

Simplify access to Regulatory Information with the AI Assistant

Cortellis Regulatory Intelligence



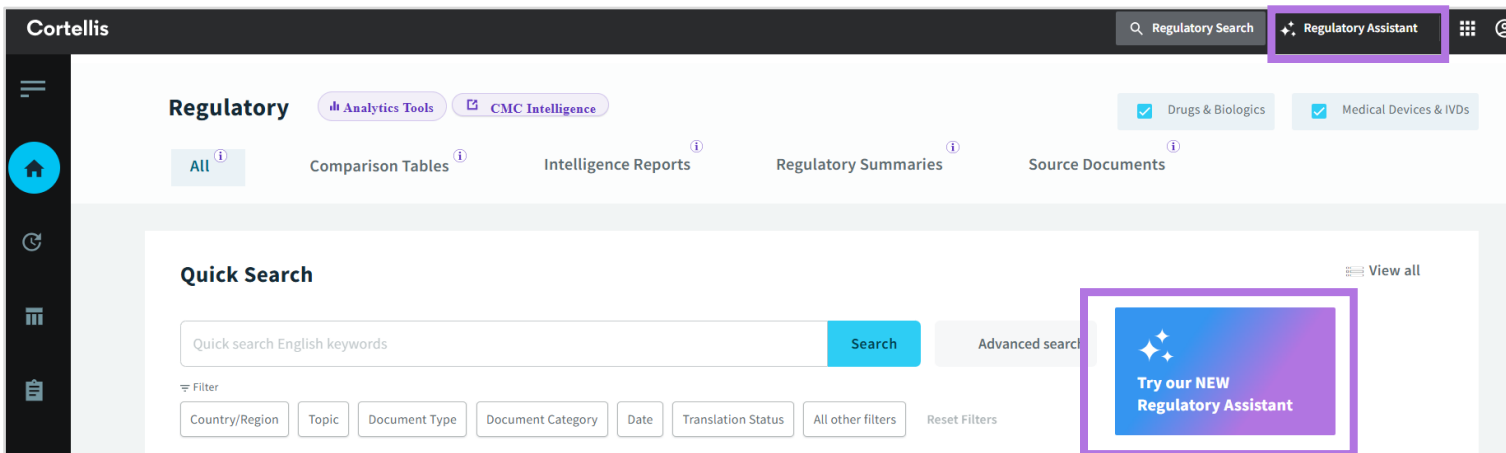
The **Cortellis Regulatory AI Assistant** streamlines global compliance by delivering precise, reference-backed answers through a conversational search interface. Simply ask questions using natural language to understand complex requirements faster and with confidence for both Drugs & Biologics and Medical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

- 1) Understand a requirement
- 2) Find a specific document
- 3) Summarize a document

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: 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 a user interface for asking regulatory questions. At the top, it says "Hi Beth, what is your regulatory question?" and "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 in China?". To the right of the search bar is a purple arrow button. Below the search bar, there are three 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 second tile, "Find a document", is also highlighted with a purple border and a callout '3'. The third tile, "Summarize a document", is not highlighted. A callout '2' points to the search bar. A "Question tips" link is visible to the right of the tiles.

2

What is the requirement for adverse drug reporting in China?

3

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"

Question tips

What is the requirement for adverse drug reactions in China?

5

Searching

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.

Answer
How was this generated?

Requirements for adverse drug reaction (ADR) reporting in China are clearly defined for Marketing Authorization Holders (MAHs).

- **MAH Responsibility:** The MAH is fully responsible for pharmacovigilance (PV), including establishing a monitoring system, designating a responsible person, setting up a dedicated agency, and employing full-time staff. Distributors and hospitals are not responsible for PV activities. ^{1a} ²
- **Information Collection:** MAHs must proactively collect ADR information from physicians, pharmacists, patients, and other healthcare providers. ^{1a} ²

Source

[NMPA Announcement No. 2018/66: Direct Reporting of Adverse Reactions by Marketing Authorization Holders of Drug Products, 29-Sep-2018 \(English and Chinese versions\)](#) ^{1a} ²

- **Reporting Timelines:** Serious ADRs occurring in China must be reported within 15 calendar days of discovery or knowledge. Deaths and drug group adverse events must be reported immediately. Other ADRs should be reported within 30 calendar days. For imported drugs, serious ADRs occurring outside China must also be reported within 15 days, while other ADRs are included in periodic safety update reports. ^{1b} ²
- **Scope of Reporting:** For new domestic pharmaceuticals, all ADRs must be reported during the monitoring period. For other domestic drugs, only new or serious ADRs are reported. For imported drugs, all ADRs are reported for the first five years after import permit; after five years, only new and serious ADRs are reported. ^{1c}
- **Evaluation and Risk Management:** MAHs must regularly evaluate ADR data, clinical research, and literature, with special attention to new and serious ADRs, abnormal increases in reports, or batch number centralization trends. They must also formulate post-marketing risk management plans and conduct regular safety evaluations. ^{1a} ²
- **Annual and Periodic Reports:** MAHs must submit an annual summary report of ADR monitoring activities to the provincial agency by March 31 each year and prepare periodic drug safety update reports as required. ²
- **Legal Consequences:** Failure to comply with ADR reporting requirements can result in investigation, fines, suspension of sales, or revocation of the drug approval certificate. ²

8. A full list of linked sources follows.

Source documents

- 1 [Pharmacovigilance and Risk Management](#)
Expert Report • Cortellis • China • Last updated 18-Sep-2025 • More info
- 2 [MOH Order No. 81: Provision for the Adverse Drug Reaction \(ADR\) Reporting and Monitoring, 04-May-2011](#)
Order • NMPA • China • Last updated 14-Aug-2025 • More info • Summarize
- 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
- 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
- 5 [Marketing Authorization Procedures: Procedure for Unapproved Drug Use / Compassionate Use](#)
Expert Report • Cortellis • China • Last updated 17-Jun-2025 • More info

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

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

11. 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:** The announcement mandates holders of drug marketing licenses in China to directly report adverse drug reactions (ADRs), strengthening their principal responsibility for drug safety.
- **Actionable Items:**
 - Holders must establish and maintain a robust ADR monitoring system, designate responsible personnel, and set up dedicated agencies with qualified staff.
 - ADRs must be reported through the National Adverse Drug Reaction Monitoring System within specified timelines: serious ADRs within 15 days, deaths or group events immediately, and other ADRs within 30 days.
 - Annual summary reports on ADR monitoring must be submitted by March 31 each year.
 - Holders must take prompt risk control measures and publicly disclose actions taken.
- **Impact on Stakeholders:**
 - Pharmaceutical manufacturers, importers, and their agents are directly affected, with increased compliance and reporting obligations.
 - Provincial drug regulatory authorities are tasked with supervision and enforcement.
- **Key Dates/Deadlines:**
 - The announcement is effective from January 1, 2019.
- **Relationships:**
 - Supports alignment with ICH guidelines and international pharmacovigilance standards.
 - Supplements existing Chinese drug safety laws and regulations.

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

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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, it says "Hi Beth, what is your regulatory question?" and "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 arrow. Below the search bar is a section titled "You can currently ask me to..." with a "Question tips" link. There are three tiles in this section: "Understand a requirement" (with a lightbulb icon), "Find a document" (with a magnifying glass icon), and "Summarize a document" (with a document icon). The "Find a document" tile is highlighted with a purple border and a circled "1" next to it. The search bar is highlighted with a purple border and a circled "2" next to it. The search button is highlighted with a purple border and a circled "3" next to it.

Hi Beth, what is your regulatory question?

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

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

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"

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:

- MHRA Guidance: Class I Medical Devices, 01-Jul-2023
- MHRA: Class I Medical Devices – Routes to CE Marking, Nov-2015
- MHRA: Guidance on Registration of Certain Medical Devices which are Reusable Class I devices, Upclassified Class I devices, and/or Reliant on Expired/Expiring CE Certificates, 17-Feb-2025

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

Source documents

- 1 [MHRA Guidance: Class I Medical Devices, 01-Jul-2023](#)
Guideline · MHRA · United Kingdom · Last updated 17-Aug-2025 · More info ·  Summarize
- 2 [MHRA: Class I Medical Devices – Routes to CE Marking, Nov-2015](#)
Fact Sheet · MHRA · United Kingdom · Last updated 15-Aug-2025 · More info ·  Summarize
- 3 [MHRA: Guidance on Registration of Certain Medical Devices which are Reusable Class I devices, Upclassified Class I devices, and/or Reliant on Expired/Expiring CE Certificates, 17-Feb-2025](#)
Guideline · MHRA · United Kingdom · Last updated 18-Feb-2025 · More info ·  Summarize



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**.

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