

Ensure compliance for a single country

Cortellis CMC Intelligence



Example: Explore Pre- or Post-Marketing reports for a country to ensure compliance

Small molecules ☒ Biologics

☐ Pre-approval ☒ Post-approval changes and clinical trial amendments

Countries/regions Clear all

China × Add countries/regions

Asia Pacific

☐ Australia

☒ China

☐ Hong Kong

☐ India

☐ Indonesia

☐ Japan

☐ Malaysia

☐ New Zealand

☐ Philippines

☐ Singapore

☐ South Korea

☐ Taiwan

☐ Thailand

☐ Vietnam

Eurasia

☐ Russian Federation

Europe

☐ Austria

☐ Belgium

☐ Bulgaria

☐ Croatia

Collapse all sections

Cancel

Apply

Organizations

Add organizations

Go to:

Summary

Detailed

Report

Updates

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

NOTE: Content available is based on your subscription. Regardless of the module/content selected the procedure for finding and navigating the Country reports is the same.

View Reports - use the menu bar to select content

The screenshot shows the 'Cortellis CMC Intelligence' interface. The top navigation bar includes 'Home', 'Summary', 'Detailed', 'Report' (highlighted with a purple box), and 'Updates'. The 'Report' tab is selected. On the left, a sidebar menu is visible with a search bar and a list of sections: 'Key facts' (highlighted with a purple box), 'Upcoming guidelines and drafts', 'Procedures', 'Detailed requirements', and 'Sources'. A purple callout box points to the 'Key facts' section in the sidebar. The main content area displays 'Key facts' for China, with a list of bullet points detailing regulatory changes and requirements. A purple callout box is overlaid on the main content area, containing the text: 'Select from the Report menu items to view content, for example, Key Facts about China's regulatory authority'. The bottom right corner of the page features a small purple circle with the number '1' and a question mark icon.

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

Home | Summary | Detailed | **Report** | Updates

Key facts Create alert Edit search

China

Search...

Expand all sections

Key facts

Upcoming guidelines and drafts

Procedures

> Detailed requirements

Sources

Select from the Report menu items to view content, for example, Key Facts about China's regulatory authority

- CFDA - China medicine agency name has now been changed as NMPA (National Medicinal Products Administration) from July 2018.
- Chinese regulations are evolving rapidly, particularly core CMC DS / DP review processes (new drug classification in March 2016 and 2020).
- Regulations are becoming tighter and more aligned to ICH, US & EU. China became a full member of the ICH in 2017.
- The National Medical Products Administration (NMPA) held a symposium on the process and prospects of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) to review the progress of China's participation in the ICH and discuss follow-up work plans. To date (June 2021), China has transformed and implemented 46 ICH guidelines by issuing announcements on application or application recommendation of ICH guidelines and publishing the Chinese version of original ICH guidelines, and assigned 69 experts to participate in the in-depth coordination of ICH issues.
- Local trials can be performed in all phases of clinical development (previously only Phase 2 and above) Review and drug control/testing can occur at both provincial and federal level during registration process. Provincial FDA (PFDA) is involved only when drug product is manufactured in China Local sample testing by NICBPB is always required; for locally manufactured drugs, NICBPB may appoint a provincial drug quality control institute For imported drugs the entire review process is done by CFDA

Drug marketing permit (DIL) required for FPP for marketing

- API and excipients are following China DMF (Technical Review for DMF of API is 200 working days)
- Normally, 60 working days for clinical trial filing
- Around 200 working days for FPP for marketing

The "China Listed Drug Catalogue" is published on the government website of the State Food and Drug Administration in the form of a web version and links to drug review reports, specifications, patent information and other databases.

- The State Food and Drug Administration will directly update the newly registered classified drugs and the drugs that have passed the evaluation of the quality and

Upcoming guidelines and drafts

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

CMC SearchCMC AI AssistantBETAAlerts

HomeSummaryDetailedReportUpdates

Upcoming guidelines and drafts

China

Search...

Expand all sections

Key facts

Upcoming guidelines and drafts

Procedures

Detailed requirements

- Administrative
- Quality

Sources

Access the latest CMC guidelines and drafts

China • Last change date 5-Jun-2026

CDE Notification: Soliciting Public Comments for the Chinese Translation of the ICH M8: Electronic Common Technical Document (eCTD) v4.0 Guideline and Q&A Documents (Draft): (Source ID)

To further promote the implementation of the ICH M8: Electronic Common Technical Document (eCTD) v4.0 guidance and Q&A document in China, our center has drafted a Chinese translation of the guidance and Q&A document and is now soliciting public comments for one month. If you have any suggestions for revision, please send them to the contact person's email address [link](#)

1. Implementation Guide for M8: Electronic Common Technical Document (eCTD) v4.0 (Chinese Version)
2. Chinese version of the Q&A document for M8: Electronic Common Technical Document (eCTD) v4.0
3. Implementation Guide for M8: Electronic Common Technical Document (eCTD) v4.0 (English Version)
4. English version of the Q&A document for M8: Electronic Common Technical Document (eCTD) v4.0

For more detailed information, refer to the [link](#).

CDE Notification No.2026/04: Issuance of Technical Documents Related to eCTD V3.2.2, 15-Jan-2026 (Source ID)

In accordance with the "Announcement of the National Medical Products Administration on the Application for Full Implementation of Electronic Common Technical Documents (eCTD) for Chemical Drugs and Biological Products" (No. 8 of 2026), to strengthen the supervision and digitalization of the entire drug lifecycle, accelerate the implementation of eCTD in my country, and improve the application service level of "Internet + Drug Supervision," eCTD will be fully implemented for chemical drugs and biological products starting from March 1, 2026. To facilitate the full implementation of eCTD, the Center for Drug Evaluation (CDE) has revised the relevant technical documents for eCTD V3.2.2 (see Annexes 1-4). Based on the requirements of the "Notice of the General Office of the National Medical Products Administration on Issuing the Procedures for the Release of Drug Technical Guidelines" (No. 9 of 2020), and with the approval of the National Medical Products Administration, this document is hereby issued and will take effect on March 1, 2026.

Attachment:

- [Current application material requirements and correspondence table of eCTD catalog elements and CTD catalog levels](#)
- [eCTD Technical Specification V1.1 and Annex Package](#)

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View Reports - Submission Procedures

Procedures

China

Search...

Expand all sections

Key facts

Upcoming guidelines and drafts

Procedures

Detailed requirements

Administrative

Quality

Manufacture

Control of Starting material/Active substances/Reagent/Intermediate

Container closure system

Stability

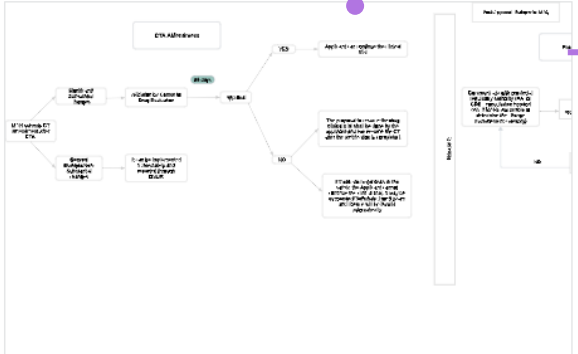
Design space and post approval management

Select Procedures to view Submission Pathways

Click visual to expand

China • Last change date 5-Jun-2026

Regulatory Submission Pathways



CTA amendment & PAC Procedure

PAC Relevant Procedure

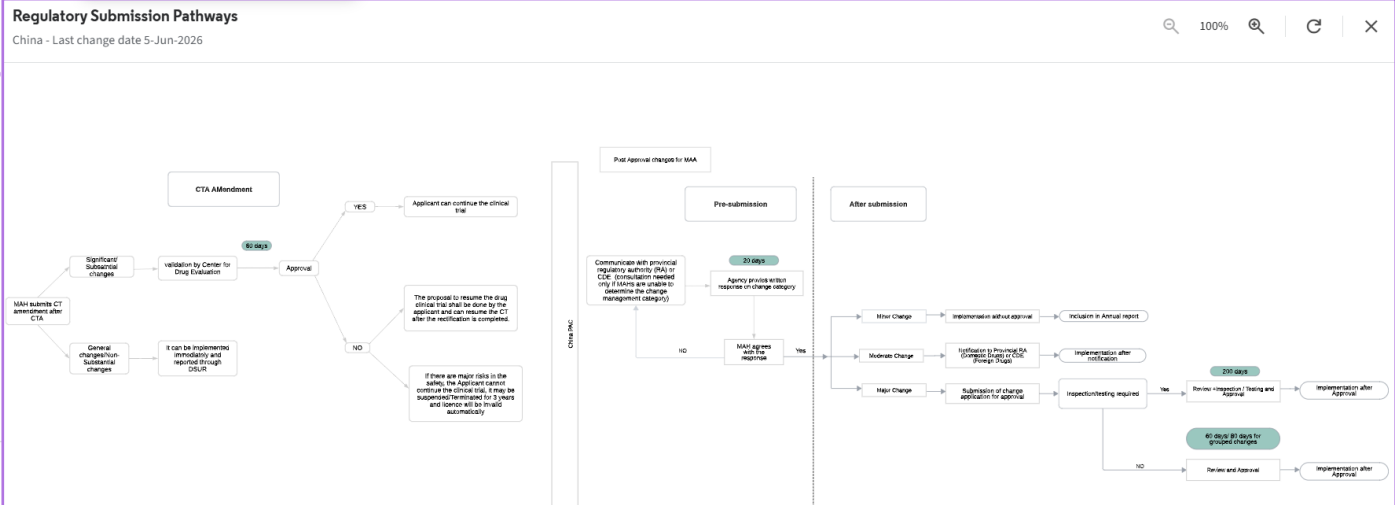
Provisions for Post-approval Changes of Drugs (Trial) [Source ID 836Z](#) -Appendix 1

General Provisions

- Marketing authorization holders (hereinafter referred to as holders) for post-marketing changes in drugs, and strengthen the connection between drug registration and production supervision and management of drug regulatory authorities, according to the "Drug Administration Law" " The Vaccine Administration Law, the Measures for the Administration of Drug Registration (Order No. 27 of the State Administration for Market Regulation), and the Measures for the Supervision and Administration of Drug Production (Order No. 28 of the State Administration for Market Regulation) formulate these measures.
- The holder should take the initiative to carry out post-marketing research of drugs to realize the full life cycle management of drugs. Encourage holders to use new production technologies, new methods, new equipment , and new scientific and technological achievements to continuously improve and optimize production processes, continuously improve drug quality, and improve drug safety, effectiveness, and quality controllability.
- The holder is the main body responsible for the post-marketing change management of drugs, and should establish a post-marketing change control system in accordance with relevant requirements of drug regulatory

Regulatory Submission Pathways

China - Last change date 5-Jun-2026



View Reports - Detailed requirements - Module 3 for Pre-approval and Changes for Post-approval changes and clinical trial amendments

Cortellis CMC Intelligence

Biologics - Post-approval changes and clinical trial amendments

CMC Search

CMC AI Assistant

BETA

Alerts

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Primary/Immediate packaging related changes

Create alert

Edit search

China

All filters

Filter...

Compare side-by-side

List view

Table view

Search...

Expand all sections

Detailed requirements

Administrative

Quality

Manufacture

Control of materials (starting, active substances, reagent, intermediates)

Container closure system

Primary/Immediate packaging related changes

Secondary packaging related changes

Primary/Immediate packaging

Countries/regions/organizations	Change description	Variation classificatio...	Implementation type	Produ	Actions
☐ China	Change in packaging format/delivery device.	Major	Tell, wait & do		
☐ China	Change the shape and size of the primary packaging container.	Major	Tell, wait & do		
☐ China	Changes to manufacturing plant/ factory/ production line (including preparation/filling and packaging of direct contact drugs).	Minor	Do & tell		
☐ China	Changes to packaging materials and containers in direct contact (including new coatings, adhesives, caps/stoppers, glass materials, etc.).	Major	Tell, wait & do		
☐ China	Changes to manufacturing plant/ factory/ production line (including preparation/filling and packaging of direct contact drugs).	Moderate	Tell & do		

Timelines

Fees

(1) 60 working days for a single change.
(2) 80 working days for grouped changes.
(3) 200 working days if inspection and testing are need...

Domestic: CN¥ 99,600
Imported: CN¥ 283,600

(1) 60 working days for a single change.
(2) 80 working days for grouped changes.
(3) 200 working days if inspection and testing are need...

Domestic: CN¥ 99,600
Imported: CN¥ 283,600

Not applicable.

No fee.

(1) 60 working days for a single change.
(2) 80 working days for grouped changes.
(3) 200 working days if inspection and testing are need...

Domestic: CN¥ 99,600
Imported: CN¥ 283,600

No approval needed, however, the CDE/ provincial drug agency completes review in 30 working days from the date of submission.

Domestic: CN¥ 9,600
Imported: CN¥ 9,600

Items per page:

10

1 - 7 of 7

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2

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Table view makes comparing data easy

Use slider bar to view all data in the table

Filtering the Menu Bar

Cortellis CMC Intelligence

Biologics - Post-approval changes and clinical trial amendments

Alerts

Home

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Manufacture

Create alert

Edit search

China

All filters

Filter...

Compare side-by-side

List view

Table view

manufac

Collapse all sections

Detailed requirements

Administrative

Manufacture name and/or address change

Deletion of Manufacturing site

Quality

Manufacture

☐	Countries/regions/organizations	Change description	Variation classificatio...	Actions
☐	China	Change in fermentation process.	Minor	Details >
☐	China	Preparation of virus cultures: Changes in the ultrafiltration concentration process (replacement of dialysis systems by membrane...	Major	Details >
☐	China	Replacement or addition of diluent source.	Moderate	Details >
☐	China	Finished product production process: Changes to the lyophilization process	Moderate	Details >

Items per page: 10 1 - 10 of 164 < > >> <<

1 ?

Search the menus and view narrowed down content by clicking each result

Filtering Report content

Cortellis CMC Intelligence Small molecules - Post-approval changes and clinical trial amendments

Click filters and select desired filters from pop-up

Enter keywords into the filter box

Control of excipients

China

All filters

excipients

Search term found - expand content to see match

Compare side-by-side

List view

Table view

Search...

Collapse all sections

Detailed requirements

Administrative

Manufacturer name and/or address change

Quality

Manufacture

Control of excipients

Other Quality changes

Description and composition

Sources

Filter

Product Type

Submission Type

Drug Type

Pharmaceutical Form

Procedure

Variation classification type

CTA Amendment Type

Product Type

IMP

FPP

Clear all

Cancel

Apply

Countries/regions/organizations

Change description

Variation classificatio...

Implementation type

Product type

Actions

China

Improving the quality standards of excipients such as tightening quality control limits) or due to pharmacopoeia version.

Minor

Do & tell

FPP

Details

Standards of excipients such as (limits) or due to

Minor

Do & tell

FPP

Details

Standards of excipients.

Moderate

Tell & do

FPP

Details

Standards of excipients.

Excipient process and control

CTA - Significant cha...

Not specified

IMP

Details

Items per page: 10

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Hit highlighting shows where your terms were found

1

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Accessing Source documents

Cortellis CMC Intelligence

Biologics - Post-approval changes and clinical trial amendments

CMC Search

CMC AI Assistant

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Expand all sections

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Click links to open documents and English translations

China • Last change date 5-Jun-2026

19-Apr-2026

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

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

Origin: Center for Drug Evaluation (CDE)- China

Original document

Translation available

14-Jan-2026

NMPA Announcement No.2026/08: Full Implementation of Electronic Common Technical Document (eCTD) Submission for Chemical Drugs and Biological Products, 14-Jan-2026

Source ID: 12763 • IDRAC: 421733 • Status: Valid

Origin: NMPA - National Medical Products Administration China

Original document

Translation available

14-Jan-2026

CDE Notification No.2026/04: Issuance of Technical Documents Related to eCTD V3.2.2, 15-Jan-2026

Source ID: 12764 • IDRAC: 421734 • Status: Valid

Origin: Center for Drug Evaluation (CDE)- China

Original document

Translation available

Create alert

Edit search

2

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