

Quick Guide Series: No. 8

<https://www.cortellis.com/intelligence>

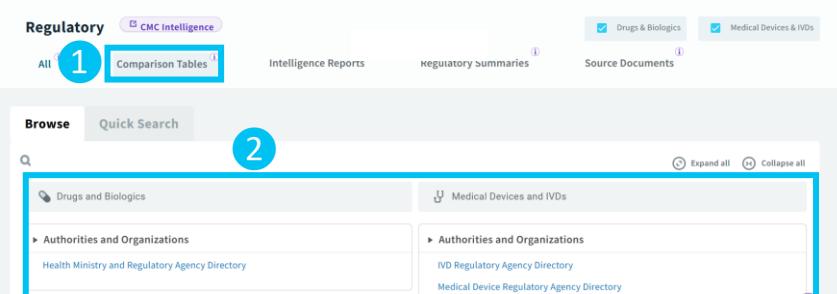
[世界の規制要件を比較する]

CortellisのGlobal Regulatory Comparisonsは、ご購読いただいている国の最新規制要件を比較・把握していただくための表です。各国における規制関連項目や要件を抽出し、一覧表にまとめ、日々更新しています。

Excel形式でエクスポートして分析いただけます。

グローバルな規制対応戦略を迅速に策定したり、各国で共通あるいは異なる規制要件を俯瞰的に把握できます。

Regulatoryホームページ



The screenshot shows the Cortellis Regulatory homepage. At the top, there are navigation tabs: 'Regulatory', 'CMC Intelligence', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. Below these are two main sections: 'Drugs & Biologics' and 'Medical Devices & IVDs'. Under 'Drugs & Biologics', there are links for 'Authorities and Organizations' (Health Ministry and Regulatory Agency Directory) and 'IVD Regulatory Agency Directory'. Under 'Medical Devices & IVDs', there are also links for 'Authorities and Organizations' (Medical Device Regulatory Agency Directory). A 'Browse' button and a 'Quick Search' bar are at the top left. A 'Comparison Tables' button is highlighted with a blue box and a circled '1'. A '2' is circled in blue over the 'Authorities and Organizations' link under 'Drugs & Biologics'.

- 1 Regulatoryホームページの"Comparison Tables"をクリックし、トピック一覧を表示します。
- 2 ご覧になりたいトピック名（青字）をクリックするとレポートが開きます。

【Global Regulatory Comparisons トピック一覧】 (Drugs and Biologics)

- Authorities and Organizations
 - ✓ Regulatory and Governmental Bodies
 - ✓ Transparency
- Legal Definitions and Marketing Requirements
 - ✓ Biosimilar products
 - ✓ Generic Products
 - ✓ Pharmaceutical Laws and Regulations
 - ✓ Pharmacopoeias
- Format & Content of Applications
 - ✓ CTD/eCTD Acceptability
 - ✓ Stability Data and Conditions for Finished Products
- Marketing Authorization Procedures
 - ✓ Access to Unapproved Drugs
 - ✓ Change of manufacturing site (finished product)
 - ✓ Market Authorization Approval Expected Authority Review Times
- Fees
 - ✓ Pre & Post-Approval Fees
- Product Information
 - ✓ Packaging / Labeling
- Clinical Research
 - ✓ Clinical Trial Application and Ethics Committee Expected Authority Review Times
 - ✓ Clinical Trial Application: Local Requirements
 - ✓ Clinical Trial Registries and Results Disclosure
 - ✓ Investigational Medicinal Product (IMP) Labelling
- Quality Assurance
 - ✓ GxPs
- Pharmacovigilance & Risk Management
 - ✓ Post-Marketing Expedited Reporting
 - ✓ Post-Marketing Periodic Reporting
 - ✓ Pre-Marketing Expedited Reporting
 - ✓ Pre-Marketing Periodic Reporting
 - ✓ Risk Management and Qualified Person for Pharmacovigilance
- Import and Export
 - ✓ Certificate of Pharmaceutical Product

【Global Regulatory Comparisons トピック一覧】 (Medical Devices and IVDs)

- Authorities and Organizations
 - ✓ Regulatory Bodies
- Legal Definitions and Marketing Requirements
 - ✓ Medical Devices and IVDs Laws and Regulations
 - ✓ Medical Devices and IVDs Product Classifications
- Market Clearance
 - ✓ Medical Devices and IVDs Marketing Application Procedures
 - ✓ Medical Devices and IVDs Post-Marketing Device Modifications
- Product Materials
 - ✓ Medical Devices and IVDs Advertising Requirements
 - ✓ Medical Devices and IVDs Labeling Requirements
- Quality Management System Requirements
 - ✓ Medical Devices and IVDs Quality Management Systems & Inspections
- Market Surveillance
 - ✓ Medical Devices and IVDs Adverse Incidents Reporting
- Import and Export
 - ✓ Medical Devices and IVDs Import and Export Requirements

【Global Regulatory Comparisonsのレポート】

【Abstract】

Market Authorization Approval Expected Authority Review Times

Abstract

This subject provides regulatory authorities' expected timelines for a standard and priority review (i.e. evaluation or assessment) of a market authorization/drug application.

When available, expected timelines for a standard application's validation (i.e. filing or screening) occurring prior to formal review of drug efficacy/safety/efficacy are indicated.

All timesframes (numeric value - maximum number of days) provided in this subject are identified as legislated (when stated in laws), regulated (if based on regulations or Agencies' guidance/s) or targeted performance times (if derived by Agencies' practice / websites).

For countries which do not have any publicly available review time information, the numeric value is left empty but locally experienced timelines are noted based on CRI

1 Abstract

各比較表のAbstractでは、収録内容や表中の記載事項についての編集方針等を確認できます

【Global Comparison】

Global Comparison

Apply Filters

Country/Region	Clock Stop / Applicant's Time to Respond to Request for Supplementary Information	Priority / Accelerated Review Approval Availability	Expected Regulatory Authority Time: Priority Review of Drug Application	Regulatory Summary [Communication, Review & Approval]	Regulatory Review
Argentina	Agency decides on the clock stop duration	Not Available in Country	Not applicable	Marketing Authorization Procedures: Review, Communication and Approval	Marketing Procedure Priority Review
Australia	Under Section 31 of the Therapeutic Goods Act, the TGA may request	New Priority Review Pathway Implemented as of 01-Jul-2017 Applicants	Not applicable	Marketing Authorization Procedures: Review, Communication and Approval	Marketing Procedure Priority Review
Austria	Agency decides on the clock stop duration. The applicant may request an extension.	Not Available in Country	Not applicable	Marketing Authorization Procedures: Review, Communication and Approval	Marketing Procedure Priority Review
Belgium	6 months; the period can be extended upon request	Yes, the call centre of the marketing authorisation department of the	No timelines have been provided by authorities	Marketing Authorization Procedures: Review, Communication and Approval	Marketing Procedure Accelerated
Brazil	120 days or the application is determined to be non-submissible	Determined by the agency	Marketing Authorization Procedures: Review, Communication and Approval	Marketing Procedure Accelerated	Marketing Procedure Priority Review

2 Global Comparison

「Global Comparison」表示エリアに比較表がテーブル形式で表示されます。

3 比較表に表示する国指定 : パターン1

My Regionを設定して、簡単に表示する国を指定できます。

4 比較表に表示する国指定 : パターン2

「Country/Region」カラムの「Apply Filters」をクリックすると、フィルター画面が開き、国を指定することができます。見たい国にチェックを入れてapplyボタンをクリックしてください。

5 比較表は、Regulatory Reports (Cortellisの文書) や外部Webサイトへのリンクを含みます。

6 折りたたまれている内容を全て表示できます

セルの内容が多く、全てが表示されない場合セル右下の「...」のアイコンをクリックすると、ポップアップウィンドウで全文を確認できます。

7 スライダーバーで画面を左右にスクロールできます

8 タイトル右端のボタンからAlertを設定し更新をモニターできます。また比較表をExcel形式でダウンロードできます。

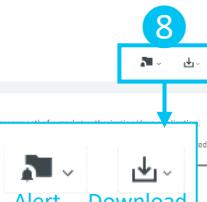
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【Change History】

Change History

Last Update Date	21-Dec-2020		
Added Date	19-Nov-2009		
Date	Country/Region	New/Updated	Section
21-Dec-2020	Algeria	Updated	Reference Texts
17-Dec-2020	Taiwan	Updated	Reference Texts
17-Dec-2020	China	Updated	Reference Texts
17-Dec-2020	China	Updated	Clock Stop / Applicant's Time to Respond to Request for Supplementary Information
17-Dec-2020	China	Updated	Expected Regulatory Authority Time: Priority Review of Drug Application
16-Dec-2020	Algeria	Updated	Expected Regulatory Authority Time: Standard Review of Drug Application
16-Dec-2020	Algeria	Updated	Standard Review Time Notes
16-Dec-2020	Sweden	Updated	Reference Texts
10-Dec-2020	Brazil	Updated	Reference Texts

Cover Sheet Subject Fields Change History +

9 「Change History」タブ (変更履歴)

Global Regulatory Comparisonsの変更履歴はExcelファイル上で確認できます。(Excelファイルは上記「7」のDownload機能で入手できます)

Excelファイルの「Change History」タブをクリックすると、全ての更新情報および追加情報の履歴を参照することができます。

10 上段部分では、比較表の最新の更新日と、この比較表がCortellisに追加された日付が表示されます。

11 下段部分では、全ての更新情報、更新日、および国の詳細が一覧表示されます。