

Cortellis CMC Intelligence: how do I compare detailed requirements such as manufacturing, trial and distribution for different countries?

Example: You are running a clinical trial 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.

1. Click on **USA** and **Russian Federation** and **China** on the map. Dark grey countries have available content. Selected countries turn green.
2. The selected countries will appear on the right. Click the “X” to the right of each selected country to deselect or click **Deselect all** to start over with the selection process.
3. Click on **Compare Detailed Requirements**.

The screenshot shows the Cortellis CMC Intelligence interface. At the top, there's a navigation bar with 'Countries/Territories', 'Regions', 'Climatic Zones', and 'Organizations'. Below this is a world map where the USA, Russian Federation, and China are highlighted in green. To the right of the map, there's a sidebar with 'Countries/Territories' (3) and 'Organizations' (0). The 'Countries/Territories' list shows 'China', 'Russian Federation', and 'USA' with 'X' icons to deselect them. Below this, there's a 'COMPARE SUMMARY REQUIREMENTS (3)' button and a 'COMPARE DETAILED REQUIREMENTS (3)' button, which is highlighted with a red box and a red number 3. At the bottom, there's a 'VIEW REPORTS (3)' button.

The screenshot shows the 'Countries/Territories' dropdown menu. It has a search bar and a list of countries. The countries listed are: Cambodia, Cameroon, Canada, Central African Republic, Chad, China, China Procurement Agency, Colombia, Congo, and Cote d'Ivoire. The 'China' option is highlighted.

For countries you can't find easily on the map, click on **Countries/Territories** and select the countries from the drop down that appears.

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This displays the detailed requirements in a “List View”. At the top of our list is China.

In the left hand column, select the requirements you’d like to compare. For our example we’ll focus on manufacturing requirements for clinical trials:

1. Open **Clinical Trial Requirements**
2. Open **Manufacturing and Authorisations**
3. Click on **Manufacturing Requirements**

Use the down arrow in front of the country names to expand the data for that country and use the scroll bar to view other countries.

The **Official Regulations** are the requirements from the regulatory authority and the **Local Practice** section displays additional guidance from local consultants.

The screenshot shows the Cortellis CMC Intelligence interface. On the left, a sidebar contains a navigation menu with categories like 'Requirements', 'Product Information', 'Manufacturing and Authorisations', and 'GCP compliance'. The 'Manufacturing Requirements' option is selected. The main content area is titled 'Detailed Requirements' and shows 'Manufacturing Requirements' for 'China'. It includes sections for 'Official Regulations' and 'Local Practice'. A 'SourceID: 9_35_335' link is highlighted, and a tooltip displays source information: '17-Aug-2018, Jiawei Hu, Senior Regulatory Affairs Manager, West, China, Subject Matter Expert'.

Clicking on the **SourceID** links allow you to view the source information.

Filters allow you to narrow down the data. For example, let’s filter to data just pertaining to new drugs:

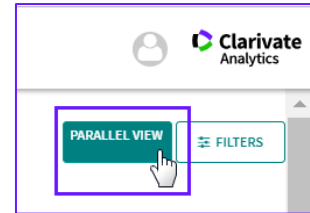
1. Click **Filters** in the top right
2. Select **New Drug** in the pop-up
3. Click **Apply**.

The screenshot shows the 'Apply Filters' pop-up window. It has sections for 'Product Type' (with 'IMP' and 'FPP' selected), 'Submission Type' (with 'New Drug' selected), and 'Drug Type' (with 'Drug Substance' selected). The 'APPLY' button is highlighted.

You can also compare detailed requirements in a table (ie. “Parallel View”).

Example: Compare Container Closure System requirements for FPPs (Finished Pharmaceutical Product) for the USA, Russian Federation and China in a table.

1. Select **Parallel View** in the upper right hand corner of the screen to view results as a table.
2. Our initial selection of China, USA and Russian Federation will remain. All other selections and filtering will clear.
3. Under **Requirements** open **CMC Requirements – Drug Substance**.
4. Select **S.6 Container Closure System**.
5. Click **Apply**.
6. Now the **Filters** will appear below.
7. Select **IMP** under **Product Type** and the table will populate with the **Official Requirements** and **Local Practice** for each country.



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Requirements (1)

CLINICAL TRIAL REQUIREMENTS
MARKETING AUTHORIZATION REQUIREMENTS
CMC REQUIREMENTS – DRUG SUBSTANCE
S.1 General Information
S.2 Manufacture
S.3 Characterization
S.4 Control of Drug Substance
S.5 Reference Standards or Materials
S.6 Container Closure System
S.7 Stability

CMC REQUIREMENTS – DRUG PRODUCT
R. CMC REQUIREMENTS – REGIONAL INFORMATION
CMC REQUIREMENTS – APPENDICES
PROCUREMENT AND ORGANIZATIONS REQUIREMENTS
Clear all **APPLY**

Filters (1)

Product Type
☐ IMP
☒ FPP
Submission Type
☐ New Drug
☐ Generic Drug
Drug Type

Detailed Requirements

China Russian Federation USA

Official Requirements

S.6 CONTAINER CLOSURE SYSTEM

1. Provide information of the type, source and related documents for packaging materials. For example, the composite film bag consisting of: polyester / aluminum / polyethylene composite film bag, polyester / LDPE composite film bag. Provide analysis reports for packaging materials (may from the manufacturer or supplier) set forth the selection basis for packaging materials.

Section of chemical, pharmaceutical and biological documentation includes documents that contain information on the drug substance and drug product for medical use, the process of its production and quality control methods, including:
1) copy of the document containing the following information about the pharmaceutical substance or the pharmaceutical substance comprising the drug:

Contains information about the container closure systems. If the application contains a sterile substance for use in a sterile drug product, this section will also contain both a description of the container closure system used for the drug substance and a validation of the container closure integrity. The applicant may refer to the DMF.
As per the information in M4Q-The Common Technical Document for the registration of Pharmaceuticals for

Local Practice

S.6 CONTAINER CLOSURE SYSTEM

No additional information available.

No additional information available.

1. This section should include all testing on final product not intermediate. Information on both (Final & Intermediate product) should be included in 3.2.P.2.4. When warranted, information on leachables. Also to be included in 3.2.P.5.1 and 3.2.P.5.5. If leachables are confirmed through shelf life as part of the formal stability studies, the results would be reported in 3.2.P.8.3.

To view a detailed report on any of the countries directly from this page, click on the “more options” tool to the right of the country’s name then click **View Report**.

The screenshot displays the Cortellis CMC Intelligence web application. At the top, the header shows 'Cortellis CMC Intelligence' and the 'Clarivate Analytics' logo. The main content area is titled 'Russian Federation' and includes tabs for 'Key Highlights', 'Procedures', 'Detailed Requirements', and 'Sources'. The 'Key Highlights' tab is active, showing a list of 'Key Facts' and 'Procedural and Administrative Requirements'. A callout box with a purple border points to a 'View Report' button located next to the 'Russian Federation' title. Another callout box with a purple border points to a question mark icon in the bottom left corner of the sidebar. A text box at the bottom of the page provides information about the help icon.

Help is available on every page. The question mark icon takes you to Customer Care, guides and recorded training.

If you have any questions or would like further training, please contact us at:
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