

# Cortellis CMC Intelligence quick start guide

1. Choose content from top menus or click the dark grey countries on the map. Selected content turns green

2. Choose how you'd like to view data for the content selected

COMPARE SUMMARY REQUIREMENTS (3)  
COMPARE DETAILED REQUIREMENTS (3)  
VIEW REPORTS (3)

View Summary Reports

Summary Requirements  
CMC Requirements  
Nomenclature  
Compendial standards  
Details of manufacturer  
Quality documentation  
Impurities  
Physicochemical and biological properties  
Accelerated Stability - Drug Substance  
Long-term Stability - Drug Substance  
Accelerated Stability - Drug Product  
Long-term Stability - Drug Product  
Marketing Authorization Application Requirements  
Licenses and certificates  
Accelerated registration procedure  
Pediatric formulations  
GMP certificate  
Recognition of SRA or WHO PQ decision  
Medicines Procurement

| My selection | Application form | Proof of payment | Brand name clearance | Free sale certificate | GMP certificate | Submission of QOS | Business license | Manufacturing license | SMF | Letter of access DMF/CEP | Lat doc |
|--------------|------------------|------------------|----------------------|-----------------------|-----------------|-------------------|------------------|-----------------------|-----|--------------------------|---------|
| China        | ✓                | ✓                | ✓                    | Not specified         | ✓               | ✓                 | ✓                | ✓                     | ✓   | ✓                        |         |
| India        | ✓                | ✓                | ✓                    | ✓                     | ✓               | ✓                 | ✓                | ✓                     | ✓   | ✓                        |         |
| Japan        | ✓                | ✓                | ✓                    | Not specified         | ✓               | ✓                 | ✓                | ✓                     | ✓   | ✓                        |         |

Compare basic data for the selected countries/territories in the tables

Display the content type of interest

View Detailed Reports

**Local Practice**

The applicant needs to include the following information with the **CTA package**:

- GMP certification\*
- Declaration of patent validity in China
- CMC data\*\*
- Pharmacology and toxicology data
- Summary of clinical trials completed anywhere else
- Investigator Brochure
- Planned Clinical Trial Protocol and Informed Consent Form
- Risk/ Benefit Analysis; for special handling procedures (Special handling procedure is a fast-track review)

\* Clinical manufacturing can be done at any time. However, in order to release and ship the products to the clinical sites in China, a CTA approval is needed. The production of clinical samples should be with GMP condition, but GMP certificates are not mandatory. The NMPA has the authority to conduct an on-site inspection, but it rarely occurs for clinical trials. NMPA accepts GMP certificates issued by a reference country. A CPP developed under the WHO certification scheme, includes the GMP compliance information, and is required for all imported products. If the applicant decides to start clinical manufacturing, it should also be considered the potential changes to the submitted specs requested by NMPA reviewers, and the shelf life approved in CTA.

\*\* The IMPD could be used for CTA submission in NMPA.

The sponsor must be able to provide supportive information on safety, efficacy and bioactivity of the new drug when the CTA is submitted. In light of these expectations, the GCP states that a new drug must meet the following requirements to be used in a clinical trial:

- Chemical structure and constituents of the API should be clearly known
- Processes used to manufacture the clinical product are relatively stable

View Individual Reports for Countries/Territories

Click tool to show export options

Click report categories to display content

Export Requirements Report to PDF  
Export Detailed Requirements to Excel

CFDA - China medicine agency name has now been changed as NMPA (National Medicinal Products Administration) from July 2018.  
Chinese regulations are evolving rapidly, particularly core CMC DS / DP review processes (new drug classification in March 2016 and 2020).  
Regulations are becoming tighter and more aligned to ICH, US & EU. China became a full member of the ICH in 2017.  
Local trials can be performed in all phases of clinical development (previously only Phase 2 and above) Review and drug control/testing can occur at both provincial and federal level during registration process. Provincial FDA (PFDA) is involved only when drug product is manufactured in China Local sample testing by NICBP is always required; for locally manufactured drugs, NICBP may appoint a provincial drug quality control institute For imported drugs the entire review process is done by CFDA  
Drug marketing permit (DIL) required for FPP for marketing  
-API and excipients are following China DMF (Technical Review for DMF of API is 200 working days)  
-Normally, 60 working days for clinical trial filing  
-Around 200 working days for FPP for marketing  
The "China Listed Drug Catalogue" is published on the government website of the State Food and Drug Administration in the form of a web version and links to drug review reports, specifications, patent information and other databases.  

- The State Food and Drug Administration will directly update the newly registered classified drugs and the drugs that have passed the evaluation of the quality and efficacy of generic drugs directly into the "China Listed Drugs Collection" and update them in real time.
- The carrier includes generic drugs approved for marketing, modified new drugs, generics registered in the new chemical classification, and specific information on drug evaluation through consistency in quality and efficacy.
- Designated reference preparations and standard preparations for generic drugs, indicating specific generic drug varieties that can replace the original research drugs, etc., for the pharmaceutical industry and medical professionals and the public to understand and inquire.

NMPA has published the guidance documents on Generic Consistency evaluation and Reference Preparation selection procedure and application requirements for the generics drugs which are approved and marketed domestically.

Set up Alerts direct from the toolbar

Click Create Alert

| Name                      | Date Created | Frequency | My Selection   | Content Type   | Alert Status |
|---------------------------|--------------|-----------|--|--|--------------|
| USA 19:05 22-May-2020     | 22-May-2020  | DAILY     | USA, European Union, ICH, Germany  | Key Facts  | Active       |
| Canada and USA            | 20-May-2020  | DAILY     | Canada, USA  | Key Facts; Key Requirements; CMC Requirements; Authorization Application; Medicines Procurement; Clinical Trial Requirement; Authorization Requirements; CMC Requirements - Drug Substance | Active       |
| Austria 17:42 10-Apr-2020 | 10-Apr-2020  | DAILY     | Austria, Belgium, Bulgaria, China, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, |  | Active       |
| China 17:30 10-Apr-2020   | 10-Apr-2020  | WEEKLY    |  |  | Active       |

Add desired content to the alert using the pop up wizard

Create Alert

1 My selection 2 Content Type & Frequency

My Selection

Countries/Territories: Afghanistan, Algeria, Angola, Argentina, Armenia, Australia, Austria, Bangladesh, Bangladesh Drug Administration  
 Organizations:

My Selection: China, India, Japan

Cancel Next

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