

# Quick start guide

Home

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Cortellis CMC Intelligence | Biologics | Pre-Approval

1. Choose Small Molecules or Biologics

2. Choose Pre-Approval or Post-Approval

Content available is based on your subscription.

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☒ Pre-Approval

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3. Select Countries, Regions, Organizations, Member States or Climatic Zones by clicking a tab and choosing the desired entities from the drop-down menus that appear.

Countries / Territories (29)

Regions

Organizations

Member States

Climatic Zones

Select Countries / Territories

Countries / Territories Selected (29)

Clear all

Austria x Belgium x Bulgaria x Croatia x Czech Republic x Denmark x Estonia x  
Finland x France x Germany x Greece x Hungary x Ireland x Italy x Latvia x  
Lithuania x Netherlands x Norway x Poland x Portugal x Romania x Serbia x

4. Choose how you'd like to view data for the content selected. Descriptions are below.

Go to:

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Summary

Summary

Compare and contrast core requirements for your selections to identify differences and similarities for your global operations.

Detailed

Detailed

Explore and search through, both official regulatory requirements and local practices organized into eCTD structure efficiently linked to the source documents.

Report

Report

View a visualization of regulatory submission pathways, read key facts, procedures and requirements to gather understanding of the regulatory submission.

Updates

Updates

See the latest updates to the content for your selected country or organization to quickly identify and locate changes to CMC regulatory content for your projects.

## View Summary Reports

Click to Export to Excel

Compare basic data for the selected countries/territories in the tables

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My selection (29)

- Summary Requirements
  - Administrative Requirements
  - General Requirements
    - Clinical Trial Application
    - Marketing Authorization Application
    - Details of Sponsors
    - Details of Contract Research Organization for Outsourced steps
    - Certificate of Analysis
    - Analytical Data
    - Accelerated Stability - Drug Substance
    - Long-term Stability - Drug Substance**
    - Accelerated Stability - Drug Product
    - Long-term Stability - Drug Product

**Long-term Stability - Drug Substance**

My selection	Storage conditions	Submission type	Temperature (°C)	Relative Humidity (%)	Real time at submission (months)	Bracketing/Matrixing acceptance	Selection of batches	Stability commitment	Post-approval ongoing program	Test frequency
Austria	Freezer	New Biologics Drug and Biosimilars	-20±5		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	
Austria	Refrigerator	New Biologics Drug	5±3		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	
Belgium	Freezer	New Biologics Drug and Biosimilars	-20±5		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	
Belgium	Refrigerator	New Biologics Drug and Biosimilars	5±3		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	
Bulgaria	Freezer	New Biologics Drug and	-20±5		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	
Bulgaria	Refrigerator	New Biologics Drug and	5±3		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	
Croatia	Freezer	New Biologics Drug and Biosimilars	-20±5		12	✓	3 Commercial size batches	3 Commercial batches until shelf life or retest period	✓	

Export

Display the content type of interest

## View Detailed Requirements

Use keywords to filter the menus

Search all Detailed Requirements

Change View, remove local practice and remove countries with Null Results

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My selection (56)

Filter Menu... stability

Detailed Requirements

- CMC Requirements - Drug Substance
  - S.7 Stability
    - S.7.1 Stability Summary and Conclusions
    - Forced degradation/stress testing**
    - Photostability
    - S.7.2 Post-approval Stability Protocol and Stability Commitment
    - S.7.3 Stability Data
      - General Information
  - CMC Requirements - Drug Product

**Forced degradation/stress testing**

Search Detailed Requirements...

Filters

Use filters to focus content

Change View: [Table View] [List View]

Local Practice [x] Null Results [x]

ICH < 1 of 2 >

Official Regulations | FPP

Stress testing of the drug substance can help identify the likely degradation products, which can in turn help establish the degradation pathways and the intrinsic stability of the molecule and validate the stability indicating power of the analytical procedures used. The nature of the stress testing will depend on the individual drug substance and the type of drug product involved.

Stress testing is likely to be carried out on a single batch of the drug substance. It should include the effect of temperatures (in 10°C increments (e.g., 50°C, 60°C, etc.) above that for accelerated testing), humidity (e.g., 75% RH or greater) where appropriate, oxidation, and photolysis on the drug substance.

The testing should also evaluate the susceptibility of the drug substance to hydrolysis across a wide range of pH values when in solution or suspension.

Algeria < 1 of 2 >

Official Regulations | FPP

Local Practice

- A CTD file format following International Conference of Harmonization (ICH) model is required for Modules 2 to 5.

Product Type: FPP  
Submission Type: New Drug, Generic Drug  
Drug Type: Drug Substance  
Pharmaceutical Form: Not Applicable  
Procedure: Standard Procedure, Stringent Regulatory Agency Approved, WHO Prequalification  
Country of Origin: Local, Foreign

SourceID: 2016, 2024, 2026, 2027

Angola

Official Regulations | IMP and FPP

Refer "Guideline for Registration of medicine" Annexure III - CTD modules.

Local Practice

Product Type: IMP, FPP  
Submission Type: New Drug, Generic Drug  
Drug Type: Drug Substance  
Pharmaceutical Form: Not Applicable  
Procedure: Standard Procedure, Stringent Regulatory Agency Approved, WHO Prequalification  
Country of Origin: Local, Foreign

SourceID: 4836

Benin

Official Regulations |

No provision exist for this

Local Practice

Product Type: IMP  
Submission Type: New Drug  
Drug Type: Drug Substance  
Pharmaceutical Form: Not Applicable  
Procedure: Standard Procedure, Stringent Regulatory Agency Approved, WHO Prequalification  
Country of Origin: Local, Foreign

Select content type from menu to view

Compare Official Regulations and Local Practice commentary from expert regional consultants

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My selection (1)

Key Facts

Key Requirements

Procedures

Detailed Requirements

Sources

Change History

China

Click the three dots to show export options

Key Facts

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 NICPBP is always required; for locally manufactured drugs, NICPBP 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 efficacy of generic drugs directly into the "China Listed Drugs Collection" and update them in real time.
- The carrier includes generic drugs approved for marketing, modified new drugs, generics registered in the new chemical classification, and specific information on drug evaluation through consistency in quality and efficacy.
- Designated reference preparations and standard preparations for generic drugs, indicating specific generic drug varieties that can replace the original research drugs, etc., for the

Click report categories to display content

## Set up Alerts

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Alerts

Click Create Alert

Create Alert

Name	Date Created	Frequency	My Selection	Content Type	Alert Status	Delete
China all content	09-Apr-2024			Key Facts; Key Requirements; Summary Requirements: CMC Requirements, Marketing Authorization Application Requirements, Medicines Procurement; Detailed Requirements: Clinical Trial Requirements, Marketing Authorization Requirements, CMC Requirements - Drug Substance, CMC Requirements - Drug Product, CMC Requirements - Appendices, CMC Requirements - Regional information, Procurement and Organizations requirements	Active	
				Key Requirements; Summary Requirements: CMC Requirements; Detailed Requirements: CMC Requirements - Drug Product, CMC Requirements - Appendices, CMC Requirements - Regional information, Procurement and Organizations requirements	Active	

Create Alert

My selection

Content Type & Frequency

Content Type

Frequency

☒ Key Facts
 ☒ Key Requirements
 ☒ Summary Requirements
 ☒ Detailed Requirements

☒ DAILY
 ☐ WEEKLY
 ☐ MONTHLY

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Cancel

Create

Indicate Countries/Organizations to track as well as Content Type & Frequency in the pop-ups that appear. Click Create to finish.

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My selection (1)

Latest Updates

View the latest official documents

Discover what report content was updated as a result of these new documents

China

Reason for Update

MOST RECENT UPDATE

Publish Date: 08/03/2024

Annual general content review for all sections have been performed. Below guidelines have been added under sources as a part of general content review:

- Source ID 3588- Notice on Guiding Principles for Submission of Drug Clinical Trial Data (Trial) (2020 No. 16)
- Source ID 9145- SFDA Order No. 4- Provision for Drug Imports
- Source ID 9278- NMPA announcement- Measures for the Supervision and Administration of Drug Production (No. 47, 2020)
- Source ID 9281- CDE Notification No. 2023/23: Common Pharmaceutical Issues and Related Technical Requirements for Phase III Pre-Clinical Trial Meeting of Innovative Chemical Drugs (Trial)
- Source ID 9288- CDE Notification No.2020-40: Issuance of Technical Requirements for Common Pharmaceutical Issues in Application for Phase I of Clinical Trials of Innovative Chemical Drugs and Summary Table of Pharmaceutical Research Information for an Application for Phase I Clinical Trials of Chemicals (Revision)
- Source ID 8764- Technical Guiding Principles for Pharmaceutical Changes During Clinical Trials of Innovative Drugs (Chemical Drugs) (Trial)-(No. 22, 2021)
- Source ID 9023 - Notice - Updating the Technical Requirements for Electronic CD-ROM Application Materials" and other documents
- Source ID 9026 -NMPA Announcement No. 2023/158: Implementation of ICH Guideline Q13: Continuous Manufacturing of Drug Substances and Drug Products
- Source ID 9168 - Announcement on the application of the Guiding Principles of the ICH "M7 (R2): Assessment and Control of DNA Reactive (Mutagenic) Impurities in Drugs to Limit Potential Carcinogenic Risks" (No. 1, 2024)
- Source ID 9169 -Notice on matters related to certification documents for overseas production of drugs

The update Concerns the general information with minor change in the sections listed below:

Key Requirement:

- Most recent updates
- Electronic and non-electronic submission section has been updated with brief information from Source ID 9023

For more information contact Customer Service at [LS Product Support](#).