



Cortellis CMC Intelligence

新規申請対応

CTD Module3に沿って各国の規制要件と現地慣行を理解する

新規申請時の各国要件の詳細について、DetailedセクションにてCTDモジュール3のセクションごとに容易に把握することが可能です。（Detailedセクションの詳細については頁5-8を参照ください。）

例：インドにおけるバイオ医薬品の新規申請において、製剤のプロセス・バリデーションの規制要件と現地慣行を理解する

The screenshot displays the Clarivate application interface. At the top, there are two tabs: "Small Molecules" and "Biologics". A blue box with an arrow points to the "Biologics" tab, labeled "Biologicsを選択". Below the tabs, there are two radio buttons: "Pre-Approval" (selected) and "Post Approval Changes & Clinical Trial Amendments". A blue box with an arrow points to the "Pre-Approval" radio button, labeled "新規申請を選択". Below the radio buttons, there are five tabs: "Countries / Territories (1)", "Regions", "Organizations", "Member States", and "Climatic Zones". A blue box with an arrow points to the "Countries / Territories (1)" tab, labeled "国を指定する". Below the tabs, there is a dropdown menu labeled "Select Countries / Territories". Below the dropdown menu, there is a section titled "Countries / Territories Selected (1)" with a "Clear all" link. In this section, "India" is listed with a close button. At the bottom, there is a "Go to:" section with four buttons: "Summary", "Detailed", "Report", and "Updates". A yellow box highlights the "Detailed" button, and a blue box with an arrow points to it, labeled "Detailedをクリックする".

例：インドにおけるバイオ医薬品の新規申請において、製剤のプロセス・バリデーションの規制要件と現地慣行を理解する
 Detailed Requirements → CMC Requirements → Manufacture → Process Validation and/or Evaluation

Cortellis CMC Intelligence | Biologics | Pre-Approval

Home | Filter Menu...

Summary | **Detailed Requirements**

- Clinical Trial Requirements
- Marketing Authorization Requirements
- CMC Requirements - Drug Substance
- CMC Requirements - Drug Product**
 - P.1 Description and Composition of the Drug Product
 - P.2 Pharmaceutical Development
 - P.3 Manufacture**
 - P.3.1 Manufacturer
 - P.3.2 Batch Formula
 - P.3.3 Description of Manufacturing Process and Process Controls
 - P.3.4 Controls of Critical Steps and Intermediates
 - P.3.5 Process Validation and/or Evaluation**
 - P.4 Control of Excipients

P.3.5 Process Validation and/or Evaluation

Filters | Search | Local Practice | Null Results

India < 1 of 2 > ☆

Official Regulations | FPP

- Description, documentation, and results of the validation and/or evaluation studies should be provided for critical steps or critical assays used in the manufacturing process (e.g., validation of the sterilization process or aseptic processing or filling). Viral safety evaluation should be provided in 3.2.A.2, if necessary.
- The information provided in the study report should support the current manufacturing process proposed for commercial use, including in-process test results and data from relevant manufacturing batches to demonstrate consistency in yield and production, and degree of purity.
- The validation study report for the extent of reuse and integrity of membranes should be provided, including data to demonstrate consistency in the quality and safety of the drug product. The suitability of any proposed reprocessing procedures described in 3.2.P.3.3 and the criteria for reprocessing of any intermediate or the drug substance should be discussed. If adjuvants are added to the drug product, information and data from the adsorption and desorption study should be submitted.
- A summary of the process validation and evaluation studies should also be provided.

Cortellis CMC Intelligence | Biologics | Pre-Approval

Home | Filter Menu...

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P.3.5 Process Validation and/or Evaluation

Filters | Search | Local Practice | Null Results

India < 1 of 2 > ☆

Official Regulations | FPP

Local Practice

Product Type: FPP
 Drug Type: Drug Product
 Submission Type: New Biological Drug, Biosimilar
 Pathway: Standard Procedure
 Category: Vaccine, Monoclonal Antibodies, Recombinant hormones/Proteins, Blood/Blood components, Cell Therapy, Gene Therapy, Tissue, Combination Product
 Dosage Form: Injectable
 Route of Administration: Parenteral, Parenteral - Combination Product
 Origin: Local, Foreign

SourceID: [17](#) [40](#) [3704](#) [3705](#) [3707](#) [3722](#) [3723](#) [3725](#) [3734](#)

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。
- 任意の国の情報が常に一番左側に表示されるようピン止めすることができます。
 - この画面の例では、“CMC Requirements – Drug Substance > Impurities > General Information” の規制要件を表示しています

Cortellis CMC Intelligence | Small Molecules | Pre-Approval

表示しているトピック

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

Official Regulations: 各国規制当局によって定められた規制要件の詳細を記載

Local Practice: 各国コンサルタントによる、現地慣行に関する追加コメント

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

Filter Menu...

Detailed Requirements

- > Clinical Trial Requirements
- > Marketing Authorization Requirements
- > CMC Requirements – Drug Substance
 - > S.1 General Information
 - > S.2 Manufacture
 - > S.3 Characterization
 - S.3.1 Elucidation of Structure and other Characteristics
 - > S.3.2 Impurities
 - General Information**
 - Residual Solvents

China < 1 of 2 > ☆

Official Regulations | IMP

3.2.S.3.2 - Impurities:

SFDA Circular No. 16 of 2018 for Phase I studies

- Preliminary impurity profile analysis results, potential genotoxic impurity control strategies, and analytical information should be provided.
- The study can be studied and submitted in accordance with the ICH M7 guidelines.

SFDA Circular No. 48 of 2018 for Phase III studies

- List describes the analysis of impurities, including impurities name and / or code, structure, source, whether set the standard safety limits and other support.
- Information on the relative retention time, whether it is a specific impurity control in the

India < 1 of 2 > ☆

Official Regulations | FPP

S.3.2: Impurities:
Information on impurities should be provided.

Local Practice

Product Type: FPP
Submission Type: New Drug, Generic Drug
Drug Type: Drug Substance
Pharmaceutical Form: Not Applicable
Procedure: Standard Procedure, Accelerated Procedure
Country of Origin: Local, Foreign

SourceID: [4](#) [15](#) [17](#) [21](#) [3734](#)

Pakistan ☆

Official Regulations | FPP

As per Guidance document for submission of application on form 5-f (CTD) for registration of pharmaceutical drug products for human use:

- List of Drug Substance / API-related impurities and process-related impurities shall be submitted along with acceptance limits.

Local Practice

Product Type: FPP
Submission Type: New Drug, Generic Drug
Drug Type: Drug Substance
Pharmaceutical Form: Not Applicable

Edit My Selection

Home

Summary

Detailed

Report

Updates

Alerts

Cortellis

Clarivate™

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 : 剤型/投与
経路
- Procedure : 申請方法
(標準審査、優先審査、WHO-PQ
etc.)
- Country of Origin :
生産国 (現地・外国)

Detailed 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。
- 現地慣行“Local Practice” の表示/非表示を切替えられます。
- 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。

The screenshot displays the 'Detailed Requirements' section of a web application. The left sidebar contains navigation options: Home, Summary, Detailed (highlighted), Report, Updates, Alerts, and Cortellis. The main content area is titled 'Clinical Trial Application Procedure' and includes a 'Filter Menu...' search bar. Below the search bar, there are filter controls: 'Filter:' with a dropdown arrow, a search input, and checkboxes for 'Local Practice' (checked) and 'Null Results' (unchecked). A 'Clear all' button is located below the filter controls. The main content area is divided into three columns representing different countries: China, India, and Pakistan. Each column shows 'Official Regulations | IMP' and provides detailed technical requirements for overseas marketed and domestic unlisted drugs. Annotations in purple boxes highlight key features: '選択中のフィルター項目' points to the filter controls; 'Local Practice 表示/非表示 Null Results 表示/非表示' points to the checkboxes; and '"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' points to the 'Clear all' button.

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

Cortellis CMC Intelligence | Small Molecules | Pre-Approval

The screenshot displays the 'Detailed Requirements' section of the Cortellis CMC Intelligence interface. The left sidebar shows a navigation menu with 'Detailed' selected. The main content area is titled 'BE waivers' and features a search bar with the keyword 'bioequivalence'. Below the search bar, there are two columns representing different regions: 'China' and 'India'. Each column contains a section titled 'Official Regulations | FPP'. In the 'China' section, the text 'Bioequivalence' is highlighted in yellow. In the 'India' section, the text 'bioequivalence' is highlighted in yellow. A callout box points to the search bar, stating: '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ます'. Another callout box points to the highlighted text in the 'India' section, stating: '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'. A third callout box points to the 'Detailed' tab in the sidebar, stating: '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'. The Clarivate logo is visible in the bottom left corner.