



# 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メンドメントに関するガイドライン、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 shows the Cortellis CMC Intelligence interface. On the left is a vertical navigation bar with icons for Home, Summary, Detailed, Report, Updates, and Alerts. The main content area has a purple header with tabs for Small Molecules and Biologics. The Biologics tab is selected, indicated by a blue box and an arrow labeled "Biologicsを選択". Below the tabs is a radio button group for Pre-Approval and Post Approval Changes & Clinical Trial Amendments. The Post Approval Changes & Clinical Trial Amendments option is selected, indicated by a blue box and an arrow labeled "市販後変更 & クリニカルアメンドメントを選択". The main search area has tabs for Countries / Territories, Regions, Organizations, Member States, and Climatic Zones. The Countries / Territories tab is selected. A search bar contains the text "china", with a blue box and an arrow labeled "中国を検索し、選択" pointing to the "China" option, which has a checked checkbox. At the bottom right are "Cancel" and "Apply" buttons, with a blue box and an arrow labeled "選択完了後にApplyをクリック" pointing to the "Apply" button.

Pre-Approval Post Approval Changes & Clinical Trial Amendments

Countries / Territories (1)

Regions

Organizations

Member States

Climate



Select Countries / Territories



Countries / Territories Selected (1)

Clear all

China

Go to:

Summary

Detailed

Report

Updates

Reportをクリック



Home



Summary



Detailed



Report



Updates



Alerts



Cortellis

## Upcoming Guidelines and Draftsを選択

Key Facts

Upcoming Guidelines and Drafts

Procedures

➤ Detailed Requirements

Sources

Change History

### 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 the 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 the common technical document for the registration of pharmaceuticals for human use: quality, which will be used for the registration of new and generic 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.