

Simplify access to Regulatory Information with the AI Assistant

Cortellis Regulatory Intelligence



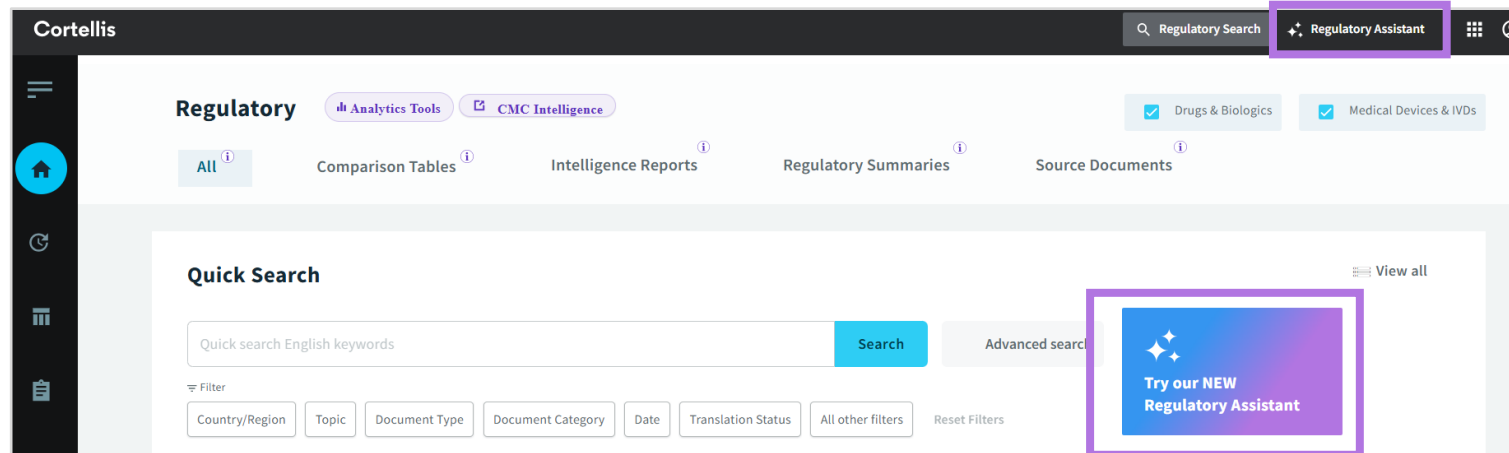
The Cortellis Regulatory AI Assistant streamlines global compliance by delivering precise, reference-backed answers through a conversational search interface. Simply ask questions using natural language to understand complex requirements faster and with confidence for both Drugs & Biologics and Medical Devices & IVDs content.

Answers are derived from Cortellis Regulatory Intelligence content: official documents from the regulatory authorities and Cortellis value-added documents. Currently the Regulatory AI Assistant supports four use cases:

- 1) Understand a requirement
- 2) Find a specific document
- 3) Summarize a document
- 4) Compare two document versions

This scope will expand as development of the tool continues. Tips for writing questions are provided after the use case questions.

NOTE: Customers opt into the AI Regulatory Assistant at the Account level. If you have questions about access, please contact lsh.support@clarivate.com



Access the Regulatory Assistant on the Home screen next to Quick Search or from any Cortellis Regulatory Intelligence screen via the black ribbon at the top.

Example: What is the requirement for ADR reporting in China?

1. Click the **Understand a requirement** tile and the search box is populated with the beginning of the question, "What is the requirement for". **Fill in the rest of the question**, for this example, "**adverse drug reporting in China?**".

2. **Search Tips:** A) Clicking the tile to start the question is optional but advised B) Be specific with your questions. The more specific your question is regarding topics, countries, agencies, and spelling out acronyms, etc. the more precise your answer.

3. Click the **purple search arrow**.

The screenshot shows the Clarivate regulatory search interface. At the top, it says "Hi Beth, what is your regulatory question?" followed by "Let me find answers from our high-quality, comprehensive, and verified regulatory data". Below this is a search bar containing the text "What is the requirement for adverse drug reporting for drugs in China?". To the right of the search bar is a purple search arrow button. Below the search bar, there are four tiles under the heading "You can currently ask me to...". The first tile, "Understand a requirement", is highlighted with a purple border and a callout '1'. The other three tiles are "Find a document", "Summarize a document", and "Compare versions". A callout '2' points to the search bar, and a callout '3' points to the search arrow button. A "Question tips" link is visible in the top right of the interface.

Hi Beth, what is your regulatory question?
Let me find answers from our high-quality, comprehensive, and verified regulatory data

2 What is the requirement for adverse drug reporting for drugs in China?

3 →

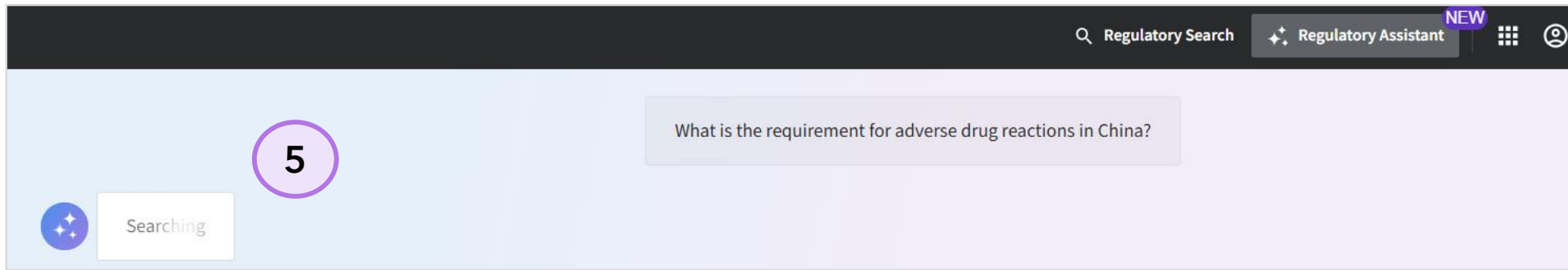
You can currently ask me to... [Question tips](#)

1 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 draft of Guideline on the Chemistry of Active Substances and the current version?"



4. On the next page, the AI assistant **might ask you to clarify questions**, for example, “What country is of interest” if you didn’t specify in your question.

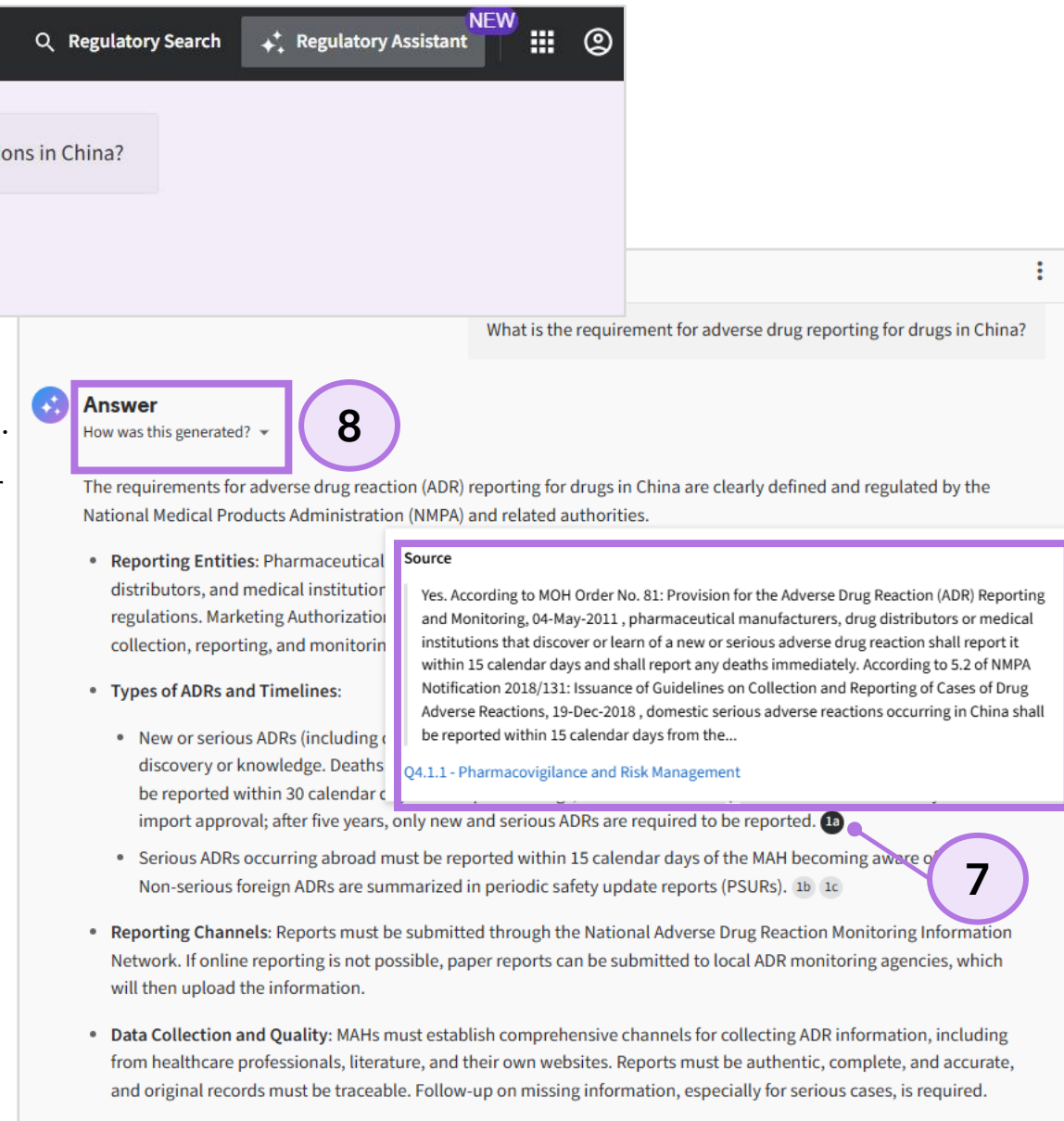
5. You’ll then see where the AI Assistant is in the process of answering your question, first **Thinking**, then **Searching** and finally, **Generating answer**.

6. The **response is organized** to make the answer quick and easy to understand.

7. Clicking the **citation numbers** opens the sources and links to the Source Documents in Cortellis.

8. **How was this generated?** Shows the search process to find your answer.

NOTE: Asking the same question again might provide answers with different wording due to the nature of large language model searching.



9. A full list of linked sources follows.

Source documents ▾

- 1 Pharmacovigilance and Risk Management
Expert Report · Cortellis · China · Last updated 27-Feb-2026 · More info
- 2 MOH Order No. 81: Provision for the Adverse Drug Reaction (ADR) Monitoring, 04-May-2011
Order · NMPA · China · Last updated 14-Aug-2025 · More info · Summarize · Version comparison
- 3 NMPA Announcement No. 2018/66: Direct Reporting of Adverse Reactions by Marketing Authorization Holders of Drug Products, 29-Sep-2018 (English and Chinese versions)
Announcement · NMPA · China · Last updated 15-Aug-2025 · More info · Summarize · Version comparison
- 4 NMPA Notification 2018/131: Issuance of Guidelines on Collection and Reporting of Cases of Drug Adverse Reactions, 19-Dec-2018 (English and Chinese Versions)
Notification · NMPA · China · Last updated 15-Aug-2025 · More info · Summarize · Version comparison

Callout 9 points to the source list. Callout 10 points to the 'Summarize' button for item 3. Callout 11 points to the 'Version comparison' button for item 4.

10. Click **Summarize** for an AI generated summary of a specific source document.

11. **Version Comparison** provides a quick way to see a summary of changes from one version to another. Example shown on page 7.

12. Use the “**Thumbs up and Thumbs down**” icons to report feedback on the quality of your answer.

13. Copy your response using the **copy icon**.

Answer

Here is a brief summary of the “NMPA Announcement on Matters Regarding Direct Reporting of Adverse Reactions by a Holder of a Drug Marketing License (No. 66, 2018)”:

- **Main Subject:** This announcement mandates that holders of drug marketing licenses in China (including manufacturers and importers) are directly responsible for establishing and operating adverse drug reaction (ADR) monitoring systems and for reporting ADRs.
- **Actionable Items:**
 - Holders must set up dedicated ADR monitoring structures, designate responsible personnel, and ensure timely and direct reporting of ADRs through the National ADR Monitoring System.
 - Serious ADRs in China must be reported within 15 days of discovery; deaths or group events immediately; other ADRs within 30 days. Similar timelines apply for overseas cases.
 - Annual summary reports on ADR monitoring must be submitted by March 31 each year.
 - Holders must take risk control measures and update product information as needed.
- **Impact on Stakeholders:** Drug marketing license holders, their agents, medical institutions, and pharmaceutical supply enterprises are directly affected. Provincial drug regulatory authorities are responsible for oversight and enforcement.
- **Key Dates/Deadlines:** The announcement is effective from 1 January 2019. Annual summary reports are due by 31 March each year.
- **Relationships:** This announcement aligns with the Drug Administration Law and supports China's harmonization with international (ICH) pharmacovigilance standards.

Would you like a more detailed version of this summary?

Source documents ▾

- 1 NMPA Announcement No. 2018/66: Direct Reporting of Adverse Reactions by Marketing Authorization Holders of Drug Products, 29-Sep-2018 (English and Chinese versions)
Announcement · NMPA · China · Last updated 15-Aug-2025 · More info · Summarize · Version comparison

Callout 12 points to the thumbs up and thumbs down icons. Callout 13 points to the copy icon.

Example: Find a document about registering a medical device in the UK

1. Click the **Find a document tile**, and the search bar is populated with, "Find a document about".
2. Fill in the rest of the question, for this example, "**registering a medical device in the UK**".
3. Click the purple search button.

The screenshot shows a user interface for asking regulatory questions. At the top, a heading asks "Hi Beth, what is your regulatory question?" followed by a sub-heading "Let me find answers from our high-quality, comprehensive, and verified regulatory data". Below this is a search bar containing the text "Find me a document about class 1 medical device classification in the UK". To the right of the search bar is a purple search button with a white right-pointing arrow. Below the search bar, there is a section titled "You can currently ask me to..." with a "Question tips" link. This section contains four tiles: "Understand a requirement" (with a question mark icon), "Find a document" (with a magnifying glass icon), "Summarize a document" (with a list icon), and "Compare versions" (with a document icon). The "Find a document" tile is highlighted with a purple border and a callout circle containing the number 1. The search bar is highlighted with a purple border and a callout circle containing the number 2. The search button is highlighted with a purple border and a callout circle containing the number 3.

Hi Beth, what is your regulatory question?
Let me find answers from our high-quality, comprehensive, and verified regulatory data

2 Find me a document about class 1 medical device classification in the UK

3

You can currently ask me to... [Question tips](#)

1

- 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 draft of Guideline on the Chemistry of Active Substances and the current version?"

UK Class 1 Medical Devices

4 Find me a document about class 1 medical device classification in the UK

Answer
How was this generated? ▾

I have found the following documents that matches with your description:

- Medical Devices Regulatory Framework
- MHRA Guidance: Class I Medical Devices, 01-Jul-2023
- MHRA: Class I Medical Devices – Routes to CE Marking, Nov-2015

If you'd like a brief summary of the document(s) please click on the Summarize button(s) below

Source documents ▾

- 1 **Medical Devices Regulatory Framework**
Expert Report • Cortellis • United Kingdom • Last updated 13-Apr-2026 • More info
- 2 **MHRA Guidance: Class I Medical Devices, 01-Jul-2023**
Guideline • MHRA • United Kingdom • Last updated 17-Aug-2025 • More info • Summarize • **Version comparison**
- 3 **MHRA: Class I Medical Devices – Routes to CE Marking, Nov-2015**
Fact Sheet • MHRA • United Kingdom • Last updated 15-Aug-2025 • More info • Summarize • Version comparison

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Type your follow-up message

Support ↑

4. The AI Assistant will go through the same conversational process of asking clarifying questions, thinking, searching and generating an answer.

5. With Find a document there's no commentary in the answer, but as before you can access **How was this generated, links to the Cortellis documents, the Feedback icons as well as the Copy icon and the ability to generate an AI Summary of a document and Version comparison.**

6. Version comparison: click for desired document, choose the versions to compare in the pop up and click compare.

Version comparison ✕

Select the two versions you want to compare

Title	Status	Version	IDRAC	Authority acceptance	Coming into force
<input checked="" type="checkbox"/> MHRA Guidance: Class I Medical Devices, 01-Jul-2023	Valid	Revision	367258	01-Jul-2023	-
<input checked="" type="checkbox"/> MHRA Guidance: Class I medical devices, 17-May-2023	Outdated	None	364740	17-May-2023	-

2 of 2 selected

Cancel **Compare**

7. The Regulatory Assistant then generates a summary of key updates between the selected versions.

Compare IDRAC 367258 to IDRAC 364740

7

Answer

Here's a summary of the key updates in the 2023 version of the **MHRA Guidance: Class I Medical Devices, 01-Jul-2023**, compared with the 2023 version of the **MHRA Guidance: Class I medical devices, 17-May-2023**.

Key Updates in the MHRA Guidance: Class I Medical Devices, 01-Jul-2023

- 1. Updated Acceptance of CE Marked Devices** The guidance now clarifies that CE marked devices continue to be accepted on the Great Britain market, with acceptance deadlines varying by device type and legislation, and the latest deadline extended to 30 June 2030.
- 2. Clarification of Legislative References** There is expanded detail on the relevant UK legislation, including explicit references to the Medical Devices Regulations 2002, device classification rules, and additional guidance documents such as those on borderline products and stand-alone software.
- 3. Expanded UKCA Mark Requirements** The requirements for UKCA marking are more thoroughly described, including explicit steps for self-certification, clinical evaluation, and notification obligations for clinical investigations.
- 4. Document Retention Requirements** The updated guidance now specifies that manufacturers must keep documentation for at least 5 years after the last product is manufactured, to facilitate MHRA investigations even after the device is no longer on the market.
- 5. Editorial and Formatting Changes** Several sections have been reworded for clarity, and minor editorial changes have been made to improve readability and consistency.
- 6. Update of Publication and Revision Dates** The document now notes the original publication date (4 October 2016) and the latest update (1 July 2023), replacing the previous last updated date.

Type your follow-up message

Support
↑

Tips for writing questions

To make the most of the **Cortellis Regulatory Assistant** and effectively find answers and evaluate sources for your regulatory questions, it's recommended to craft well-structured questions.

- 1. Click the appropriate task button** below the search bar to start your question in a format the Regulatory Assistant will easily recognize.
- 2. Be Specific:** The more specific your question, the more precise the results.
- 3. Provide Details:** Include pertinent information such as agencies, regions, countries, and product type (drug, biologic, medical device, IVD, or combination) to get the most relevant answer.
- 4. Specify Subjects or Topics:** Mention the subject or topic of interest to ensure relevant results. Use appropriate keywords.
- 5. Spell out acronyms.** For clarity and to avoid ambiguity, always use the full form of acronyms in your questions.
- 6.** When switching to a **new topic**, select to **start a "New chat"** in the upper left corner of the Regulatory Assistant chat page.
- 7.** The examples in this guide are in English, but you can **interact with the assistant in your preferred language.**

By following these guidelines, you can maximize the effectiveness of the Cortellis Regulatory Assistant. The more details you provide, the more likely the Regulatory Assistant will be able to find the right information. The Regulatory Assistant will help narrow down results and continue the conversation beyond your initial request.

For more information contact Customer Care at LSH.support@clarivate.com