (1481)' filter is highlighted with a purple box. At the bottom right, there is a light blue 'Apply' button. A 'Try our NEW Regulatory Assistant' banner is visible on the right side of the interface.

Quick Search View all

Quick search English keywords Search Advanced search

Filter

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

Guideline

Regulatory Procedures (1610) **Clinical Research (1481)** Authorities and Organizations (1181) Dossier Format and Submission (900) Pharmacovigilance Technovigilance Risk Management (865)

Manufacturing and Control (721) Packaging and Labelling (626) Compliance and Inspection (587) Legislative Framework (489) GXP (477) Generics and Biosimilars (476)

Non Clinical Studies (443) Active Pharmaceutical Ingredient (323) CMC (252) Pediatrics (216) Other Topic (200) Product Assessment (197) Distribution (185) GMP (180)

Cancel Apply

Try our NEW Regulatory Assistant

1. Add your country in **Country/Region** filter (e.g. European Union)
2. Select **Topic Filter**: (e.g. Clinical Research)
3. Add **Guideline** as Document Type
4. Click **Apply** with each filter
5. Click **Search**

What are the latest guidelines relevant to your topic or indication in the EU, US, and beyond? Sort results so Most Recent appear at the top*

530 results

[Switch to Comparison Tables](#)

Refine Search ^

Quick search English keywords

Search

Advanced Search

Filter

Country/Region

Topic

Document Type

Document Category

Date

Translation Status

All other filters

Reset Filters

Side by Side Viewer

Showing **1-10** of 530 results

Customize Columns	Summary	Sorted by Authority Acceptance Date ▲	Abstract
☒	Relevance	Highest to Lowest ▾	
☒	Title	A to Z ▾	
☒	Country/Region	A to Z ▾	
☒	Authority Acceptance Date	Most Recent ▾	
☒	IDRAC Number	Highest to Lowest ▾	

☒	22-Jul-2026 EN RD	Concept Paper on Similar Biological Medicinal Products - July-2026	This document provides information on EMA's concept paper proposing the revision of the Guideline on Similar Biological Products.
☒	14-Jul-2026 EN RD	ICH E6 (R3) Guideline on Good Clinical Practice (GCP), Step 5, 14-Jul-2026	This guidance document describes the specific requirements for the demonstration of bioequivalence for Semaglutide and...
☒	14-Jul-2026 V EU EN RD	EMA/CHMP/ICH/162879/2026: ICH E6 (R3) Guideline on Good Clinical Practice (GCP), Step 5, 14-Jul-2026	This document provides information on the ICH E6 (R3) Guideline for Good Clinical Practice (GCP) – Step 5, which establishes a...

*Results depend on the topic and when the search was run. Sorted by date, most recent documents appear on the top.

Enhance your search: What are the latest guidelines relevant to your topic or indication in the EU, US, and beyond?

Quick Search

asthma **Search** Advanced search

Filter

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

Country/Region

European Union (10) Japan (8) China (6) USA (3) Algeria (1) South Korea (1)

Cancel **Apply**

1. Open the **Country/Region** filter and add additional countries (e.g. USA, China, and Japan)
2. Click **Apply**
3. Add the indication as a keyword in the search box (e.g., asthma)
4. Select **Guideline** as Document Type
5. Click **Search** to update your results

Can I set up alerts to make sure I won't miss new guidelines or important updates?

Setting up an Alert from a results page

The screenshot shows a search results page for 'asthma'. At the top, there is a search bar with 'asthma' entered and a 'Search' button. Below the search bar is a 'Filter' section with buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters', along with a 'Reset Filters' button. The results section shows 'Showing 1-10 of 11 results'. A purple arrow points to the 'Alert Bell' icon (a bell with a plus sign) in the top right corner of the results list. A purple box highlights the 'Alert Bell' icon. Another purple box highlights the 'Query' button in the 'Save and Alert on' dropdown menu. The table below shows search results with columns: Summary, Title, Abstract, New Version, Previous Version, Last Updated Date, and a description. The first result is 'Notice: PSB/PED: Correction of Optimal Use Promotion Guideline of TEZSPIRE (tezepelumab) (Genetical Recombination) for the Treatment of Chronic Rhino'.

Summary	Title	Abstract	New Version	Previous Version	Last Updated Date	Description	
☒	14-Apr-2026 V JP	Notice: PSB/PED: Correction of Optimal Use Promotion Guideline of TEZSPIRE (tezepelumab) (Genetical Recombination) for the Treatment of Chronic Rhino	This document corrects Notification: PSB/PED No. 0219/1: Optimal Use Promotion Guideline of TEZSPIRE	N/A	423840	05-Jun-2026	This source document reflect a system class There are no changes
☒	14-Apr-2026 V JP	Notification: PSB/PED No. 0414/1: Optimal Use Promotion Guideline of EXDENSUR (depemokimab) (Genetical Recombination) for Treatment of Bronchial	This document presents the new optimal use promotion guideline of EXDENSUR (depemokimab) for the treatment of	N/A	N/A	05-Jun-2026	This source document reflect a system class There are no changes

1. Click the **Alert Bell** icon at the top right of the results list
2. Select **Query**

Can I set up alerts to make sure I won't miss new guidelines or important updates?

Setting up an Alert from a results page

Save Search Query

Title **Asthma Guidelines: EU, US, China & Japan**

Details

Query asthma

Content Set Regulatory

Filters 5 Filters Applied

☒ **Create Alert**

Format

HTML Text

Frequency

Daily

Weekly

Monthly

Share

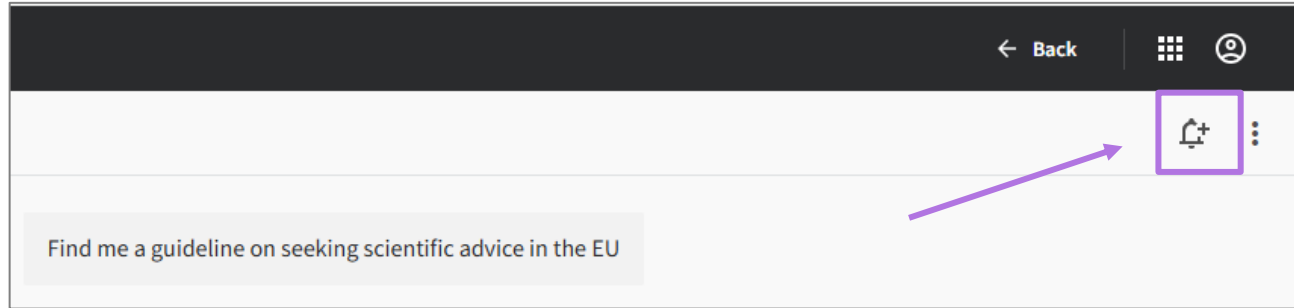
claudia.haas@clarivate.com

Cancel Save

1. In the pop-up that appears, give your Alert **a title** - this will be in the subject heading of the email Alert
2. Update the Format and Frequency as desired
3. Optional: Add email addresses to share the alert
4. Click **Save**

Can I set up alerts to make sure I won't miss new guidelines or important updates?

Setting up an Alert from the Regulatory Assistant



1. Click the **Alert Bell icon** in the upper right-hand corner of the Assistant's screen

2. In the pop-up window, select the document(s) you want to monitor

3. Click **Create**

A screenshot of the 'Create document alert' pop-up window. The window has a title bar with a close button (X). Below the title, it says 'Get an email when documents used in this chat are updated'. There is a 'Name' field with the text 'Scientific Advice Guidelines EU - 02-Aug-2026 17:37:41'. Below this is a section titled 'Documents to track' with a note: 'Only valid documents are shown. Outdated documents are not eligible for alerts.' There are three document entries, each with a checkbox and a text label. The first entry is 'Marketing Authorization Procedures: Procedure for Scientific Advice' with a checkbox. The second entry is 'EMA/4260/2001 Rev. 16: European Medicines Agency Guidance for Applicants Seeki...' with a checked checkbox; this entry is highlighted by a purple rectangle. The third entry is 'Scientific Advice on Medicines for Human use in the EU Medicines Regulatory Netw...' with a checkbox. At the bottom right, there are two buttons: 'Cancel' and 'Create', with the 'Create' button highlighted by a purple rectangle.

Recap/ Key Takeaways

1. During this session, we demonstrated how Cortellis Regulatory Intelligence can help you with:

- Finding specific guidelines in seconds
- Discovering recently published and updated guidance
- Searching by country, topic, and indication
- Using AI-generated summaries and version comparisons
- Creating alerts to proactively monitor regulatory changes

2. Additional Resources

Additional training materials, product guidance, and support resources are available through the **Support Center** (see next slide)

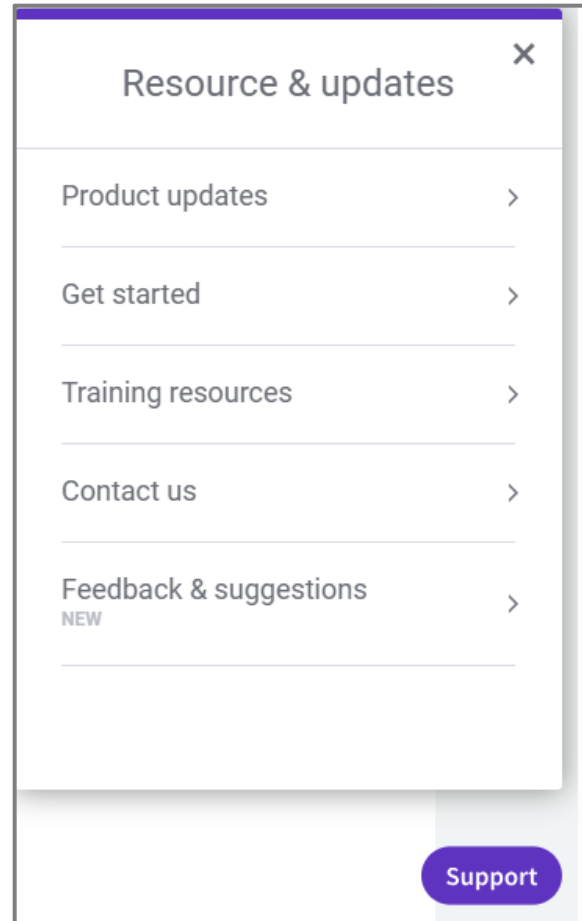
Get assistance with Cortellis

In-product guidance to assist you with your questions

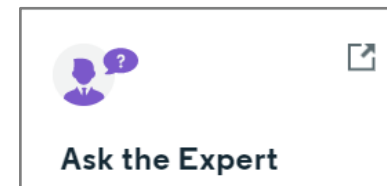
- Click the **Support button** in the lower-right hand corner of the screen

If not visible, please enable Functional Cookies under "Manage cookies preferences" at the bottom of the page.

Manage cookie preferences



- Help & contact us - contact Customer Care
- Guided tours - walk through the Cortellis platform
- Training resources - recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)



“Research shows that an average learner forgets 70% of what they learned within 24 hours...”



Thank you! Questions?

About Clarivate

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