

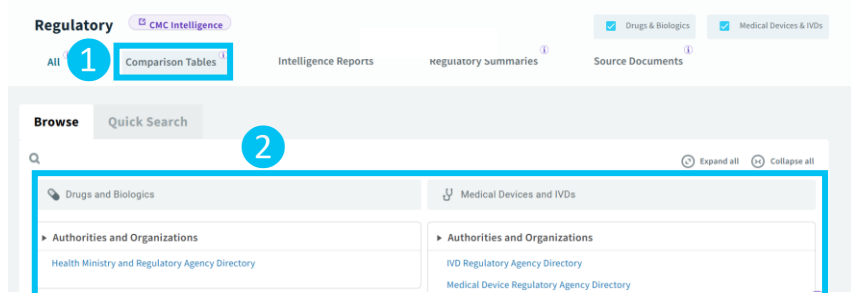
[世界の規制要件を比較する]

CortellisのGlobal Regulatory Comparisonsは、ご購入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



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
 - ✓ GXP
- 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】

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Market Authorization Approval Expected Authority Review Times

5783 Drugs and Biologics Marketing Authorization Procedures

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 timeframes (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 experimented 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】

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Global Comparison

3 My Regions

4 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: Accelerate
Brazil	120 days or the application is	Determining the timeline	Processing time: 120 days, if	Marketing Authorization Procedures: Review, Communication and Approval	Marketing Procedure: Accelerate

5 ?

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Market Authorization Approval Expected Authority Review Times

5783 Drugs and Biologics Marketing Authorization Procedures

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Alert Download

- 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の指定：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の指定：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。

【Change History】

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Change History

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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

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- 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。



クラリベイト
ライフサイエンス & ヘルスケア 事業部
〒107-6118 東京都港区赤坂5丁目2番20号赤坂パークビル18階

【製品に関する問い合わせ】クラリベイト カスタマーケア
ish.support@clarivate.com