

Cortellis CMC Intelligence Pre-approval User Guide

Table of Contents

<u>Cortellis CMC Intelligenceとは</u>	<u>3</u>
<u>Home Page</u>	<u>4</u>
<u>Summary</u>	<u>7</u>
<u>Detailed</u>	<u>8</u>
<u>Report (各国規制要件のレポート)</u>	
• Key Facts (概要)	<u>15</u>
• Key Requirements (主要な規制の枠組み)	<u>16</u>
• Upcoming Guidelines and Drafts (今後の規制変更)	<u>17</u>
• Procedures (申請・審査プロセス)	<u>18</u>
• Detailed Requirements (規制要件詳細)	<u>19</u>
• Sources (規制要件の情報源を確認)	<u>20</u>
<u>Updates (各国新着情報)</u>	<u>21</u>
<u>Alerts (アラート設定)</u>	
• アラート設定画面	<u>22</u>
• アラートメール	<u>23</u>
• アラート管理画面	<u>24</u>
<u>サポート情報</u>	<u>26</u>

Cortellis CMC Intelligenceとは

Cortellis CMC Intelligence は、低分子医薬品およびバイオロジクス製品に関する世界各国のCMC要件を網羅するデータベースです。大きく移り変わるグローバル薬事規制環境下において、最新のCMC要件を提供し、効率的な薬事申請をサポートします。

各国の規制当局の公式文書や、現地規制に精通したスペシャリストの知見によって収集された情報を活用し、各国のCMC規制要件に関する効率的な情報収集を可能にします。

CMC Intelligence ログインページ : <https://www.cortellis.com/cmc>

Home page | 概要

データベースを使用するには、最初にホーム画面にて調査対象の製品カテゴリ(Small MoleculesまたはBiologics)、申請区分(新規申請 Pre-Approvalまたは変更申請 Post-Approval)および調査対象の国・地域・組織を選択します。※Small MoleculesおよびBiologicsの製品カテゴリについては、[頁28](#)を参照ください。

The screenshot shows the Cortellis CMC Intelligence interface. At the top left is the logo 'Cortellis CMC Intelligence'. The main content area has a dark header with 'Alerts' and a user profile icon. Below this, there are two main sections: 'Product Category' and 'Geography/Organizations'. The 'Product Category' section has two tabs: 'Small molecules' (selected) and 'Biologics'. Below the tabs are two radio buttons: 'Pre-approval' (selected) and 'Post-approval changes and clinical trial amendments'. The 'Geography/Organizations' section has two input fields: 'Countries/regions' and 'Organizations', each with an 'Add' button. At the bottom right, there is a 'Go to:' section with buttons for 'Summary', 'Detailed', 'Report', and 'Updates', and a circular help icon with a question mark. Annotations in Japanese boxes with arrows point to these elements: 1. A purple box points to the product category and application type selection, stating: '①自社のライセンス範囲に準じた製品カテゴリと申請区分を選択します。ここでは例として、Small MoleculesおよびPre-approvalを選択しています。' 2. A purple box points to the 'Countries/regions' and 'Organizations' input fields, stating: '②調査対象の国・地域・組織を選択します。(次頁参照)'. 3. A red box points to the 'Alerts' icon, stating: 'アラートの管理画面へアクセスします。' 4. A red box points to the user profile icon, stating: 'Cortellis の統合 Platformへアクセスします。' 5. A red box points to the help icon, stating: 'サポートメニューを表示します。'

①自社のライセンス範囲に準じた製品カテゴリと申請区分を選択します。ここでは例として、Small MoleculesおよびPre-approvalを選択しています。

②調査対象の国・地域・組織を選択します。(次頁参照)

アラートの管理画面へアクセスします。

Cortellis の統合 Platformへアクセスします。

サポートメニューを表示します。

Home page | 概要

Pre-approval Post-approval changes and clinical trial amendments

Countries/regions

Add countries/regions

▼ Asia Pacific

<input type="checkbox"/> Afghanistan	<input type="checkbox"/> Australia	<input type="checkbox"/> Bangladesh	<input type="checkbox"/> Bangladesh Procurement Agency
<input type="checkbox"/> Cambodia	<input checked="" type="checkbox"/> China	<input type="checkbox"/> China Procurement Agency	<input type="checkbox"/> Hong Kong
<input checked="" type="checkbox"/> India	<input type="checkbox"/> India Procurement Agency	<input type="checkbox"/> Indonesia	<input checked="" type="checkbox"/> Japan
<input type="checkbox"/> Malaysia	<input type="checkbox"/> Myanmar	<input type="checkbox"/> Nepal	<input type="checkbox"/> New Zealand
<input type="checkbox"/> Pakistan	<input type="checkbox"/> Philippines	<input type="checkbox"/> Singapore	<input type="checkbox"/> South Korea
<input type="checkbox"/> Taiwan	<input type="checkbox"/> Thailand	<input type="checkbox"/> Vietnam	

▼ Caribbean

Haiti

[Collapse all sections](#)

Pre-approval Post-approval changes and clinical trial amendments

Countries/regions

China X India X Japan X Add countries/regions [Clear all](#)

選択中の国名が表示されます。
国名の右側のX印をクリック
すると選択解除できます。

③調査対象の国・地域・組織を
選択後に、Applyを選択します。

Organizations

Add organizations

<input type="checkbox"/> European Union	<input checked="" type="checkbox"/> ICH	<input type="checkbox"/> IDA	<input type="checkbox"/> PAHO
<input type="checkbox"/> PFSCM	<input type="checkbox"/> The Global Fund	<input type="checkbox"/> UNFPA Procurement Services Branch	<input type="checkbox"/> WHO PQ

Home page | 概要

✓ Small molecules Biologics

Pre-approval Post-approval changes and clinical trial amendments

Countries/regions Clear all

China × India × Japan × Add countries/regions

Organizations Clear all

ICH × Add organizations

④調査対象の国・地域・組織を選択後に、Cortellis CMC Intelligenceの各コンテンツにアクセスできるようになります。ここではまず、Summaryを選択します。（次頁参照）

Go to: Summary Detailed Report Updates

Summary | 規制要件の概要比較

- “Summary”では、Home pageで選択した国・組織におけるCMC要件の概要を比較表形式で確認できます。
- この表示では、特定のトピックについて複数の国での規制要件を一覧することが可能です

Cortellis CMC Intelligence Small molecules - Pre-approval Alerts

Home **Summary** Detailed Report Updates

Home画面またはその他のメインコンテンツに移動します。

テーブル表の用語解説 情報更新時に通知を受け取る為のアラート設定 比較テーブルのExcel出力 対象国、地域等の再変更

Table glossary Create alert Download Edit search

Nomenclature

Search... Expand all sections

- CMC Requirements
- Nomenclature**
- Compendial standards
- Details of manufacturer
- Quality documentation
- Impurities
- Physicochemical and biological properties
- Accelerated Stability... Drug

Countries/regions/organizations	INN	CAS Registry Number®	Other non-proprietary	Compendial name	Chemical name
China	Yes	Yes	Yes	Yes	Yes
ICH	Yes	Yes	Yes	Yes	Yes
India	Yes	Yes	Yes	Yes	Yes
Japan	Yes	Not specified	Yes	Yes	Yes

Items per page: 10 1 - 4 of 4

トピック一覧から確認したい規制Sectionを選択します。上部の検索ボックスからsectionの検索、左上のHide/Show Navigation Panelからセクションの表示・非表示の切り替えが可能です。

バーをスライドすることで、全ての項目を確認します。

画面上での表示件数の変更が可能です。

Detailed | 詳細要件比較

- Home pageで選択した国や組織の規制要件の詳細について、テーブル表示またはリスト表示で比較できます。
- 国の表示はアルファベット順です。
- 任意の国の情報が常に一番左側に表示されるようピン止めすることができます。
 - この画面の例では、“CMC Requirements – Drug Substance > Impurities > General Information” の規制要件を表示しています

任意のコラムの表示順の変更やピン止めが可能です。

トピック一覧から確認したい規制Sectionを選択します。上部の検索ボックスからsectionの検索、左上のHide/Show Navigation Panelからセクションの表示・非表示の切り替えが可能です。

Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Submission type	Pharmaceutical form	Actions
<input type="checkbox"/> China	FPP	3.2.S.3.2 Impurities: List all impurities that products may contain (include organic impurities, inorganic impurities...)	The limits for impurities should comply with Ch.P. If not in Ch.P. then follow the requirements in the general chapter. Frequently the standards are...	Drug Substance	New Drug, Generic Drug	Not Applicable	Details >
<input type="checkbox"/> China	IMP	3.2.S.3.2 - Impurities: SFDA Circular No. 16 of 2018 for Phase I studies	Substances which comply with a monograph of the Ph. Eur., the pharmacopoeia of an EU Member State, USP or JP, no further details are required- ...	Drug Substance	New Drug	Not Applicable	Details >
<input type="checkbox"/> ICH	FPP	Information on impurities should be provided include classification and identification of impurities, report generation, listing of impurities in specifications, an...	No local practice reported by local consultants.	Drug Substance	New Drug, Generic Drug	Not Applicable	Details >
<input type="checkbox"/> ICH	IMP	No provision exist for this requirement.	No local practice reported by local consultants.	Drug Substance	New Drug	Not Applicable	Details >
<input type="checkbox"/> India	FPP	S.3.2: Impurities: Information on impurities should be provided.	Information on impurities should be provided. All potential impurities, including degradation products arising from manufacturing, storage or found in...	Drug Substance	New Drug, Generic Drug	Not Applicable	Details >
<input type="checkbox"/> India	IMP	S.3.2 Impurities: Identity or quantification of impurities, Enantiomeric purity details to be provided.	No local practice reported by local consultants	Drug Substance	New Drug	Not Applicable	Details >
<input type="checkbox"/> Japan	IMP FPP	Information on impurities should be provided. Here the discussion on impurities and information on their qualification should take place (reference to or...	No local practice reported by local consultants	Drug Substance	New Drug, Generic Drug	Not Applicable	Details >

Detailed | All filters

All filterを展開することで、Filter項目の条件にそった要件詳細のみを表示することが可能です。例えば下図のように、Product TypeからIMPにチェックをつけApplyを選択することで、全ての規制セクションに共通してIMP要件のみが表示されます。

The screenshot displays the 'Detailed' view of the regulatory database. The 'All filters' button is highlighted in the top left. A 'Filter' dialog box is open, showing the 'Product Type' filter with 'IMP' selected and 'FPP' unselected. The background table shows regulatory requirements for various countries/regions/organizations, with 'IMP' and 'FPP' tags indicating the applicable filter status.

Countries/regions/organizations	Product type	Official regulation
<input type="checkbox"/> China	IMP	3.2.S.1.3 - Gen SFDA Circular Kev ohvisoch
<input type="checkbox"/> ICH	IMP	No provision e
<input type="checkbox"/> India	IMP	Chemical and Physicochemi provided....
<input type="checkbox"/> Japan	IMP FPP	A list should be other relevant including biol

フィルター項目

- Product Type :
治験用医薬品 / 医薬品最終製品
- Submission Type :
新規医薬品/ジェネリック etc.
- Drug Type : 原薬 / 製剤
- Pharmaceutical Form : 剤型/投与経路
- Procedure : 申請方法
(標準審査、優先審査、WHO-PQ etc.)
- Country of Origin :
生産国 (現地・外国)

Detailed | テキストフィルター機能

検索ボックスに任意の用語を入力しEnterボタンを押すことで、全ての規制セクションに共通して、検索した任意の用語を含むセクションのみが表示されます。横軸カラムの各規制項目のセクション右下にて**オレンジのマーク**がついているものが、検索用語を含んでいる項目になります。該当箇所をクリックすると、全文からハイライトされた記載箇所を確認可能です。

The screenshot displays the Cortellis CMC Intelligence interface. The top navigation bar includes 'Home', 'Summary', 'Detailed', 'Report', and 'Updates'. The main content area is titled 'Manufacturing Requirements' and features a search bar with 'DMF' entered. A search term found notification is visible. The table below shows regulatory requirements for 'China' under the 'Local practice' column. A specific regulation is highlighted with a yellow box, and its details are shown in a pop-up window on the right. The pop-up window, titled 'China: Local practice', contains the following text:

All CTA whatever from imported drugs or local drugs should be submitted to CDE directly.

Good Manufacturing Practice for Phase 1 Investigational Drugs: Clinical manufacturing must guarantee to comply with NMPA's GMP. Actually Phase 1 period have not developed to the stable process, but should try to comply the basic requirement of the cGMP.

The primary focus for a CTA review is on safety, efficacy and bioactivity.

- In practice, the entire CTA review process can take up to 3 years due to the current volume of applications at NMPA. At the end of 2014, the total applications reached nearly 19,000.
- NMPA announced that this timeline will be significantly reduced by 2018 presumably via simplifying the CTA application process, at least partially.
- Based on current situation in 2018, the CTA duration covers 3 months.

The API, excipient and packaging material are following China DMF procedure which is similar with FDA-DMF. In CTA period, imported API, excipients and packaging materials are not required for DMF number, but for NDA period, the DMF filing number is necessary.

2017 update: Previously all drugs were required to complete a clinical trial in China using local subjects for approval. Recently NMPA revised the requirement to allow clinical studies conducted outside of China which included subjects of Chinese ethnicity. Clinical manufacturing can be performed at any time, but in order to release and ship the IMP, a Drug Clinical Trial approval is needed.

Subject Matter Expert has clarified that there are no restrictions on the number of DP manufacturers included in a CTA in China. It is acceptable to include more than one DP manufacturer.

※2つ以上の単語で構成される検索用語から検索を実施したい場合は、必ず単語の前後をダブルクォーテーションで囲んでください。

例：① packaging materialで検索→packagingまたはmaterialの記載があるセクション全てを抽出します。

② "packaging material"で検索→packaging materialと1フレーズになっている記載があるセクションのみを抽出します。

Detailed | Source ID & Actions Details

- テーブルをスライドすることで、各要件ごとのソース一覧と、Detailsセクションから要件の詳細を確認することが可能です。
- Source IDからソース番号をクリックすると、ソースとなるウェブサイトへのアクセス (Web linkをクリック)、規制文書の原文や英訳文のダウンロードが可能です (Original document/Machine translated document (English))。
- Cortellis Regulatory Intelligenceへのアクセスを有するユーザは、IDRAC番号をクリックして当該データベース上で文書確認することも可能です。

27-Mar-2024
 CFDI Notification: Redaction Guidelines for Site Master File (Trial), 27-Mar-2024
 Source ID: 10590 - **IDRAC: 381636** Status: Valid
 Origin: Center for Food and Drug Inspection(CFDI)

↓ Original document

↓ Machine translated document (English)

China

Product type: FPP | Drug type: Drug Substance, Drug Product | Submission type: New Drug, Generic Drug

Official regulations
 Per the Chapter II Production Authorisation, of Provision on Drug Supervision and Manufacturing Revision 2020
 Article 6: Those who intend to engage in drug production shall meet the following conditions:
 1. Have legally qualified pharmaceutical technicians, engineering technicians and corresponding technical workers.
 The legal representative, head of enterprise, head of production management, head of quality management, qualified person and other relevant personnel shall meet the conditions stipulated in the Drug Administration Law

Local practice
 A Drug Manufacturing Certificate is required in order to manufacture pharmaceuticals. The applicant should submit an application to the local government office where the manufacturing site is located. The office will review the application within 30 working days and inform the applicant of their decision to approve or reject. Once an applicant receives approval, they may then apply to the same government office for a facility inspection. The inspection generally takes place within 30 days of making the request and a Drug Manufacturing Certificate is granted upon passing the inspection.

Home	Summary	Detailed	Report	Updates																																				
<p>Manufacturing Requirements</p> <p>☰ All filters 🔍 Filter...</p> <p>📄 Compare side-by-side 📄 List view 📄 Table view</p>																																								
<p>manu</p> <p>Expand all sections</p> <ul style="list-style-type: none"> Clinical Trial Requirements Marketing Authorization Requirements <ul style="list-style-type: none"> Manufacturing and Authorisations Manufacturing Requirements CMC Requirements - Drug Substance <ul style="list-style-type: none"> S.2 Manufacture <ul style="list-style-type: none"> S.2.1 Manufacturer(s) S.2.2 Description of Manufacturing Process and 	<table border="1"> <thead> <tr> <th>Countries/regions/organizations</th> <th>Form</th> <th>Procedure</th> <th>Country of origin</th> <th>Source ID</th> <th>Actions</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> China</td> <td></td> <td>Standard Procedure, Accelerated Procedure</td> <td>Local, Foreign</td> <td>10590 7351 10588 4838 4839 4840 3746 9278 2830 1393 7752 7751 705 7</td> <td>Details ></td> </tr> <tr> <td><input type="checkbox"/> China</td> <td></td> <td></td> <td></td> <td>4838 4839 4840 4647 4646 9535 7554 3589</td> <td>Details ></td> </tr> <tr> <td><input type="checkbox"/> ICH</td> <td></td> <td></td> <td></td> <td>13121 12246 11952 11878 11877 10745 9161 6751 21 6 17</td> <td>Details ></td> </tr> <tr> <td><input type="checkbox"/> India</td> <td></td> <td></td> <td></td> <td>2605</td> <td>Details ></td> </tr> <tr> <td><input type="checkbox"/> India</td> <td></td> <td>Special Procedure Covid-19</td> <td>Local, Foreign</td> <td></td> <td>Details ></td> </tr> </tbody> </table>	Countries/regions/organizations	Form	Procedure	Country of origin	Source ID	Actions	<input type="checkbox"/> China		Standard Procedure, Accelerated Procedure	Local, Foreign	10590 7351 10588 4838 4839 4840 3746 9278 2830 1393 7752 7751 705 7	Details >	<input type="checkbox"/> China				4838 4839 4840 4647 4646 9535 7554 3589	Details >	<input type="checkbox"/> ICH				13121 12246 11952 11878 11877 10745 9161 6751 21 6 17	Details >	<input type="checkbox"/> India				2605	Details >	<input type="checkbox"/> India		Special Procedure Covid-19	Local, Foreign		Details >	<p>13-Sep-2019 Pharmeng Technology Pte Ltd 1 Fusionopolis Place, #03-20 Galaxis Singapore 138522. Source ID: 1393 - Status: Valid Origin: Subject Matter Expert</p> <p>🔗 Web link</p>		
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<input type="checkbox"/> India				2605	Details >																																			
<input type="checkbox"/> India		Special Procedure Covid-19	Local, Foreign		Details >																																			

Detailed | 詳細要件の並列表示

各国/組織別の要件において、各行の最も左側に表示されるコラムにチェックをつけ、画面右上のCompare side-by-sideを選択することで、それぞれの規制要件詳細の全文を並列表示して確認することが可能です。

The screenshot displays the 'Import/Export requirements' section of a software interface. On the left, a sidebar menu lists various regulatory categories, with 'Import/Export requirements' highlighted. The main area features a table with columns for 'Countries/regions/organizations', 'Product type', 'Official regulations', 'Local practice', 'Drug type', 'Submission type', 'Pharmaceutical form', and 'Actions'. The 'China' and 'Japan' rows have checkboxes in the first column that are checked. A yellow box highlights the 'Compare side-by-side' button in the top right corner, which is also highlighted by a yellow box in the original image. The table content is as follows:

Countries/regions/organizations	Product type	Official regulations	Local practice	Drug type	Submission type	Pharmaceutical form	Actions
<input checked="" type="checkbox"/> China	FPP	Per the Chapter V Drug Trading of China Drug Administration Law (DAL) ...	The import authorization is required, including the marketing authorization and the Import drug Customs Form....	Drug Substance, Drug Product	New Drug, Generic Drug	Not Applicable	Details >
<input type="checkbox"/> ICH	FPP	No provision exist for this requirements	No local practice reported by local consultants.	Drug Substance, Drug Product	New Drug, Generic Drug	Not Applicable	Details >
<input type="checkbox"/> India	FPP	Special Procedure during COVID-19 pandemic: As per the Public Notice No.: Import/Misc./101/2020-DC: Submission of notarized/ apostilled documents...	No local practice reported by local consultants	Drug Substance, Drug Product	New Drug, Generic Drug	Not Applicable	Details >
<input type="checkbox"/> India	FPP	Import of the Drugs: Submission of application in Form 40 to CDSCO for Registration Certificate and issuing License for impo...	Import of the Drugs: Submission of application in Form 40 to CDSCO for Reistration Certificate and issue License for...	Drug Substance, Drug Product	New Drug, Generic Drug	Not Applicable	Details >
<input checked="" type="checkbox"/> Japan	FPP	Export 1. Manufacturers of pharmaceuticals (excluding in-vitro diaenostics: hereinafter the same apolies in...	Before applying for accreditation, a Japanese marketing approval holder for an applicant needs to submit "Business Number Registration Form",...	Drug Substance, Drug Product	New Drug, Generic Drug	Not Applicable	Details >

Detailed | 詳細要件の並列表示

2つ以上のセクションにチェックをつけた場合

← Back Sync scroll

Comparing 2 regulations

China

Product type: **FFP** Drug type: **Drug Substance, Drug Product** Submission type: **New Drug, Generic Drug**

Official regulations
Per the Chapter V Drug Trading of China Drug Administration Law (DAL)

DAL Article 64: Drugs shall be imported from a port where import of drugs is permitted, and the enterprise that imports drugs shall file with the drug regulatory authority at the place where the port is located.

The Customs shall go through the customs formalities on the premise that the Drug Import Customs Clearance issued by the Drug Regulatory Authorities is provided. Drugs without the Drug Import

[Show more](#)

Local practice
The import authorization is required, including the marketing authorization and the import drug Customs Form.

NOTES FROM SUBJECT MATTER EXPERT:
For the local batch release testing of imported products, the remaining drug validity should not be less than 12 months when arrived in China. For the drugs which approved validity is less than 12 months, the remaining drug validity should not be less than 6 months when arrived in China. And the sample quantity should be three times the amount required for one test.

[Show more](#)

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure, Accelerated Procedure
Country of origin: Local, Foreign

Source documents
13-Sep-2019
Pharmeng Technology Pte Ltd 1 Fusionopolis Place, #03-20 Galaxis Singapore 138522.
Source ID: 1330 - Status: Valid
Origin: Subject Matter Expert

Japan

Product type: **FFP** Drug type: **Drug Substance, Drug Product** Submission type: **New Drug, Generic Drug**

Official regulations
Export

- Manufacturers of pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this paragraph), quasi-pharmaceutical products or cosmetics for export must, when the pharmaceuticals, quasi-pharmaceutical products or cosmetics which they manufacture are specified by Cabinet Order, undergo a document-based or on-site investigation by the MHLW regarding whether or not the methods to control manufacturing or the quality of the item at the manufacturing facility comply with the standards specified by Order of the MHLW at the time of manufacturing, or in every period of not less than three years specified by Cabinet Order after the start thereof.
- Upon request, the MHLW issues a certificate indicating to the effect that a drug, quasi-drug, or medical device to be exported has been manufactured in compliance with provisions of the

[Show more](#)

Local practice
Before applying for accreditation, a Japanese marketing approval holder for an applicant needs to submit "Business Number Registration Form", reporting information on the applicant's business and manufacturing establishments, in order to obtain "Business Number".

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure
Country of origin: Local, Foreign

Source documents
27-Jun-2024
Notice: PSB/PED, PSB/PSD, PSB/CND: Q&A on Issuance of Certificate for Drugs or Quasi-drugs To Be Exported, 19-Jun-2024
Source ID: 11826 - IDRAC: 386240 - Status: Valid
Origin: Ministry of Health, Labour and Welfare (MHLW)- Japan

← Back Sync scroll

Comparing 3 regulations

China

Product type: **FFP** Drug type: **Drug Substance, Drug Product** Submission type: **New Drug, Generic Drug**

Official regulations
Per the Chapter V Drug Trading of China Drug Administration Law (DAL)

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[Show more](#)

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[Show more](#)

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure, Accelerated Procedure
Country of origin: Local, Foreign

Source documents
13-Sep-2019
Pharmeng Technology Pte Ltd 1 Fusionopolis Place, #03-20 Galaxis Singapore 138522.

Japan

Product type: **FFP** Drug type: **Drug Substance, Drug Product** Submission type: **New Drug, Generic Drug**

Official regulations
Export

- Manufacturers of pharmaceuticals (excluding in-vitro diagnostics; hereinafter the same applies in this paragraph), quasi-pharmaceutical products or cosmetics for export must, when the pharmaceuticals, quasi-pharmaceutical products or cosmetics which they manufacture are specified by Cabinet Order, undergo a document-based or on-site investigation by the MHLW regarding whether or not the methods to control manufacturing or the quality of the item at the manufacturing facility comply with the standards specified by Order of the MHLW at the time of manufacturing, or in every period of not

[Show more](#)

Local practice
Before applying for accreditation, a Japanese marketing approval holder for an applicant needs to submit "Business Number Registration Form", reporting information on the applicant's business and manufacturing establishments, in order to obtain "Business Number".

Pharmaceutical form: Not Applicable
Procedure: Standard Procedure, Accelerated Procedure
Country of origin: Local, Foreign

Source documents
27-Jun-2024
Notice: PSB/PED, PSB/PSD, PSB/CND: Q&A on Issuance of Certificate for Drugs or Quasi-drugs To Be Exported, 19-Jun-2024

India

Product type: **FFP** Drug type: **Drug Substance, Drug Product** Submission type: **New Drug, Generic Drug**

Official regulations
Special Procedure during COVID-19 pandemic:
As per the Public Notice No. Import/Misc./321/2020-DC: Submission of notarized/ apostilled documents for import and Registration of drugs in view of COVID-19: Import Permit/ Import Registration

- Due to COVID-19 pandemic, there are difficulties in submission of notary, apostille and embassy attestation of regulatory

[Show more](#)

Local practice
No local practice reported by local consultants

Pharmaceutical form: Not Applicable
Procedure: Special Procedure Covid-19
Country of origin: Local, Foreign

Source documents
6-May-2022
Special Condition under which the permission for import of drug with residual shelf life less than 60% is allowed

3つ以上チェックをつけた場合

Detailed | List view

画面右上のViewコマンドの切り替えから、全体の要件項目表示形式をテーブルからリストにスイッチすることが可能です。

Home Summary **Detailed** Report Updates

Content of the Clinical Trial Application Create alert Edit search

All filters

Compare side-by-side ✓ List view Table view

Search...
Expand all sections

- ▼ Clinical Trial Requirements
 - ▼ Administrative Requirements
 - Clinical Trial Application Procedure
 - Content of the Clinical Trial Application**
 - > Manufacturing and Authorisations
 - > GCP compliance
 - ▼ Marketing Authorization Requirements
 - > Administrative Requirements
 - > Manufacturing and Authorisations
 - > CMC Requirements – Drug Substance
 - ▼ CMC Requirements – Drug Product
 - P.1 Description and Composition of the Drug Product
 - > P.2 Pharmaceutical Development
 - ▼ P.3 Manufacture

China

Official regulations
Per the **Drug Registration Regulation (DRR) (SFDA Order No. 27)**.

DRR Article 23: When an Applicant files an application for drug clinical trial after completing the pharmaceutical, pharmacological and toxicological researches for supporting drug clinical trials, it shall submit relevant research materials in accordance with the requirements for application materials.

If the application materials meet the requirements after formal examination, the application shall be accepted. CDE shall organize pharmaceutical, medical and other technical personnel to review accepted applications for drug clinical trials.

CTA application Timelines:
[Read more](#)

Local practice
Summary of the content of clinical trial application
Brief summary of all application document for CTA :

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

- GMP certification(not mandatory)
- Cover letter

[Read more](#)

Product type	Drug type	Submission type
IMP	Drug Substance, Drug Product	New Drug

View full details >

ICH

Official regulations
Guideline for Good Clinical Practice (E 6)

The Institution Review Board/Independent Ethic Committee should review a proposed clinical trial within a reasonable time and document its views in writing, clearly identifying the trial, the documents reviewed and the dates for the following:

- approval/favourable opinion;
- modifications required prior to its approval/favourable opinion;
- disapproval / negative opinion; and

Report | Key Facts (概要ページ)

- Reportでは、下記の黄色枠から個々の国・地域・組織ごとに切り替えて、以下の表示項目に沿った規制要件レポートを示します。
- 表示項目：Key Facts, Key Requirements, Upcoming Guidelines and Drafts, Procedures, Detailed Requirements, Sources

Key Facts : 表示中の国の規制対応に影響を与える重要かつ特異的な事柄に関する現地規制エキスパートの解説を提供します。

Home Summary Detailed **Report** Updates

Key facts

China

Create alert Download Edit search

PDF/Excelでのレポート出力が可能です。

China • Last change date 24-Apr-2026

- 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.
- The National Medical Products Administration (NMPA) held a symposium on the process and prospects of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) to review the progress of China's participation in the ICH and discuss follow-up work plans. To date (June 2021), China has transformed and implemented 46 ICH guidelines by issuing announcements on application or application recommendation of ICH guidelines and publishing the Chinese version of original ICH guidelines, and assigned 69 experts to participate in the in-depth coordination of ICH issues.
- 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 NICBPB is always required; for locally manufactured drugs, NICBPB 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.

Report | Key Requirements (主要な規制の枠組み)

Key Requirements : 現在選択中の国における最新の規制情報や、重要あるいは特異的な要求事項に関する現地規制エキスパートの解説を提供します。

Key requirements

China

Search...

Expand all sections

Key facts

Key requirements

Upcoming guidelines and drafts

Procedures

> Detailed requirements

Sources

China • Last change date 24-Apr-2026

Inspection Process in Place

Matters Related to the Implementation of Certification and Provision for Good Laboratory Practice (No. 81, 2023) (Source ID 7973)

- Starting from July 1, 2023, non-clinical drug research institutions must follow the new "Measures" for GLP certification and supervision. GLP institutions that pass the certification will receive a new certificate.
- Institutions with existing GLP certification must apply for renewal within 6 months if their last inspection was not completed within 3 years by June 30, 2023. Failure to renew will result in the cancellation of the certificate.
- Will introduce an electronic process for GLP certification from July 1, 2023. Provincial food and drug administrations can access the GLP certificate through the national drug smart supervision platform.
- Provincial food and drug administrations are responsible for ensuring GLP institutions comply with the new "Measures" and regulations.

NMPA Announcement No.2025/125: Adoption of ICH Guideline E6 (R3) Good Clinical Practice: (Source ID 12738)

- To continuously promote the alignment of drug registration technical standards with international standards, the National Medical Products Administration has decided, after research, to apply the Requirements for Pharmaceuticals for Human Use (ICH) Guidelines E6(R3): Technical Guidance on Good Clinical Practice for Drug Clinical Trials (hereinafter referred to as E6(R3) Guidelines)
- All drug clinical trials conducted after **March 31, 2026** shall be subject to the E6 (R3) guidelines.

Electronic or non-Electronic Submission

各リンクからソースへのアクセスが可能です。

Report | Upcoming guidelines and drafts (今後のガイドライン変更予定やドラフト文書情報)

Upcoming guidelines and drafts : 現在選択中の国における今後発効予定のガイドラインや、ドラフト版の文書、意見募集中のガイドライン案などの情報を提供します。

Upcoming guidelines and drafts 🔔 Create alert 📄 Download ✎ Edit search

China

Search...

Expand all sections

Key facts

Key requirements

Upcoming guidelines and drafts

Procedures

> Detailed requirements

Sources

China • Last change date 24-Apr-2026

Draft guidelines updated as on date: 24/04/2026

CDE Notification: Soliciting Public Comments on Technical Guideline for Physicochemical and Structural (Q3) Characterization of Locally Acting Generic Chemical Drugs (Draft): (Source ID 12835)

- To clarify the technical requirements for studying the physicochemical and structural (Q3) characteristics of locally administered, locally acting generic drugs, better guide companies in conducting relevant studies, and harmonize regulatory expectations, the Center for Drug Evaluation (CDE) has drafted the Technical Guideline for Physicochemical and Structural (Q3) Characteristic Studies of Locally Acting Generic Chemical Drugs, and is soliciting public comments.
- The time limit for soliciting comments is one month from the date of publication of this guideline.
- The draft guideline applies to locally acting generic drugs for topical or transdermal delivery. The purpose is to ensure robust quality control and scientific comparability between test and reference products. The guideline outlines general principles for Q3 studies for the specific product and dosage form.

For more detailed information, refer to the [link](#).

CDE Notification: Soliciting Public Comments for the Chinese Translation of the ICH M8: Electronic Common Technical Document (eCTD) v4.0 Guideline and Q&A Documents (Draft): (Source ID 13235)

To further promote the implementation of the ICH M8: Electronic Common Technical Document (eCTD) v4.0 guidance and Q&A document in China, our center has drafted a Chinese translation of the guidance and Q&A document and is now soliciting public comments for one month. If you have any suggestions for revision, please send them to the contact person's email address [link](#)

1. Implementation Guide for M8: Electronic Common Technical Document (eCTD) v4.0 (Chinese Version)
2. Chinese version of the Q&A document for M8: Electronic Common Technical Document (eCTD) v4.0
3. Implementation Guide for M8: Electronic Common Technical Document (eCTD) v4.0 (English Version)
4. English version of the Q&A document for M8: Electronic Common Technical Document (eCTD) v4.0

For more detailed information, refer to the [link](#).

各リンクからソースへのアクセスが可能です。

Report | Procedures (申請・審査プロセス)

Procedures : 医薬品の申請・審査・承認プロセスの情報を表示します。

(標準審査プロセスに加え、優先審査、ジェネリック医薬品、WHO-PQなどの情報を含みます)

※標準審査や迅速審査といった審査プロセスはフローチャートで表示され、審査のタイムライン（当局の公式情報と実際に必要なおおよその期間）の情報を併せて提供します。

The screenshot displays the 'Regulatory Submission Procedures' for China, last updated on 24-Apr-2026. The page features a navigation sidebar on the left with options like 'Expand all sections', 'Key facts', 'Key requirements', 'Upcoming guidelines and drafts', 'Procedures', 'Detailed requirements', and 'Sources'. The main content area shows a flowchart of the regulatory process. The flowchart starts with 'package to' and 'Issuance of notice of acceptance by CDE'. It then branches into two paths: one for 'CDE technical review (possible supplemental data request)' which takes 60 working days + (40 working days), and another for 'Site inspection and collect samples by CFDI' which takes 30 working days. Both paths lead to 'Provide inspection reports and testing reports to CDE', which also takes 30 working days. The process continues through 'review comments from CDE', 'Download CTP from CDE website', 'Submit Clinical Trial Protocol to Ethics Committee', 'Ethics Committee approval', 'Clinical Trial', 'Prepare documents for pre-NDA meeting with CDE', and finally 'pre-NDA meeting'. A note at the bottom states: 'In changed from an application to a filing testing and inspection are based on the technical review procedure takes 60 working days without deficiency letters are issued by sample testing, site inspection and deficiency letter are low, due to the filing procedure.' A legend on the right explains that the applicant can apply for sample testing prior to standard specification review, and that CFDI and NIDFC coordinate to take the sample, with both reports from CFDI and NIDFC being sent.

Regulatory Submission Procedures
China - Last change date 24-Apr-2026

China • Last change date 24-Apr-2026
Regulatory Submission Procedures

Accelerated Procedure
There four procedures in place to accelerated the review and approval of the drugs.

1) Procedures regarding breakthrough treatment drugs
During the clinical trials, the applicant may apply for the application of the procedures regarding breakthrough treatment drugs if

- The drug is an innovative drug, modified new drug

Report | Detailed Requirements (規制要件詳細)

- “Detailed”と同一のフォーマットでCMC要件の詳細を表示します。
- ここでは単一国・地域の情報だけを表示しますが、Compare side-by-sideから同一国における2つの規制項目を並列表示することは可能です。

The screenshot displays a web application interface for 'Manufacturing Requirements'. At the top left, the title 'Manufacturing Requirements' is shown. To the right, there are utility links: 'Create alert', 'Download', and 'Edit search'. Below the title, a dropdown menu is set to 'China', followed by an 'All filters' button and a search box labeled 'Filter...'. On the right side, there are buttons for 'Compare side-by-side', 'List view', and 'Table view' (which is selected).

A left-hand navigation sidebar is visible, containing a search bar and several menu items: 'Expand all sections', 'Key facts', 'Key requirements', 'Upcoming guidelines and drafts', 'Procedures', 'Detailed requirements' (highlighted in yellow), 'Clinical Trial Requirements', 'Administrative Requirements', 'Manufacturing and Authorisations', and 'Manufacturing Requirements' (at the bottom).

The main content area is a table with the following columns: 'Countries/regions/organizations', 'Product type', 'Official regulations', 'Local practice', 'Drug type', and 'Actions'. A single row is displayed for 'China'. The 'Product type' is 'IMP'. The 'Official regulations' section contains text: 'Per the China GCP Revision 2020' and 'Article 44: The investigational product shall be manufactured, packaged, labelled and coded in...'. The 'Local practice' section contains text: 'All CTA whatever from imported drugs or local drugs should be submitted to CDE directly.' and 'Good Manufacturing Practice for Phase 1...'. The 'Drug type' column shows 'Drug Substance, Drug Product'. The 'Actions' column has a 'Details >' button.

At the bottom right of the table, there is a pagination control showing 'Items per page: 10' and '1 - 1 of 1' with navigation arrows.

Report | Sources (規制要件の情報源を確認)

- 各規制要件の情報源、参照文書をリスト化しています。
- ソースとなる規制文書の原文や英訳文のダウンロード、規制当局のウェブサイトへのリンクをご利用頂けます。Cortellis Regulatory Intelligenceのご契約を有するお客様は、IDRAC番号をクリックすることで同プラットフォーム上での文書確認も可能です。

Search...

[Expand all sections](#)

- Key facts
- Key requirements
- Upcoming guidelines and drafts
- Procedures
- > Detailed requirements
- Sources**

🔍 文A Asked Questions (FAQ) regarding Application for Product Approval

Source ID: 2437 • IDRAC: [356280](#) • Status: Valid

Origin: PMDA-Pharmaceuticals and Medical Devices Agency_Japan

↓ Original document

Export certificate

Source ID: 4267 • IDRAC: [343753](#) • Status: Valid

Origin: PMDA-Pharmaceuticals and Medical Devices Agency_Japan

↓ [Original document](#) • ↓ [Translation available](#)

Essential Principles in Japan

Source ID: 1102 • IDRAC: [266132](#) • Status: Valid

Origin: PMDA-Pharmaceuticals and Medical Devices Agency_Japan

↓ Translation available

Drug Master File (DMF) System

Source ID: 1006 • IDRAC: [52182](#) • Status: Valid

Origin: PMDA-Pharmaceuticals and Medical Devices Agency_Japan

Source document: [web link](#)

DECLARATION OF HELSINKI

Source ID: 1103 • Status: Valid

Origin: PMDA-Pharmaceuticals and Medical Devices Agency_Japan

↓ Original document

Correspondence to drug condition early approval system

Source ID: 1008 • Status: Valid

Origin: PMDA-Pharmaceuticals and Medical Devices Agency_Japan

Source document: [web link](#)

Consultation on Applying for INN

Updates | 新着情報

- “Updates”では、データベースのあらゆるセクションの更新情報を国ごとに確認できます。
- 最近新規収録された規制文書(Source Document)や、それに伴うデータベースの更新箇所を確認できます。

Home Summary Detailed Report **Updates**

Updates

China

China

Most Recent Update

Publish Date: April 24, 2026

Following new / updated guidance documents added under sources:

- Source ID 12835: CDE Notification: Soliciting Public Comments on Technical Guideline for Physicochemical and Structural (Q3) Characterization of Locally Acting Generic Chemical Drugs (Draft), 23-Jan-2026
- Source ID 13235: CDE Notification: Soliciting Public Comments for the Chinese Translation of the ICH M8: Electronic Common Technical Document (eCTD) v4.0 Guideline and Q&A Documents (Draft), 20-Apr-2026
- Source ID 13035: NHC Order No. 86: Amendment and Revision to the Provision for Drug Imports, 24-Aug-2012

Sections updated with released guidelines are listed below:

- Sources
- Updates
- Upcoming Guidelines section has been updated with the draft guidance on Physicochemical and Structural (Q3) Characterization from source ID 12835 and Chinese Translation of the ICH M8 from Source ID 13235.

FPP Detailed Requirements:

- Import/Export Requirements section has been updated with brief information on the provision for drug imports from Source ID 13035.

Previous Update

Publish Date: January 23, 2026

Following guidance documents added under sources:

Alerts | アラート設定画面

情報更新時にメールで通知を受け取る為のアラート設定は、全コンテンツ共通の設定仕様となり、画面右上に位置するCreate alertから設定します。

Alert name

Alert name*

Frequency

Daily Weekly Monthly

Choose countries/regions/organizations

Select all

China India ICH

Japan

Choose content type

Select all

Key facts > Summary requirements

Key requirements > Detailed requirements

Updates

Cancel Apply

アラート名称を編集します

アラートの送信頻度を選択します

アラート対象にする国・組織を一覧から選択します

更新情報を受け取りたいトピックを選択します

アラート名を入力し、任意の項目全てにチェックをした後にApplyを選択することで、アラートが設定されます。

Frequency – Alert頻度設定

Daily

毎日、日本時間 午前にアラートメールを送信します

Weekly

毎週 日本時間日曜日にアラートメールを送信します

Monthly

- アラート設定翌日に最初のアラートメールを送信し、過去1ヶ月の最新情報をカバーします。
- それ以降は30日おきにアラートが送信されます。

Alerts | Email 形式

- アラートのeメールはこのメールアドレスから送信されます cmc.alerts@clarivate.com
- アラートメールに返信することはできません、ご質問等をお送りにならないようお願いいたします

Cortellis CMC Intelligence



26-May-2026

設定されたアラート頻度によって表記が変わります

CORTELLIS CMC INTELLIGENCE | SMALL MOLECULES | POST-APPROVAL ALERT

Your MONTHLY alert contains information that was updated on or after 26-Apr-2026

Name: China 05:58 26-Nov-2025
Product: [Cortellis CMC Intelligence](#)
Owner:
Contact:

UPDATED - SINCE LAST ALERT

China

Date	Event Type	Description
27-Apr-2026	Updates update	Updates has new information

Taiwan

Date	Event Type	Description
27-Apr-2026	Updates update	Updates has new information

Thailand

Date	Event Type	Description
20-May-2026	Updates update	Updates has new information

- Date : コンテンツ更新日
- Event Type : 更新種別
- Description : 更新内容

詳細を確認するにはCortellis CMC Intelligenceにログインする必要があります。

[Click to login to Cortellis CMC Intelligence now](#)

If you need help, please contact your [local Customer Service team](#) | To unsubscribe, please click [here](#)

eメールメッセージ下部の'To unsubscribe...' からアラート設定をオフ (inactive) に変更することができます。アラートを再開するにはCMC Intelligenceのアラート設定ページから操作してください。

Alerts | アラート管理画面

アラート管理画面には画面右上のベルアイコンからアクセスできます。

Cortellis CMC Intelligence Alerts

Small molecules **Biologics**

Pre-approval Post-approval changes and clinical trial amendments

Countries/regions [Clear all](#)

China × India × Japan × Add countries/regions

Organizations [Clear all](#)

ICH × Add organizations

Alerts | アラート管理画面

設定済みのアラートは作成日順に一覧表示されます

Cortellis CMC Intelligence

Home Summary Detailed Report Updates

Alerts

Alert name	Alert status	Regulatory phase	Modality	Countries/regions/organizations	Content type	Date created	Frequency	Actions
China 05:58 26-Nov-2025	Active <input checked="" type="checkbox"/>	Post-approval changes and clinical trial amendments	Small molecules	China, South Korea, Taiwan, Thailand	Updates	26-Nov-2025	Monthly	
China 02:19 26-Nov-2025	Active <input checked="" type="checkbox"/>	Pre-approval	Small molecules	China, India, Pakistan	Key facts	26-Nov-2025	Monthly	

Items per page: 10 1 - 2 of 2

個別のアラートごとに、機能をONまたはOFFへと変更できます。

設定が不要になったアラートの削除が可能です。

サポートメニューの表示（英語）

- 画面右下の「？」ボタンをクリックするとサポートメニューが表示されます
- 日本語でのサポートをご希望の方は、次頁のユーザーサポートサイトをご参照頂くか、弊社カスタマーケアまでご連絡ください。

The screenshot displays the Clarivate website interface. At the top, there are tabs for 'Small molecules' (selected) and 'Biologics'. Below this, there are radio buttons for 'Pre-approval' (selected) and 'Post-approval changes and clinical trial amendments'. The main content area is divided into 'Countries/regions' and 'Organizations' sections. The 'Countries/regions' section includes buttons for 'China', 'India', and 'Japan', along with an 'Add countries/regions' button. The 'Organizations' section includes a button for 'ICH' and an 'Add organizations' button. A 'Resources and updates' menu is open on the right side, listing 'Product updates', 'Training resources', 'Contact us', and 'Feedback and suggestions New'. A yellow box highlights a question mark icon in the bottom right corner of the page. A callout box with a purple border points to this icon, containing the text: '“？”ボタンをクリックしてメニューを開きます'. Four other callout boxes with purple borders point to the menu items: 'Product updates' (with text: 'コンテンツや機能のアップデートをお知らせします'), 'Training resources' (with text: '本マニュアルの英語版やその他のサポート資料にアクセスできます'), 'Contact us' (with text: '製品Helpファイルへのアクセスや、Ask the Expert等の弊社グローバルのサービス窓口への連絡窓口です。日本語でのサポートをご希望される方は次頁の日本国内のカスタマーケアにご連絡ください。'), and 'Feedback & suggestions' (with text: '製品への機能追加、改善要望等をお送り頂けます。').

Product updates
コンテンツや機能のアップデートをお知らせします

Training resources
本マニュアルの英語版やその他のサポート資料にアクセスできます

Contact us
製品Helpファイルへのアクセスや、Ask the Expert等の弊社グローバルのサービス窓口への連絡窓口です。日本語でのサポートをご希望される方は次頁の日本国内のカスタマーケアにご連絡ください。

Feedback & suggestions
製品への機能追加、改善要望等をお送り頂けます。

Resources and updates

- Product updates
- Training resources
- Contact us
- Feedback and suggestions New

“？”ボタンをクリックしてメニューを開きます

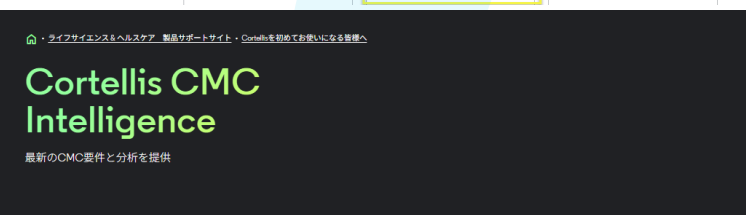
ユーザーサポートの充実

ウェブセミナー録画版・ビデオ

日本語サポートサイト

<https://clarivate.com/life-sciences-healthcare/ja/training-support/>

日本スタッフによる日本語マニュアル・資料をご用意。



基本編

- Cortellis CMC Intelligence新規申請版ユーザーガイド
- Cortellis CMC Intelligence 市販後変更申請版ユーザーガイド
- データベース内の検索
- Cortellis CMC Intelligence - Factsheet (英語)

利用事例

待望の市販後変更申請にも対応！複雑なCMC規制要件をシンプルに整理したデータベースのご紹介（45分）（開催日：2024年5月）

本ウェビナーでは、世界各国の複雑なCMC要件に特化したCMC事業業務のためのデータベースとして、Cortellis CMC Intelligenceをご紹介します。従来からご提供しているCortellis CMC Intelligence新規申請対応版では、eCTDモジュールに準拠して構成することで、複雑な操作を必要とせず、重要な規制情報を短時間で把握することを可能にしています。市販後変更申請にも対応した新製品では、承認や製造所の変更、製造工程・試験・添加剤の変更など、様々な品質関連の規制情報にアクセス可能です。

Cortellis薬事規制ソリューション：ガイドラインの効率的な入手と最新情報のモニタリング

1. イントロダクション(00:00)
2. ガイドライン検索のコツ(04:40)
3. 規制文書の表示画面の構成、規制の英語翻訳の確認方法(13:00)
4. 規制変更のモニタリング・検索をカスタマイズするアラートの設定(15:40)
5. "Document Type"フィルタ(19:00)
6. ガイドラインのモニタリングのご紹介(22:20)
7. CMC Intelligenceを用いたライン文書へのアクセス
8. CMC Intelligenceを用いたタリク(37:50)
9. サポートのご案内(42:10)

パブリックWebセミナー

<https://clarivate.com/life-sciences-healthcare/ja/training-support/training-calendar/>

ユーザー様ならどなたでも参加できるWebセミナーを年間を通じて開催。参加できなくても録画版を視聴できます。



カスタマーケア

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専門スタッフが対応。使い方、アクセスなどにお困りの際は、気軽に日本語で問合せが可能です。

Ask the Expert

各製品で提供するコンテンツや分析結果について直接アナリストに問合せいただけます。

Cortellis CMC Intelligence

収録対象医薬品カテゴリ

低分子医薬品

- Cream
- Drops
- Inhaler
- Liquid injectable
- Liquid oral
- Powder
- Solid oral
- Solid, modified release
- Spray

バイオ医薬品

- Biosimilars
- Blood derivatives
- Cell therapy
- Drug - devices combination products
- Gene therapy
- Monoclonal antibodies
- Recombinant hormones and proteins
- Vaccines
- Tissue therapy



Think forward

About Clarivate

Clarivate is a leading global provider of transformative intelligence. We offer enriched data, insights & analytics, workflow solutions and expert services in the areas of Academia & Government, Intellectual Property and Life Sciences & Healthcare. For more information, please visit clarivate.com.

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