



# Cortellis CMC Intelligence

## 市販後変更申請対応

発効予定ガイドラインやドラフト版文書、意見募集中のガイドライン案  
情報をアップデートする

例：中国におけるバイオロジクス製品の市販後変更申請または臨床試験アmendメントに関連するガイドライン、ドラフト版の文書、意見募集中のガイドライン案を確認する

Cortellis CMC Intelligence | Biologics | Post Approval Changes & Clinical Trial Amendments

The screenshot displays the Cortellis CMC Intelligence web application. On the left is a dark sidebar with navigation icons and labels: Home, Summary, Detailed, Report, Updates, and Alerts. The main content area has a purple header with two tabs: 'Small Molecules' and 'Biologics'. A blue arrow points to the 'Biologics' tab with the label 'Biologicsを選択'. Below the tabs are two radio buttons: 'Pre-Approval' and 'Post Approval Changes & Clinical Trial Amendments'. A blue arrow points to the second radio button with the label '市販後変更 & クリニカル アmendメントを選択'. Under these radio buttons are five tabs: 'Countries / Territories', 'Regions', 'Organizations', 'Member States', and 'Climatic Zones'. The 'Countries / Territories' tab is active. Below it is a search bar labeled 'Search Countries / Territories' containing the text 'china'. A blue arrow points to the search bar with the label '中国を検索し、選択'. Below the search bar, the result 'China' is listed with a checked checkbox. At the bottom right of the modal are two buttons: 'Cancel' and 'Apply'. A blue arrow points to the 'Apply' button with the label '選択完了後にApplyをクリック'.

Home

Summary

Detailed

Report

Updates

Alerts

Small Molecules

Biologics

Pre-Approval

Post Approval Changes & Clinical Trial Amendments

Countries / Territories

Regions

Organizations

Member States

Climatic Zones

Search Countries / Territories

china

China

Cancel

Apply

☐ Pre-Approval ☒ Post Approval Changes & Clinical Trial Amendments

< **Countries / Territories (1)** Regions Organizations Member States Clima >

Select Countries / Territories

Countries / Territories Selected (1)

Clear all

China



Go to:



Summary



Detailed



Report



Updates

Reportをクリック

## Upcoming Guidelines and Draftsを選択

## Upcoming Guidelines and Drafts

Last Change Date 18-Sep-2025

China

**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

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 comments.
- 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.