

Source documents and English translations

Cortellis CMC Intelligence



Example: Find Source documents and English translations for China

The screenshot shows a search interface with the following elements:

- 1**: A dropdown menu with "Small molecules" and "Biologics" selected.
- 2**: Radio buttons for "Pre-approval" and "Post-approval changes and clinical trial amendments", with the latter selected.
- 3**: A "Countries/regions" section with a search bar containing "China" and a list of regions including Asia Pacific, Eurasia, and Europe. The "China" checkbox is checked.
- 4**: "Cancel" and "Apply" buttons at the bottom of the regions list.
- 5**: A "Report" button in the "Go to:" navigation bar, which is highlighted.

1. Choose Small molecules or Biologics
2. Choose Pre-Approval or Post-Approval
3. Click Countries/regions and/or Organizations to choose the desired entities from the drop-down menus that appear. For this example, select China
4. Click Apply.
5. Select Report

**Content available is based on your subscription. Regardless of the module/content selected the procedure for finding Sources is the same.*

View Sources and English translations in Reports

Cortellis CMC Intelligence | Biologics - Post-approval changes and clinical trial amendments

Home Summary Detailed **Report** Updates

Sources Create alert Edit search

China

Search...

Expand all sections

Key facts

Upcoming guidelines and drafts

Procedures

> Detailed requirements

6 Sources

China • Last change date 5-Jun-2026

19-Apr-2026

7 CDE Notification: Soliciting Public Comments for the Chinese Translation of the ICH M8: Electronic Common Technical Document (eCTD) v4.0 Guidelines and Q&A Documents (Draft), 20-Apr-2026

Source ID: 13235 • IDRAC: **427953** • Status: Valid

Origin: Center for Drug Evaluation (CDE)- China

8 Original document **9** Translation available

14-Jan-2026

9 Machine translated document (English)

NMPA Announcement No.20: Drugs and Biological Products

Source ID: 12763 • IDRAC: 427953

Origin: NMPA - National Medical Products Administration

Original document

6. Select Sources in the report menu. This provides the list of Sources used to create the structured report content for China.

7. Clicking IDRAC Number opens the document in Cortellis Regulatory Intelligence (requires additional subscription).

8. Click Original document to open the official document

9. Click Translation available and the link that appears - in this case Machine translated document (English) to open the Google Translate version of the document

NOTE: Source documents and English translations are also available in Detailed Requirements.

Cortellis CMC Intelligence | Biologics - Post-approval changes and clinical trial amendments

Home Summary **Detailed** Report Updates

Container closure system

Create alert Download Edit search

Compare side-by-side List view Table view

All filters Filter...

Search...

Collapse all sections

- Other administrative changes
- Quality
- Manufacture
- Control of Starting material/Reagent/Intermediates
- Control of Active substance
- Reference Standards or Materials
- Container closure system**
- Description and composition
- Control of excipients
- Control of Finished Product
- Stability

<input type="checkbox"/>	Countries/regions/organizations	Category	Route of administration	Source ID	Actions
<input type="checkbox"/>	China	Vaccines, Monoclonal Antibodies, Blood and blood components, Recombinant Hormones, Cell Thera...	Parenteral, Parenteral - Combination Product	7072 8370 8372 8367 2804 8374	Details >
<input type="checkbox"/>	China	Combination products			
<input type="checkbox"/>	China				
<input type="checkbox"/>	China	Vaccines, Monoclonal Antibodies, Blood and blood components, Recombinant Hormones, Cell Thera...	Parenteral, Parenteral - Combination Product		
<input type="checkbox"/>	China	Monoclonal Antibodies, Blood and blood components, Recombinant Hormones, Cell Therapy, Gene...			
<input type="checkbox"/>	China	Vaccines, Monoclonal Antibodies, Blood and blood components, Recombinant Hormones, Cell Thera...	Parenteral, Parenteral - Combination Product		

10. Scroll to Source ID

11. Select links as per previous example

29-Nov-2022
Announcement of the State Food and Drug Administration on the implementation of electronic reporting of drug registration (2022 No. 110)
IDRAC: [356279](#) Status: Valid
National Medical Products Administration China

Original document
Machine translated document (English)

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