

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. On the left is a vertical navigation bar with icons for globe, list, document, and question mark, labeled "Cortellis". The main area has a header "Cortellis CMC Intelligence" and a Clarivate Analytics logo. Below the header are tabs: Countries/Territories, Regions, Climatic Zones, and Organizations. A world map is displayed with two regions highlighted in purple: North America (labeled 1) and East Asia/Pacific (labeled 2). To the right of the map is a sidebar titled "Countries/Territories" which lists "China", "Russian Federation", and "USA" with an "X" icon next to each. Below this is a section for "Organizations" with a count of "(0)" and a note: "Click on an organization to view that report or select multiple organizations to view or compare". Three buttons are shown: "COMPARE SUMMARY REQUIREMENTS (3)", "COMPARE DETAILED REQUIREMENTS (3)" (which is highlighted with a purple border), and "VIEW REPORTS (3)".

This screenshot shows the "Countries/Territories" dropdown menu. It includes a header with tabs: Countries/Territories, Regions, and Climatic Zones. Below is a search bar with placeholder text "Select one or multiple countries/territories to view or compare". A grid of letters A through Z allows for letter-based filtering. The "C" section shows "China" selected. The "D" section shows "Democratic Republic of Congo" and "Djibouti". The "E" section is partially visible.

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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Analytics

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**

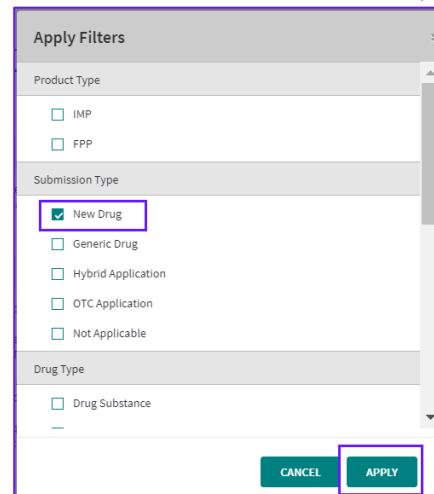
Use the down arrow in front of the country names to expand the data for that country and use the scroll bar to view other countries.

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

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:

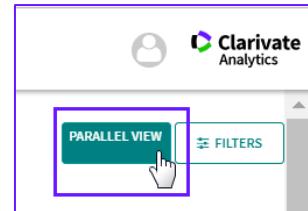
1. Click **Filters** in the top right
2. Select **New Drug** in the pop-up
3. Click **Apply**.



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

- 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

- IMP**
- FPP**
- Submission Type

 - New Drug
 - Generic Drug

Drug Type

Detailed Requirements

China Russian Federation USA

Official Requirements	Official Requirements	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	S.6 CONTAINER CLOSURE SYSTEM 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;	S.6 CONTAINER CLOSURE SYSTEM 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	Local Practice	Local Practice
S.6 CONTAINER CLOSURE SYSTEM No additional information available	S.6 CONTAINER CLOSURE SYSTEM No additional information available.	S.6 CONTAINER CLOSURE SYSTEM 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.

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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**.

Russian Federation

View Report

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Russian Federation

Last Change Date
21-Nov-2018

EXPORT TO PDF

Reports 2 of 3

Key Highlights Procedures Detailed Requirements Sources

Key Facts

Procedural and Administrative Requirements

CMC Requirements

Registration

Key Facts

Roszdravnadzor (Federal Service for Surveillance in Healthcare) is responsible for control, and surveillance of medicinal products.

Registration applications are reviewed by a commission of experts authorized by the federal executive body. The head of the expert institution ensures proper examination of medicines.

Russia maintains a State Register of medicines which contains a list of drugs that have passed state registration.

From 2016 onwards, foreign products will not be included in tenders if there are at least 2 Russia-produced products involved.

Registration approval is granted for an unlimited period. Prior to 2008, drugs were granted registration for 5 years. Currently, drugs are registered for a period of 5 years. After 5 years, applicants are required to go through re-registration. Once re-registration is completed, the registration certificate is valid for an unlimited period of time.

Applicants can submit the European registration file translated in the Russian language as the structure includes all of the required elements.

Procedural and Administrative Requirements

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:
cortellislearningcenter@clarivate.com