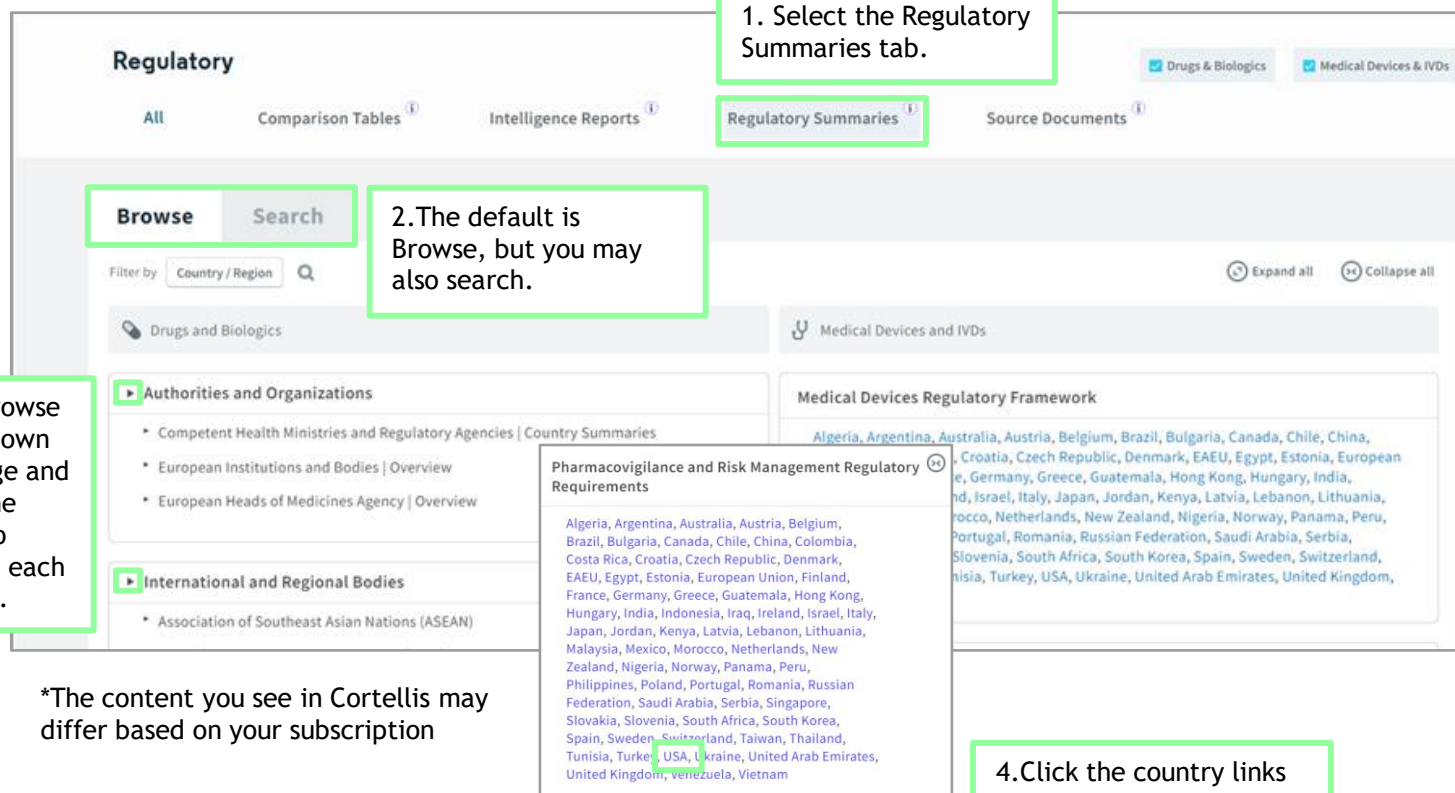


# Find answers to common questions with Regulatory Summaries

The Regulatory Summaries are time saving value add reports created by Cortellis editors and consultants that help you get your products to market faster. These English language documents provide step-by-step instructions on common regulatory procedures from compiling and submitting dossiers, market authorization, clinical trials, PV, QA and so much more. They are a great starting point when you need to understand a procedure - especially if you don't speak the native language. Plus, all relevant official documents from the authorities on a topic are easy to access from the Regulatory Summaries.

Searching the Summaries creates a way to conveniently search common regulatory questions and compare answers across countries.

## Browse the Regulatory Summaries



1. Select the Regulatory Summaries tab.

2. The default is Browse, but you may also search.

3. To Browse scroll down the page and click the icons to expand each section.

4. Click the country links to open the Regulatory Summaries.

\*The content you see in Cortellis may differ based on your subscription

Click Expand  
to view full

 Expand

- Recent updates  
are at the top.

Click bookmarks to view content or scroll to view the full report.

Link directly to official documents.

Reason for update	Date	Reason for update description
Formatting Change	2023-05-26	Last update contains minor edit only.
Formatting Change	2023-03-13	Last review adds updated reference to <a href="#">SOPP 8413: Postmarketing Requirement/Commitment Related Submissions - Administrative Handling, Review, and CBER Reporting, 27-Feb-2023</a> (IDRAC 361343). Refer to Q2.1.1.
Content Update	2023-01-20	Last review adds the following changes: - Updated reference to the final <a href="#">Guidance for Industry: Format and Content of a REMS Document, Jan-2023</a> (IDRAC 357920) (for a prescription drug product, including a biologics), which finalizes the previous revised draft guidance. Refer to Q6.2. - Adds reference to <a href="#">Guidance for Industry: REMS Document Technical Conformance Guide, Jan-2023</a> (IDRAC 357983), which contains specific sections and provides standardized language to describe common REMS requirements. Refer to Q6.2.
Content Update	2022-11-28	Last review adds information applicable to: Q3 Pre-marketing case reporting Q3.1 Expedited case reporting Q3.1.1 Reporting to the Competent Authority/-ies Q3.1.1.1 Is the reporting of domestic suspected unexpected serious adverse reactions (SUSARs) to the Competent Authority/-ies required? If so, who reports (sponsor, investigator)? What is the reporting timeline?

Sponsors are required to notify the FDA in a written IND safety report of:

(A) Any adverse experience associated with the use of the drug that is both serious and unexpected; or

(B) Any finding from tests in laboratory animals that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity, or carcinogenicity.

### Timelines:

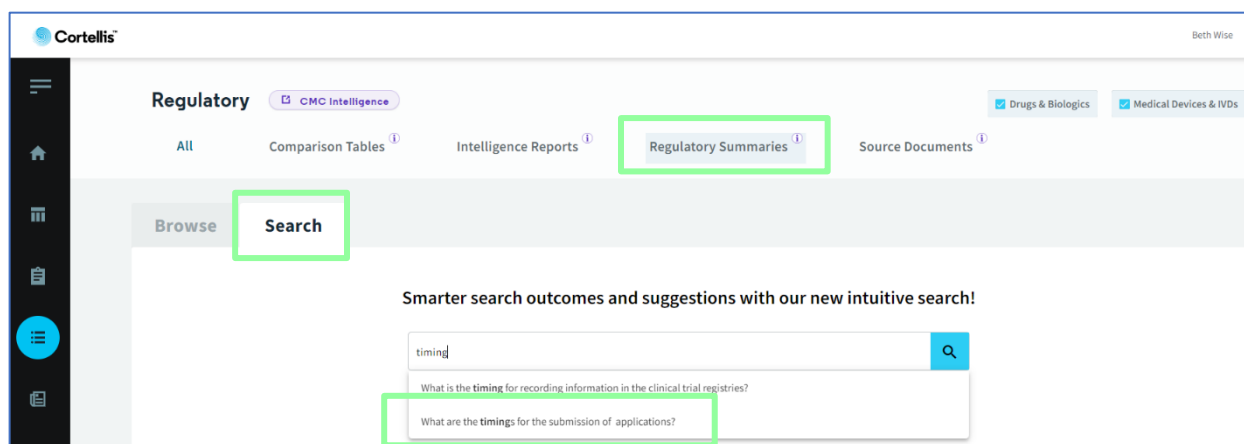
- For unexpected **fatal or life-threatening** suspected adverse reactions, **represent especially important safety information** and must be reported to FDA as soon as possible but no later than **calendar days** following the sponsor's initial receipt of the information **21 CFR 312.32(c)(2)** (IDRAC 8714).
- For unexpected **serious** suspected adverse reactions and observations from animal studies suggesting significant risk to human subjects must be reported to FDA as soon as possible but no later than within **15 calendar days** following the sponsor's initial receipt of the information **21 CFR 312.32(c)(1)** (IDRAC 8714).

## Search the Regulatory Summaries

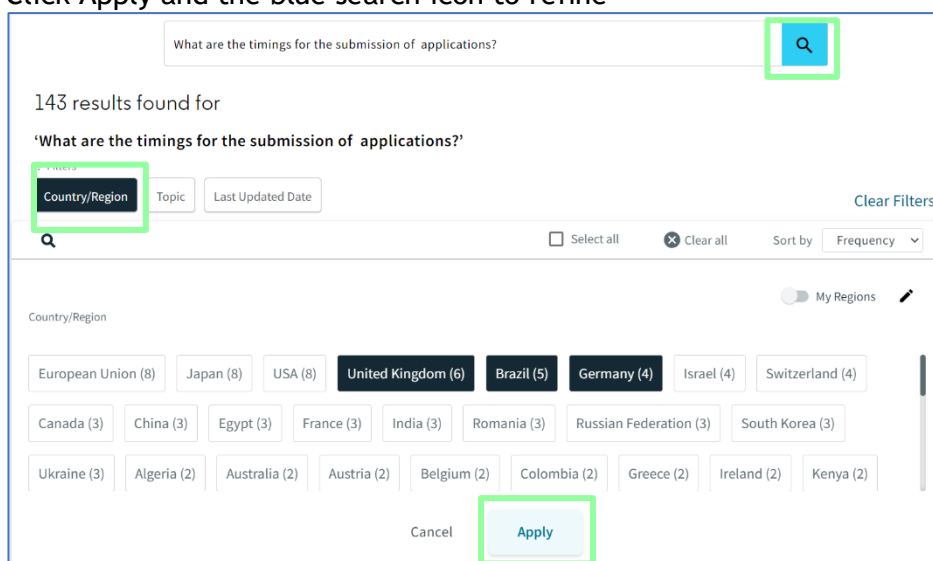
Intuitive search in the Regulatory Summaries provides a way to compare answers across countries on common regulatory questions.

**Example: view timings for the submission of Marketing Authorization Applications in Spain, Germany, the UK, Brazil, and Argentina.**

1. Click the Regulatory Summaries tab
2. Select Search
3. Begin typing keywords from your question into the box, for example *timing*
4. Select a question from those appearing in the drop down menu



5. Use the filters to narrow down your result. For example, use the Country/Region filter to narrow down to just Spain, Germany, the UK, Brazil and Argentina
6. Click Apply and the blue search icon to refine



7. Select “Expand All” and scroll to compare the answers to your question country by country in the results.

14 results found for

**‘What are the timings for the submission of applications?’**

Filters

Country/Region Topic Last Updated Date

Sorted by Relevance Expand All Collapse All

**Summary**

- 03-Sep-2021 V

SP EN RS

**Marketing Authorization Procedures: Review, Communication and Approval**

This document provides the principal marketing authorization application stages through the national procedure.

Country/Region: Spain  
IDRAC Number: 229  
Last Updated Date: 03-Sep-2021

**What are the timings for the submission of applications?** ^

According to the regulation Royal Decree 1345/2007, the maximum time limit to obtain the authorization is 210 calendar days from the reception of a dossier considered as complete. The clock is stopped when the Authorities request additional information.
- 02-Aug-2021 V

DE EN RS

**Marketing Authorization Procedures: Review, Communication and Approval**

This document provides the principal marketing authorization application stages through the national procedure.

Country/Region: Germany  
IDRAC Number: 311  
Last Updated Date: 02-Aug-2021

**What are the timings for the submission of applications?** ^

1. Applications to BfArM For national marketing authorization applications, the agency does not necessarily have to be notified in advance, the application can be submitted at any time. For MRP procedures, there is no need for a slot request, prior notification is however recommended, especially if an MRP procedure with Germany acting as RMS is planned. An informal application to the process management of the licensing unit should be sent well in advance. For DCP procedures where the BfArM is planned as RMS, applications can be submitted without a slot request and can be started after validation of the application. However, to support internal planning, BfArM is asking that even in cases where slot requests are not required, information with regard to a planned submission is e-mailed to [slotrequest-DCP@bfarm.de](mailto:slotrequest-DCP@bfarm.de) at least 3 months in advance. However advance slot requests are still required for products with certain ATC codes for which the BfArM has published a list in their BfArM Information on slot requests. For products with these ATC codes, the slot request must be e-mailed to [slotrequest-DCP@bfarm.de](mailto:slotrequest-DCP@bfarm.de) and contain the following information: E-mail request or cover letter including correct ATC code for the product and reference to the relevant licensing unit in BfArM (for ATC code assignment to licensing unit see Organization of BfArM; for herbal medicinal products the letters “PHY” and “HOM” are to be used instead of the ATC code. Completed HMA/CMD (h) request for RMS in a DCP form (<https://www.hma.eu/219.html>). A binding statement of the applicant's preferred submission date Further information has been given by BfArM in their Allocation of Slots in the Decentralised Procedure (DCP) at BfArM guidance document. A few days after receipt of the request, BfArM will respond and propose a slot which the applicant has to confirm or decline within 3 days. 2. Applications to PEI The PEI has not published information on slot requests. Purely national applications can be submitted at any time. For MRP or DCP procedures where the PEI is planned as RMS, a specific procedure has not been defined. It is recommended to contact the relevant PEI licensing unit to discuss the request well in advance (commonly 3 months in advance).
- 28-Sep-2021 V

AR EN RS

**Marketing Authorization Procedures: Review, Communication and Approval**

This document provides detailed, practical information and flow charts about the national authority review process, for the type of products detailed below: - Article 3 and 5 products (see Definitions in Decree 150/92), - Article 4 products (see Definitions in Decree 150/92), - Biological and biosimilar products.

Country/Region: Argentina  
IDRAC Number: 26800  
Last Updated Date: 28-Sep-2021

**What are the timings for the submission of applications?** ^

The normative do not describe timelines for submission.
- 06-Sep-2021 V

BR EN RS

**Marketing Authorization Procedures: Review, Communication and Approval**

This document provides an overview of the principal marketing authorization application stages as well as detailed information about the review process of each major category of product in Brazil. It includes comprehensive, practical information about the national authority review, communication and approval process.

Country/Region: Brazil  
IDRAC Number: 25629

Add the Regulatory Summary to the Side By Side Viewer, Set up an alert to be notified of future updates and export using the tools in the upper right hand corner.



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