

Quick start guide

Cortellis CMC Intelligence



Cortellis CMC Intelligence

1. Small molecules Biologics

2. Pre-approval Post-approval changes and clinical trial amendments

3. Countries/regions

Argentina x Bolivia x Brazil x Chile x Colombia x Costa Rica x
USA x Venezuela x Add countries/regions

Organizations

ICH x Add organizations

4. Go to: [Summary](#) [Detailed](#) [Report](#) [Updates](#)

1. Choose Small molecules or Biologics
2. Choose Pre-Approval or Post-Approval
**Content available is based on your subscription.*

3. Click Countries/regions and/or Organizations to choose the desired entities from the drop-down menus that appear and click Apply.

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

Summary: Compare and contrast core requirements for your selections to identify differences and similarities across countries

Detailed: Explore official regulatory requirements and local practices organized into eCTD structure efficiently linked to the source documents

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

Updates: The latest updates to the content for your selected country or organization to quickly identify and locate changes

View Summary Reports

Home **Summary** Detailed Report Updates

Tabs take you to content types

Tools to understand table terms, create Alerts, Download or Edit search to change the countries/organizations displayed

Licenses and certificates

Table glossary Create alert Download Edit search

- Search...
- Expand all sections
- Impurities
- Physicochemical and biological properties
- Accelerated Stability - Drug Substance
- Long-term Stability - Drug Substance
- Accelerated Stability - Drug Product
- Long-term Stability - Drug Product
- Marketing Authorization Application Requirements
- Licenses and certificates**
- Accelerated registration procedure
- GMP certificate
- Recognition of SRA or WHO PQ decision

Countries/regions/organizations	Application form	Proof of payment	Brand name clearance	Free sale certificate	GMP certificate	Submission of QOS	Business li
Argentina	Yes	Yes	No	No	Yes	Yes	No
Bolivia	Yes	Yes	No	Not specified	Yes	Yes	Yes
Brazil	Yes	Yes	No	Not specified	Yes	Yes	Yes
Chile	Yes	Yes	Not required	Yes	Yes	Not required	Not requir
Colombia	Yes	Yes	Not specified	Yes	Yes	Yes	Yes
Guatemala	Yes	Yes	Not specified	Yes	Yes	Yes	Yes

Display the Summary Table of interest

Items per page: 10 1 - 10 of 15

View Detailed Requirements

Cortellis CMC Intelligence Small molecules - Pre-approval Alerts

Home Summary **Detailed** Report Updates

S.4.4 Batch Analyses Create alert Edit search

All filters Filter... Compare side-by-side List view Table view

<input type="checkbox"/>	Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Actions
<input type="checkbox"/>	Bolivia	FPP	A copy of the Certificate of Analysis of the Drug Substance issued by the corresponding laboratory should be included....	Following document is required to be part of initial submission apart from stated in official guidance <ul style="list-style-type: none">DS CoAs	Drug Substance	Details >
<input type="checkbox"/>	Brazil	FPP	According to RDC 359/2020 An analysis of at least three (3) batches of API manufactured in accordance with the process...	The COIFA website was modified to simply state what is on the RDC 359/2020, however, detailed expectation previously provided by Anvisa has not changed. The...	Drug Substance	Details >
<input type="checkbox"/>	Brazil	IMP	No provisions exist for this requirement in CTD format, however, as per the Manual of submission for quality data relating to products under investigation the...	There is no specific common practice regarding the information to be included in Module 3, Section 3.2.S.4.4 Batch Analyses, as reported by our local...	Drug Substance	Details >
<input type="checkbox"/>	Chile	FPP	The Certificate of Analysis of the API and its spectrograms or chromatograms by any instrumental methods, if applicable shall be included.	No local practice reported by local consultants	Drug Substance	Details >
<input type="checkbox"/>	Chile	IMP	There is no guidance or regulations applicable to information about the Drug substance's requirements for clinical trials in Chile.	No local practice reported by local consultants	Drug Substance	Details >
<input type="checkbox"/>	Costa Rica	FPP	No provisions exist for this requirement.	In local practice, simple copies of Certificates of Analysis are accepted by the Authority.	Drug Substance	Details >

Items per page: 10 1 - 10 of 23

Compare Official regulations and Local practice

Change views as desired

Select from menu desired content

View Detailed Requirements

Find all report content that mentions your term

Click Details to expand

Find all menu items that mention your term

The screenshot shows a web application interface for viewing detailed requirements. At the top left, the page title is "S.4.4 Batch Analyses". A search bar contains the term "excipients" and a notification states "Search term found - expand content to see match". On the right, there are options for "Create alert", "Edit search", "Compare side-by-side", "List view", and "Table view". A left-hand navigation menu is open, showing a tree structure with "batch" selected and "S.4.4 Batch Analyses" highlighted. The main content area is a table with columns: "Countries/regions/organizations", "Product type", "Official regulations", "Local practice", "Drug type", and "Actions". The first row shows "Mexico" with "FPP" product type, "Drug Substance" drug type, and a "Details" button. A modal window titled "Mexico" is open, displaying detailed information for that entry, including "Official regulations", "Local practice", "Pharmaceutical form", "Procedure", "Country of origin", and "Source documents".

Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Actions
<input type="checkbox"/> Mexico	FPP	Certificates of analysis issued by the API manufacturer and by the FPP manufacturer or laboratory where the analysis of the API takes place shall be included in...	Cofepris has been a member of ICH since November 2021 and harmonisation with ICH guidance is being achieved that allows application content quality &...	Drug Substance	Details >

Modal Window: Mexico

Product type: FPP | Drug type: Drug Substance | Submission type: New Drug, Generic Drug

Official regulations
Certificates of analysis issued by the API manufacturer and by the FPP manufacturer or laboratory where the analysis of the API takes place shall be included in section 2.1.5.4 of the dossier.

Local practice
Cofepris has been a member of ICH since November 2021 and harmonisation with ICH guidance is being achieved that allows application content quality & CMC information presented in accordance with ICH guidance.
For drug registrations in Mexico, it is always expected to provide Certificates of Analysis (CoAs) for all formulation components, including APIs, excipients, and packaging materials.

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure, Stringent Regulatory Agency Approved
Country of origin: Local, Foreign

Source documents
18-Nov-2024
Dr. Maria Cristina Torres Moore; IAM Holistic Consulting LLC.
Source ID: 10556 - Status: Valid
Origin: Subject Matter Expert

View Detailed Requirements

Narrow down content using filters

S.4.4 Batch Analyses

☰ All filters 🔍 excipients ✕ ● Search term found - expand content to see match

🔊 Compare side-by-side List view ✓ Table view

Product Type: FPP ✕ Clear all filters

☰ batch ✕

Expand all sections

- Marketing Authorization Requirements
- ▼ CMC Requirements – Drug Substance
 - S.1 General Information
 - ▼ S.4 Control of Drug Substance
 - S.4.1 Specification
 - S.4.4 Batch Analyses

<input type="checkbox"/>	Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Actions
<input type="checkbox"/>	Mexico	FPP	Certificates of analysis issued by the API manufacturer and by the FPP manufacturer or laboratory where the analysis of the API takes place shall be included in...	Cofepris has been a member of ICH since November 2021 and harmonisation with ICH guidance is being achieved that allows application content quality &...	Drug Substance	Details >

Items per page: 10 1 – 1 of 1 |< < > >|

Filter ✕

Product Type > Product Type Select all

Submission Type >

Drug Type >

Pharmaceutical Form >

Procedure >

Country of Origin >

Clear all Cancel Apply

View Detailed Requirements

Tick boxes in front of selections and click **Compare side-by-side** for detailed cross country/organization comparison

<input type="checkbox"/>	Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Actions
<input checked="" type="checkbox"/>	Bolivia	FPP	A copy of the Certificate of Analysis of the Drug Substance issued by the corresponding laboratory should be included.	Following document is required to be part of initial submission apart from stated in official guidance	Drug Substance	Details >
<input checked="" type="checkbox"/>	Brazil	FPP				
<input type="checkbox"/>	Brazil	IMP				
<input type="checkbox"/>	Chile	FPP				
<input type="checkbox"/>	Chile	IMP				
<input type="checkbox"/>	Costa Rica	FPP				

← Back

Comparing 2 regulations

Brazil

Product type: FPP | Drug type: Drug Substance | Submission type: New Drug, Generic Drug

Official regulations
According to RDC 359/2020
An analysis of at least three (3) batches of API manufactured in accordance with the process described and the specification proposed in the DIFA shall be submitted. For significant variables of the manufacturing process, the number of batch evaluate should follow the post-approval requirements sets out in the RDC 359/2020, Annex II.
For API classified as a new chemical entity, analysis of the batches referenced in the section 3.2.S.2.6 should be presented.
Batch analysis shall contain at least the following information:
[Show more](#)

Local practice
The COIFA website was modified to simply state what is on the RDC 359/2020, however, detailed expectation previously provided by Anvisa has not changed. The following instruction was provided previously by the Agency and still applies.
As stated on the regulation, for new chemical entities, Section 3.2.S.4.4 is expected to comprise all batches whose data support the dossier, including those used in pre-clinical and clinical trials, stability studies, pilot scale batches and, if available, production scale batches.
For APIs that are not new or are compendial, batch analyses of three production scale batches are generally provided (commonly the same...)
[Show more](#)

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure, Accelerated Procedure
Country of origin: Local, Foreign

Bolivia

Product type: FPP | Drug type: Drug Substance | Submission type: New Drug, Generic Drug, Hybrid Application

Official regulations
A copy of the Certificate of Analysis of the Drug Substance issued by the corresponding laboratory should be included.
This certificate should provide: References to the Pharmacopoeia of reference or the in-house Analytical Methods and the Specifications at release.
If not, an attached document including this information should be provided according to the Registration Dossier Guideline.

Local practice
Following document is required to be part of initial submission apart from stated in official guidance

- DS CoAs

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure
Country of origin: Local, Foreign

View Reports

Procedures

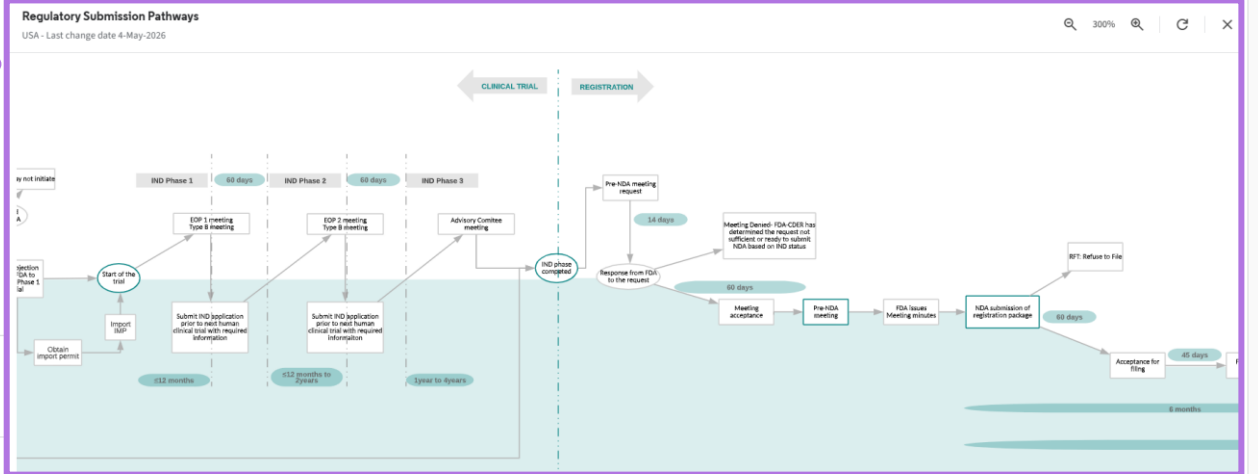
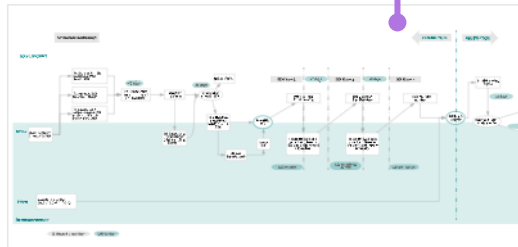
USA

Use drop down to go to Report for selected countries

Click visual to expand

USA - Last change date 4-May-2026

Regulatory Submission Pathways



Select Report menu items to view

Detailed requirements

- Clinical Trial Requirements
- Marketing Authorization Requirements
- CMC Requirements - Drug Substance
- CMC Requirements - Drug Product
- Product Interchangeability
- CMC Requirements - Appendices

Stringent Regulatory Authority Approved

No specific pathway for SRA Approved Products.

WHO Prequalification

WHO lists the US FDA approved products with the reference "USFDA" have been added to the list of medicinal products prequalified by WHO, on the basis of assessments and inspections conducted by US FDA. Provision is made for the exchange of relevant information between the US FDA and WHO (under the terms of a corresponding confidentiality agreement).

No specific pathway for WHO PQ Products to gain approval in US; the usual approval procedure for assessment by FDA need to be followed prior to marketing drug in US.

Accelerated Procedure

Set up Alerts

2

In the pop-up:

- name the alert,
- select Frequency,
- Choose countries/regions/organizations,
- choose content type to track and
- click Apply

1

Click Create alert

Set up an email alert

Create alert

Download

Edit search

Compare side-by-side

List view Table view

Countries/regions/organizations	Change description	Variation classificatio...	Implementation type	Product type	Timelines	Actions
		Type IAIN	Immediate impleme...	FPP	For MRP/DCP/	Details >
		Type IAIN	Immediate impleme...	FPP	Type IA variat ('IAIN') must b Competent Au	Details >

Set up an email alert [X]

Alert name
Alert name*
Post-approval Europe

Frequency
 Daily Weekly Monthly

Choose countries/regions/organizations
Clear all

<input checked="" type="checkbox"/> Lithuania	<input checked="" type="checkbox"/> Netherlands	<input checked="" type="checkbox"/> Norway
<input checked="" type="checkbox"/> Poland	<input checked="" type="checkbox"/> Portugal	<input checked="" type="checkbox"/> Romania
<input checked="" type="checkbox"/> Serbia	<input checked="" type="checkbox"/> Slovakia	<input checked="" type="checkbox"/> Spain
<input checked="" type="checkbox"/> Sweden	<input checked="" type="checkbox"/> Switzerland	<input checked="" type="checkbox"/> Turkey
<input checked="" type="checkbox"/> United Kingdom		

Choose content type

Clear all

<input checked="" type="checkbox"/> Updates	>	<input checked="" type="checkbox"/> Detailed requirements
<input checked="" type="checkbox"/> Upcoming guidelines and drafts		
<input checked="" type="checkbox"/> Procedures		
<input checked="" type="checkbox"/> Sources		
<input checked="" type="checkbox"/> Summary requirements		

Cancel Apply

Updates

Updates

Germany

Change country by clicking the drop down

Germany

Czech Republic

Denmark

Estonia

Finland

France

Germany

Germany

Most Recent Update

Publish Date: March 30, 2026

- Source ID 12758- BfArM Q&A: On Variations, 15-Jan-2026
- Source ID 12829- Joint Announcement by the Federal Institute for Drugs and Medical Devices 1234/2008 as of 04-Aug-2013, 15-Jan-2026

Sections updated with released guideline/s are listed below:

- Sources
- Updates
- Summary Requirements

- Question and answer document section has been updated with the recent Source ID 12758. No change in content

- Grouping of Variations section has been updated with brief information from source ID 12829.

- Pathway Summary

- PAC relevant procedure section has been updated with brief information from source ID 12829.

Previous Update

Publish Date: 24/11/2025

Following new guidance/updated documents added under sources:

- Source ID - 11490- New validation criteria for eCTD submissions - mandatory since 1st March 2025
- Source ID - 11177- BfArM Information Note on Variations

View the latest Source documents

Discover where in the country report was updated because of these new documents

If you have questions,
please contact
lsh.support@clarivate.com