

Compare Detailed requirements such as manufacturing, trial and distribution for different countries/entities

Cortellis CMC Intelligence



Example: You are running a clinical trial for a small molecule in the USA and are looking to also run a trial in China or the Russian Federation. You want to compare manufacturing requirements and note similarities and differences across these countries for the drug substances used in your clinical trials to help with your country selection..

Cortellis CMC Intelligence

1 Small molecules Biologics

Pre-approval Post-approval changes and clinical trial amendments

2 Countries/regions

Add countries/regions

<input type="checkbox"/> Cambodia	<input checked="" type="checkbox"/> China	<input type="checkbox"/> China Procurement Agency	<input type="checkbox"/> Hong Kong
<input type="checkbox"/> India	<input type="checkbox"/> India Procurement Agency		
<input type="checkbox"/> Malaysia	<input type="checkbox"/> Myanmar		
<input type="checkbox"/> Pakistan	<input type="checkbox"/> Philippines	<input type="checkbox"/> Singapore	<input type="checkbox"/> South Korea
<input type="checkbox"/> Taiwan	<input type="checkbox"/> Thailand	<input type="checkbox"/> Vietnam	
<input type="checkbox"/> Caribbean			
<input type="checkbox"/> Haiti			
<input type="checkbox"/> Eurasia			
<input type="checkbox"/> Armenia	<input type="checkbox"/> Georgia	<input type="checkbox"/> Kyrgyzstan	<input checked="" type="checkbox"/> Russian Federation

Go to:

3

4 Go to:

1. Select Small molecules and Pre-approval
2. Open Countries/regions and select China and Russian Federation
3. Select Apply
4. Select Detailed

View Detailed Requirements - example continued

Cortellis CMC Intelligence Small molecules - Pre-approval Alerts

Home Summary **Detailed** Report Updates

Manufacturing Requirements Create alert Edit search

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

Search... Expand all sections

- Clinical Trial Requirements**
- Administrative Requirements
 - Clinical Trial Application Procedure
 - Content of the Clinical Trial Application
- Manufacturing and Authorisations
 - Manufacturing Requirements**
 - GCP compliance
 - Marketing Authorization Requirements
 - CMC Requirements - Drug Substance
 - CMC Requirements - Drug Product

<input type="checkbox"/>	Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Actions
<input type="checkbox"/>	China	IMP	Per the China GCP Revision 2020 Article 44: The investigational product shall be manufactured, packaged, labelled and coded in...	All CTA whatever from imported drugs or local drugs should be submitted to CDE directly. Good Manufacturing Practice for Phase 1...	Drug Substance, Drug Product	Details >
<input type="checkbox"/>	Russian Federation	IMP	As per the information available in the guidelines; RUSSIAN FEDERATION FEDERAL LAW, ON CIRCULATION OF MEDICINAL PRODUCTS ,...	<ul style="list-style-type: none">All local manufacturers as well as all foreign manufacturers should confirm that have a manufacturing license and the drug samples for...	Drug Substance, Drug Product	Details >

Items per page: 10 1 - 2 of 2

1 ?

5. Compare Official regulations and Local practice in the table

4. Select from menu desired content. For this example, Clinical Trial Requirements and Manufacturing Requirements

View Detailed Requirements - filter and expand results

The screenshot shows a web application interface for viewing detailed requirements. The main content area displays a table of results for the search term "excipients". The table has columns for Countries/regions/organizations, Product type, Official regulations, Local practice, Drug type, and Actions. A callout box labeled "6" points to the search bar, which contains the text "excipients" and a message "Search term found - expand content to see match". A callout box labeled "7" points to the "S.4.4 Batch Analyses" menu item in the left sidebar. A callout box labeled "8" points to the "Details" button in the Actions column of the table. The detailed view for the selected item shows the following information:

- 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 - filter results

S.4.4 Batch Analyses 🔔 Create alert [Edit search](#)

All filters Search term found - expand content to see match 9

Product Type: FPP Clear all filters 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"/>	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

9. Narrow down content using filters

Filter ×

Product Type > Product Type Select all

Submission Type >

Drug Type >

Pharmaceutical Form >

Procedure >

Country of Origin >

IMP

FPP

Clear all Cancel Apply

View Detailed Requirements - Compare countries side-by-side

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

The screenshot shows a web application interface for comparing drug regulations. At the top, there is a header with a search bar and a '2 selected' indicator. Below the header is a table with columns: Countries/regions/organizations, Product type, Official regulations, Local practice, Drug type, and Actions. The table lists several countries: Bolivia, Brazil, Chile, and Costa Rica. The 'Compare side-by-side' button is highlighted in a purple box. Below the table, a detailed comparison view is shown for Brazil and Bolivia. The comparison view is titled 'Comparing 2 regulations' and shows details for each country, including Product type, Drug type, Submission type, Official regulations, Local practice, and Pharmaceutical form. The 'Compare side-by-side' button is also highlighted in a purple box in the comparison view.

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				

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