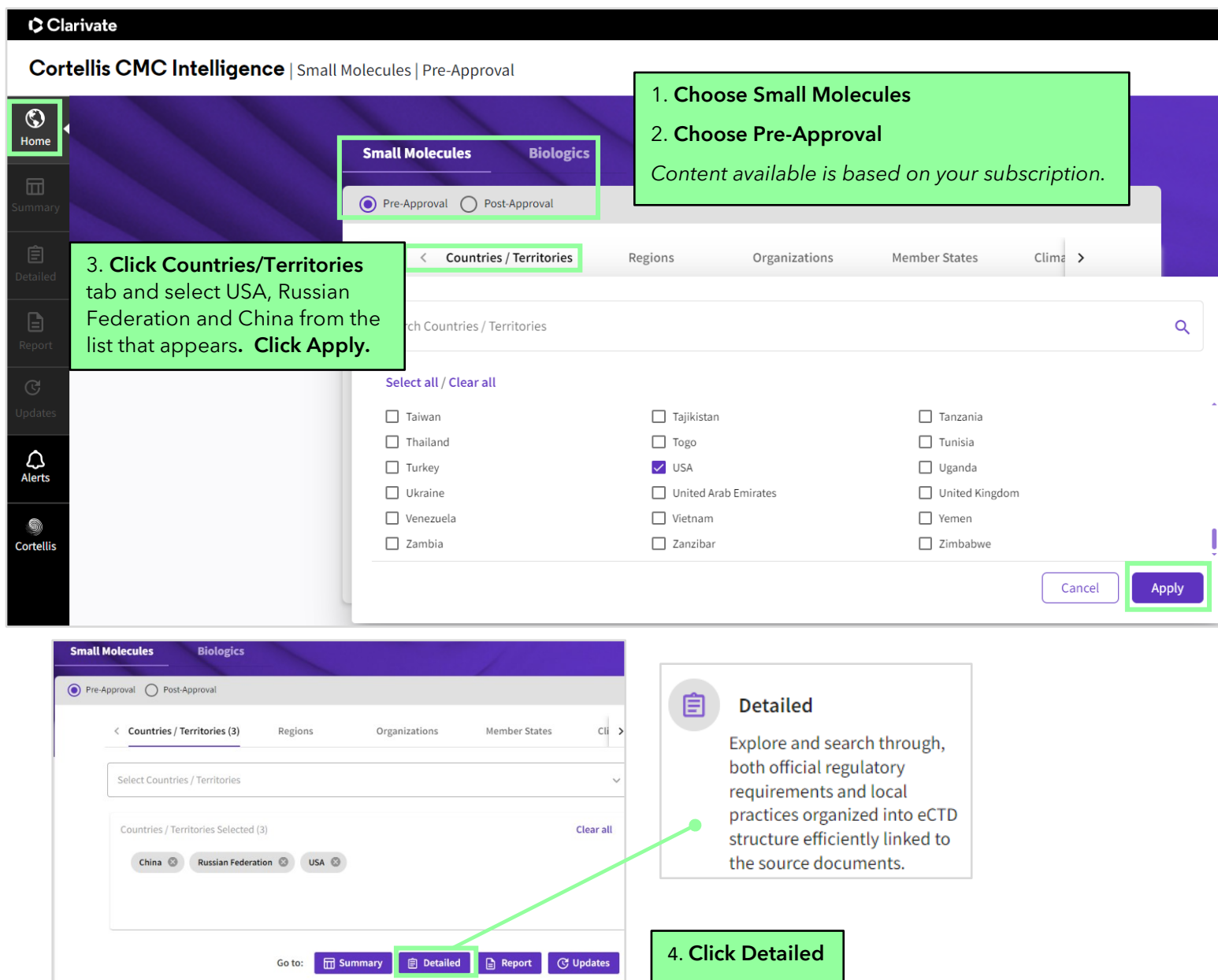


# Compare Detailed requirements such as manufacturing, trial, and distribution for different countries/entities

**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.



**1. Choose Small Molecules**

**2. Choose Pre-Approval**

Content available is based on your subscription.

**3. Click Countries/Territories tab and select USA, Russian Federation and China from the list that appears. Click Apply.**

**4. Click Detailed**

**Detailed**

Explore and search through, both official regulatory requirements and local practices organized into eCTD structure efficiently linked to the source documents.

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.

**Select Clinical Trial**

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

**Select Manufacturing Requirements**

**Click the arrows to open and close the content**

**Click the links to view the Source documents and click the links to access from the pop-up.**

**Click Filters**

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

**Click Filters**

**Select New Drug**

**Click Apply**

## Filtering the Menus

Type a term into the Filter Menu field to search the table of contents.

Click the sections that appear to view that content

The screenshot shows the Cortellis CMC Intelligence interface. On the left, there is a sidebar with a 'Filter Menu' search bar. A green box highlights this search bar with the text 'Type a term into the Filter Menu field to search the table of contents.' Below the search bar, the 'Detailed Requirements' menu is expanded, and the 'General Provisions' section is highlighted with a green box and the text 'Click the sections that appear to view that content'. The main content area displays 'General Provisions' for three regions: China, Russian Federation, and USA. The 'China' section is further expanded, showing 'S.7.1 - Stability Summary and Conclusions'.

## Searching Detailed Requirements

Type a term into into the box and click the search icon.

Click the sections that appear in the table of contents to find the content with the search term highlighted in the Detailed Requirements

The screenshot shows the Cortellis CMC Intelligence interface. On the left, there is a sidebar with a 'Filter Menu' search bar. A green box highlights this search bar with the text 'Type a term into into the box and click the search icon.' Below the search bar, the 'Detailed Requirements' menu is expanded, and the 'P.1 Description and Composition of the Drug Product' section is highlighted with a green box and the text 'Click the sections that appear in the table of contents to find the content with the search term highlighted in the Detailed Requirements'. The main content area displays 'Search Detailed Requirements' for three regions: China, Russian Federation, and USA. The 'China' section is further expanded, showing 'Dosage form and product composition: SFDA Circular No. 16 of 2018 for Phase I studies'. The search term 'excipient' is entered in the search bar, and the results are filtered to show 'excipients' in the 'Detailed Requirements' section.

For more information contact Customer Service at **LS Product Support**.