



Cortellis CMC Intelligence

Post-approval variations

User Guide

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Cortellis CMC Intelligenceとは

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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、ホーム画面で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。
- 製品カテゴリや申請区分、国などの選択方法は次頁以降で解説します。

ホーム画面（本頁で示している画面）に戻る

Small MoleculesとBiologicsのモジュール切替ボタンおよびPre-ApprovalとPost-Approval切り替えボタン（いずれも該当ユーザー様のみ）

画面左のパネル内のアイコンをクリックして、データベース内の異なるコンテンツ/機能を表示させます。このパネルは常に画面の左側に表示されています。

国・地域・組織の選択ウィンドウ

Cortellis CMC Intelligenceのコンテンツカテゴリの簡易説明

サポートメニューを表示します

Small Molecules Biologics

Pre-Approval Post Approval Changes & Clinical Trial Amendments

Countries / Territories (3) Regions Organizations Member States Climatic Zones

Select Countries / Territories

Countries / Territories Selected (3)

China South Korea Thailand

Clear all

Go to: Summary Detailed Report Updates

Summary

Detailed

Report

Updates

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Home page | Countries/Territories - 国の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します。 (該当ユーザ様のみ)
- 続いてPre-ApprovalまたはPost Approval Changes & Clinical Trial Amendmentsのどちらかを選択します。 (該当ユーザ様のみ)
- 次に"Countires/Territories"タブ内の"Select Countries / Territories"クリックして、国名一覧から調査対象国を選択します。
 - 目的の国がすぐに見つからない場合は検索も可能です。

Small Molecules Biologics

Pre-Approval Post Approval Changes & Clinical Trial Amendments

Countries / Territories (3)

Select Countries / Territories

Regions Organizations Member States Climatic Zones

Countries / Territories Selected (3)

China South Korea Thailand

Clear all

③ Countries / Territories (4) Regions Organizations Member States Climatic Zones

Search Countries / Territories

china

China China Pro

④ Countries / Territories (4) Regions Organizations Member States Climatic Zones

Select Countries / Territories

Countries / Territories Selected (4)

China South Korea Taiwan Thailand

Clear all

Apply

② Countries / Territories Regions Organizations Member States Climatic Zones

Search Countries / Territories

Select all / Clear all

Sierra Leone Singapore South Korea Somalia South Sudan Spain

Slovenia South Sudan Sweden Switzerland Tanzania Tunisia Uganda

Sudan Tajikistan Togo USA

Taiwan Thailand Turkey

Cancel Apply

④ Countries / Territories (4) Regions Organizations Member States Climatic Zones

Select Countries / Territories

Countries / Territories Selected (4)

China South Korea Taiwan Thailand

Clear all

Go to: Summary Detailed Report Updates

Home page | Regions - 地域の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します。 (該当ユーザ様のみ)
- 続いてPre-ApprovalまたはPost Approval Changes & Clinical Trial Amendmentsのどちらかを選択します。 (該当ユーザ様のみ)
- "Regions"タブを使用すると、特定の地域の国をまとめて選択できます。

①

Small Molecules Biologics

Pre-Approval Post Approval Changes & Clinical Trial Amendments

Countries / Territories (3) Regions Organizations Member States Climatic Zones

Select Countries / Territories by Regions

Countries / Territories Selected (3)

China (X) South Korea (X) Thailand (X) Clear all

②

Countries / Territories Regions Organizations Member States Climatic Zones

Asia Pacific Caribbean Eurasia
 Europe Latin America Middle East, Africa
 North America

③

Countries / Territories (13) Regions Organizations Member States Climatic Zones

Select Countries / Territories by Regions

Countries / Territories Selected (13)

Argentina (X) Bolivia (X) Brazil (X) Chile (X) Colombia (X) Costa Rica (X) Guatemala (X)
Guyana (X) Honduras (X) Mexico (X) Panama (X) Peru (X) Venezuela (X) Clear all

③

Countries / Territories (13) Regions Organizations Member States Climatic Zones

Select Countries / Territories by Regions

Countries / Territories Selected (13)

Argentina (X) Bolivia (X) Brazil (X) Chile (X) Colombia (X) Costa Rica (X) Guatemala (X)
Guyana (X) Honduras (X) Mexico (X) Panama (X) Peru (X) Venezuela (X) Clear all

④

選択した地域内の国がまとめて選択されます。国名の右側のX印をクリックすると選択解除できます。

②

Countries / Territories Regions Organizations Member States Climatic Zones

Asia Pacific Caribbean Eurasia
 Europe Latin America Middle East, Africa
 North America

④

地域の選択が完了したら"Apply"をクリックして選択を確定します。

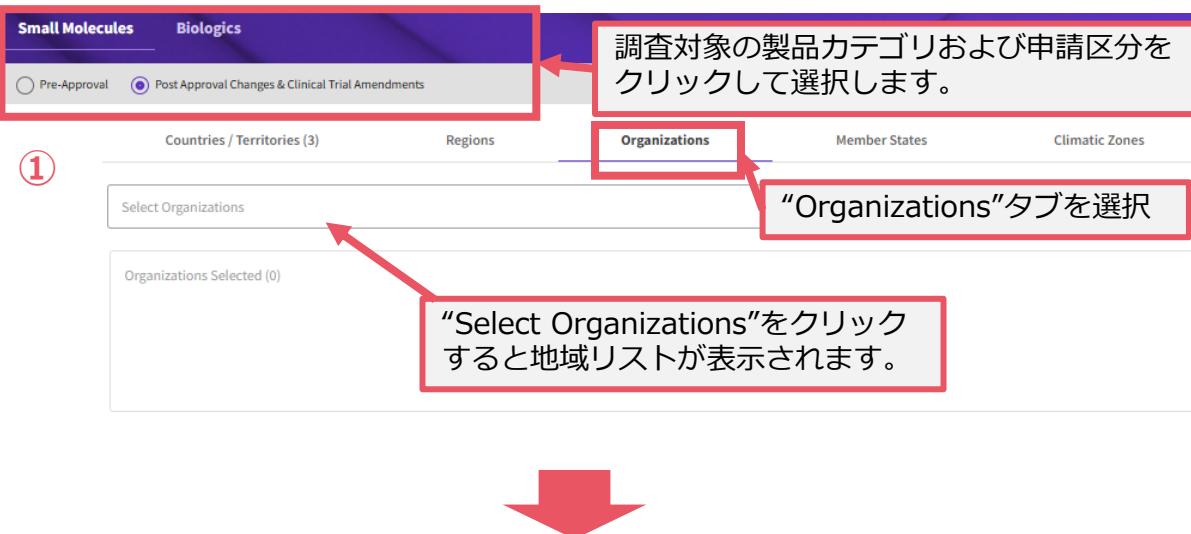
Cancel Apply

Home page | Organizations - 様々な組織の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します。 (該当ユーザ様のみ)
- 続いてPre-ApprovalまたはPost Approval Changes & Clinical Trial Amendmentsのどちらかを選択します。 (該当ユーザ様のみ)
- "Organizations"タブを使用すると、規制情報の入手が可能な国際機関名を表示します。

①



調査対象の製品カテゴリおよび申請区分をクリックして選択します。

Organizations

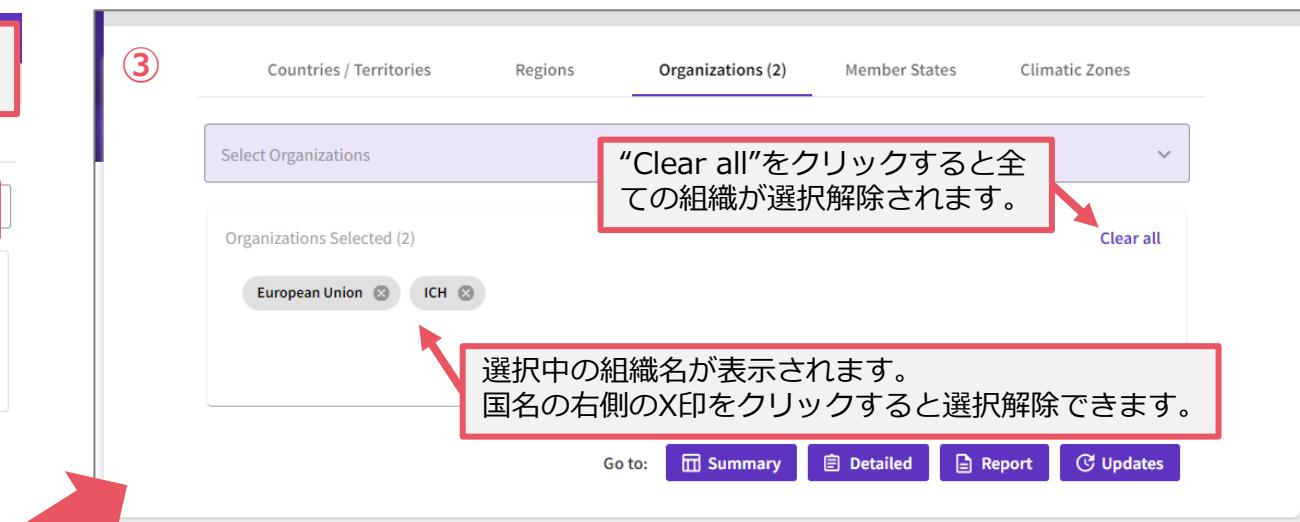
"Organizations"タブを選択

Select Organizations

Organizations Selected (0)

②

③



Countries / Territories Regions Organizations (2) Member States Climatic Zones

Select Organizations

Organizations Selected (2)

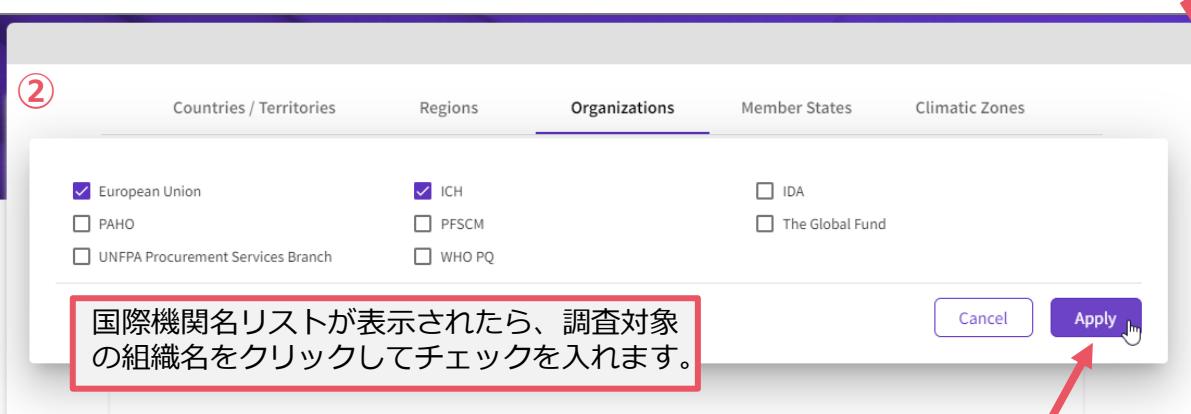
European Union ICH

Clear all

④

Go to: Summary Detailed Report Updates

②



Countries / Territories Regions Organizations Member States Climatic Zones

European Union ICH

PAHO PFSCM

UNFPA Procurement Services Branch IDA

The Global Fund

Cancel Apply

国際機関名リストが表示されたら、調査対象の組織名をクリックしてチェックを入れます。

Home page | Member States - 国際組織加盟国の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します。 (該当ユーザ様のみ)
- 続いてPre-ApprovalまたはPost Approval Changes & Clinical Trial Amendmentsのどちらかを選択します。 (該当ユーザ様のみ)
- "Member States"タブを使用すると、特定の国際組織の加盟国をまとめて選択できます。

Small Molecules Biologics

Pre-Approval Post Approval Changes & Clinical Trial Amendments

Countries / Territories (3) Regions Organizations Member States Climatic Zones

① Select Countries / Territories by Member States

② Countries / Territories Selected (3)

China (x) South Korea (x) Thailand (x)

③ Select Countries / Territories by Member States

Countries / Territories Selected (8)

Cambodia (x) Indonesia (x) Malaysia (x) Myanmar (x) Philippines (x) Singapore (x) Thailand (x)

Vietnam (x)

Clear all

④ Go to: Summary Detailed Report Updates

⑤ Countries / Territories Regions Organizations Member States Climatic Zones

⑥ ASEAN (checked) EAEU (unchecked) GCC (unchecked) ZaZiBoNa (unchecked)

African Union (unchecked) ECOWAS (unchecked) ICH (unchecked) CARICOM (unchecked) European Union (unchecked) MERCOSUR (unchecked)

⑦ 国際組織リストが表示されたら、調査対象の組織名をクリックしてチェックを入れます。

⑧ 組織の選択が完了したら"Apply"をクリックして選択を確定します。

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Home page | Climatic Zones - 気候区域の選択

CMC要件のコンテンツを閲覧するには、関心のある国や地域を選択する必要があります。

- まずSmall MoleculesまたはBiologicsのどちらかをクリックして製品カテゴリを選択します。 (該当ユーザ様のみ)
- 続いてPre-ApprovalまたはPost Approval Changes & Clinical Trial Amendmentsのどちらかを選択します。 (該当ユーザ様のみ)
- "Climatic Zones"タブを使用すると、特定の気候区域内の国をまとめて選択できます。

Small Molecules Biologics

Pre-Approval Post Approval Changes & Clinical Trial Amendments

① Countries / Territories (3) Regions Organizations Member States Climatic Zones

Select Countries / Territories by Climatic Zones

② Countries / Territories Regions Organizations Member States Climatic Zones

③ Countries / Territories (25) Regions Organizations Member States Climatic Zones

Select Countries / Territories by Climatic Zones

Countries / Territories Selected (25)

Bolivia Brazil Cambodia Cameroon Central African Republic Ethiopia
Ethiopia Procurement Agency Ghana Guyana India India Procurement Agency
Indonesia Mali

④ "Clear all"をクリックすると全ての国が選択解除されます。

選択した気候区域内の国が全て選択されます。国名の右側のX印をクリックすると選択解除できます。

⑤ 気候区域リストが表示されたら、調査対象の気候区域をクリックしてチェックを入れます。

選択が完了したら"Apply"をクリックして選択を確定します。

⑥ Go to: Summary Detailed Report Updates

Home page | コンテンツへのアクセス

- 調査対象の国・地域・組織を選択すると、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。

Cortellis CMC Intelligence | Small Molecules | Post Approval Changes & Clinical Trial Amendments

Small Molecules Biologics

Pre-Approval Post Approval Changes & Clinical Trial Amendments

Countries / Territories (14) Regions Organizations Member States Climatic Zones

Select Countries / Territories by Regions

Countries / Territories Selected (14) Clear all

Australia × China × Hong Kong × India × Indonesia × Japan × Malaysia ×
New Zealand × Philippines × Singapore × South Korea × Taiwan × Thailand × Vietnam ×

Go to: **Summary** **Detailed** **Report** **Updates**

Summary Compare and contrast core requirements for your selections to identify differences and similarities

Detailed Explore and search through, both official regulatory requirements and local practices organized into CTD

Report View a visualization of regulatory submission pathways, read key facts, procedures and requirements

Updates See the latest updates to the content for your selected country or organization to quickly identify and

Summary comparison | 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の概要を一覧することができます。

Cortellis CMC Intelligence | Small Molecules | Post Approval Changes & Clinical Trial Amendments

選択した規制トピック

Home pageで選択した国について要件を比較可能

規制のトピック一覧から確認したい項目を選択

Home Pageで選択した国

| My selection | Grouping of Variation / Supplements | Relevant Information |
|--------------|-------------------------------------|---|
| China | Yes | Changes can be grouped, however, associated changes need to be evaluated separately with reference to each change requirement, and an overall change comparability study is needed and classification would be according to the highest change category. When multiple lower-risk change items are associated, it may lead to an increase in the risk of the overall change. It is recommended to pay attention to the superimposed impact of multiple associated changes on drug safety, effectiveness, and quality. |
| South Korea | Yes | Grouping is only possible among quality changes, only among simple changes, and only among annual changes. Grouping between quality change and simple change is not possible |
| Taiwan | Yes | (Source ID 1291, 10095) There is no specific regulation to specify grouping in terms of PACs. Before PACs application, the applicant may contact the TFDA person in charge to check if the PACs can be grouped under a single application. For PAC requirement, please refer to "Chapter 2 Western Medicine: section 3" of Regulations for Registration of Medicinal Products. For changes in the pharmaceutical company's name without transfer of rights, the applicant can include all drug licenses in one application. Please refer to Article 60 of Regulations for Registration of Medicinal Product. Modifications to domestic products (transfers and contract manufacturing) can be done at the same time, and can be included in the same application for registration of a change (Refer to Q173 of TFDA Consultation Window for Medicinal Products Q & A). Receiving a license transfer and changing the commissioned factory can be handled together with changing the drug name (because of the factory change) (Refer to Q176 of TFDA Consultation Window for Medicinal Products Q & A). The application requirements could refer to Article 50, 61, 64, and 70 of Regulations for Registration of Medicinal Product |
| Thailand | Yes | Grouping variations may be acceptable under one of the two conditions below. <ul style="list-style-type: none">• If the same variations are applied to multiple products; or• If multiple variations are applied to the same drug product. |

Detailed Requirements comparison | 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、並列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“Administrative > Marketing Authorization holder name and/or address change”の規制要件を表示しています。

Cortellis CMC Intelligence | Small Molecules | Post Approval Changes & Clinical Trial Amendments

表示しているトピック

選択中の国の規制要件が横並びで表示されます

各トピック名をクリックして詳細要件を表示

Source IDをクリックすると規制の情報源についてポップアップで表示します

ピンのマークをクリックすると、その国の情報が常に画面の一番左側に固定表示されます

各セクションをクリックして、規制要件や申請に必要な情報を展開します。

Detailed Requirements comparison | 詳細要件比較（フィルター選択画面）

- フィルター機能を使用して、表示するCMC要件を一定の条件に従って絞り込むことができます。

Filters"をクリックして
フィルター項目を表示

表示させたいCMC要件
の条件を選択

全てのフィルター項目
を見るにはスクロール
してください

最後に"Apply"をクリックし
てフィルター条件を適用し
ます

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 : 効能/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 Requirements comparison | 詳細要件比較（フィルター適用後画面）

- 選択されたフィルター条件に従って、表示する規制要件が絞り込まれます。
- 初期状態では"Null Results"のチェックは外れています。この場合、フィルター条件に合致する規制項目が無い国は非表示になります。"Null Results"のチェックをオンにすると、表示すべき項目がない国であっても国名の表示が維持されます。

Cortellis CMC Intelligence | Small Molecules | Post Approval Changes & Clinical Trial Amendments

Home

Filter Menu...

Summary

Detailed

Report

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Cortellis

Marketing Authorization holder name and/or address change

Filters Search Null Results

FPP X New Drug 0 Clear all

China

Change Description

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Languages: Chinese
Implementation type: Tell, wait & do

Product Type: FPP
Submission Type: New Drug, Generics
Drug Type: Drug Substance, Drug Product
Pharmaceutical Form: Solid oral, Liquid oral, Liquid

aiwan

Change Description

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Languages: English, Korean
Implementation type: Do & tell

Product Type: FPP
Submission Type: New Drug, Generics
Drug Type: Drug Product
Pharmaceutical Form: Solid oral, Liquid oral, Liquid

Thailand

Change Description

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Languages: Chinese, English
Implementation type: Not specified

Product Type: FPP
Submission Type: New Drug, Generics

Languages: English, Thai
Implementation type: Tell, wait & do

Product Type: FPP
Submission Type: New Drug, Generics

Null Results 表示/非表示

“Clear all”をクリックするとフィルターを全て一括解除できます

このセクションに表示すべき規制のサマリーが複数用意されている場合はページ数が表示されます。左右の<>ボタンをクリックしてページを送ります。

Detailed Requirements comparison | 詳細要件比較 (テキストフィルター機能)

- “Detailed”タブでは、フリーテキスト入力によるコンテンツフィルタ機能を使用できます。
- 任意のテキストが含まれるコンテンツだけにコンテンツ表示を絞り込むことができます。
- 単一キーワードおよび複数単語で構成されるフレーズどちらにも対応します。

The screenshot shows the 'Detailed Requirements' section of the interface. On the left, a sidebar lists various categories like 'Administrative', 'Quality', and 'Container closure system'. The 'Container closure system' section is highlighted with a purple box and an arrow pointing to it from the text '指定したテキストを含むセクションだけに表示が絞り込まれます' (Only sections containing the specified text are displayed). The main content area shows a search bar with 'packaging material' entered, with an arrow pointing to it from the text '画面上部のフリーテキスト入力欄に任意のキーワードやフレーズを入力して検索を実行します' (Enter任意のキーワードやフレーズを入力して検索を実行します). The search results for 'Container closure system' are displayed for four regions: China, South Korea, Taiwan, and Thailand. The 'Change Description' section in the Taiwan results is highlighted with a yellow box and an arrow pointing to it from the text '指定したテキストが含まれる部分が黄色でハイライトされます' (The part containing the specified text is highlighted in yellow). The Taiwan results also show a detailed description of changes related to 'Container closure system'.

Detailed Requirements comparison | 詳細要件比較 (Select Change Description) 1/2

- 国名の下に"Select Change Description"と表示されている場合は、当該国のガイドラインで規定されている製品変更内容をリストで確認しながら、調査対象として関心のある規制要件を選択することができます。

調査対象国の"Select Change Description"をクリックして、当該国の製品変更要件リスト(次頁参照)から関心のあるものを選択します

Container closure system

China

South Korea

Taiwan

Thailand

Change Description

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Change Description

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Change Description

Change of Container closure system:

- Change in immediate packaging of the active substance, and the proposed packaging material is different with the approved material.
- Changes of the immediate packaging materials of sterile and liquid active ingredients.

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Change Description

Conditions

Documents Required

Additional Information

Fees

Timelines

Submission Format

Product Type: FPP

Submission Type: New Drug, Generics

Drug Type: Drug Substance, Drug Product

Pharmaceutical Form: Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops

Product Type: FPP

Submission Type: New Drug, Generics

Drug Type: Drug Product

Pharmaceutical Form: Solid oral, Liquid oral, Liquid Injectable, Inhaler, Powder, Cream, Spray, Drops

Procedure: Standard Procedure

Product Type: FPP

Submission Type: New Drug, Generics

Drug Type: Drug Product

Pharmaceutical Form: Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops

Product Type: FPP

Submission Type: New Drug, Generics

Drug Type: Drug Product

Pharmaceutical Form: Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops

Languages: Chinese
Implementation type: Tell, wait & do

Languages: English, Korean
Implementation type: Tell & do

Languages: English, Thai
Implementation type: Tell, wait & do

Languages: English, Thai
Implementation type: Tell, wait & do

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Detailed Requirements comparison | 詳細要件比較 (Select Change Description) 2/2

- 任意の国の"Select Change Description"を開くと、トピック内で用意されている様々な変更要件サマリーの表題 (Change Description)のリストを確認することができます。
- Change Descriptionのキーワード検索も可能です。
- 関心のある変更内容にチェックを入れ"Go"をクリックすると、選択した変更内容に関する規制要件のサマリーを表示させることができます。

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Container closure system

China - Choose an option from the list to navigate to its corresponding section

Use a word or phrase to refine your search

Filters

China

Select Change Description

Change Description

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Timelines

Submission Format

Languages: Chinese

Implementation type: Tell, wait & do

Implementation type: Tell & do

Fee

Implementation type: Eng

Implementation type: Eng

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Marketing Authorization holder name and/or address change

Manufacturer name and/or address change

Quality

Manufacture

Control of Starting material/Active substances/Reagent/Int...

Container closure system

Stability

DMF/PMF/VAMF (Drug/Plasma/Vaccine Antigen Master File)

Extension of Marketing Authorization

Description and composition

キーワード、フレーズでの検索可

関心のある変更内容にチェックを入れる

Go

Detailed Requirements comparison | 詳細要件比較 (Download)

- “Detailed”画面にはDownload機能が用意されています。
- 現在の画面上に表示されている各国の規制要件のサマリーやSource IDをExcel形式で出力することができます。
- 画面右上の“Download”ボタンをクリックし、“Export”ポップアップ画面にてExcelファイルに含める国や出力項目を選択します。

The screenshot shows the Cortellis CMC Intelligence interface for Small Molecules, Post Approval Changes & Clinical Trial Amendments. The left sidebar includes Home, Summary, Detailed Requirements (Administrative, Marketing Authorization holder name and/or address change, Manufacturer name and/or address change), Quality (Manufacture, Control of Starting material/Active substances/Reagent/Int...), Container closure system, Stability, DMF/PMF/VAMF (Drug/Plasma/Vaccine Antigen Master File), Extension of Marketing Authorization, and Description and composition. The main content area shows a search for 'packaging material' with results for 'Container closure system'. A 'Download' button in the top right of this area opens a 'Download' dialog box. The dialog box has two main sections: 'Select:' (listing China, South Korea, Taiwan, Thailand) and 'Select the fields you wish to download:' (listing various data points like Change Description, Conditions, Fees, etc.). A blue box labeled 'Excel出力対象の国、項目を選択' (Select countries and items for Excel output) points to the 'Select:' section. A blue box labeled 'Download' points to the 'Download' button in the dialog. A callout box labeled '“Download”をクリックして、出力項目選択ポップアップを開く' (Click 'Download' to open the export item selection pop-up) points to the main 'Download' button. A callout box labeled '“Download”をクリックしてExcelファイルを出力' (Click 'Download' to output an Excel file) points to the 'Download' button in the dialog. At the bottom, a preview of the generated Excel file is shown, with a blue box labeled '出力されたExcelファイルイメージ' (Image of the generated Excel file) pointing to it.

“Download”をクリックして、出力項目選択ポップアップを開く

Excel出力対象の国、項目を選択

“Download”をクリックしてExcelファイルを出力

出力されたExcelファイルイメージ

| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | R | |
|---|----------|-----------|---------------|----------|----------|----------|----------|-----------|------------|------------|---------|----------|-----------|----------------------|-----------------------|------------|------|----|---------|
| 1 | Territor | Change | Conditic | Docume | Addition | Fees | Timeline | Submiss | Langua | Impleme | Product | Submiss | Drug Ty | Pharma | Procedu | Variatio | CTA | Ar | Sources |
| 2 | South Ko | Change 1. | All che (P.7) | Da | Not spec | NA | 20 worki | Not Spe | English; K | Do tell | FPP | New Drug | Drug Proc | Solid oral; Standard | Annual Report(AR) | 9110; 9959 | | | |
| 3 | China | Chang | Not Spec | Not Spec | Not Spec | Not Spec | Not Spec | CTD | Chinese | Not spec | IMP | New Drug | Drug Proc | Solid oral; Standard | Procedure | Significan | 8764 | | |
| 4 | Thailand | Change i | 1. The cl | 1. Amend | Variatio | Applicat | 40-95 | · The var | English; T | Tell, wait | FPP | New Drug | Drug Proc | Solid oral; Standard | Minor variation (Pric | 10073; 100 | | | |
| 5 | | | | | | | | | | | | | | | | | | | |
| 6 | | | | | | | | | | | | | | | | | | | |

Report | Key Facts (概要ページ)

- 個々の国・地域・組織の規制要件に関するレポートを表示します
 - 表示項目 : Key Facts, Procedures, Detailed Requirements, Sources, Change History
 - “Report”画面の初期表示は“Key Facts”です

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ついて現地のエキスパートが解説します

Cortellis CMC Intelligence | Small Molecules | Post Approval Changes & Clinical Trial Amendments

当該国のレポートの最終更新日を示しています

表示する国・地域の選択

Key Facts

Last Change Date 18-Sep-2025

China

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“Report”内のコンテンツ切替え

当該国のレポートの最終更新日を示しています

表示する国・地域の選択

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Last Change Date 18-Sep-2025

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“Report”内のコンテンツ切替え

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 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 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 by NICPBP is always required; for locally manufactured drugs, NICPBP 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.

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)

- 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アップデートします。

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CDE Notification: Soliciting Public Comments on ICH Guideline M4Q (R2) The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality (Draft), 14-Aug-2025 (Source ID-11986)

ICH Guideline Draft Topic M4Q(R2) Step 2: The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality, 14-May-2025, has entered the third stage of regional public consultation. According to document from their respective regions and provide feedback to ICH. The feedback form is also available in this document.

This document contains the English original and Chinese translation of the M4Q (R2) guideline draft. The content of the guideline and its Chinese translation are now open for public consultation. The M4Q(R2) guideline establishes medicinal products for human use.

It supports various submission types, including those referring to or consisting of master files, and applies to both initial marketing authorisation and post-approval submissions. This guideline is structured to be flexible to accommodate different types of pharmaceutical products.

Deadline for comments: before October 31, 2025.

This document contains:

- 1. Scope and organization
- 2. Module 2 Common technical document summaries
- 3. Module 3 Quality
- 4. Abbreviations
- 5. Glossary
- 6. Reference

CDE Notification: Soliciting Public Comments on Technical Guidelines for Post-approval Pharmaceutical Change Management Protocols of Chemical Drugs (Draft), 09-Jun-2025

- Link to the document: [LINK](#)
- Release Date: 09 June 2025
- Deadline for comments: 09 July 2025
- To strengthen the management of post-marketing changes of chemical drugs and promote the implementation of ICH Q12 in China, the Center for Drug Evaluation drafted the Technical Guidelines for Post-approval Pharmaceutical Change Management Protocols (PACMP).
- This guideline aims to provide reference for marketing authorization holders/active pharmaceutical ingredient registration or manufacturing enterprises (hereinafter referred to as holders/registration enterprises) to implement the use of post-approval change management protocols (PACMP).
- This document was drafted in the following sections:

1. Overview
2. Application of PACMP. The application process for PACMP typically involves two steps: submitting the protocol and implementing it.
3. Dossier requirements for PACMP
4. Amendment to the approved PACMP. Revising an approved PACMP requires submitting a supplementary application.

Reports | Procedures (申請・審査プロセス)

- 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

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Regulatory Submission Pathways

CTA amendment & PAC Procedure

Process to report Master File (MF) change/DMF/ASMF amendments

The information below is as per SME(subject matter expert)

China does have DMF system for API, excipients and packaging material. Although no specific DMF changes are listed in the regulations, Article 19 of Source ID 8367 is approved as part of a drug registration ('active' DMFs).

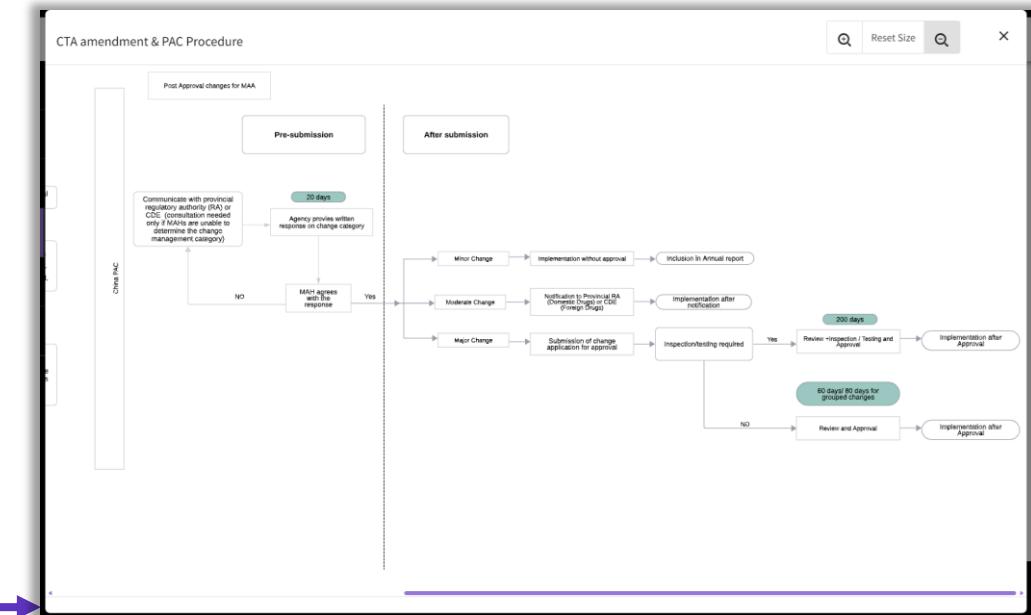
Article 19

In the case of changes in APIs that have passed review and approval, the API registrant shall first determine the change management category according to the record before implementation, or report

it. The MAH registrant shall timely update the change information on the registration platform. Before the change is implemented, the API registrant shall promptly study the degree of risk that the change may affect the pharmaceutical preparation's quality, file a supplementary application for the change, file it on record, or re-procedures yet, the API registrant may update the relevant information via the registration platform on CDE website anytime

PAC Relevant Procedure

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



Reports | Detailed Requirements (規制要件詳細)

- ・ 各国CMC要件の詳細画面を表示します (12ページで説明した"Detailed Requirements Comparison"と同じ内容です)
- ・ フィルター機能も使用可能です
- ・ この画面では単一の国の情報だけを表示します、並列表示の機能は使用できません

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Submission Format
Languages: Chinese
Implementation type: Tell, wait & do
Product Type: FPP
Submission Type: New Drug, Generics
Drug Type: Drug Substance, Drug Product
Pharmaceutical Form: Solid oral, Liquid oral, Liquid Injectable, Inhaler, Solid, Modified Release, Powder, Cream, Spray, Drops
Procedure: Standard Procedure
Variation Classification type: Major
SourceID: 2804 7072 8367 8368 8369 8374

現在表示中の規制トピック
Change Descriptionや Conditions等の各セクションをクリックして規制要件の英語サマリーを開く

Change Description: 変更内容
Conditions: 規制の適用条件
Documents Required: 申請に必要な文書
Additional Information: 規制エキスパートからの追加情報
Fees: 申請手続き費用
Timelines: 審査タイムライン
Submission Format: 申請書式

Change Descriptionや Conditions等の各セクションをクリックして規制要件の英語サマリーを開く

1. Not applicable to changes relating to manufacturer responsible for batch release or a site where only batch release takes place.
2. For addition or replacement of the company or party responsible for batch release, please refer to MIV3.
3. If there are changes to the manufacturing process, Mav-9 is also applicable

Documents Required

1. Proof that the proposed site is appropriately authorized for the pharmaceutical form concerned, such as a valid Good Manufacturing Practice (GMP) certificate and/or a Certificate of Pharmaceutical Product (CPP) which covers GMP certification.
2. Comparative batch analysis data of drug product of at least two production batches (or one production batch and two pilot batch) from the proposed site and last three batches from the current site; batch analysis data on the next two full production batches should be available upon request or reported if outside specifications (with proposed action).
3. Stability data as per ASEAN Guideline On Stability Study Of Drug Product and report if any results fall outside shelf life specifications (with proposed action).
4. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable).
5. Validation scheme and/or report of the manufacturing process as per ASEAN Guideline on Submission of Manufacturing Process Validation Data for Drug Comp. 6. Comparative batch analysis data of drug product of at least two production batches (or one production batch and two pilot batch) from the proposed site and last three batches from the current site; batch analysis data on the next two full production batches should be available upon request or reported if outside specifications (with proposed action).
7. Revised drafts of the package insert and labelling incorporating the proposed variation (where applicable).
8. Stability data as per ASEAN Guideline On Stability Study Of Drug Product and report if any results fall outside shelf life specifications (with proposed action).
9. Validation scheme and/or report of the manufacturing process as per ASEAN Guideline on Submission of Manufacturing Process Validation Data for Drug Comp. 10. Stability data as per ASEAN Guideline On Stability Study Of Drug Product and report if any results fall outside shelf life specifications (with proposed action).
11. Headline and sub-headline of the proposed variation.
12. In the case of a major variation, the proposed variation should be submitted as a separate document.

Report | Sources (規制要件の情報源の確認 1/2)

- 各規制要件の情報源、参照文書をリスト化しています
- この画面から規制文書の原文PDFや英語翻訳の入手、当該規制文書が掲載されている規制当局のURLを確認できます。

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文書の発出日、発出元機関別などの並べ替えできます

文書の発出日、タイトル、情報源の種類（規制当局の名称など）、Source ID、IDRAC番号（Cortellis Regulatory Intelligenceの文書と連携している場合）

"GETSOURCE"をクリックして規制文書入手できます（次頁を参照）

IDRAC番号のリンクをクリックして、規制文書をCortellis Regulatory Intelligence内で開きます（Cortellis Regulatory Intelligenceのご契約が必要です）

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Report | Sources (規制要件の情報源の確認 2/2)

- Sourcesの参照文書リストで“GET SOURCE”をクリック（前頁参照）すると詳細ポップアップが展開します。
- ポップアップから規制文書の原文PDF、機械翻訳PDFの入手ができるほか、当該規制文書が掲載されている規制当局ウェブサイトのURLを確認できます。

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Sort by Order by

14-Aug-2025
CDE Notification: Soliciting Public Comments on ICH Guideline M4Q (R2) The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality (Draft), 14-Aug-2025
Center for Drug Evaluation (CDE)- China [GET SOURCE](#)
IDRAC Number: 412499
SourceID: 11986
Status: Valid

14-Jul-2025
NIFDC Notification: Drug Registration Inspection Procedures and Technical Requirements for National Institutes for Food and Drug Control (中国食品药品检定研究院) [GET SOURCE](#)
IDRAC Number: 410766
SourceID: 11762
Status: Valid

09-Jun-2025
CDE Notification: Soliciting Public Comments on Technical Guidelines for Post-Approval Changes (PAC) for New Chemical Entities (NCEs) [GET SOURCE](#)
Center for Drug Evaluation (CDE)- China [GET SOURCE](#)
IDRAC Number: 408614
SourceID: 11546
Status: Valid

06-May-2025
CDE Notification: Soliciting Public Comments on ICH Guideline Q1 Stability Testing of Drug Substances and Drug Products (Draft), 06-May-2025
Center for Drug Evaluation (CDE)- China [GET SOURCE](#)
IDRAC Number: 406656
SourceID: 11317
Status: Valid

Source: 11986
Title: CDE Notification: Soliciting Public Comments on ICH Guideline M4Q (R2) The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality (Draft), 14-Aug-2025
Date: 14-Aug-2025
Origin: Center for Drug Evaluation (CDE)- China
Status: Valid
IDRAC Number: [412499](#)

Download
Original Document
Machine Translated Document (English)

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IDRAC番号のリンクをクリックして、規制文書をCortellis Regulatory Intelligence内で開きます
(Cortellis Regulatory Intelligenceのご契約が必要です)

Get PDF : 規制文書をダウンロードできます
Get Translated PDF : 規制文書が英語以外の言語の場合は英語の機械翻訳入手できます (一部の対象文書のみ)

Reports | Change History (Report更新履歴)

- “Change History”では、現在表示中の国のレポートの更新履歴を確認できます
- 更新履歴は更新日が最近のものを上位に表示します

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Cortellis CMC Intelligenceのコンテンツが更新された日付

更新されたコンテンツ種別を確認できます

コンテンツ内のどのトピックが更新されたのか確認できます

Change History

Last Change Date 18-Sep-2025

China

| Date | Event Type | Description |
|-------------|--------------------------------|--|
| 18-Sep-2025 | Updates | Updates has new information |
| 18-Sep-2025 | Upcoming Guidelines and Drafts | Upcoming Guidelines and Drafts has new information |
| 17-Sep-2025 | Sources | Source CDE Notification: Soliciting Public Comments on ICH Guideline M4Q (R2) The Common Technical Document for Medicinal Products for Human Use |
| 13-Aug-2025 | Sources | Source NIFDC Notification: Drug Registration Inspection Procedures and Technical Requirements |
| 13-Aug-2025 | Upcoming Guidelines and Drafts | Upcoming Guidelines and Drafts has new information |
| 13-Aug-2025 | Procedures | Procedure Additional PAC-Related Details was updated |
| 13-Aug-2025 | Updates | Updates has new information |
| 11-Aug-2025 | Sources | Source CDE Notification: Soliciting Public Comments on Technical Guidelines for Post-approval Evaluation of New Medicinal Products |
| 05-Aug-2025 | Sources | Source NIFDC Notification: Drug Registration Inspection Procedures and Technical Requirements |
| 14-Jul-2025 | Sources | Source NMPA Announcement No.2025/01: Issuance of the Appendix for Pharmaceutical Excipient |
| 11-Jul-2025 | Sources | Source NMPA Announcement No.2025/01: Issuance of the Appendix for Pharmaceutical Excipient |
| 11-Jul-2025 | Sources | Source CDE Notification: Soliciting Public Comments on ICH Guideline Q1 Stability Testing of Drugs |
| 11-Jul-2025 | Sources | Source NMPA Announcement No.2022/43: Good Manufacturing Practice (GMP)—Appendix for Drugs |
| 03-Jul-2025 | Procedures | Procedure PAC Relevant Procedure was updated |
| 03-Jul-2025 | Summary Requirements | Summary Requirements were updated |
| 03-Jul-2025 | Procedures | Procedures were updated |
| 03-Jul-2025 | Updates | Updates has new information |

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。

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Latest Updates

China

Reason for Update

MOST RECENT UPDATE

Publish Date: 18/09/2025

The following new guidance documents have been added under sources:

- Source ID 11986: CDE Notification: Soliciting Public Comments on ICH Guideline M4Q (R2) The Common Technical Document For The Registration Of Pharmaceuticals For Human Use: Quality (Draft)

Sections updated with released guidelines are listed below:

- Sources
- Updates
- Upcoming Guidelines section has been updated with brief information from the source ID 11986

PREVIOUS UPDATE

Publish Date: 13/08/2025

Following the new guidance documents added under sources:

- Source ID: 11546- CDE Notification: Soliciting Public Comments on Technical Guidelines for Post-approval Pharmaceutical Change Management Protocols of Chemical Drugs (Draft)
- Source ID: 11836- CDE Notification No.2025/30: Questions and Answers on the Study of Pharmaceutical Similarity of Biosimilars
- Source ID: 11762- NIFDC Notification: Drug Registration Inspection Procedures and Technical Requirements Specifications (2025 Revision)

Sections updated with released guidelines are listed below:

- Sources
- Updates
- Summary Requirements:
 - The Question-and-Answer section has been updated with brief information from Source ID: 11836
- Pathway summary:
 - Additional PAC-related details section has been updated with brief information from source ID: 11762
- The upcoming guideline section has been updated with brief information from Source ID: 11546

Alerts | アラート設定画面

- 新規アラートの設定や、過去に設定したアラートの管理ができます
- 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 | Small Molecules | Post Approval Changes & Clinical Trial Amendments

Alerts

設定済みのアラートが作成日順にリスト表示されます

| Name | Date Created | Frequency | My Selection | Content Type | Alert Status | Delete |
|-----------------------------|--------------|-----------|---|---|--|--------|
| Australia 01:51 02-Oct-2024 | 02-Oct-2024 | DAILY | Australia, China, Japan, New Zealand, Philippines, Singapore, South Korea, Taiwan, Thailand, Vietnam, European Union, Belgium, Brazil | Sources; Detailed Requirements: Administrative, Quality | Active <input checked="" type="checkbox"/> | |
| Brazil 06:54 03-Jul-2024 | 03-Jul-2024 | DAILY | Brazil, China, Japan, USA, United Kingdom, European Union, Canada, Czech Republic, France | Detailed Requirements: Admin | | |
| Brazil 06:52 03-Jul-2024 | 03-Jul-2024 | DAILY | Brazil, China, Japan, USA, United Kingdom, European Union | Detailed Requirements: Quality | | |

アラート名称の編集ができます

“CREATE ALERT”ボタンをクリックすると、アラート設定ポップアップ画面が開きます

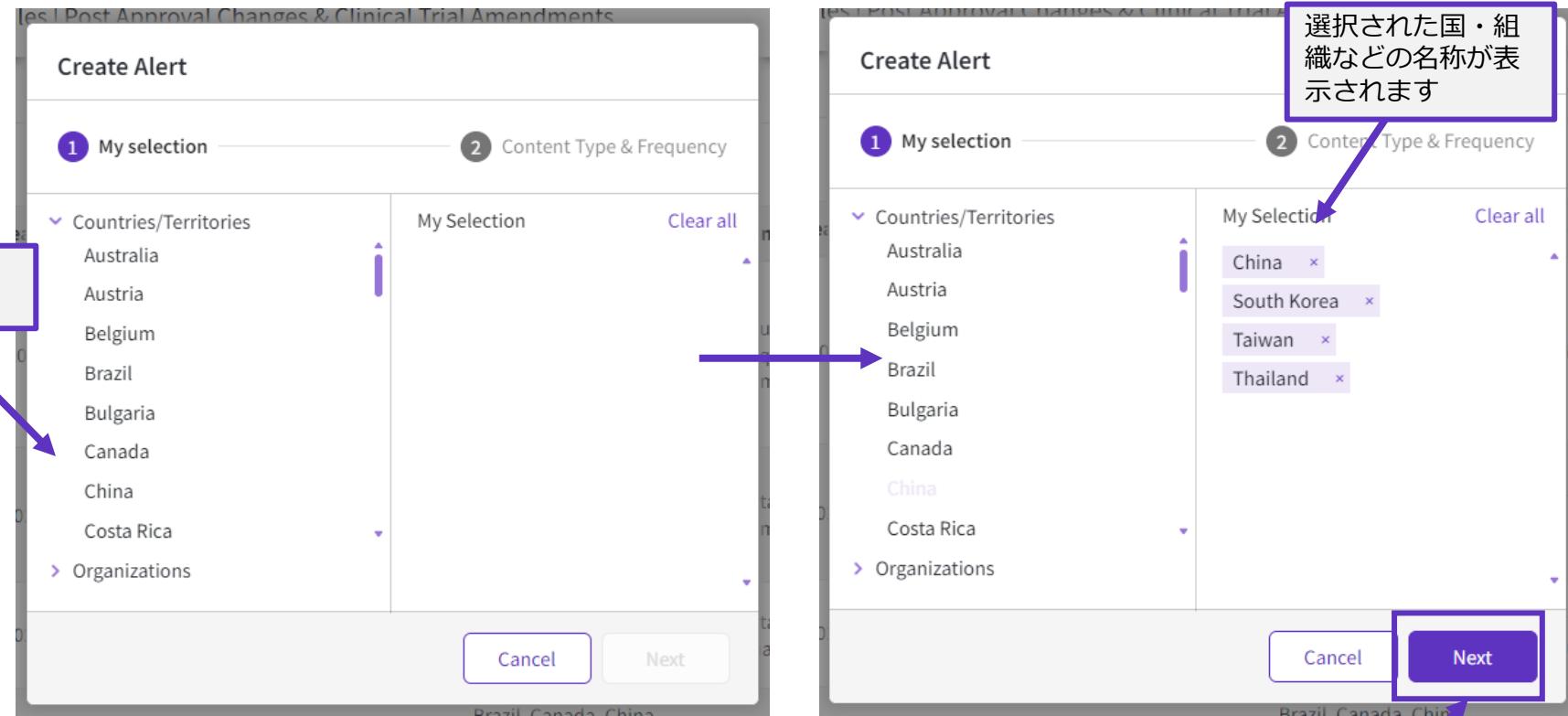
アラートはオン (Active)、オフ (Inactive) の切替ができます。アラートを削除しなくとも、一時的に停止することができます。

設定済みアラート一覧 表示項目

- Name – アラート名称（自動的に付与されます、任意の名称に変更可能です）
- Date Created – アラート設定日
- Frequency – アラート頻度 (daily, weekly, monthly)
- My Selection – アラートの対象として選択されている国名一覧
- Content Type – アラート対象のコンテンツ
- Alert Status – アラートのActive / Inactive状態表示、Inactiveの場合はアラートメールは送信されません
- Delete – アラートを完全に削除します

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Alerts | Create Alert (新規アラート設定画面 – My selection)



1 My selection 2 Content Type & Frequency

My Selection

Clear all

選択された国・組織などの名称が表示されます

My Selection

Clear all

Next

Cancel

Next

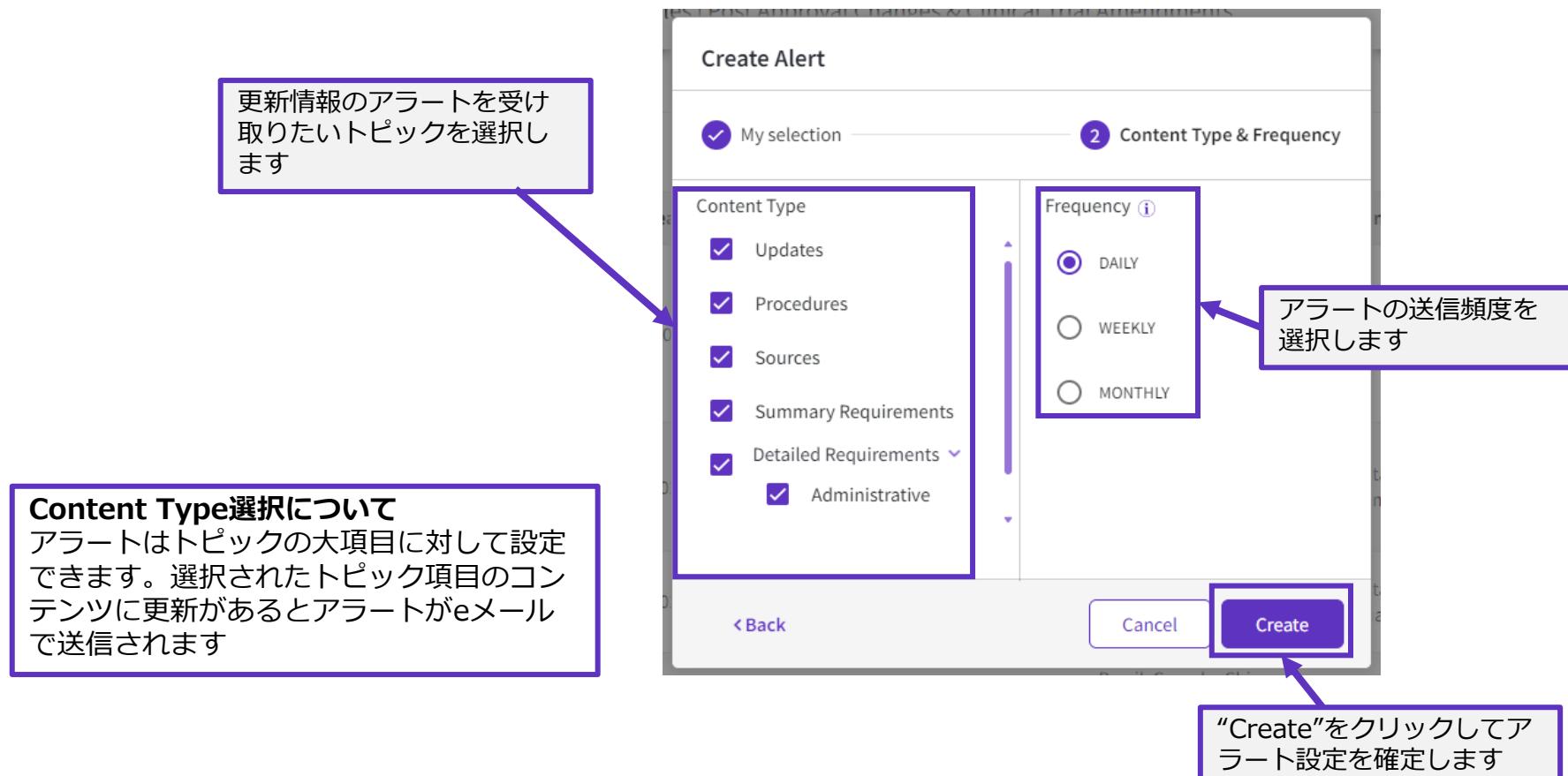
Cancel

注 : Create Alert画面を開くとHome pageで選択した国や組織がMy selectionとして予め選択されています

Alerts | Create Alert (新規アラート設定画面 – Content Type & Frequency)

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  20-Nov-2025

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 DAILY alert contains information that was updated on or after 19-Nov-2025

Name: Australis
Product: Cortellis
Owner:
Contact: akira.mori@clarivate.com

UPDATED - SINCE LAST ALERT

| South Korea | | |
|-------------|----------------|--|
| Date | Event Type | Description |
| 19-Nov-2025 | Sources update | Source MFDS Guide-1261-03: Q&A on Management of Manufacturing Method Change after Drug Approval, 22-Sep-2025 was added |

• 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](#)

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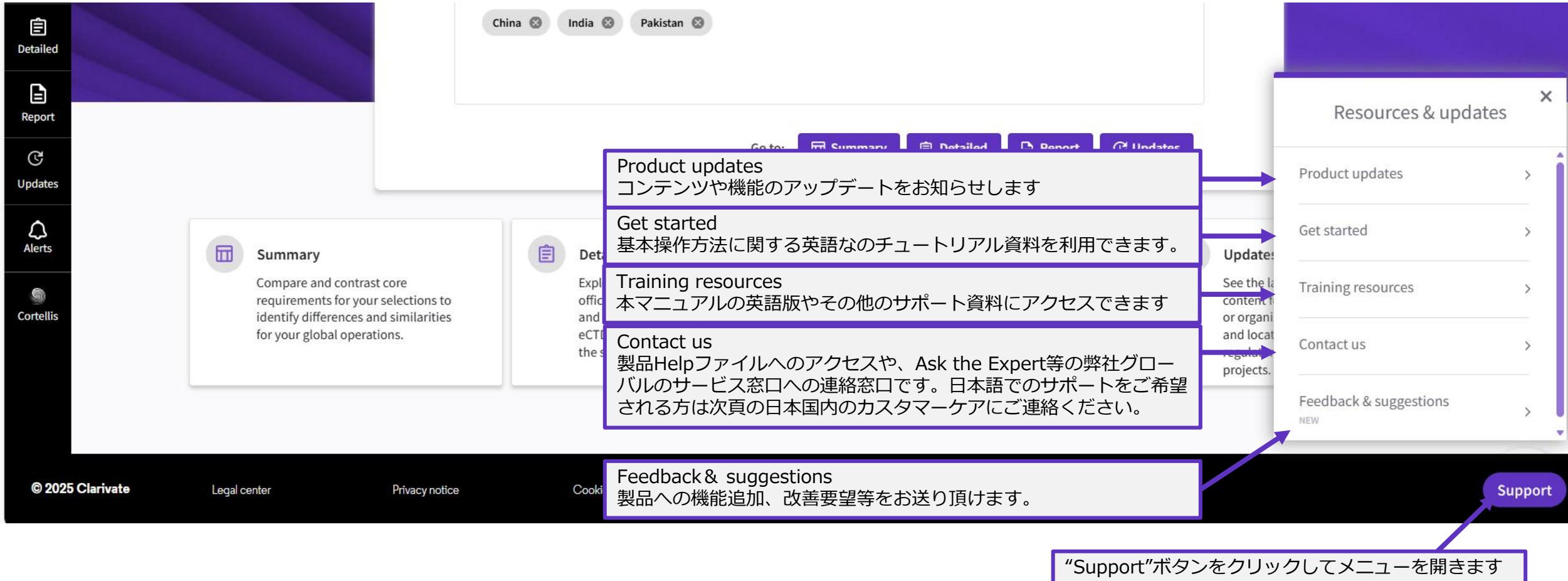
To unsubscribe, please click [here](#)

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。



サポートメニューの表示（英語）

- 画面右下の「Support」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、カスタマーケアの窓口にご連絡ください



ユーザーサポートの充実

・ライフサイエンス&ヘルスケア 製品サポートサイト・Cortellisを初めてお使いになる皆様へ

Cortellis CMC Intelligence

最新のCMC要件と分析を提供

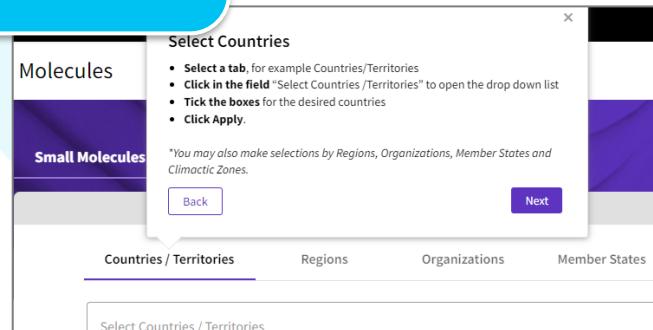
基本編

- 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
- データベース内の略語集
- Cortellis CMC Intelligence - Factsheet (英語)

利用事例

製品内ガイドツアー

データベースの基本ワークフローの各ステップを解説するツアーでスムーズに使い始めていただけます。



ウェブセミナー録画版・ビデオ

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業務のためのデータベースとして、Cortellis CMC Intelligenceをご紹介いたします。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に、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できます。

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・検索タグによるアラートの設定(15:40)
5. "Document Type" フィルタ(19:08)
6. ガイドラインのモニタリーポートのご紹介(22:20)
7. CMC Intelligenceを用いたライン文書へのアクセス
8. CMC Intelligenceを用いたターリング(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

☎ 0800-170-5577(フリーダイヤル)
(土日祝日を除く) 9:30~17:30
✉ 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。

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していただけます。