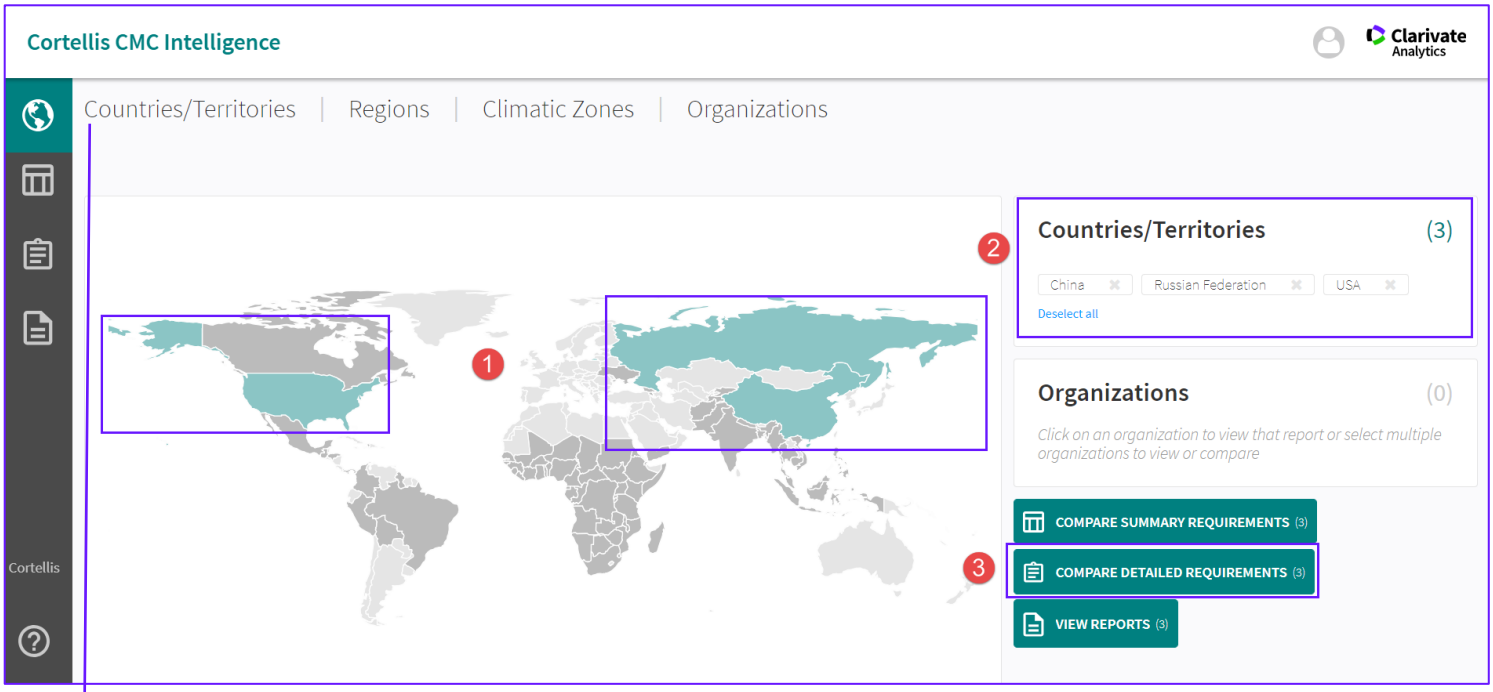
Cortellis CMC Intelligence: how do I compare detailed requirements such as manufacturing, trial and distribution for different countries?

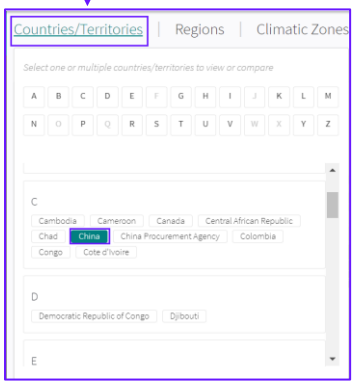
Example: You are running a clinical trial in the USA and are looking to also run a trial in China or the Russian Federation. You want to compare manufacturing requirements and note similarities and differences across these countries for the drug substances used in your clinical trials to help with your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





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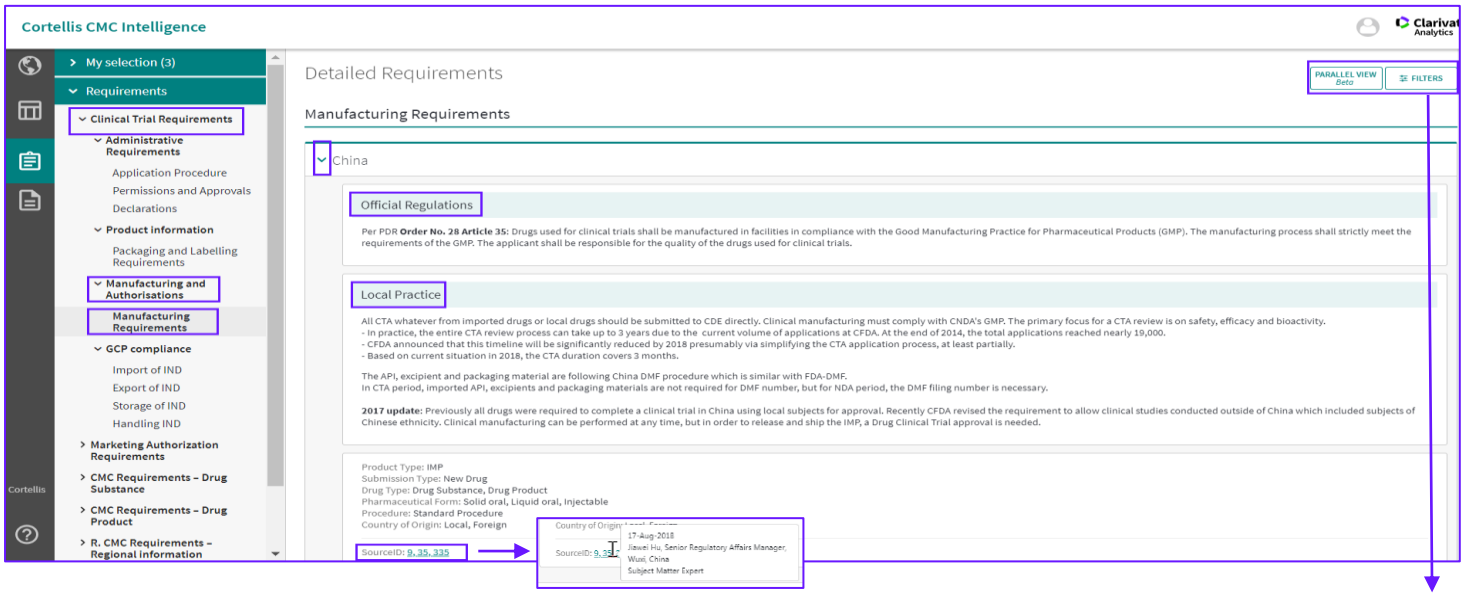
This displays the detailed requirements in a “List View”. At the top of our list is China.

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.

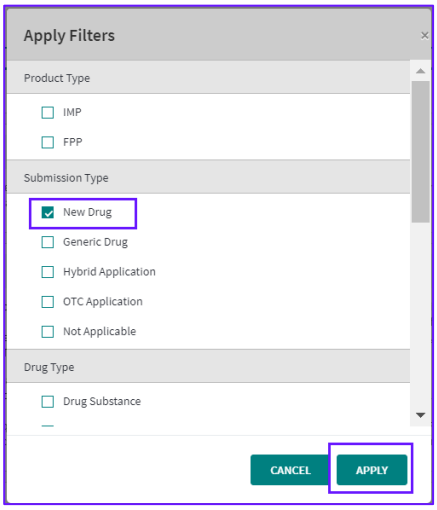
The **Official Regulations** are the requirements from the regulatory authority and the **Local Practice** section displays additional guidance from local consultants.



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**.



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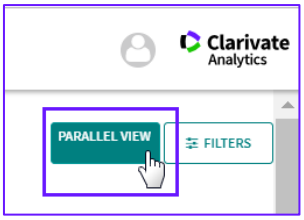
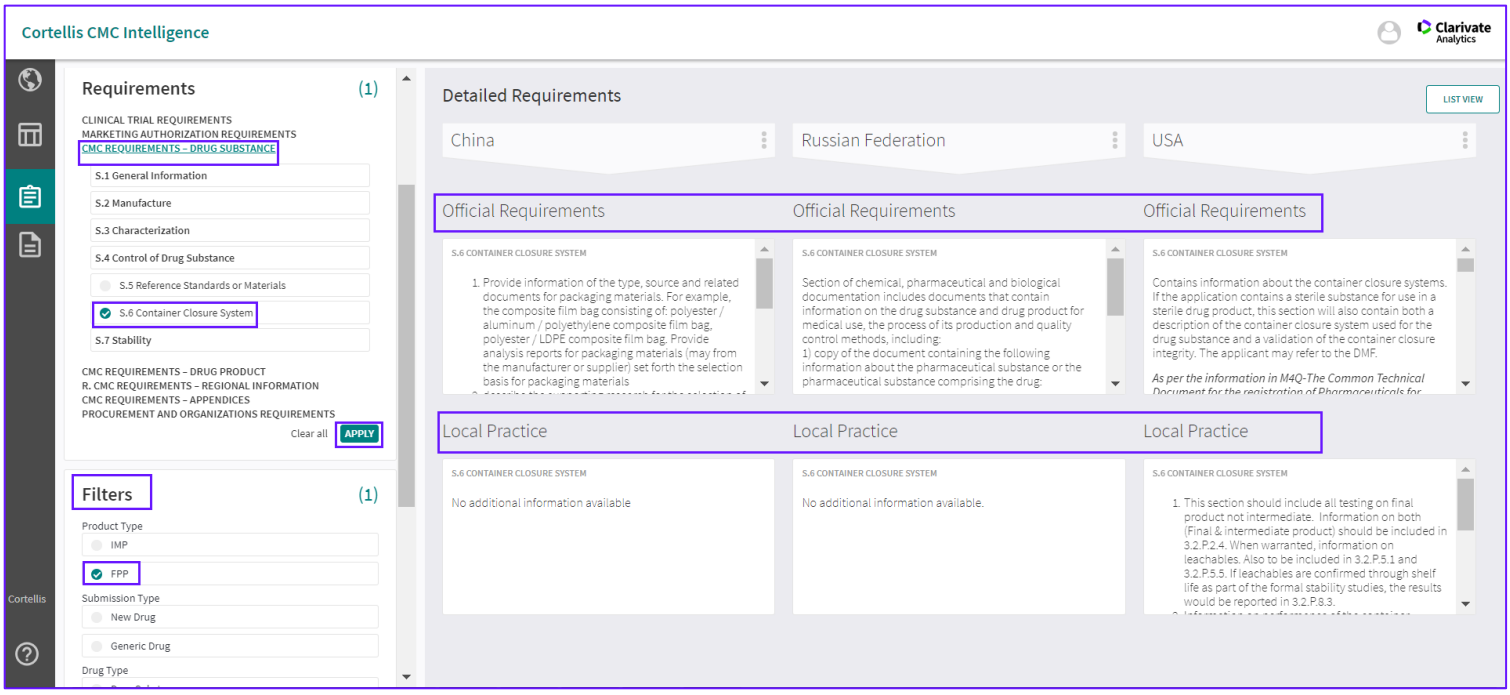
You can also compare detailed requirements in a table (ie. “Parallel View”).

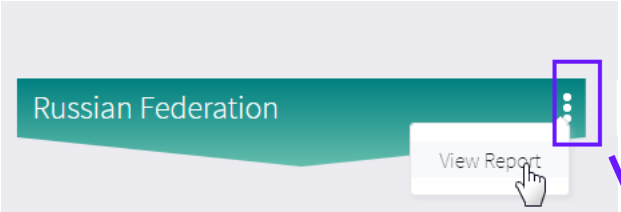
Example: Compare Container Closure System requirements for FPPs (Finished Pharmaceutical Product) for the USA, Russian Federation and China in a table.

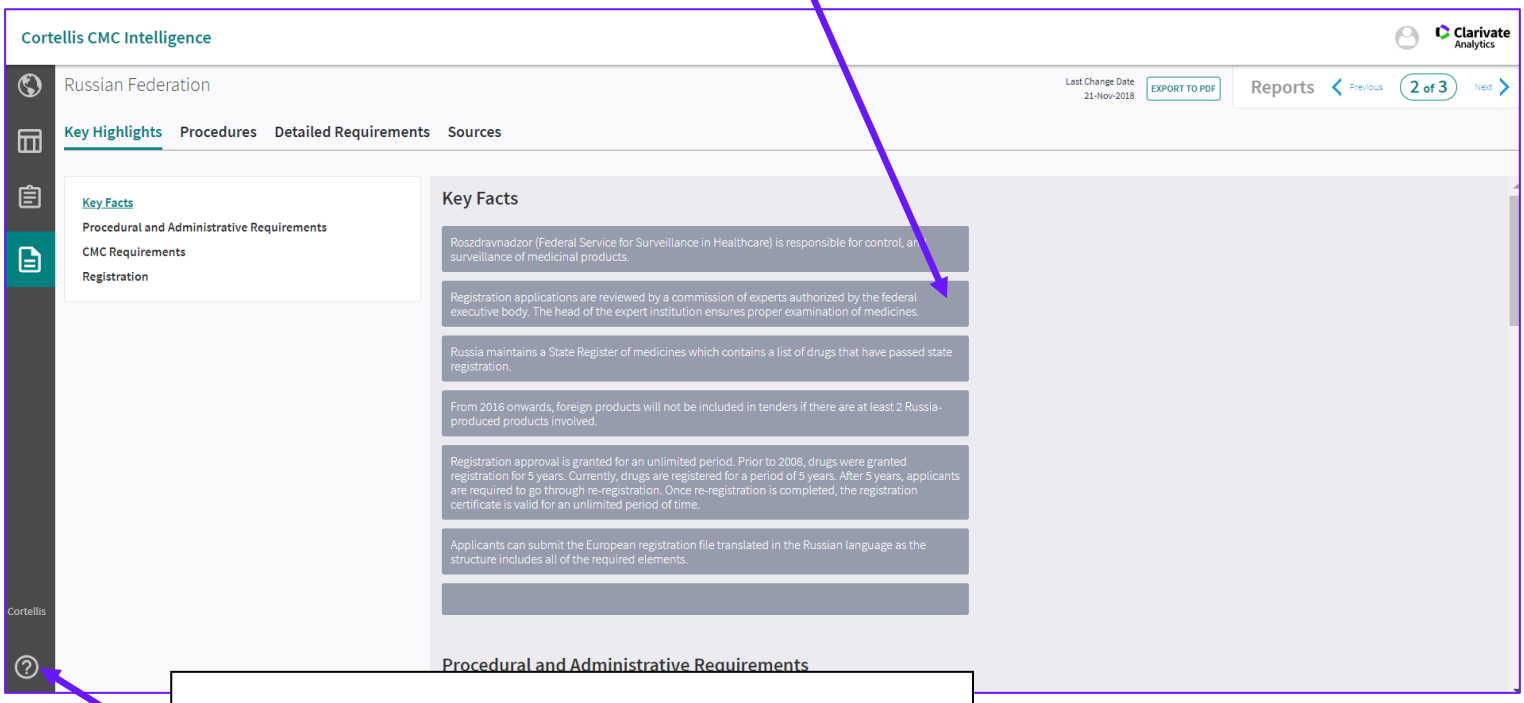


1. Select **Parallell View** in the upper right hand corner of the screen to view results as a table.
2. Our initial selection of China, USA and Russian Federation will remain. All other selections and filtering will clear.
3. Under **Requirements** open **CMC Requirements – Drug Substance**.
4. Select **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 **Offical Requirements** and **Local Practice** for each country.



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**.





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

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