

# Cortellis CMC Intelligence Post-approval variations User Guide

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# Cortellis CMC Intelligenceとは

Cortellis CMC Intelligence は、低分子医薬品およびバイオリ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の製品カテゴリーについては、[頁27](#)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'. On the right side of the header, there are 'Alerts' and a user profile icon. The main content area is divided into several sections:

- Product Category and Application Type:** A section with two tabs: 'Small molecules' (selected) and 'Biologics'. Below the tabs are two radio buttons: 'Pre-approval' and 'Post-approval changes and clinical trial amendments' (selected).
- Countries/regions:** A section with a text input field labeled 'Add countries/regions'.
- Organizations:** A section with a text input field labeled 'Add organizations'.

Annotations with arrows point to various elements:

- A purple box with text: 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Post-approval changes and clinical trial amendmentsを選択しています。
- A red box with text: アラートの管理画面へアクセスします。
- A red box with text: Cortellis の統合 Platformへアクセスします。
- A purple box with text: ②調査対象の国・地域・組織を選択します。(次頁参照)
- A red box with text: サポートメニューを表示します。 (pointing to a question mark icon in the bottom right corner).

# Home page | 概要

Pre-approval  Post-approval changes and clinical trial amendments

## Countries/regions

Add countries/regions

▼  Asia Pacific

<input type="checkbox"/> Australia	<input checked="" type="checkbox"/> China	<input type="checkbox"/> Hong Kong	<input checked="" type="checkbox"/> India
<input type="checkbox"/> Indonesia	<input checked="" type="checkbox"/> Japan	<input type="checkbox"/> Malaysia	<input type="checkbox"/> New Zealand
<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		

[Collapse all sections](#)

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

European Union

# 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

Go to:    Summary    Detailed    Report    Updates

選択中の国・地域・組織名右側のX印をクリックすると選択解除できます。

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）

# 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。
- ここでは特定のトピックについて複数の国における規制要件の一覧を確認可能です。

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

対象国、地域等の再変更

Table glossary Create alert Edit search

### Local Practices

Search...

Collapse all sections

- General Requirements
- Grouping of Variation / Supplements
- Work-Sharing Procedure
- Relevant Regulations - Pharmaceutical Forms Regulation Coverage
- Question and Answer Document
- Local Practices**
- Application Submission

Countries/regions/organizations	Local Practices
China	<p><b>1. Clarity on whether only 1 DP manufacturer is allowed per CTA in China?</b></p> <p>There is no restrictions on the number of DP manufacturers for submitted CTA, more than one DP manufacturers are acceptable. According to Announcement on the Appendix of Good Manufacturing Practice for Pharmaceutical Products (Revised in 2010) for Clinical Trial Drugs issued by NMPA of 2022, Article 23, if clinical trial DP are manufactured in...</p>
European Union	<ul style="list-style-type: none"><li>Local requirements (e.g. any signed document/COA's, chromatograms, notarized document) by Health authority other than official guidelines to be provided.</li><li><b>THE BELOW NOTES ARE AS PER SME (subject matter expert)</b></li><li>"change in the supplier of excipients"- Excipient manufacturers are not required to be mentioned in the dossier however many old dossiers have this information mentioned....</li></ul>
India	<p>As per Subject Matter Expert (SME) :</p> <ul style="list-style-type: none"><li>For India PAC content - there is no clarity on special requirements specific to molecule. However generally its the same for small molecules and biologicals.</li><li>For CTA Quality Amendments: There are no clear requirements stated in the guidelines for <i>CT amendment for the quality part...</i></li></ul>
Japan	<ul style="list-style-type: none"><li>It is up to applicant to decide change type. Japan is founding member of ICH and ICH Quality guidelines are to be consulted when assessing change for its impact to quality/safety/efficacy of the products.</li><li>PMDA consultation is recommended when there is uncertainty around the classification of change....</li></ul>

Items per page: 10 1 - 4 of 4

画面上での表示件数の変更が可能です。

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。

# 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、“Quality > Stability”の規制要件を表示しています

Home Summary **Detailed** Report Updates

Stability

All filters Filter...

Search... Expand all sections

- Administrative
- Quality
- Manufacture
- Control of Starting material/Active substances/Reagent/Intermediate
- Container closure system
- Stability**
- Design space and post approval management protocol
- Control of Finished Product
- Control of excipients

<input type="checkbox"/>	Countries/regions/organizations	Change description	Variation classificatio...	Implementation type	Product type	Timelines	Actions
<input type="checkbox"/>	China	Change of storage condition.	Major	Tell, wait & do	FPP	(1) 60 working c (2) 80 working c (3) 200 working	Details >
<input type="checkbox"/>	China	Change of re-test date/ storage period.	Moderate	Tell & do	FPP	No approval ne drug agency coi from the date o	Details >
<input type="checkbox"/>	China	Formulation changes (Change in storage conditions) Significant changes:	CTA - Significant cha...	Not specified	IMP	The decision or supplementary days from the d	Details >
<input type="checkbox"/>	China	Formulation changes (Change in storage conditions) General changes:	CTA - General changes	Not specified	IMP	If the sponsor a of the subjects, reported in the	Details >
<input type="checkbox"/>	European Union	Q.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance or intermediates used in the manufacturing process of t	Type IA	Do & tell	FPP	Timeline: 30 da	Details >

Sort Ascending  
Sort Descending  
Pin Column  
Reset Columns

任意のコラムの表示順の変更やピン止めが可能です。

Download

Choose countries/regions/organizations

Choose fields to download

Create alert Download Edit search

Compare side-by-side List view Table view

Items per page: 10 1 - 10 of 46

テーブルのExcel出力が可能です。

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。

バーをスライドすることで、全ての項目を確認します。

## Detailed | All filters

- All filters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FPP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FPP要件のみが表示されます。

The screenshot shows the 'Detailed' view of a regulatory database. A 'Filter' dialog box is open, allowing users to refine search results. The 'Product Type' filter is selected, and the 'FPP' (Final Product) option is checked. The 'Apply' button is highlighted, indicating that the filter will be applied to the search results. The background shows a list of regulatory entries with columns for 'Product type' and 'FPP'.

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、EU中央審査方式etc.)
- Variation Classification type : 変更区分  
(Type IA, Type IB, Minor, Major etc.  
国によって異なります)
- CTA Amendment Type : 変更対象製品が  
治験薬の場合の変更申請区分

## 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 main header shows 'Cortellis CMC Intelligence' and 'Small molecules - Post-approval changes and clinical trial amendments'. The navigation bar includes 'Home', 'Summary', 'Detailed', 'Report', and 'Updates'. The current view is 'Detailed', showing 'Marketing Authorization holder name and/or address change'. A search filter is applied: 'packaging material'. The search results table has columns for 'Countries/regions/organizations' and 'Documents required'. The 'China' entry is highlighted, and a detailed view of the 'Documents required' section is shown on the right. This view lists 12 numbered requirements for the change of the production site, including details on equipment, production raw materials, and stability studies.

※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。

30-Nov-2022

**Announcement of the State Food and Drug Administration on the implementation of electronic reporting of drug registration applications (2022 No. 110)**

Source ID: 7072 • IDRAC: 356279 • Status: Valid

Origin: NMPA - National Medical Products Administration China

[Original document](#)

[Machine translated document \(English\)](#)

**China**

Variation classification / CTA amendment type: **Major**

Implementation type: **Tell, wait & do**

**Change description**  
Change in MAH is accompanied by change in site, other technical changes.

**Timelines**  
(1) 60 working days for single change  
(2) 80 working days for grouped changes  
(3) 200 working days if inspection and testing is needed

**Cortellis CMC Intelligence** Small molecules - Post-approval changes and clinical trial amendments

Home Summary **Detailed** Report Updates

Marketing Authorization holder name and/or address change

Filter... Compare side-by-side List view **Table view**

Countries/regions/organizations	Procedure	Drug type	Pharmaceutical form	Source ID	Actions
China	cedure	Drug Substance, Drug Product	Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops	<a href="#">7072</a> <a href="#">8367</a> <a href="#">2804</a> <a href="#">8374</a>	<a href="#">Details &gt;</a>
European Union	cedure, EU - Centralised P), EU - Mutual Procedure (MRP), EU -...	Drug Substance, Drug Product	Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops	<a href="#">12789</a> <a href="#">12657</a> <a href="#">12525</a> <a href="#">12184</a> <a href="#">12114</a> <a href="#">10317</a> <a href="#">9900</a> <a href="#">9626</a> <a href="#">8439</a> <a href="#">8455</a> <a href="#">8415</a> <a href="#">8450</a> <a href="#">8420</a> <a href="#">8451</a>	<a href="#">Details &gt;</a>
European Union	cedure	Drug Substance, Drug Product	Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops	<a href="#">12924</a> <a href="#">12789</a> <a href="#">12657</a> <a href="#">12525</a> <a href="#">12184</a> <a href="#">12114</a> <a href="#">10317</a> <a href="#">11070</a> <a href="#">11059</a> <a href="#">9900</a> <a href="#">10101</a> <a href="#">9626</a> <a href="#">8439</a> <a href="#">8437</a> <a href="#">8434</a> <a href="#">8455</a> <a href="#">8468</a> <a href="#">8415</a> <a href="#">8450</a> <a href="#">8420</a> <a href="#">8421</a> <a href="#">8484</a> <a href="#">8451</a> <a href="#">8430</a>	<a href="#">Details &gt;</a>
Japan	e				<a href="#">Details &gt;</a>

Items per page: 10 1 - 4 of 4

1-Jul-2025

**CMDh/006/2008, Rev. 28: Requirements on Submissions for Variations and Renewals within MRP and National Procedures, Jun-2025**

Source ID: 10317 • IDRAC: 342651 • Status: Valid

Origin: HMA-The Heads of Medicines Agencies

[Web link](#)

# 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 'Control of Finished Product' interface. At the top right, there are buttons for 'Create alert', 'Download', and 'Edit search'. Below these, a search bar contains 'Filter...'. A yellow box highlights the '2 selected' indicator and the 'Compare side-by-side' button. The main table has columns for 'Countries/regions/organizations', 'Change description', 'Variation classificatio...', 'Implementation type', 'Product type', 'Timelines', and 'Actions'. Two rows for 'China' are selected, indicated by checkboxes in the first column. The table lists various change descriptions, such as 'Formulation changes (Changes in preparation quality standards)', with associated variation classifications like 'CTA - General changes' and 'CTA - Significant cha...'. Implementation types include 'Not specified', 'Do & tell', and 'Tell, wait & do'. Product types are 'IMP' and 'FPP'. Timelines range from 30 to 60 days. Each row has a 'Details >' button.

Countries/regions/organizations	Change description	Variation classificatio...	Implementation type	Product type	Timelines	Actions
<input checked="" type="checkbox"/> China	<b>Formulation changes</b> (Changes in preparation quality standards) General changes:...	CTA - General changes	Not specified	IMP	If the sponsor a of the subjects, reported in the	<a href="#">Details &gt;</a>
<input checked="" type="checkbox"/> China	<b>Formulation changes</b> (Changes in preparation quality standards) Significant changes:...	CTA - Significant cha...	Not specified	IMP	The decision or supplementary days from the d	<a href="#">Details &gt;</a>
<input type="checkbox"/> European Union	<i>Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the finished product</i> • (a) Change within the specifications acceptance...	Type IA	Do & tell	FPP	Timeline: 30 da	<a href="#">Details &gt;</a>
<input type="checkbox"/> European Union	<i>Q.II.d.2 Change to analytical procedure for the finished product</i> • (b) Deletion of an analytical procedure if an...	Type IA	Do & tell	FPP	Timeline: 30 da	<a href="#">Details &gt;</a>
<input type="checkbox"/> European Union	<i>Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the finished product</i> • (e) Change outside of the specification acceptanc...	Type II	Tell, wait & do	FPP	Timeline: 60 da	<a href="#">Details &gt;</a>
<input type="checkbox"/> European Union	<i>Q.II.d.2 Change to analytical procedure for the finished product</i>	Type IA	Do & tell	FPP	Timeline: 30 da	<a href="#">Details &gt;</a>

# 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

Comparing 2 change descriptions

China

Variation classification / CTA amendment type: **CTA - Significant changes** | Implementation type: **Not specified**

**Change description**  
Formulation changes (Changes in preparation quality standards)

**Significant changes:**

- Deletion of key inspection items.
- Relaxation of acceptable limits for safety, formulation of critical performance-related tests (e.g., relaxation of impurity limits, relaxation of dissolution limits)

[Show more](#)

**Timelines**  
The decision on whether to approve the supplementary application should be made within **60 days** from the date of acceptance, and the applicant should be notified of the approval result through the website of the Drug Review Center; if no notification is given within the time limit, it will be deemed as approval.

China

Variation classification / CTA amendment type: **CTA - General changes** | Implementation type: **Not specified**

**Change description**  
Formulation changes (Changes in preparation quality standards)

**General changes:**

- Tighten acceptable limits (not for safety reasons).
- Increase in inspection programs (non-safety reasons)
- Adaptation of analytical methods (comparable or better validation results within existing n...)

[Show more](#)

**Timelines**  
If the sponsor assesses that it will not affect the safety of the subjects, it can be directly implem during the research and development period.

China

Variation classification / CTA amendment type: **CTA - Significant changes** | Implementation type: **Not specified**

**Change description**  
Formulation changes (Changes in preparation quality standards)

**Significant changes:**

- Deletion of key inspection items.
- Relaxation of acceptable limits for safety, formulation of critical performance-related tests (e.g., relaxation of impurity limits, relaxation of dissolution limits)

[Show more](#)

**Timelines**  
The decision on whether to approve the supplementary application should be made within **60 days** from the date of acceptance, and the applicant should be notified of the approval result through the website of the Drug Review Center; if no notification is given within the time limit, it will be deemed as approval.

China

Variation classification / CTA amendment type: **CTA - General changes** | Implementation type: **Not specified**

**Change description**  
Formulation changes (Changes in preparation quality standards)

**General changes:**

- Tighten acceptable limits (not for safety reasons).
- Increase in inspection programs (non-safety reasons)
- Adaptation of analytical methods (comparable or better validation results within ...)

[Show more](#)

**Timelines**  
If the sponsor assesses that it will not affect the safety of the subjects, it can be directly implemented and reported in the safety update report during the research and development period.

European Union

Variation classification / CTA amendment type: **Type IA** | Implementation type: **Do & tell**

**Change description**  
*Q.II.d.1 Change in the specification attribute and/or acceptance criteria of the final product*

- (a) Change within the specifications acceptance criteria

**Timelines**  
Timeline: 30 days

## 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。

The screenshot displays the 'Control of Finished Product' interface. At the top right, there are navigation options: 'Create alert', 'Download', and 'Edit search'. Below these, a 'Compare side-by-side' button is visible. A view toggle menu is highlighted with a blue box, showing 'List view' selected with a checkmark and 'Table view' as an alternative. On the left, a sidebar contains a search bar and a list of sections: 'Administrative', 'Quality', 'Manufacture', 'Control of Starting material/Active substances/Reagent/Intermediate', 'Container closure system', 'Stability', 'Design space and post approval management protocol', 'Control of Finished Product' (highlighted), and 'Control of excipients'. The main content area shows a list of requirements, each with a checkbox and a description. The first requirement is for 'China' and includes 'Formulation changes (Changes in preparation quality standards)'. It lists 'General changes' such as 'Tighten acceptable limits (not for safety reasons)', 'Increase in inspection programs (non-safety reasons)', and 'Adaptation of analytical methods'. Below this, there are buttons for 'CTA - General changes' and 'Not specified', and a 'View full details >' button. The second requirement is also for 'Formulation changes' and lists 'Significant changes' like 'Deletion of key inspection items' and 'Relaxation of acceptable limits for safety, formulation of critical performance-related tests (e.g., relaxation of impurity limits, relaxation of dissolution limits)'. A help icon (?) is located in the bottom right corner.

# 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, 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。

**Cortellis CMC Intelligence** Small molecules - Post-approval changes and clinical trial amendments

Home Summary Detailed **Report** Updates

Key facts Create alert Edit search

China

Search...  
Expand all sections  
Key facts  
Upcoming guidelines and drafts  
Procedures  
Detailed requirements  
Sources

**China** • Last change date 27-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 | 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。

Home Summary Detailed Report Updates

Upcoming guidelines and drafts 🔔 Create alert ✎ Edit search

China

Search...

Expand all sections

Key facts

Upcoming guidelines and drafts

Procedures

> Detailed requirements

Sources

**China** • Last change date 27-Apr-2026

**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)**

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](#).

**CDE Notification No.2026/04: Issuance of Technical Documents Related to eCTD V3.2.2, 15-Jan-2026 (Source ID)**

In accordance with the "Announcement of the National Medical Products Administration on the Application for Full Implementation of Electronic Common Technical Documents (eCTD) for Chemical Drugs and Biological Products" (No. 8 of 2026), to strengthen the supervision and digitalization of the entire drug lifecycle, accelerate the implementation of eCTD in my country, and improve the application service level of "Internet + Drug Supervision," eCTD will be fully implemented for chemical drugs and biological products starting from March 1, 2026. To facilitate the full implementation of eCTD, the Center for Drug Evaluation (CDE) has revised the relevant technical documents for eCTD V3.2.2 (see Annexes 1-4). Based on the requirements of the "Notice of the General Office of the National Medical Products Administration on Issuing the Procedures for the Release of Drug Technical Guidelines" (No. 9 of 2020), and with the approval of the National Medical Products Administration, this document is hereby issued and will take effect on March 1, 2026.

**Attachment:**

- [Current application material requirements and correspondence table of eCTD catalog elements and CTD catalog levels](#)
- [eCTD Technical Specification V1.1 and Annex Package](#)
- [eCTD Implementation Guidelines V1.1](#)
- [eCTD Validation Standard V1.1](#)

各リンクからソースへのアクセスが可能です。

関連文書のダウンロードが可能です。

# Report | Procedures (申請・審査プロセス)

- 以下の中国の例では、CTAのamendment (≒治験薬の変更申請) および市販後製品の変更申請と、その審査・承認プロセスの情報を表示しています。
- 申請ルートおよび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。
- また、画面下部では各国の変更申請区分に関する情報等を提供します。

The screenshot displays a web interface for regulatory submission pathways. The main content area is titled "Regulatory Submission Pathways" for "China - Last change date 27-Apr-2026". It features a flowchart for "CTA Amendment" and "PAC Relevant Procedure".

**CTA Amendment Flowchart:**

- Start: MAH submits CT amendment after CTA
- Branch 1: Significant/Substantial changes → validation by Center for Drug Evaluation (60 days) → Approval
- Branch 2: General changes/Non-Substantial changes → It can be implemented immediately and reported through DSUR
- Approval Decision:
  - YES: Applicant can continue the clinical trial
  - NO: The proposal to resume the drug clinical trial shall be done by the applicant and can resume the CT after the rectification is completed. If there are major risks in the safety, the Applicant cannot continue the clinical trial, it may be suspended/terminated for 3 years and licence will be invalid automatically.
- Final Step: Communicate with provincial regulatory authority (RA) or CDE (consultation needed only if MAHs are unable to determine the change management category)

**PAC Relevant Procedure:**

Provisions for Post-approval Changes of Drugs (Trial) [Source ID 8367](#) -Appendix 1

**General Provisions**

- Marketing authorization holders (hereinafter referred to as holders) for post-marketing changes in drugs, and strengthen the connection between drug registration and production supervision and management of drug regulatory authorities, according to the "Drug Administration Law" " The Vaccine Administration Law, the Measures for the Administration of Drug Registration (Order No. 27 of the State Administration for Market Regulation), and the Measures for the Supervision and Administration of Drug Production (Order No. 28 of the State Administration for Market Regulation) formulate these measures.
- The holder should take the initiative to carry out post-marketing research of drugs to realize the full life cycle management of drugs. Encourage holders to use new production technologies, new methods, new equipment, and new scientific and

クリックして申請  
プロセスフロー  
チャートを表示

表示中の国における  
変更申請区分や審査プロ  
セス等に関する情報

# 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。

Home Summary Detailed **Report** Updates

Manufacturer name and/or address change Create alert Edit search

China All filters Filter... Compare side-by-side List view Table view

<input type="checkbox"/>	Countries/regions/organizations	Change description	Variation classificatio...	Implementation type	Product type	Actions
<input type="checkbox"/>	China	Changes in manufacturing site include change of manufacturing address, newly increased manufacturing address, or newly...	Major	Tell, wait & do	FPP	<span>Details &gt;</span>
<input type="checkbox"/>	China	Changes in manufacturing site include change of manufacturing address, newly increased manufacturing address, or newly...	Major	Tell, wait & do	FPP	<span>Details &gt;</span>
<input type="checkbox"/>	China	Formulation changes (Change of manufacturing site for preparation) General changes:...	CTA - General changes	Not specified	IMP	<span>Details &gt;</span>
<input type="checkbox"/>	China	Formulation changes (Change of manufacturing site for preparation)	CTA - Significant cha...	Not specified	IMP	<span>Details &gt;</span>

Items per page: 10 1 - 4 of 4 < > ?

# 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。

The screenshot shows the 'Sources' section of the Cortellis Regulatory Intelligence platform. The navigation bar includes 'Home', 'Summary', 'Detailed', 'Report', and 'Updates'. The 'Sources' section is currently selected. A dropdown menu is set to 'China'. The left sidebar contains a search bar, 'Expand all sections', and a list of categories: 'Key facts', 'Upcoming guidelines and drafts', 'Procedures', 'Detailed requirements', and 'Sources' (which is highlighted). The main content area displays a list of regulatory sources for China, with the last change date of 27-Apr-2026. Three entries are visible:

- China** • Last change date 27-Apr-2026
- 20-Apr-2026  
**CDE Notification: Soliciting Public Comments for the Chinese Translation of the ICH M8: Electronic Common**  
Source ID: 13235 • IDRAC: **427953** • Status: Valid  
Origin: Center for Drug Evaluation (CDE)- China  
[Original document](#) • [Translation available](#)
- 15-Jan-2026  
**NMPA Announcement No.2026/08: Full Implementation of Electronic Common Technical Document (eCTD)**  
Source ID: 12763 • IDRAC: **421733** • Status: Valid  
Origin: NMPA - National Medical Products Administration China  
[Original document](#) • [Translation available](#)
- 15-Jan-2026  
**CDE Notification No.2026/04: Issuance of Technical Documents Related to eCTD V3.2.2, 15-Jan-2026**  
Source ID: 13764 • IDRAC: **421734** • Status: Valid

# 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。

**Cortellis CMC Intelligence** | Small molecules - Post-approval changes and clinical trial amendments

Home Summary Detailed Report **Updates**

## Updates

China

### China

#### Most Recent Update

Publish Date: April 27, 2026

Following new / updated guidance document added under sources:

- Source ID 13235: CDE Notification: Soliciting Public Comments for the Chinese Translation of the ICH M8: Electronic Common Technical Document (eCTD)

Sections updated with released guidelines are listed below:

- Sources
- Updates
- The upcoming guidelines section has been updated with brief information from Source ID 13235

#### Previous Update

Publish Date: Mar 02, 2026

Following guidance documents added under sources:

- Source ID 12763 - NMPA Announcement No.2026/08: Full Implementation of Electronic Common Technical Document (eCTD) Submission for Chemical Dr

# 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。

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](mailto: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。

The screenshot shows the 'Alerts' management interface in Cortellis CMC Intelligence. The top navigation bar includes the product name and an 'Alerts' button highlighted with a yellow box. Below the navigation, there are two tabs: 'Small molecules' (selected) and 'Biologics'. The main content area features two radio buttons for 'Pre-approval' (selected) and 'Post-approval changes and clinical trial amendments'. There are two filter sections: 'Countries/regions' with buttons for 'China', 'India', and 'Japan', and 'Organizations' with a button for 'ICH'. Each filter section has a 'Clear all' link on the right.

# 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** Alerts

Home Summary Detailed Report Updates

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' 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', with an 'Add countries/regions' link. The 'Organizations' section includes a button for 'European Union' and an 'Add organizations' link. A 'Resources and updates' menu is open on the right side, listing 'Product updates', 'Training resources', 'Contact us', and 'Feedback and suggestions'. A 'New' link is also visible. A question mark icon is located in the bottom right corner of the page. Four callout boxes with arrows point to the menu items: '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' (製品への機能追加、改善要望等をお送り頂けます。). A callout box at the bottom right points to the question mark icon with the text '“？”ボタンをクリックしてメニューを開きます'.

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。

“？”ボタンをクリックしてメニューを開きます

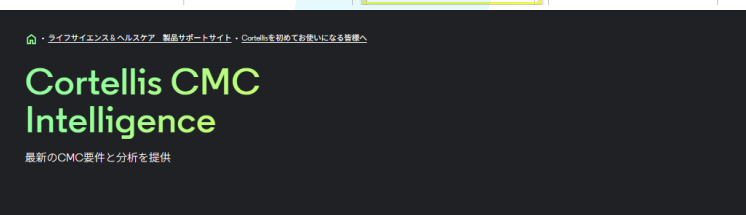
# ユーザーサポートの充実

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。



## カスタマーケア

✉ [lsh.support@clarivate.com](mailto:lsh.support@clarivate.com)

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。

## 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。

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・検索を自動化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)

# 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](https://clarivate.com).

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