



Cortellis Regulatory Intelligence ユーザーガイド

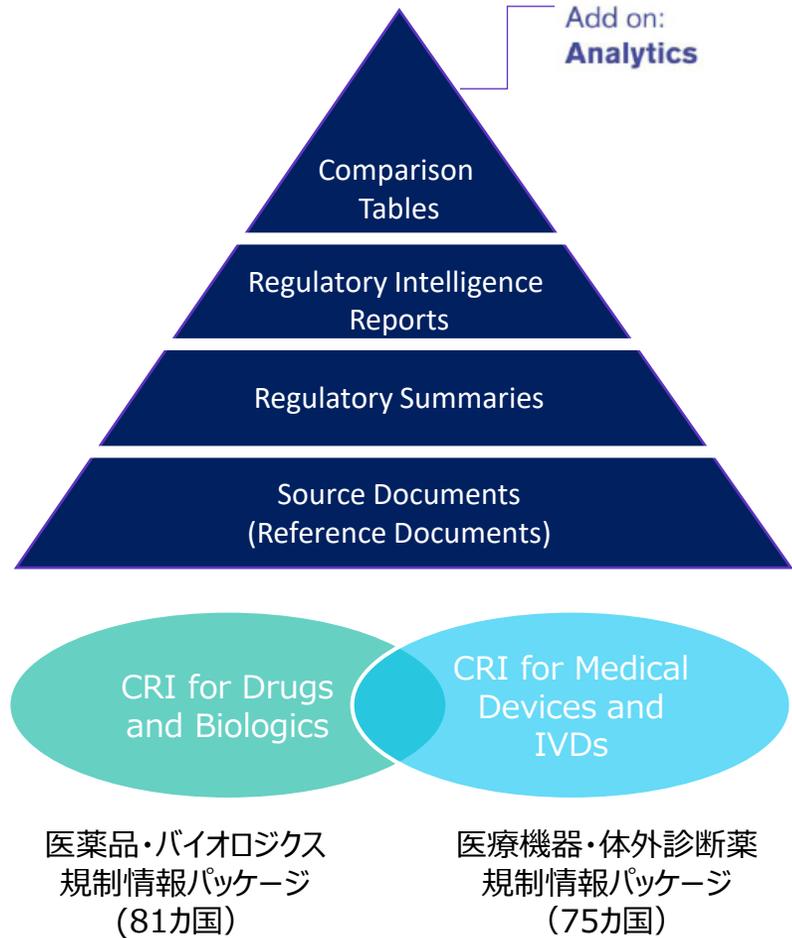
クラリベイト ライフサイエンス&ヘルスケア事業部 | Mar 2024

目次

1. Cortellis Regulatory Intelligence収録文書概要.....	3
2. CortellisログインおよびRegulatoryホームページへのアクセス.....	5
3. 各国規制の解説や分析コンテンツをトピック一覧から選択して閲覧する.....	10
4. Regulatory Report（各種文書）の表示画面、文書のダウンロードやアラート設定.....	16
5. 基本的な検索方法および検索結果画面の各種操作、ダウンロードやアラート設定.....	22
6. その他の検索機能.....	34
7. 設定済みアラートの管理.....	38
8. My Regionsの設定.....	40
9. Side by Side Viewerの使用方法.....	42
10. Cortellis日本語版ユーザーサポートサイト.....	47
11. お問い合わせ先（カスタマーサービス）.....	50
12. 付録： Regulatory Summaries, Intelligence Reports, Comparison Tables主要トピック一覧.....	51

Cortellis Regulatory Intelligence

薬事規制対応のワークフローを支えるコンテンツ



■ Analytics

- 戦略的対応に役立つ実用的インサイトを提供する分析機能
- ※Drugs and Biologicsのみで提供/各国モジュールとは別にご契約が必要

■ Comparison Table

- 各国規制比較
 - Drugs and Biologics:25トピック
 - Medical Devices and IVDs:18トピック

■ Regulatory Intelligence Report

- 規制変更の追跡、競合品との比較、当局とのミーティングや査察準備など、実務にすぐに役立つ分析レポート

■ Regulatory Summary

- 各国の登録プロセス（開発から市販後まで）と主要規制を英語で解説
- 申請ルートや各国の規制実務の理解に役立つコンテンツ
- Cortellisの薬事専門家と各国薬事コンサルタントが作成
- 随時更新

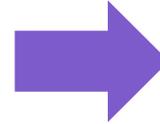
■ Source Document (Reference Document)

- 世界各国の規制文書
 - 旧バージョンや情報公開請求で取得した文書含む
- 200以上の情報源を毎日チェックし、更新
- 英語のタイトル・抄録を付与
- ※一部の国について規制文書全文英訳を作成
- ハイパーリンクや一覧表で新旧バージョンの追跡が可能

Cortellis Regulatory Intelligenceで薬事規制対応の課題を解決



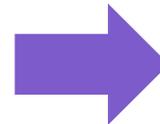
製品を開発・販売する各国の規制を探るのは大変



Cortellisウェブサイトから世界中の薬事規制情報に一度にアクセスできる



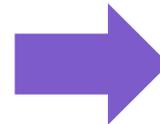
最新規制をタイムリーに入手するのは困難



毎日更新のデータベースで最新情報を確認し、新しい規制をニュースとして入手できる



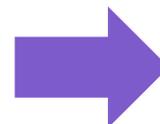
ローカル言語の規制が読めない



Cortellis独自の英語コンテンツを使って、非英語圏の規制を英語で調査・理解できる



国によって規制のレベルや枠組みが異なる中で、規制を比較したり、変更点を随時、把握・理解するのに多大な労力がかかる



規制の変更のモニターや規制の国間の比較といった、規制情報の理解と分析を大幅に効率化できる

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

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innovation
spanning
regulatory

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By signing in, you acknowledge and agree to our [Terms of Use and Privacy Statement](#).

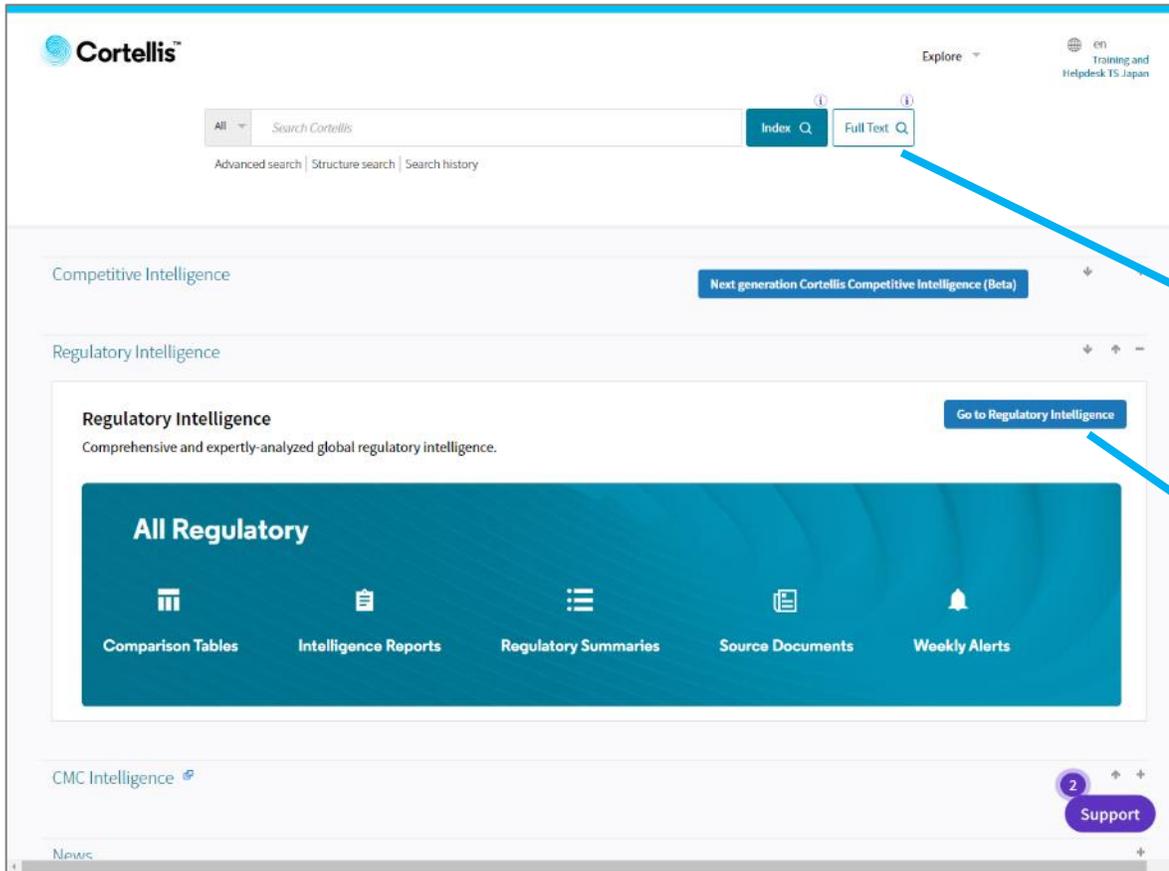
[Cortellis Customer Care](#)

[System Requirements](#)

登録済みのEmailアドレスおよび
パスワードを入力し“Sign in”をクリックします

Cortellisの複数モジュールをご利用の場合

Cortellis の総合ホームページからRegulatory Intelligenceホームページへ

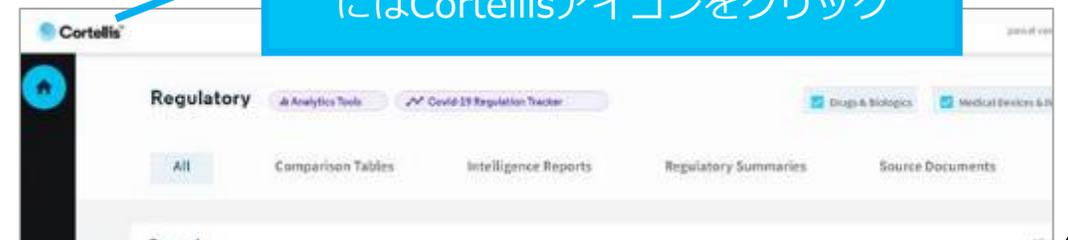


複数データベースをご利用の場合、ログイン後は、Cortellisのホームページ（左図）が表示されます

Cortellis総合ホームページにあるQuick Search・Advanced SearchからのRegulatory Intelligence検索も引き続き可能です

“Go to Reulatory Intelligence” からホームページにアクセス

Regulatory IntelligenceホームページからCortellis総合ホームページに戻るにはCortellisアイコンをクリック



Cortellis Regulatory Intelligenceの ホームページ

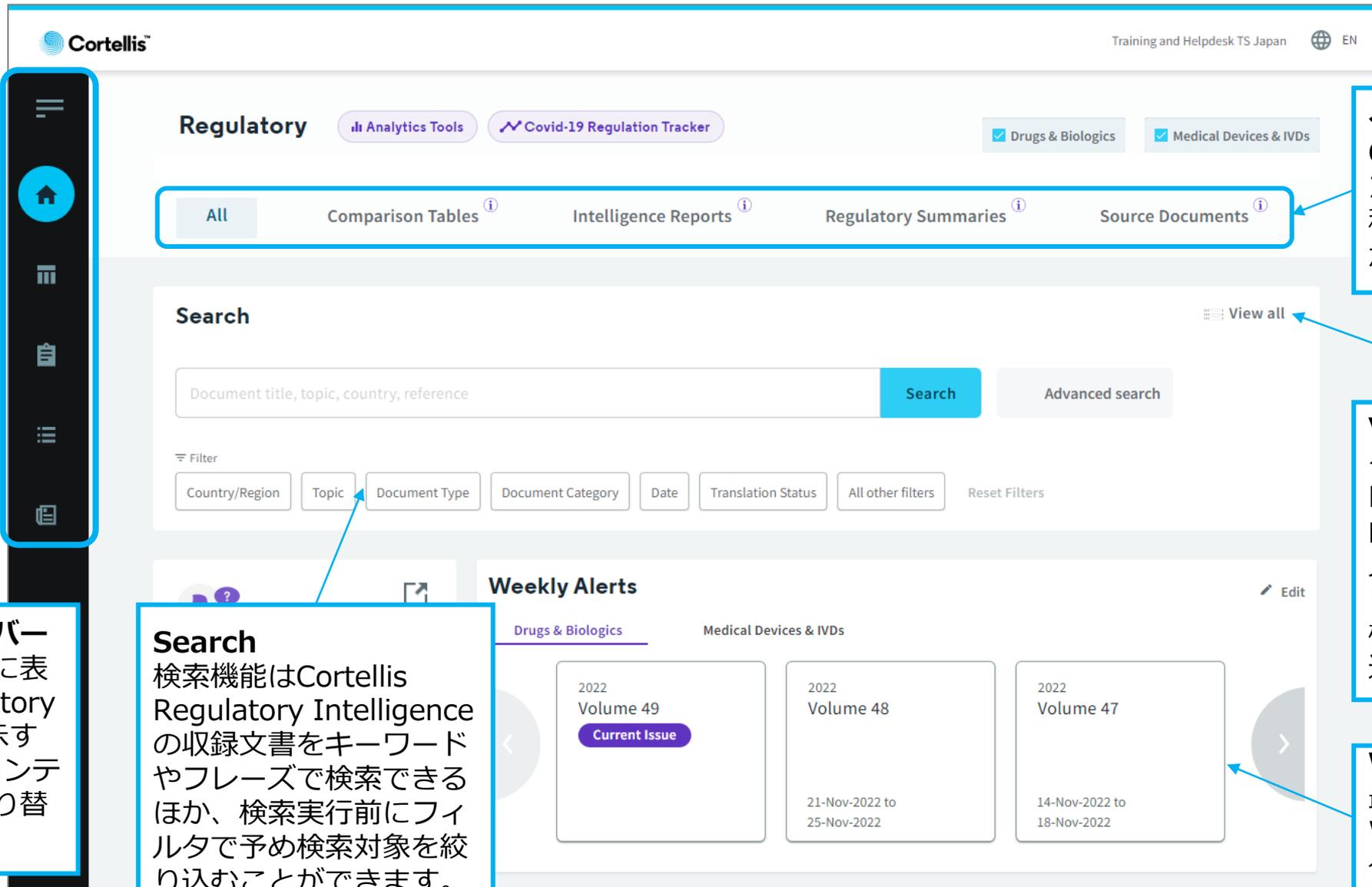
- Regulatory Intelligenceに特化したホームページが開きます

The screenshot displays the Cortellis Regulatory Intelligence homepage. At the top, there's a navigation bar with 'Regulatory' and 'Analytics Tools' tabs. Below this, a search bar is available with a 'Search' button and an 'Advanced search' link. A filter section includes options for Country/Region, Topic, Document Type, Document Category, Date, Translation Status, and All other filters. The 'Weekly Alerts' section features two categories: 'Drugs & Biologics' and 'Medical Devices & IVs'. Under 'Drugs & Biologics', there are three alert cards for 2022: Volume 49 (Current Issue), Volume 48, and Volume 47. The 'Last updates' section contains a bar chart showing the number of updates for different document types over time. The chart data is as follows:

Date	Comparison Tables (12)	Regulatory Intelligence Report (91)	Regulatory Summary (260)	Reference Document (7530)
Nov 14	~100	~100	~100	~100
Nov 21	~100	~100	~100	~100
Nov 28	~100	~100	~100	~100
Dec 05	~100	~100	~100	~100

The 'Analytics Tools' section includes 'Side by Side Viewer', 'FDA warning and untitled letters', and 'FDA advisory committee meetings'. A 'Help' section provides links to 'Quick Start Guide' and 'Contact Us'.

Regulatory Home画面の構成1 (画面上部)



タブの切替
Cortellis独自の規制解説コンテンツなど、特定の種類の文書の閲覧や検索ができます。

View all
クリックするとCortellis Regulatory Intelligence内の全ての収録文書のリストを表示します。リスト表示後、フィルタ機能で必要な文書に絞り込むことも可能です。

Weekly Alerts
最新および過去12週のWeekly Alertsを閲覧、ダウンロードできます

ナビゲーションバー
常に画面の左側に表示され、Regulatory Home (本頁で示す画面)および各コンテンツページに切り替えできます

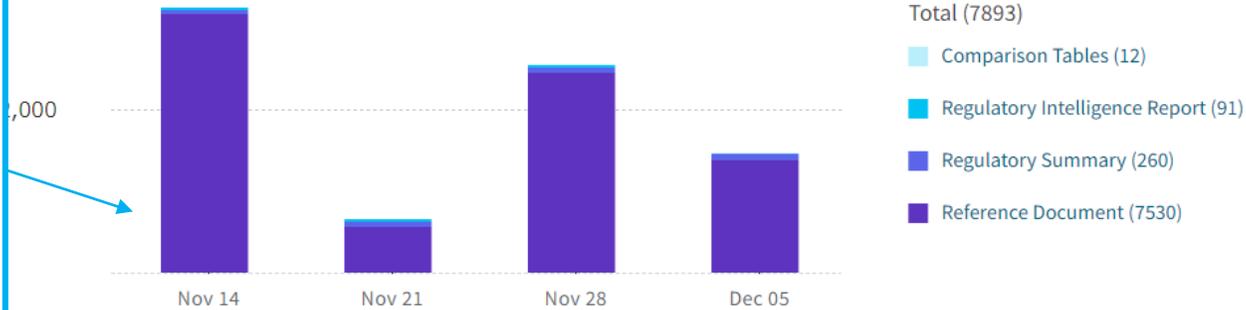
Search
検索機能はCortellis Regulatory Intelligenceの収録文書をキーワードやフレーズで検索できるほか、検索実行前にフィルタで予め検索対象を絞り込むことができます。

Regulatory Home画面の構成2 (画面下部)

Last updates

Cortellis Regulatory Intelligence内の新規文書や更新件数を確認できます。
クリックして最新文書をリストアップ可能です。

Last updates



Analytics Tools



Side by Side Viewer



FDA warning and untitled letters



FDA advisory committee meetings

Analytics Tools

ご契約内容により表示が異なります

Help

- Quick Start Guide
- Contact Us

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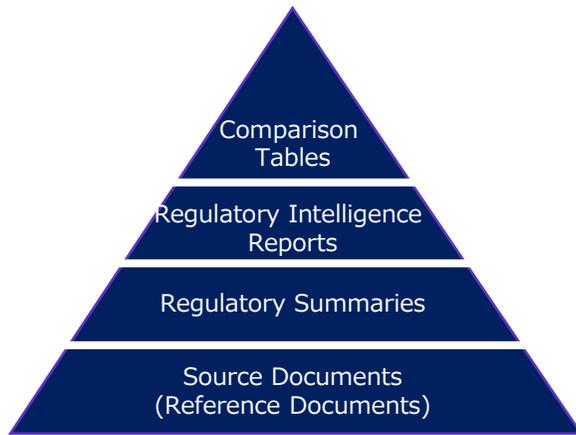
Clarivate™





各国規制の解説や分析コンテンツを
トピック一覧から選択して閲覧する

規制の解説や分析コンテンツへのアクセス



Comparison Tables

- 各国規制比較
- Drugs and Biologics:25トピック
- Medical Devices and IVDs:19トピック

Regulatory Intelligence Reports

- 規制変更の追跡、競合品との比較、当局とのミーティングや査察準備など、実務にすぐに役立つ分析レポート

Regulatory Summaries

- 製品開発から市販後に渡る主要規制を英語で解説
- 申請ルートや各国の規制実務を効率よく理解

本ユーザーガイドの付録（51ページ）で各コンテンツのトピック概要を確認できます。

Cortellis

TrainingandHelpdesk TS Japan EN

Regulatory CMC Intelligence

Drugs & Biologics Medical Devices & IVDs

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents

Browse Search

Filter by Country / Region

Drugs and Biologics Medical Devices and IVDs

Authorities and Organizations

Competent Health Ministries and Regulatory Agencies | Country Summaries

European Institutions and Bodies | Overview

European Heads of Medicines Agency | Overview

Medical Devices Regulatory Framework

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Egypt, Estonia, European Union, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Nigeria, Norway, Panama, Peru, Philippines, Poland

International and Regional Bodies

Association of Southeast Asian Nations

All Comparison Tables Intelligence Reports Regulatory Summaries Source Documents

Browse Search

Drugs and Biologics Medical Devices & IVDs

Authorities and Organizations

Regulatory and Governmental Bodies

Transparency

Regulatory Bodies

Legal Definitions and Marketing Requirements

Biosimilar Products

Medical Devices and IVDs Laws and Regulations

Medical Devices and IVDs Product Classifications

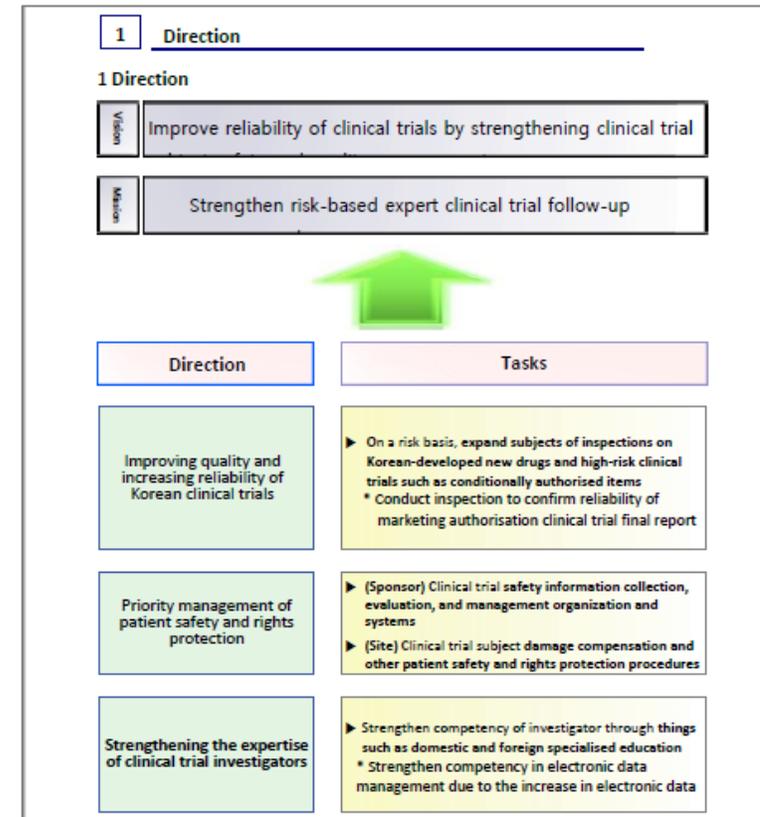
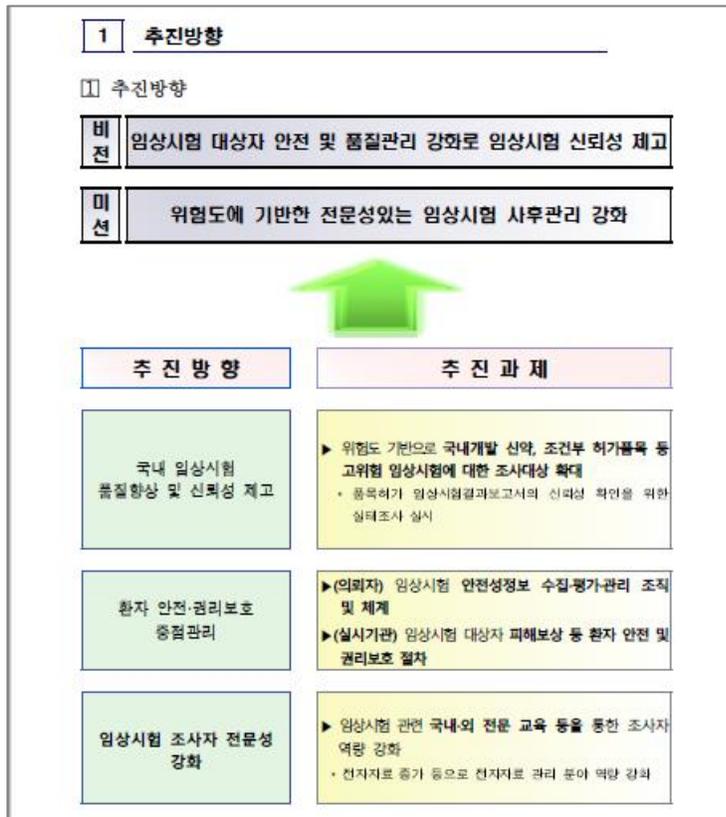
タブを切替えて各コンテンツのトピックを表示 (この画面ではRegulatory Summariesを選択中)

Comparisons Tablesではトピック名をクリックすると比較表が開きます

Source Documents

各国の最新規制文書および過去の文書のアーカイブを提供

- **Source Documents - 各国の規制の知識を持つコンサルタントによってキュレーションされた規制文書**を入手
- 全ての国の現地語の規制文書に加え英語の機械翻訳を付与
- さらに、以下の国を対象にクラリベイトの専門編集員によるマニュアル英語翻訳を付与
- Drugs and Biologics英訳対象国 : China, South Korea, Taiwan, Japan, Brazil, Mexico, Israel, Russia
- Medical Devices & IVDs英訳対象国 : 上記に加えArgentina, Austria, France, Germany, Italy, Spain, Switzerland, Turkey



Regulatory Summaries

各国規制について統一書式で用意された英語での解説文を活用し、規制の全体像を把握

- **Regulatory Summaries**は医薬品の開発段階～市販後までの様々な規制対応プロセスを英語で解説
- 各国で同じトピックの解説文を統一された文書構成で用意、**現地の規制変更に合わせて解説内容も随時アップデート**

- ▼ Q1 Introduction
 - Q1.1 Introduction
 - Q1.2 Legal basis and regulatory framework
- ▼ Q2 GMP requirements
 - Q2.1 General principles
 - Q2.2 Product specific requirements
 - Q2.3 International agreements
- ▼ Q3 GMP certificate
 - Q3.1 GMP certificate
- ▼ Q4 GMP inspections
 - Q4.1 GMP inspections
- ▼ Q5 Additional local information
 - Q5.1 Additional local information

Regulatory Summary

Continuously monitored and updated



Quality Assurance: Good Manufacturing Practice and Inspections (Brazil)

Reason for update	Date	Reason for update description
Content Update	2022-11-21	This update adds Guide 9: On the Conduction of Product Quality Review, 03-Nov-2022 (Version 4) (IDRAC 355160) to Q2.1 and Resolution RDC 757: Transposes to the National Regulation the Mercosur Resolution GMC 31/20 on the Levels of Storage Security in Manufacturing Sites that Work with Controlled Substances, 28-Sep-2022 (IDRAC 355672) to 5.1.
Content Update	2022-09-16	The last update concerns section Q3.1, as impacted by Resolution RDC 743: Establishes the Risk Classification and the Deadlines for Response to the Requirements Subject of Liability Release for Public Acts by Anvisa, 10-Aug-2022 (IDRAC 352208)
General Review	2022-06-08	This update concerns the general information validation with minor changes only
Content Update	2022-05-09	The last review concerns all sections, as impacted by: Resolution RDC 658 (IDRAC 345532) of 30-Mar-2022 Resolution RDC 672 (IDRAC 345472) of 30-Mar-2022 Resolution RDC 654 (IDRAC 345392) of 24-Mar-2022 Resolution RDC 637 (IDRAC 345397) of 24-Mar-2022 Normative Instruction 131 (IDRAC 345606) of 30-Mar-2022 Resolution RDC 669 (IDRAC 345498) of 30-Mar-2022
Formatting Change	2022-02-02	This update contains a change to metadata
Content Update	2022-01-12	The last update concerns section Q2.2 as a result of a general review
Content Update	2021-12-23	The last review concerns sections Q1.2 and Q5.1, as impacted by Normative Instruction 100 of 23-Aug-2021 (Official Consolidated Version up to Amendments Brought by NI 108 of 25-Nov-2021)

Q2.2 Product specific requirements

A) Finished Medicinal Products

ANVISA has published several Normative Instructions (NI) to guide on the specificities of good practices of the different types of products. Please, see section Q1.2 Legal basis and regulatory framework above.

B) Active Pharmaceutical Ingredients (API)

[Resolution RDC 654](#) (IDRAC 345392) of 24-Mar-2022 determines about the Good Manufacturing Practices of Active Pharmaceutical Ingredients (API). The regulation applies to API manufacturers.

ANVISA performs inspection to grant the Good Manufacturing Practices of Intermediate Products and of the Active Pharmaceutical Ingredients (API) Certificate. The Figure 1 below present the steps to ensure GMP compliance for manufacturers of synthetic APIs.

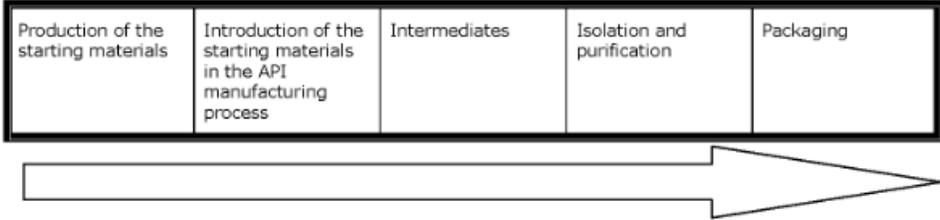


Figure 1- Good Manufacturing Practices - Major steps to focus on in obtaining APIs by synthesis

[Technical Note 06-001/2015-COISC/GGINP/SUINP/ANVISA](#) (IDRAC 218969) presents a set of GMP requirements applicable to starting material to of APIs.

As part of the actions for the surveillance of the Active Pharmaceutical Ingredients Quality Resolution RDC 176 of 07-Jun-2005 (currently outdated) aimed at updating ANVISA's database of importers, distributors and local APIs manufacturers, [Resolution RDC 637](#) (IDRAC 345397) of 24-Mar-2022 organizes a database of the API's marketed in the country and enables the track of all manufacturers and distributors of a certain API. .

B.1) Good Manufacturing Practice of Active Pharmaceutical Ingredients obtained from cell

Intelligence Reports

様々な分析レポートを活用し、規制変更の追跡や競合品の承認情報収集を効率的に実行

- **Intelligence Reports**は規制の最新情報、先行承認品の情報、他社の査察事例、市場アクセス環境など多様な分析レポートを活用した情報収集が可能

Name	Active Ingredient(s)	Application/ Submission/ Type	Application Number	Active Substance Status	FDA Biological Type	FDA Chemical Type
MEN'S ROGAINE	minoxidil	sNDA	21812/016	Known active substance	Not applicable	New dosage form
CADUET	amlodipine ; atorvastatin	sNDA	21540/047	Known active substance	Not applicable	New combination
GONAL-F RFF	folitropin alfa	sBLA	21765/013	Known active substance	Therapeutic biologic	Not applicable
GONAL-F RFF	folitropin alfa	sBLA	21765/014	Known active substance	Therapeutic biologic	Not applicable
GONAL-F RFF	folitropin alfa	sBLA	21765/044	Known active substance	Therapeutic biologic	Not applicable
PROGRAF	tacrolimus	sNDA	210115/004	Known active substance	Not applicable	New dosage form
ASTAGRAF XL	tacrolimus	sNDA	204096/009	Known active substance	Not applicable	New dosage form
GONAL-F	folitropin alfa	sNDA	20378/045	Known active substance	Therapeutic biologic	Not applicable
GONAL-F	folitropin alfa	sNDA	20378/067	Known active substance	Therapeutic biologic	Not applicable
GONAL-F	folitropin alfa	sNDA	20378/075	Known active substance	Therapeutic biologic	Not applicable
JALYN	dutasteride ; tamsulosin hydrochloride	sNDA	22460/011	Known active substance	Not applicable	New combination
MARGENZA	marquetumab-cmkb	NDA	761150	New active substance	Therapeutic biologic	Not applicable
OPDIVO	nivolumab	NDA				

Boxed Warning	Medication Guide	REMS	Pediatric Use	FDA Supplement Type	FDA Supplement Rationale	Link to Product Approval Document
No	No	No	No	Non-efficacy supplement	For revised container (can) label, consumer informat	232584
No	No	No	Yes	Non-efficacy supplement	For revise the drug product established name to "Am	232583
No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labeli	232519
No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labeli	232519
No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labeli	232519
Yes	No	No	Yes	Non-efficacy supplement	Provided for updates to sections of the labeling base	232517
Yes	Yes	No	Yes	Non-efficacy supplement	Provided for updates to sections of the labeling base	232510
No	No	No	No	Non-efficacy supplement	Provided to include updated safety information consi	232372
No	No	No	No	Non-efficacy supplement	Provided to comply with content and format of labeli	232372

米国の承認医薬品一覧とApproval Packageへの一括アクセスを提供するApproval Trackerの例

The screenshot shows the FDA's 'Evaluation Decision' page for a BLA. The left sidebar lists various regulatory categories like 'Licensing', 'Manufacturing Locations', and 'Labeling'. The main content area includes the FDA logo, the STN number (BL 125761/0), the approval date (July 20, 2023), and the recipient's name (Preeya Lowe). The text of the decision states that the BLA for Anthrax Vaccine Adsorbed, Adjuvanted is approved effective as of the date of the decision. It also mentions the associated National Clinical Trial (NCT) numbers.

Comparison Tables

- **Comparison Tables**では各国規制の比較表を用意し**随時アップデート**
例：各国の安定性試験要件の比較表

Abstract

An overview of stability testing requirements for finished pharmaceutical products, as required at the time of submission. Information is provided for long-term (real-time), accelerated, and intermediate testing conditions including: minimum time period, testing frequency (time points), minimum number of batches. Country climatic zone is provided, as defined by the

Last Updated Date
21-Mar-2024

Global Comparison My Regions 

▼ Apply Filters

Country/Region	Climatic Zone	Requirements for Site Specific Stability Data	Long-Term (real time) Testing Conditions	Long-Term (real time) Testing Conditions Notes	Minimum Time Period (real; months)	Time Points (real time)
Algeria	II	Required. Stability batches should be manufactured at the drug ...	25° C ± 2° C/60% RH ± 5% RH	For refrigerated storage: 5° C ± 3° C	Full shelf life. MoH may accept submission with 12 months data but wi ...	First year: every 3 months Second year: every 6 months Third year and ...
Argentina	II	The submission of a stability study is required for purposes of pharm ...	25° C ± 2° C/60% RH ± 5% RH	Data from stability studies must be provided on at least three primar ...	12	0, 3, 6, 9, 12, 18, 24 months
Australia	Ensure stability studies for medicines to be registered in Australia ...	Not required. In the original marketing authorisation application, ...	30° C ± 2° C/65% RH ± 5% RH. If studies under Z ...	N/A	12	As per ICH Topic Q 1 A (R2)
Austria	I	Required	25° C ± 2° C/60% RH ± 5% RH or 30° C & plusm ...	Choice of testing condition made by applicant.	12	0, 3, 6, 9, 12, 18, 24, 36 months, etc



Regulatory Report（各種文書）の表示画面、 文書のダウンロードやアラート設定

Regulatoryレポート（各種文書）表示画面

文書PDFのほか、英語のタイトル、アブストラクト、発出日、関連文書等の情報を確認できます

The screenshot displays the 'Application Format, Content and Submission' page. It includes a navigation sidebar on the left with a table of contents: 1. Summary, 2. Document, 3. Reason For Update, 4. Mentioned Documents, and 5. Mentioned By. The main content area shows the 'Summary' section with an abstract and a table of dates. Below that is the 'Document' section with a language filter set to 'English'. A PDF viewer is open at the bottom, showing a 'Regulatory Summary' document with a table of updates.

Reason for update	Date	Reason for update description
Content Update	2023-12-19	This update revised the NTA Volume 2B Revision 15 Version 1.26.0.0: Application Form for Medicinal Products for Human Use (electronic version) (IDRAC 375790) in sections Q1.5 and Q2.1.4 and the EMA/672643/2017 Rev. 7: Guidance on Paediatric Submissions - Supplcity Web Client (IDRAC 375846) in section Q2.1.3

文書の英語タイトルや索引



ダウンロードやアラート設定等の操作

“Summary”では文書の抄録、バージョン情報、規制の発出日や発効予定日などを確認可能

PDF文書の全画面表示



PDF文書表示エリア

PDF文書内のリンクの他、PDF表示エリア以下の“Mentioned Documents”からも関連文書を確認可能

Source Documentsの翻訳入手方法

Notification: PSB/MDED: No. 1226/1: Revision of Guidance on the Ministerial Ordinance on Standards for the Conduct of Clinical Trials of Medical Devices (Good Clinical Practice), 26-Dec-2023

Valid 379445 Japan Reference Document Notification Translation: Cortellis Translation

Document

Revision English Japanese

File 1

- ▶ Cortellis Translation English version
- ▼ Original file
 - 「医療機器の臨床試験の実施の基準に関する省令」のガイダンスについて」の一部改正について
 - (別添)
 - 1. 第一章 総則
 - ▼ 2. 第二章 治験の準備に関する基準
 - 2-1 第一節 治験の依頼をしようとする者による治験の準備に関する基準

PSB/MDED N

To: Directors of Pharmaceutical Affairs Divisions,
Health Departments (Bureaus),
Prefectural Governments

Medical Devi
Pharma
Ministry of Health

Partial Revision of the "Guidance for the 'Ministerial Ordinance

Cortellis Translationは現地語版と同一PDFファイル内に統合

DPM Announcement Concerning Changes Undertaken by Establishments Manufacturing Medicinal Products for Human Use, 04-Mar-2024

Valid 380444 Tunisia Reference Document Announcement Translation: Machine Translation

Document

Final French

Machine Translated Document

Preview (English) Download (English) View on Side by side

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REPUBLICUE TUNISIENNE
MINISTERE DE LA SANTE
UNITE DE LA PHARMACIE
ET DU MEDICAMENT

Note concernant les changements de fabrication des m

I. Objet et date d'application :

La présente note a pour objet de définir les modalités de traitement des changements entrepris par les établissements de fabrication des médicaments à usage humain au niveau de leur site de fabrication.

La note est applicable dès sa publication sur le site officiel de la Direction de la

機械翻訳はPDF viewer上部のMachine Translated Documentボタンをクリックして入手

一部のIntelligence ReportのExcelファイル取得方法について

一部の収録文書ではダウンロードの方法が異なる場合があります

ダウンロードボタンで文書をダウンロードした場合、下記“取得方法2”と同様の方法で、PDF文書の添付ファイルとしてExcelファイルを取得できます

取得方法1
“Download Excel”ボタン

取得方法2
PDF文書への添付ファイル欄（クリップ型アイコン）からExcelファイルを取得

Document

None English

Download Excel

xlsx-report-165575.xlsx

To download the Excel Spreadsheet attached to this PDF, please click the paperclip icon. paperclip icon, please ensure you have the PDF viewer extension for your browser. difficulties please check the [System Requirements](#) or contact [Customer Support](#) for Help.

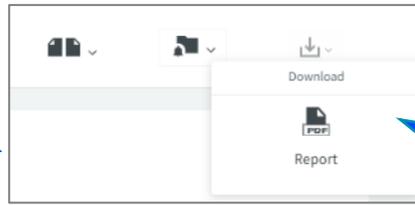
	A	B	C	D	E	F	G
1	Copyright©2020 Clarivate Analytics. All right reserved.						
2	Inspection Starting Date	Inspection Ending Date	FDA Inspector	FDA District Office	Center	Company or Individual Inspected	State/Country/Region
5495	4-Jan-13	17-Jan-13		Kansas City	CDER	Mobius Therapeutics	MO
5496	25-Oct-12	13-Nov-12		Kansas City	CDER	Dyna Labs	MO
5497	30-May-01	8-Jul-01		Team Biologics	CBER	Lonza Biologics	NH
5498	20-Apr-15	27-May-15		Chicago	CDRH	Hospira	IL

この方式でExcelファイルが提供されている文書の例

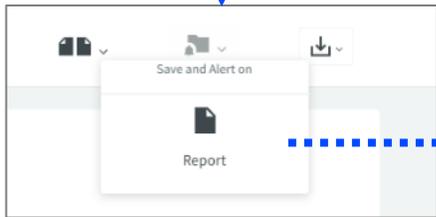
- ICH Guidelines Implementation (IDRAC 165575)

Regulatoryレポート（各種文書）のダウンロードおよびアラート設定

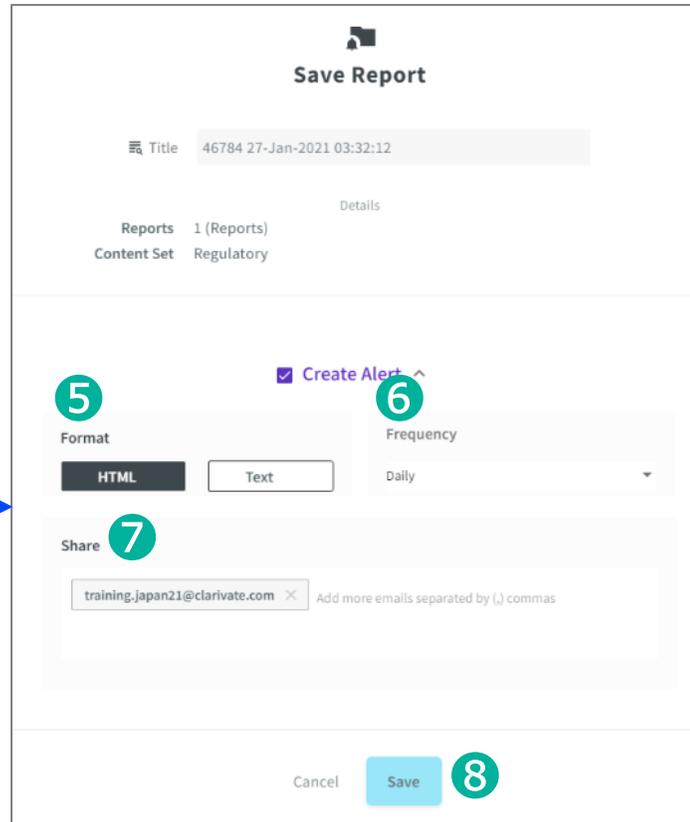
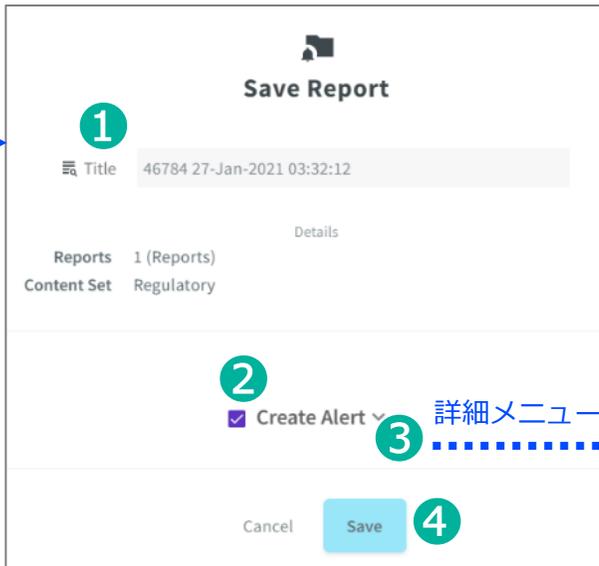
文書タイトル右側のボタンで操作します



“Download”メニュー内の“Report”をクリックすると、すぐに文書のダウンロードが始まります。文書のローカル保存や印刷が可能になります。



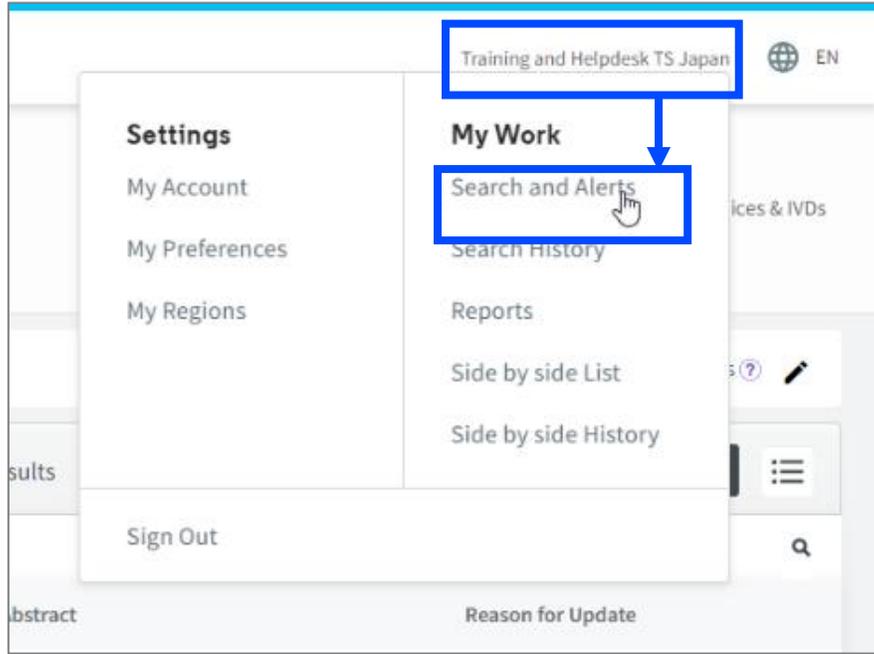
アラート設定



- 1 アラート名を書き換えられます。
- 2 “Create Alert”にチェックが入っている場合、Cortellis内に文書を保存し、かつアラートを設定します。チェックを外すと保存のみ実行しアラートは設定されません。
- 3 “Create Alert”の右側の下向き矢印をクリックすると詳細メニューが開きます。
- 4 詳細設定が不要な場合は“Save”ですぐに設定完了できます。
- 5 アラートメールのフォーマット選択。
- 6 アラート頻度をDaily, Weekly, Monthlyの3種類から選択できます。
- 7 “Share”にご自分以外のeメールアドレスを入力すると、そのeメールアドレスにもアラートメールが送信されます。
- 8 “Save”で設定完了します

上記②のチェック有無にかかわらず、文書はCortellis内に保存されます。この方法で保存した文書はダウンロードとは異なり、Cortellis内でのみ閲覧可能となります。保存済み文書の確認・管理方法は次頁をご覧ください。

設定済みアラートや保存文書の管理



画面右上のユーザー名にカーソルを合わせ、
My Workメニューから“Search and Alerts”をクリック



	Content	Name	Date Created	Alert	Alert Frequency	Options
<input type="checkbox"/>	Regulatory	46801 14-Jan-2021 03:43:55	14-Jan-2021	<input checked="" type="checkbox"/> ON Edit	DAILY	Run Search View Query

“Saved Searches”タブに切り替えると保存済み検索条件、アラート設定済み検索条件を確認できます

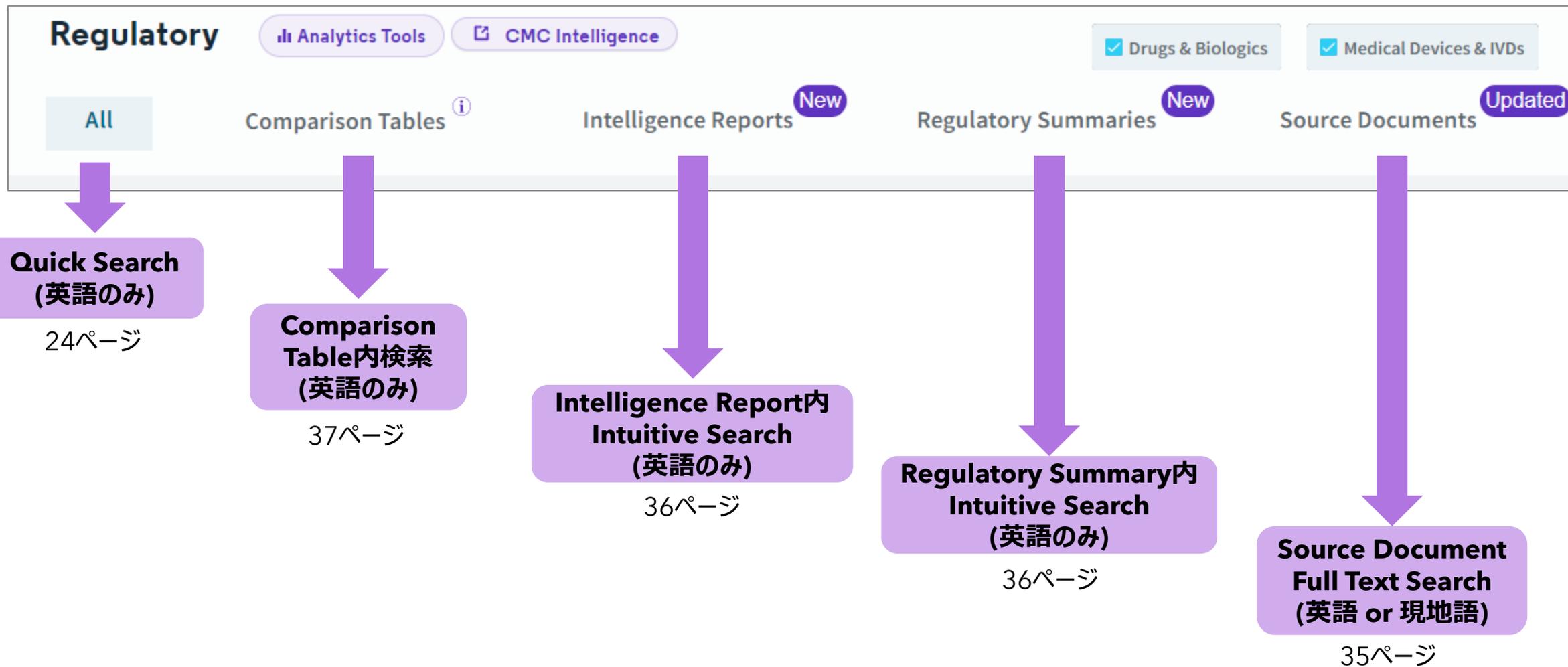
“Saved Reports”タブで保存済み文書、アラート設定済み文書の管理ができます

アラートのON/OFFや削除など



基本的な検索方法および検索結果画面の
各種操作、ダウンロードやアラート設定

コンテンツタブごとの検索機能の役割



検索の基本操作 - Quick Search (Regulatoryホームページ : All)

1. 検索ボックスに任意のキーワードを入力してSearchをクリック

The screenshot shows the 'Regulatory' homepage with a navigation bar containing 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'All' tab is selected. A callout points to the 'All' tab with the text: 'ここでは“All”のタブでの検索機能 (Quick Search)を使用します'. Below the navigation bar is the 'Quick Search' section. A search input field contains the text '"risk management plan"'. To the right of the input field are two buttons: 'Search' and 'Advanced search'. A callout points to the 'Search' button with the text: 'キーワードを入力し “Search”をクリック'. Below the search input field is a 'Filter' section with several filter buttons: 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters'. A callout points to the 'Document Type' button with the text: '予めフィルターで複数の検索条件を指定できます'. On the far left, there is a vertical sidebar with icons for home, list, clipboard, and document.

検索Tips

- “Quick Search”では、検索ワードがタイトルやアブストラクトに含まれる文書が検索結果にリストアップされます。検索語と特に関連性が高い文書を効率的にピックアップできます。
- 検索ワードを入力せずに、フィルターだけを指定して“Search”をクリックすると、フィルター条件に合致する文書を全て抽出できます。キーワードを指定せずに、特定の国や、特定のTopicの文書を網羅的に探せます。

検索の基本操作 - 検索結果の確認

2. “Valid”（最新版/現在有効なバージョン）な文書だけが検索結果に表示されます

The screenshot shows the Cortellis search interface. At the top left is the Cortellis logo. The main header displays 'Regulatory > All Results' and '23,967 results for "risk management plan"'. Below this, there are filters for 'Drugs & Biologics' (checked) and 'Medical Devices & IVDs' (unchecked). A 'Refine Search' dropdown is visible. The search results are sorted by relevance, showing 'Showing 1-10 of 23,967 results'. The first two results are highlighted with blue callouts. The first result is '295252 - TFDA Risk Management Plan(RMP)on Drugs of Truxima - 29-May-2019' with a 'Valid' status. The second result is '202698 - Report: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) - Sep-2014' with a 'Valid' status. A table with columns 'Summary', 'Title', and 'Reason for Update' is shown. The 'Reason for Update' column contains 'N/A' for both results.

検索対象としたいモジュールを切替えることができます (該当するユーザー様のみ)

“Outdated”ステータスの文書を検索結果に含めるためには “Include Outdated”をオンにします

タイトルをクリックすると文書を開きます

検索の基本操作 - “Refine Search” (フィルター)

3. さらに条件を追加して検索結果を絞り込むには“Refine Search”を使用します

検索結果が多すぎる場合や、細かく条件指定したい場合は…

“Refine Search”検索ボックスが閉じている場合は、クリックして展開します 国、トピック、文書の種類などの検索条件を追加して再検索できます

Regulatory > All Results

23,967 results for “risk management plan”

Switch Comparison Tables

Drugs & Biologics Medical Devices & IVDs

Refine Search

Side by Side Viewer

Showing 1-10 of 23,967 results

Include Outdated My Regions

Customize Columns Sorted by Relevance

<input checked="" type="checkbox"/>	Summary	Title	Abstract	Reason for Update
<input checked="" type="checkbox"/>	29-May-2019 <input checked="" type="checkbox"/> TW ZH <input type="checkbox"/> RD <input type="checkbox"/>	295252 - TFDA Risk Management Plan(RMP)on Drugs of Truxima - 29-May-2019	TFDA issues the risk management plan of Truxima.This document includes the information of the product	N/A
<input checked="" type="checkbox"/>	Sep-2014 <input checked="" type="checkbox"/> US EN <input type="checkbox"/> RD <input type="checkbox"/>	202698 - Report: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) - Sep-2014	As part of its PDUFA V commitments, FDA agreed to measure the effectiveness of REMS and to continue to develop	N/A

検索の基本操作 - "Refine Search" (フィルター)

4. 任意のフィルター項目を選択し、改めて"Search"をクリック

Refine Search ⌵ Include Outdated My Regions

"risk management plan" Search

Filter

Country/Region Topic Document Type Document Category Date Filter Last Updated All other filters Reset Filters

Select all Clear all Sort by Frequency

Meeting (3216) Supplemental Approval - NDA (2081) Original Approval - NDA (1847) Public Comment (727)

Supplemental Approval - BLA (467) Inspection Report (427) Federal Register Announcement (347) **Guideline (334)**

Original Approval - BLA (290) Warning Letter (289) Report (254) Citizen Petition (249) Curriculum Vitae (198) Agreement (195)

Cancel Apply

フィルターの選択が終わったら Searchをクリックして全ての条件を適用します

各フィルター項目ごとに "Apply"をクリックして選択を確定します

Regulatory > All Results

334 results for "risk management plan"

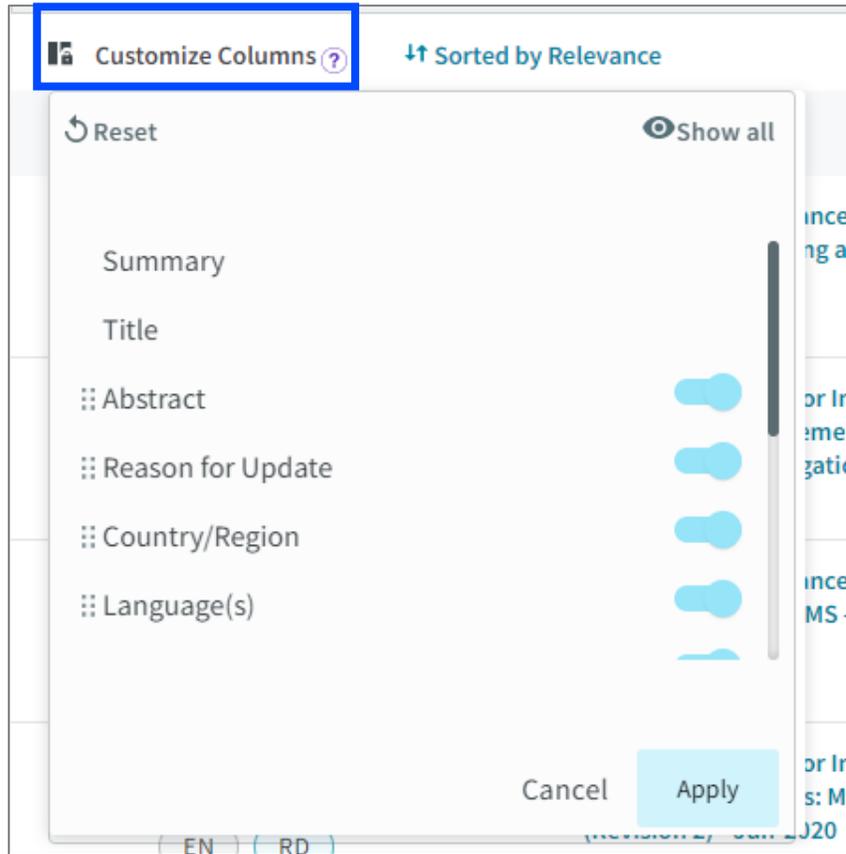
Switch to Comparison

設定条件に合致する文書に絞り込まれます

検索結果画面の表示方法の変更 1 – 検索結果の並べ替え

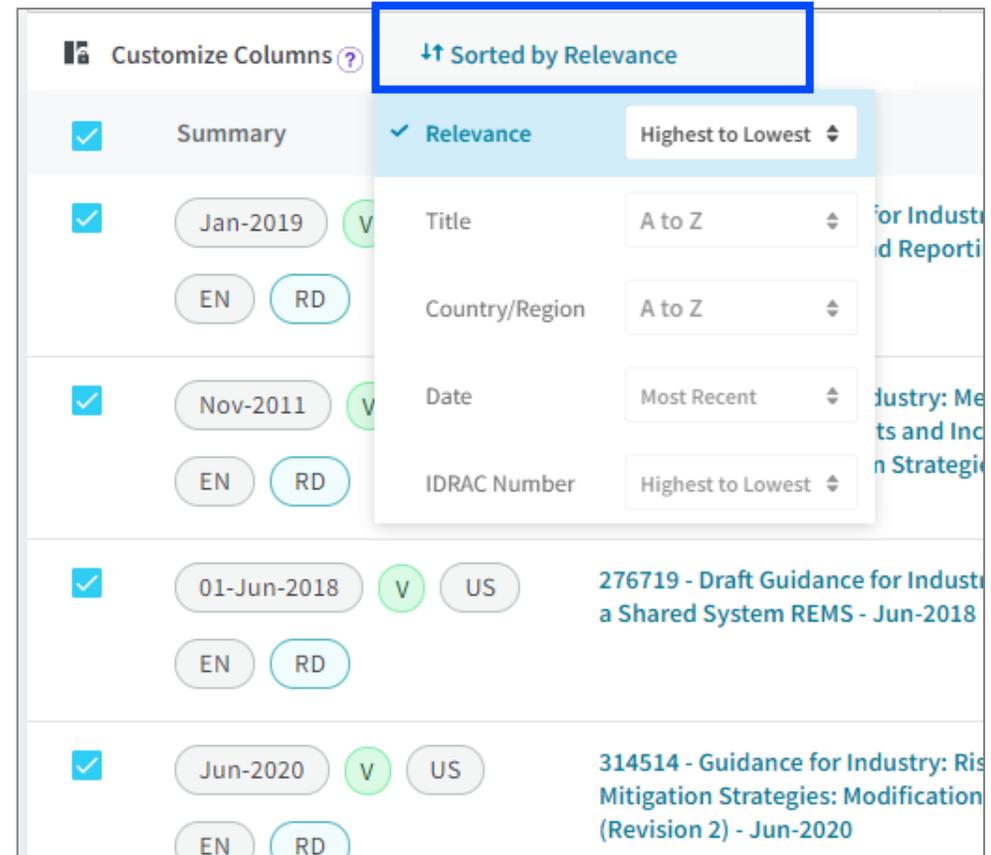
Customize Columns

- 検索結果項目の表示/非表示切替え
- 検索結果項目の表示順序変更



Sorted by...

- 関連度順、発出日順などで検索結果を並べ替え



検索結果画面の表示方法の変更 2 – 検索結果表示方法の変更

Side by Side Viewer | Showing 1-10 of 334 results

Customize Columns ? | Sorted by Relevance

Summary	Title	Abstract	Reason for Update
<input checked="" type="checkbox"/> Jan-2019 V US EN RD	289434 - Draft Guidance for Industry: REMS Assessment: Planning and Reporting - Jan-2019	This document provides guidance to industry on the assessment of risk evaluation and mitigation strategies (REMS)	Formatting Change: Draft guidelines are now available in Public Comments Tracker (IDRAC 290989)
<input checked="" type="checkbox"/> Nov-2011 V US EN RD	134776 - Guidance for Industry: Medication Guides - Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS) (Final) - Nov-2011	This guidance provides information for industry, healthcare providers, and authorized dispensers of prescription drug	Formatting Change: Final guidelines are now available in Public Comments Tracker (IDRAC 290989).
<input checked="" type="checkbox"/> 01-Jun-2018 V US EN RD	276719 - Draft Guidance for Industry: Development of a Shared System REMS - Jun-2018	This guidance provides recommendations to industry on the development of a shared system risk evaluation and mitigation	Formatting Change: Draft guidelines are now available in Public Comments Tracker (IDRAC 290989)

Grid View
標準の表示方法

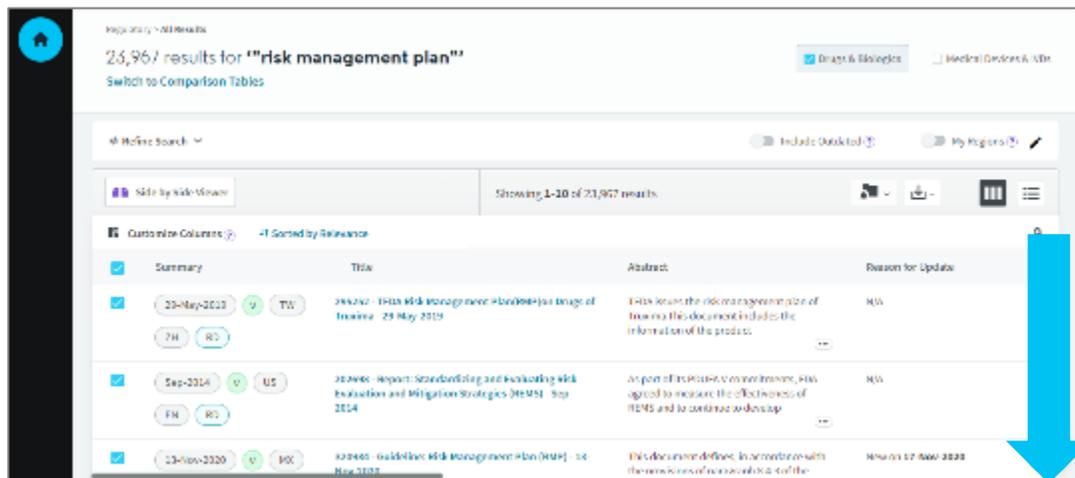
List View
タイトルとAbstractに絞って検索結果を表示

Summary

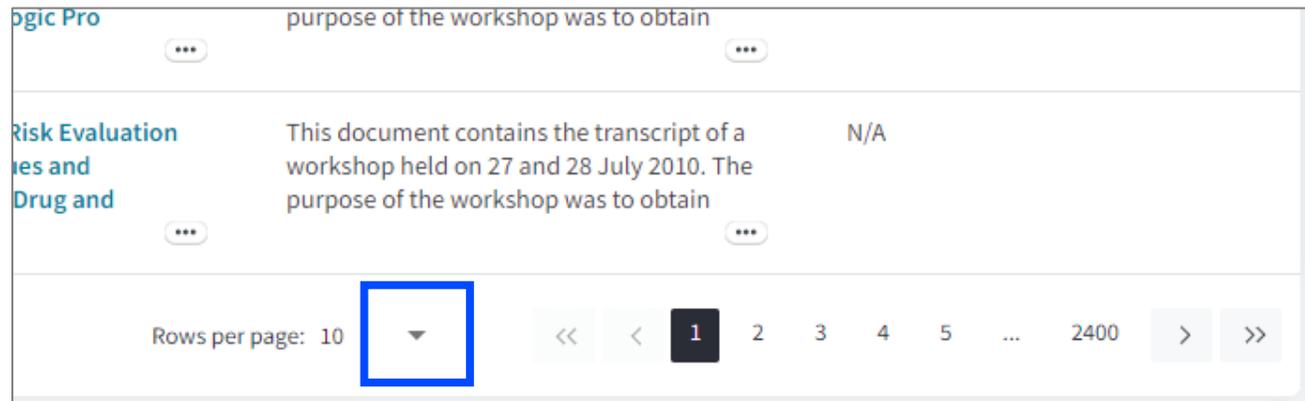
<input checked="" type="checkbox"/> Jan-2019 V US EN RD	289434 - Draft Guidance for Industry: REMS Assessment: Planning and Reporting - Jan-2019	This document provides guidance to industry on the assessment of risk evaluation and mitigation strategies (REMS) for prescription drug products, inc
<input checked="" type="checkbox"/> Nov-2011 V US EN RD	134776 - Guidance for Industry: Medication Guides - Distribution Requirements and Inclusion in Risk Evaluation and Mitigation Strategies (REMS) (Final) - Nov-2011	• When a Medication Guide will be required as part of a risk evaluation and mitigation strategy (REMS).

検索結果画面の表示方法の変更 3 - 1ページ内の検索結果表示件数の変更

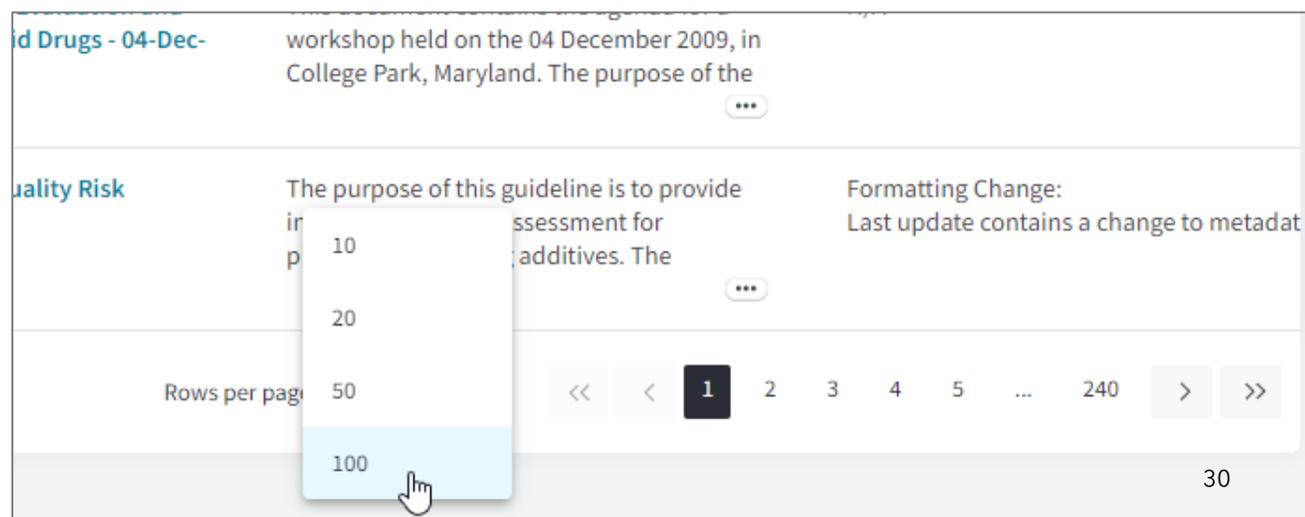
1. 検索結果ページ最下部までスクロール



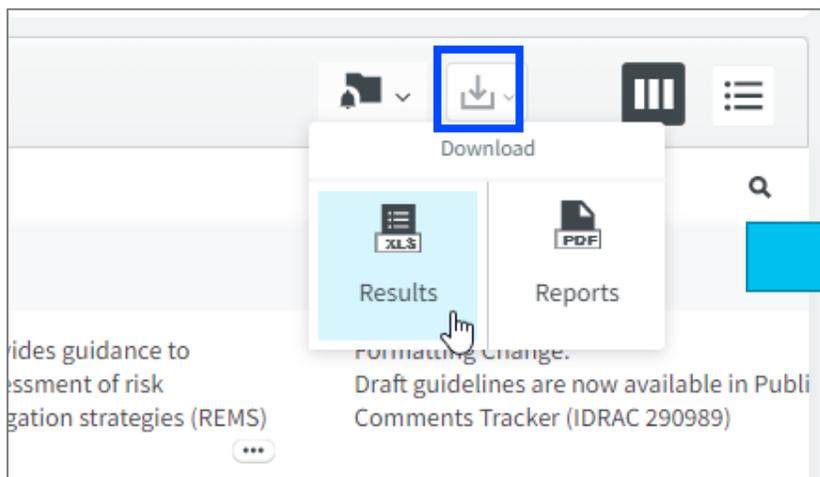
2. "Rows per page"の右側の▼をクリック



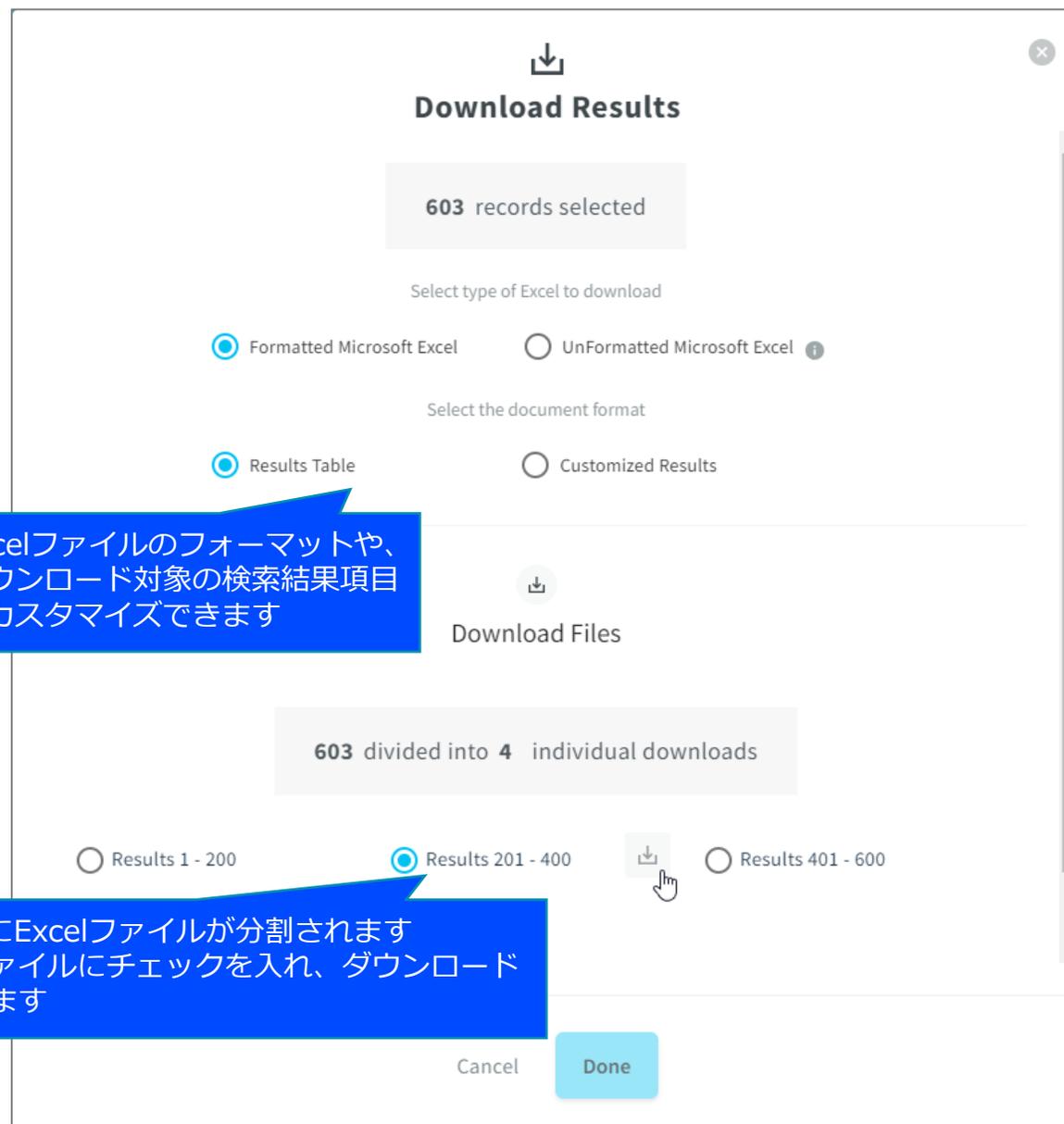
3. 任意の表示件数を指定



検索結果のダウンロード



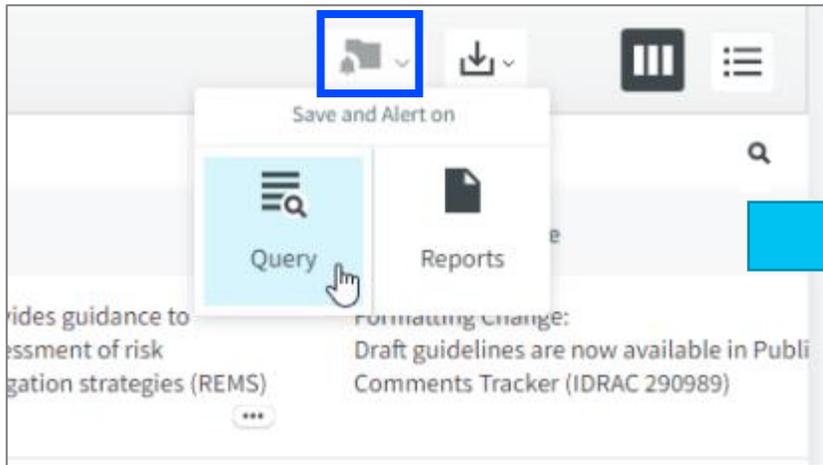
検索結果右上のDownloadメニューからResultsをクリック



Excelファイルのフォーマットや、ダウンロード対象の検索結果項目をカスタマイズできます

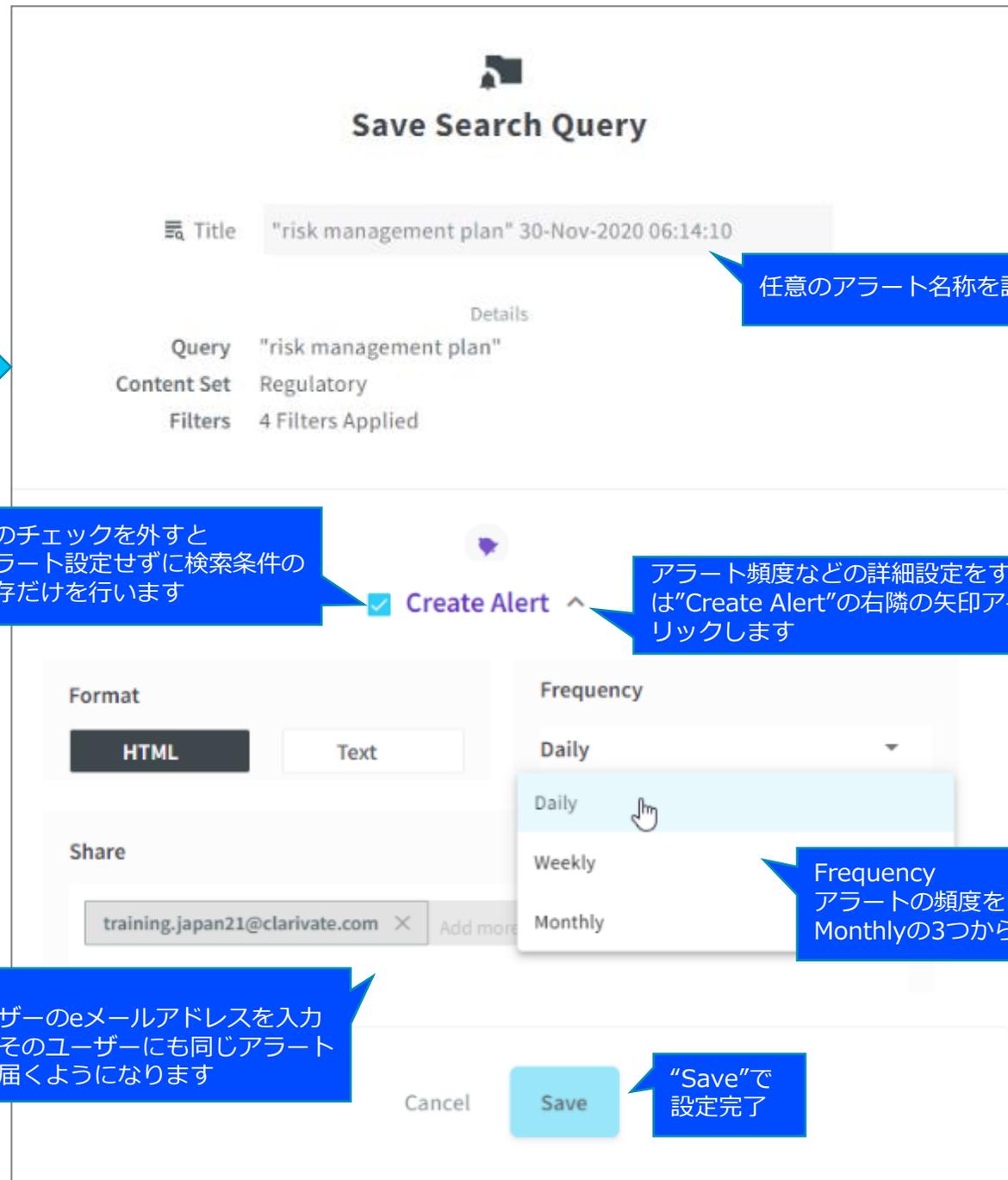
検索結果200件ごとにExcelファイルが分割されます
ダウンロード対象ファイルにチェックを入れ、ダウンロードボタンをクリックします

検索条件のアラート設定 (Alert on Query)



検索結果右上のSave and Alert on Queryをクリック

検索条件に合致する新規文書の収録を追跡するには検索結果画面でアラートを設定します



Share
他のユーザーのメールアドレスを入力すると、そのユーザーにも同じアラートメールが届くようになります

検索結果に表示された文書にまとめてアラート設定 (Alert on Reports)

文書を1つ1つ開かなくとも複数文書に一括でアラート設定できます

The screenshot shows a search results page for 'GMP'. The search bar contains 'GMP' and a 'Search' button. Below the search bar are filter buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date Filter', 'Last Updated', and 'All other filters', along with a 'Reset Filters' button. The results section shows 'Showing 1-10 of 275 results'. Two document entries are visible, each with a checked checkbox in the left margin. A blue callout box points to these checkboxes with the text: '1. アラート設定したい文書に✓が入っていることを確認します'. A 'Save and Alert on' menu is open over the first document, with the 'Reports' option selected. A blue callout box points to this menu with the text: '2. Save and Alert on Reports を選択'. The document titles are: '111749 - Inspections - Good Manufacturing Practice GMP - EU GMP Guide Annexes - Supplementary requirements: Annex 6 Manufacture of Medicinal' and '50550 - Ad Hoc GMP Inspection Services Concept Paper EMEA/INS/GMP/147444/2005: Revision of Some Annexes to the European GMP Guide in the Context of'.

Alert on Reportsは収録済みの個々の文書の更新情報をモニタリングするアラートです。新規収録文書をモニターするためにはAlert on Queryを設定する必要があります。(前頁参照)



その他の検索機能

Source Documents(現地規制文書)に特化した全文検索

現地語を含む全文検索に対応。機械翻訳の英文も検索対象になります。

The screenshot shows the 'Regulatory' search interface. At the top, there are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Source Documents' tab is highlighted with a purple box. Above the tabs, there are checkboxes for 'Drugs & Biologics' and 'Medical Devices & IVDs'. Below the tabs is a search bar containing the text '適合性調査 and リモート調査'. To the right of the search bar is a 'Search' button. Below the search bar are filter buttons for 'Document Type', 'Country/Region', 'Topic', 'Date', 'Translation Status', 'Medical Devices Specialty', and 'All other filters'. A purple callout box points to the search bar with the text '英語および現地語での全文検索に対応'.

“Source Documents”タブに切り替えて検索を実行

英語および現地語での全文検索に対応

- “Source Documents”のタブ内で検索を実行すると、検索対象文書が自動的に**Source Documentのみに限定**されます。
- “All”タブの“Quick Search”は**文書のタイトル、アブストラクトがキーワード検索の対象**になりますが、**Source Documents SearchではPDFの文書全文も検索対象**になります。
- Full Text Searchでは検索範囲が広がって網羅的な調査ができますが、検索ワードとの関連性が低い文書も検索結果に含まれる可能性が高まります。
- Source Documentsタブ内の検索では、検索ワードとして**現地語も使用可能**です。
- Source Documentsタブ内の検索では、**機械翻訳された英語文書も検索対象**となります。

The screenshot shows the search results page for 'Regulatory > Source Documents'. The page title is '12 results for “適合性調査 and リモート調査”'. Below the title is a 'Switch to Comparison Tables' link. There is a 'Refine Search' section with a search bar containing '適合性調査 and リモート調査' and a 'Search' button. Below the search bar are filter buttons for 'Document Type', 'Country/Region', 'Topic', 'Date', 'Translation Status', 'Medical Devices Specialty', and 'All other filters'. The results section shows 'Showing 1-10 of 12 results'. There are options for 'Customize Columns' and 'Sorted by Relevance'. The results table has columns for 'Summary', 'Title', and 'Abstract'. The first result is a document with a date of '03-Jul-2023', a status of 'V', and a country of 'JP'. The title is 'Notification: PSEHB/MDED No. 0703/1: Implementation Guidelines for Document-based Compliance Inspection for Approval Application'. The abstract is 'This document presents the conducting the document-based GCP on-site inspection and C'.

Regulatory SummariesおよびIntelligence Reportsの検索オプション

Regulatory SummariesおよびIntelligence Reports対象に、検索語に関連性の高いコンテンツをより効率的に探すことができる検索方法です。

The screenshot shows the top navigation bar with tabs for 'All', 'Comparison Tables', 'Intelligence Reports', and 'Regulatory Summaries'. A 'Search' tab is highlighted. Below the navigation, a search input field contains the text 'advanced therapy'. A dropdown menu is open, showing several search suggestions. A callout box points to the 'Search' tab with the text '“Search”タブを選択'. Another callout box points to the 'Regulatory Summaries' tab with the text '各コンテンツタブに切り替え'. A third callout box points to the search input field with the text '“Search”タブを選択'.

- 英語のキーワード、フレーズ等で検索
- 検索候補が表示されなくても検索実行可

The screenshot shows the search results page. The search input field contains the text 'Is there specific information regarding clinical investigations for Advanced Therapy Products?'. Below the search bar, there are 7 results found for the search query. The first result is titled 'How to Market Advanced Therapy Products' and includes a summary. A callout box points to the 'Country/Region' filter with the text 'フィルター使用可'. Another callout box points to the search results with the text '検索結果画面から移動せずにコンテンツのプレビューを確認可能'. The search results are sorted by relevance and include filters for Country/Region, Topic, and Last Updated Date.

Comparison Tables検索オプション

Comparison Tablesだけに対象を絞った検索が可能です

The screenshot shows the 'Regulatory' homepage. The 'Comparison Tables' tab is highlighted with a purple box and a callout bubble that says '“Comparison Tables” タブに切り替え'. The 'Quick Search' tab is also highlighted with a purple box and a callout bubble that says '“Quick Search” タブを選択'. A search bar contains the keyword 'pharmacovigilance' and a 'Search' button. A callout bubble at the bottom says '英語のキーワードで検索'. A large purple arrow points from this screenshot to the search results page.

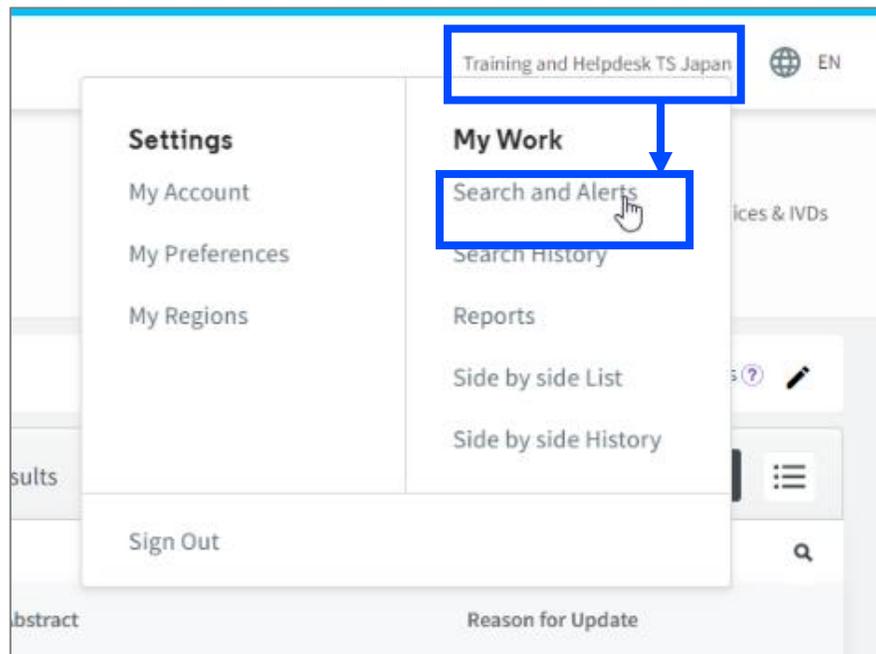
The screenshot shows the search results page for 'pharmacovigilance'. The page title is '7 results in Comparison Tables for “pharmacovigilance”'. The search bar contains 'pharmacovigilance' and a 'Search' button. Below the search bar, there are filter options: 'Section', 'Country/Region', and 'Last Updated'. The results are sorted by 'Relevance'. A callout bubble says 'キーワードに関連のある比較表がリストアップされます'. The results list includes:

- Summary
- 22-Mar-2024 National Good Practices (GxP) Directory
A directory of references to Good Laboratory Practice (GLP), Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Good Distribution Pract
- 20-Mar-2024 Expanded/Compassionate Access Requirements
An overview of country-specific procedures for making unapproved (i.e. unlicensed/unregistered) medicinal products available. Procedures can include:
- 22-Mar-2024 Risk Management Submission Requirements and Qualified Person for Pharmacovigilance (QPPV) Guidance
It also covers country-specific requirements for applicants/marketing authorization holders to have a Qualified Person for



設定済みアラートの管理

設定済みアラートや保存した検索条件の管理



画面右上のユーザー名にカーソルを合わせ、
My Workメニューから“Search and Alerts”をクリック



<input type="checkbox"/>	Content	Search Type	Name	Date Created	Alert	Alert Frequency	Options
<input type="checkbox"/>	Regulatory	Quick Search - Full Text Search	"risk management plan" 30-Nov-2020 06:14:10	30-Nov-2020	<input checked="" type="checkbox"/> ON Edit	DAILY	Run Search View/Edit Query

“Saved Searches”タブで保存済み検索条件、アラート設定済み検索条件の管理ができます

“Saved Reports”タブに切り替えると保存済み文書、アラート設定済み文書を確認できます

アラートのON/OFFや削除など





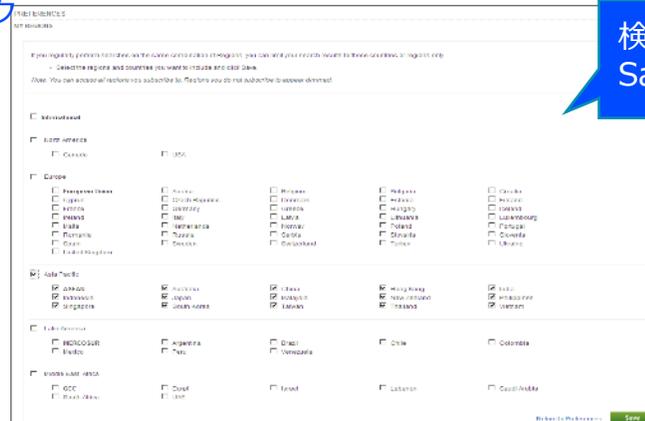
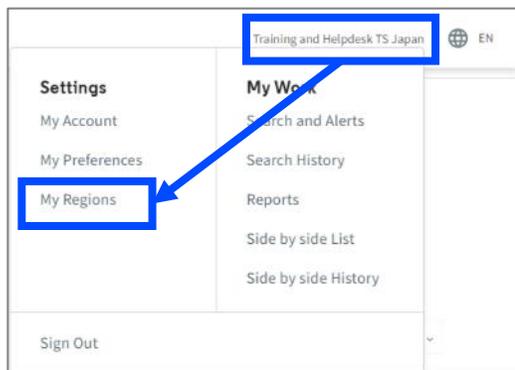
My Regionsの設定

My Regionsの設定

My Regionsを設定すると、Cortellis Regulatory Intelligenceの検索対象の国をワンボタンで限定できるようになります。

また、Regulatory Summaries, Intelligence Reports, Comparison Tablesの表示対象国をワンボタンで絞り込みできるようになります。

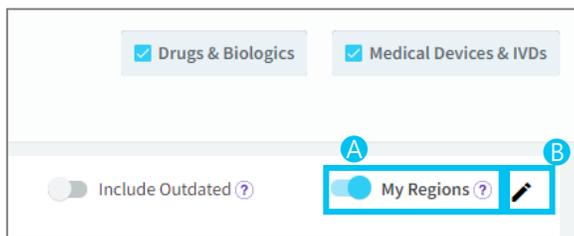
画面右上のユーザー名にカーソルを合わせ、
My Workメニューから“Search and Alerts”をクリック



検索対象にしたい国に✓を入れ、右下の Saveをクリックして設定を保存します。

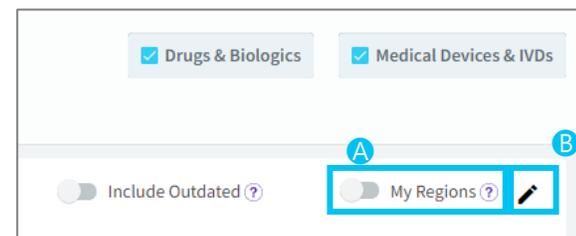
Drugs and BiologicsとMedical Devices and IVDsの両方のパッケージを購読している場合、各々のタブが表示され、独立してMy Regionを設定できます

[My Region設定している場合の検索結果]

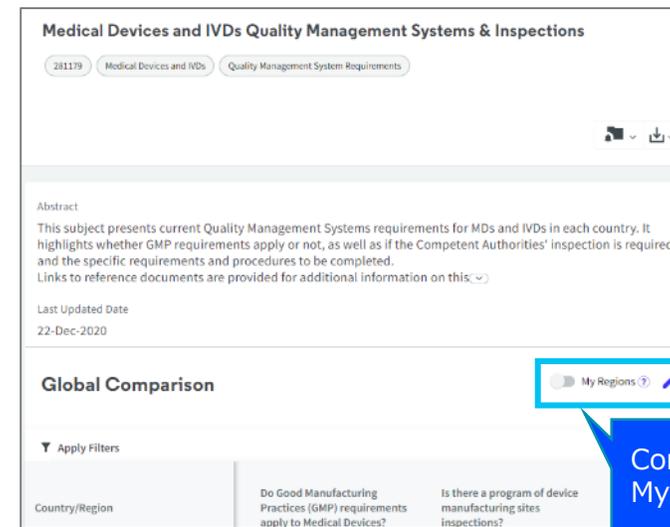


- A My Regionが [ON]
Country/Regionフィルターが無効
- B 編集ボタンでMy Regions設定画面に移動

[My RegionをOFFに切り替え]



- A My Regionが [OFF]
Country/Regionフィルターが有効
- B 編集ボタンでMy Regions設定画面に移動



Comparisons Tableの My Regions操作ボタン



Side by Side Viewerの使用方法

Side by Side Viewer

ブラウザ内で2つの文書を並べて表示できる機能です

The screenshot displays the 'Side by Side Viewer' interface. The top navigation bar includes 'Inspections - Good Manufacturing Practice GMP - EU GMP Guide Annexes - Sr' and 'Ad Hoc GMP Inspection Services Concept Paper EMEA/INS/GMP/147444/2005'. The left pane shows a document titled 'Inspections - Good Manufacturing Practice - Questions & Answers' with sections for 'EU GMP guide annexes - Supplementary requirements: Annex 6 Manufacture of Medicinal Gases', 'Question (H+V July 2010): What is traceability?', 'Answer:', and 'Question (H+V July 2010): Which items should be recorded in the case of medicinal gases filled into cylinders to enable traceability?'. The right pane shows the 'Ad Hoc GMP Inspection Services' concept paper, dated London, 25 April 2005, with a 'See History' button. Below the title is a table with columns 'AGREED BY AD HOC GMP INSPECTION SERVICES' (May 2005) and 'DEADLINE FOR COMMENTS' (August 2005). The bottom of the right pane contains a paragraph of text and contact information for Sabine Atzger and David Cockburn.

利用シーン

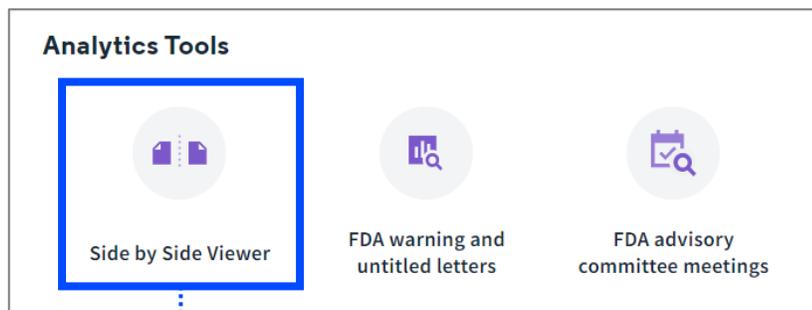
- 規制文書の新旧比較
- Regulatory Summaryの2カ国間比較
- 製品承認文書の記載内容の対比 etc.

Side by Side Viewerのアクセス方法

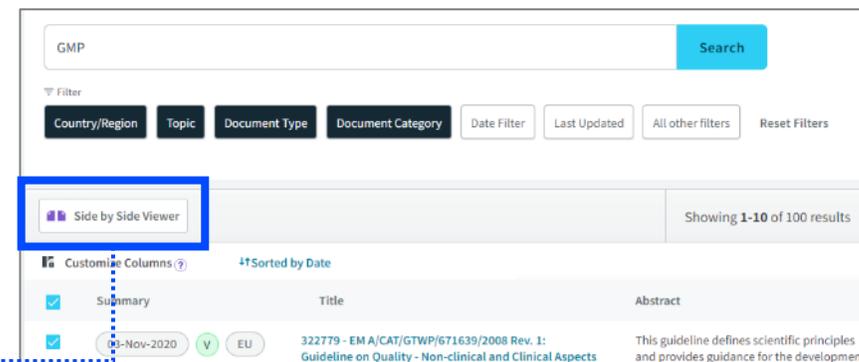
1. Regulatoryホーム画面の“Analytics Tools”
2. 検索結果画面の“Side by Side Viewer”ボタン
3. 検索結果にリストされた各文書のポップアップ
4. 各種文書、レポート表示画面
5. Side by side ListおよびSide by side History

Side by Side Viewerへのアクセス方法

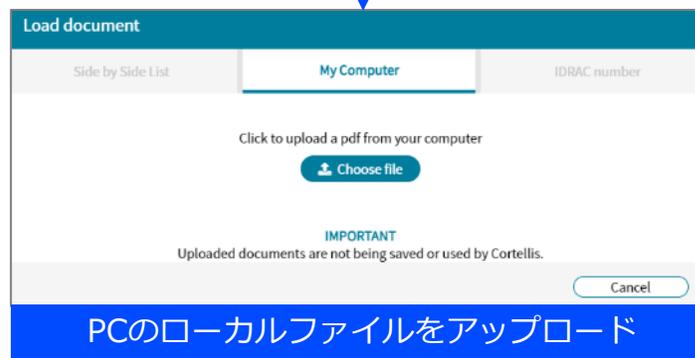
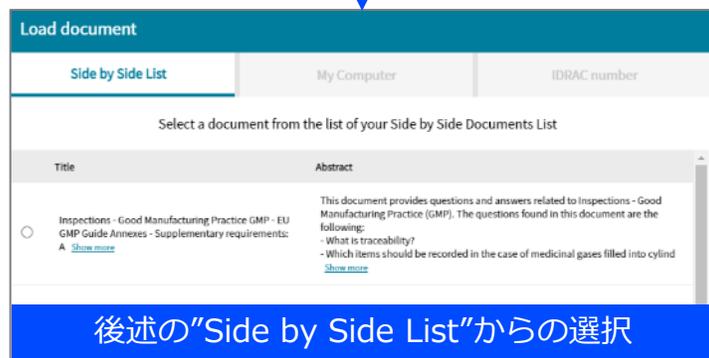
方法1. Regulatoryホーム画面のAnalytics Toolsから



方法2. 検索結果画面の“Side by Side Viewer”ボタンから



Viewerが起動したら“UPLOAD”ボタンをクリックして、表示させる文書を以下の3種類の方法のいずれかで選択します



Side by Side Viewerへのアクセス方法

方法3. 検索結果にリストされた各文書のポップアップから

検索結果に表示された各文書の左側にカーソルを合わせるとSide by Side Viewerの操作ボタンが現れます

Document Title	Abstract
Guideline on Quality - Non-clinical and Clinical Aspects of Medicinal Products Containing Genetically Modified	This guideline defines scientific principles and provides guidance for the development and evaluation of medicinal products
310883 - Eudralex Volume 10: Guidance on the Management of Clinical Trials during COVID-19 Pandemic - Version 3 - 28-Apr-2020	The following document of the European Commission is the Guidance document on the management of clinical trials during
307010 - European Commission Targeted Stakeholders Consultation on the Revision of Annex 1 - on Manufacturing of Sterile Medicinal Products - of the	The following document of the European Commission is the targeted stakeholders consultation on the revision of Annex 1
14-Jan-2020 305084 - EMA/457570/2019: Draft Reflection Paper on	This reflection paper is focussed on the

方法4. 各種文書、レポート表示画面から

各文書タイトル右側にSide by Side Viewerの操作ボタンがあります

Medical Devices Regulatory Framework

Valid 59120 South Korea Regulatory Summary Expert Report

Medical Devices and IVDs No specific Speciality

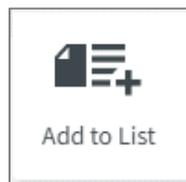
Compliance and Inspection Device Classification Advertising and Promotion Clinical Research

- Summary
- Document
- Mentioned By

Summary

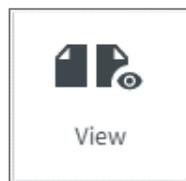
Abstract

This Regulatory Summary is related to Medical Devices Regulation. It provides definitions and outlines legal framework from different points of view (manufacturers, importers and distributors). It gives information about Registration procedures, quality assurance requirements, classification of Medical Devices and provides practical help on how to obtain the medical device Certification in South Korea. This document also contains detailed information about fees,



Add to List

当該文書を後述のSide by Side Listに追加します

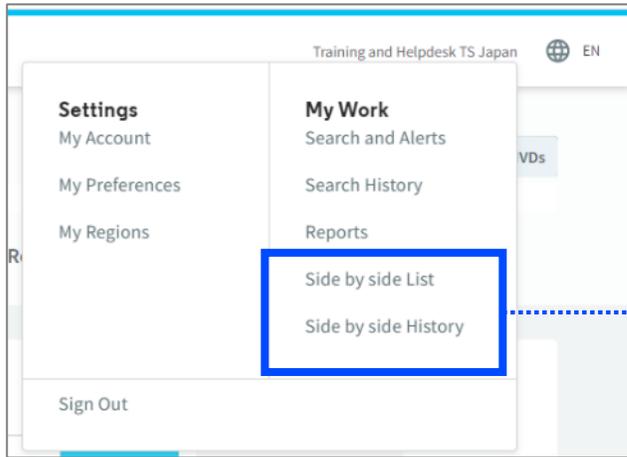


View

当該文書をSide by Side Viewerで開きます

Side by Side Viewerへのアクセス方法

方法5. Side by side ListおよびSide by side History



画面右上のユーザー名にカーソルを合わせ、My Workメニューから“Side by side List”または“Side by side History”をクリック

< Back | Forward > My Searches and Alerts Side by side document viewer Delete Item

Saved Searches Saved Reports Search History Side by Side Document List Side by Side History

The side by side documents list contains Cortellis documents only.

<input type="checkbox"/>	Content	Title	Abstract	Date	Region	IDRAC Number
<input type="checkbox"/>	Regulatory	Inspections - Good Manufacturing Practice GMP - EU GMP Guide Annexes - Supplementary requirements: Annex 6 Manufacture of Med Show more	This document provides questions and answers related to Inspections - Good Manufacturing Practice (GMP). The questions found in this document are the following: - What is traceability? - Which items should be recorded in the case of medicinal gases filled into cylind Show more	28-Jan-2021	European Union	111749
<input type="checkbox"/>	Regulatory	Ad Hoc GMP Inspection Services Concept Paper EMEA/INS/GMP/147444/2005: Revision of Some Annexes to the European GMP Guide in Show more	This document proposes the revision of s The EU GMP guide is currently structured classes of products or with particular mar Show more			

Side by Side List
検索結果画面や文書表示画面でSide by Side Listに追加済みの文書が表示されます。Side by Side Viewerで表示させたい文書を選択します

< Back | Forward > My Searches and Alerts Side by side document viewer Delete Item

Saved Searches Saved Reports Search History Side by Side Document List Side by Side History

The side by side history can include a maximum of 50 files.

<input type="checkbox"/>	Content	Title	Abstract	Date	Region	IDRAC Number
<input type="checkbox"/>	Regulatory	Inspections - Good Manufacturing Practice GMP - EU GMP Guide Annexes - Supplementary requirements: Annex 6 Manufacture of Med Show more	This document provides questions and answers related to Inspections - Good Manufacturing Practice (GMP). The questions found in this document are the following: - What is traceability? - Which items should be recorded in the case of medicinal gases filled into cylind Show more	28-Jan-2021	European Union	111749
<input type="checkbox"/>	Regulatory	Ad Hoc GMP Inspection Services Concept Paper EMEA/INS/GMP/147444/2005: Revision of Some Annexes to the European GMP Guide in Show more	This document proposes the revision of s The EU GMP guide is currently structured classes of products or with particular mar Show more	28-Jan-2021	European	50550

Side by Side History
Side by Side Viewerで表示させた文書の履歴を過去50件まで遡って再度表示させることができます



日本語版製品サポートサイト

日本語版ユーザーサポートサイト

Cortellis製品共通のサポートサイトをご用意しております。すべての製品サポート資料にまとめてアクセスできます。業界トレンド・ニュースもご提供します。 <https://clarivate.com/cortellis/ja/learning/cortellis-training-home-1564/>

Clarivate™ | Training Solutions ▾ Live Training

ライフサイエンス & ヘルスケア 製品サポートサイト

操作解説資料、動画、セミナー録画など

こちらにない内容はお問い合わせください。

何をお探しですか？

- 初めてお使いになる方はこちらから**
ようこそCortellisスイートへ。初めてお使いになる方へ向けたコンテンツをご用意いたしました。
- 競合情報**
包括的な競合情報の収集・分析のためのCortellis Competitive Intelligence
- 薬事・規制**
医薬品・医療機器の薬事情報：Cortellis Regulatory Intelligence
- 臨床開発**
臨床開発を成功に導くためのCortellis Clinical Trials Intelligence

Cortellis Regulatory Intelligence

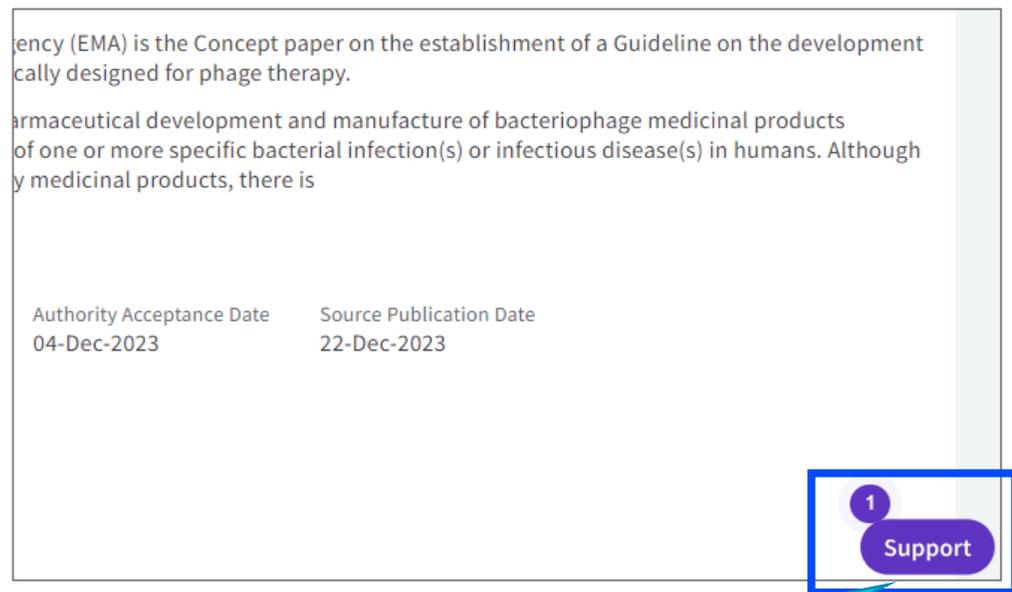
医薬品・医療機器の薬事情報

- 基本編
- 利用事例
- ウェビナー録画版・ビデオ

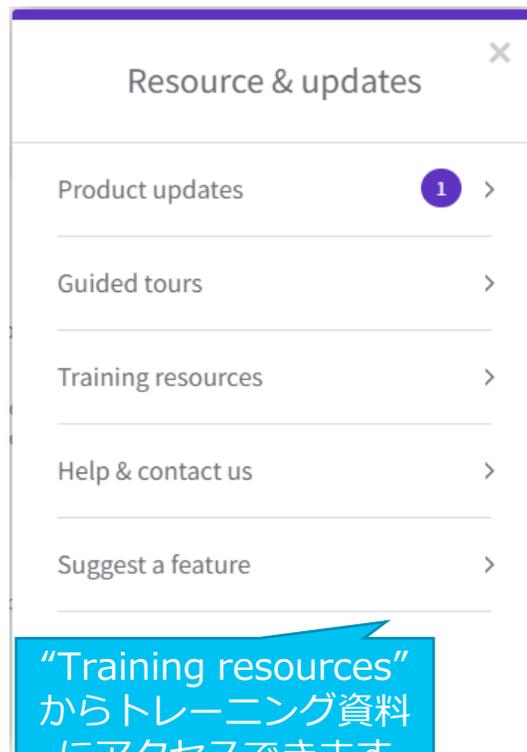
- 特定の国の文書を検索する
- 規制文書の英語翻訳を入手する
- 各国の規制要件や慣行についての英語の解説文を読む
- Guidelineを効率的に収集する

“Support”ボタン（各種製品ガイド）の活用

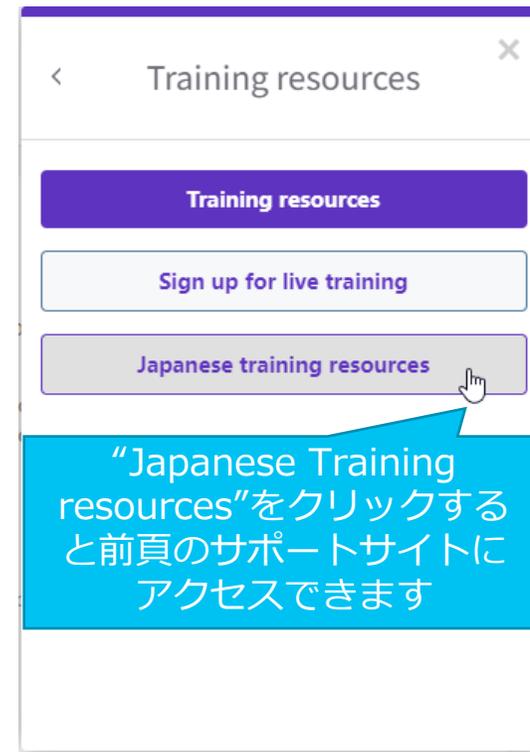
- アップデートのお知らせ
- 使い方ガイド
- 各種トレーニング資料（日本語ページへのリンクあり）
- ユーザコミュニケーションツールによるフィードバック etc



Cortellis 画面右下の
“Support”をクリック



“Training resources”
からトレーニング資料
にアクセスできます



お問い合わせ先

クラリベイト
カスタマーケア

Tel: 0800-170-5577 (フリーダイヤル)
03-4589-3107

Email: ts.support.jp@clarivate.com



付録

1. Regulatory Summaries トピックス一覧
2. Intelligence Reports トピックス一覧
3. Comparison Tables トピックス一覧

上記コンテンツのトピックスは、
Drugs & Biologics および Medical Devices & IVDs の各モジュールでそれぞれ異なります。

薬事規制業務に必要な実用的なインサイト

Cortellis Regulatory Intelligenceの付加価値コンテンツ



Source documents

- 世界各国の規制当局・機関の公式文書
- 最新および過去バージョンを蓄積（バージョン管理情報付与）
- 全ての規制文書に英語のタイトル・抄録・更新理由等付加
- 専門家による全文英訳（Drug&Biologics：8か国 / Medical Device&IVDs: 16か国）



Regulatory Summaries

- 薬事専門家による各国の規制の枠組み・プロセスの英語解説文
- 標準化されたフォーマット
- 主要な規制文書をリスト
- 規制変更により随時更新



Regulatory Intelligence Reports

- 様々な重要トピックについて実務に役立つ規制分析レポート
 - 規制変更追跡
 - 競合品承認情報
 - ガイドライン一覧
 - FDA査察情報等



Global Regulatory Comparisons

- 重要トピックに関する世界各国の規制比較表
- 規制の共通点・相違点を簡単に把握
- 主要な規制文書へのリンクで簡単に詳細を確認可能
- 随時更新

Regulatory Summaries (規制の解説文書) – Drugs & Biologics

Authorities and Organizations	医薬品・医療機器規制に関与する当局の情報
International and Regional Bodies	ICH, PIC/S, ASEANなどの国際組織の情報
Legal Definitions and Marketing Requirements	医薬品や医療機器の定義や分類
Prescription and Supply Requirements	処方薬の定義や流通に関する基本的な要件
Registration Application Application Format, Content and Overview	医薬品申請書式、提出データ要件など
Registration Application Submission Process Overview	申請方法や電子申請ファイルの取扱いなど
Marketing Authorization Procedures	審査プロセス、事前相談、製造販売業の認可、薬局方、スイッチOTC、優先審査制度、承認承継、未承認薬の使用、変更申請など
Fees Payable	各種申請費用
Labeling, Packaging and Product Information Requirements	添付文書、パッケージ、ラベルに関する要件など
Clinical Trial Regulatory Requirements	臨床試験実施プロセスや、治験薬の管理、ラベル、輸出入の要件など
Quality Assurance Requirements	GXP関連の要求事項など
Pharmacovigilance and Risk Management Regulatory Requirements	市販前/後の安全管理要件、ADE報告要件など
Import and Export Regulatory Requirements	輸出入関連規制、ライセンスなど
Advertising and Promotion Regulations	広告規制
Market Access Guidance	薬価算定、保険償還プロセス、HTA制度の解説
Pricing and Reimbursement System and Policy Overview	薬価制度、保険償還（上記Market Access Guidanceでカバーされない国の情報）
Environmental Assessment and Impact Guidance	環境関連規制
How to Market...	遺伝子治療、細胞治療、再生医療、コンビネーション製品、小児適応、後発品、漢方薬、オーファンドラッグなどに特化した規制情報の解説

Regulatory Intelligence Report (分析レポート) – Drugs & Biologics

Brexit Tracker	英国のEU離脱によって必要となる対応やその期限などの情報
FDA Citizen Petitions	FDAに提出された請願書の一覧と本文へのリンク
Committee Meeting Trackers and Expert Profiles	FDA諮問委員会、EMA Scientific Committeeなど専門家組織やミーティングの情報
European Procedure Fees Trackers	欧州 (EU, EEU) における医薬品申請に係る費用の情報
Compliance and Inspection Trackers	査察官名、サイト、Form 483, Warning Letterなど査察関連情報を集約
Global Market Access Insights	HTA, 薬価算定プロセス、保険償還システムなど市場アクセスに関する情報
Regulatory Authority Guideline Overview	各国・地域のガイドラインの一覧、変更の追跡に役立つ資料
Legislative Trackers	米国CFRなど規制変更の追跡資料
Product Approval Information	競合品のNDA, BLAなど申請・承認情報、承認までの期間、リスク管理計画の情報や審査報告書の入手
Public Comments and Outcomes Consultation Documents	ドラフトガイドライン、パブリックコメント内容、最終的な告示内容などの情報
Regulatory Authority Structure and Document Classification Guide	各国規制当局から発出される文書の種類や法的拘束力など

Comparison Tables (規制の比較表) トピックス一覧- Drugs & Biologics

Comparison Tables

- Authorities and Organizations
 - Health Ministry and Regulatory Agency Directory
- Legal Definitions and Marketing Requirements
 - Legislative/Regulatory Framework: Biosimilar Products
 - Legislative/Regulatory Framework: Generic Products
 - National Pharmaceutical Laws and Regulations Directory
 - National Pharmacopeia Directory
- Format and Content of Applications
 - CTD Acceptability Framework
 - Finished Product Stability Data Requirements
- Marketing Authorization Procedures
 - Change of Manufacturing Site Requirements : Finished Product
 - Expanded/Compassionate Access Requirements
 - Expected Authority Review Timelines: Market Authorization Approval
- Fees
 - Pre- and Post-Approval National Fees Directory
- Product Information
 - Package Labeling Requirements

Comparison Tables

- Clinical Research
 - Clinical Trial Application Research Requirements: Local Requirements
 - Expected Authority Review Timelines: Clinical Trial Application and Ethics Committee
 - Investigational Medicinal Product (IMP) Labeling Requirements
 - Legislative/Regulatory Framework: Clinical Trial Registries and Results Disclosure
- Quality Assurance
 - National Good Practices (GXP) Directory
- Market Access Guidance
 - Health Technology Assessment Overview
 - Pharmaceutical Pricing and Reimbursement
- Pharmacovigilance and Risk Management
 - Post-Marketing Expedited Reporting
 - Post-Marketing Periodic Reporting
 - Pre-Marketing Expedited Reporting
 - Pre-Marketing Periodic Reporting
 - Risk Management Submission Requirements and Qualified Person for Pharmacovigilance (QPPV) Guidance
- Import and Export
 - Certificate of Pharmaceutical Product (CPP) Overview

Medical Devices & IVDs

Regulatory Summaries (規制の解説文書)

Regulatory Summaries

Medical Devices Regulatory Framework

In Vitro Diagnostics Regulatory Framework

Combination Products Regulatory Framework

International Medical Device Regulators Forum
(IMDRF)

Regulatory Intelligence Report (分析レポート)

Regulatory Intelligence Reports

- Committee Meeting Trackers
 - FDA Advisory Committees
 - FDA Workshops
- Compliance and Inspection Trackers
 - FDA Inspection Report Directory
 - FDA Warning Letter Directory
- Legislative Trackers
 - US Federal Register | Regulatory Timetable
 - EU IVD 2017 Regulation Highlights
 - EU Medical Device 2017 Regulation Highlights
- Product Approval Information
 - Medical Device Registration | Submission and Approval Tracker
 - Combination Product Registration | Submission and Approval Tracker
- Product Approval Information
 - Combination Product Submission and Approval Overview
 - Medical Devices Submission and Approval Overview
- Public Comments and Outcomes | Consultation Documents

Medical Devices & IVDs Comparison Tables (規制の比較表)

Comparison Tables

- Authorities and Organizations
 - IVD Regulatory Agency Directory
 - Medical Device Regulatory Agency Directory
- Legal Definitions and Product Classification
 - IVD Classification Summary
 - IVD Laws and Regulations Summary
 - Medical Device Classification Summary
 - Medical Device Laws and Regulations Summary
- Market Clearance
 - IVD Marketing Application Procedures
 - IVD Post-Marketing Procedures
 - Medical Device Marketing Application Procedures
 - Medical Device Post-Marketing Procedures

Comparison Tables

- Labeling and Promotion
 - IVD Labeling Requirements
 - Medical Device Advertising Requirements
 - Medical Device Labeling Requirements
- Quality Management System Requirements
 - IVD Quality Management System and Inspection Requirements
 - Medical Device Quality Management System and Inspection Requirements
- Market Surveillance
 - IVD Adverse Incident Reporting Requirements
 - Medical Device Adverse Incident Reporting Requirements
- Import and Export
 - Medical Device Import and Export Requirements