Cortellis Regulatory Intelligence

ウィークリーアップデートおよびカスタムアラートの設定方法

Clarivate Life Sciences & Healthcare

Nov.2025

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速報eメールサービス

Weekly Updates

1週間ごとに規制の変更をお知らせ

Dear *Cortellis Regulatory Intelligence User*,

Please find our ***Weekly Update - Medical Devices and IVDs***, 2025 Volume 29 of 14-Jul-2025 - 20-Jul-2025.

The *Cortellis Regulatory Intelligence Weekly Update* provides you with a summary of the Global Regulatory Landscape by highlighting latest updates (including new and updated official and exclusive expert documents for each country or territory) in a weekly basis.

Cortellis Regulatory Intelligence Weekly Update: Medical Devices and IVDs

Your inside source of product & regulatory updates

Volume 29, 14-Jul-2025 to 20-Jul-2025

Latest News

CONFERENCE REPORT: Drug Information Association (DIA) – 2025 Annual Global Meeting, Washington DC, USA | 15-19 June 2025

The Drug Information Association (DIA) hosted its Global Annual Meeting in Washington DC, bringing more than 4,000 attendees from government, industry, academia, and healthcare to discuss the future of drug development and regulatory science across multiple sessions. This report summarizes presentations and panel discussions centered on global collaborations to address chronic diseases, potential impacts of the new US administration, real-world data (RWD) and real-world evidence (RWE) in clinical trials, the use of artificial intelligence (AI) in drug development, and key priorities for the US Food and Drug Administration (FDA).

By Jennifer Nguyen, Senior STEM Content Analyst, Cortellis Regulatory Intelligence

CONFERENCE REPORT: 2025 DIA China Annual Meeting, Shanghai, China, 22-25 May 2025

	A	B	C	D	E	F	G	H	I
1	Country/Region	Document Types	Topics	Title	Abstract	IDRAC Number	Last Updated Date	Reason for Update Description	Previous Versio
2	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 18, 2025, FDA cleared	411138	18-7-2025	N/A	N/A
3	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 13, 2025, FDA cleared	411134	18-7-2025	N/A	N/A
4	USA	510(k)	eHealth; Product Assessment	510(k) Premarket Notification K2	On June 30, 2025, FDA cleared	411131	18-7-2025	N/A	N/A
5	USA	510(k)	eHealth; Product Assessment	510(k) Premarket Notification K2	On June 17, 2025, FDA cleared	411123	18-7-2025	N/A	N/A
6	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 03, 2025, FDA cleared	411115	18-7-2025	N/A	N/A
7	USA	510(k)	eHealth; Product Assessment	510(k) Premarket Notification K2	On June 27, 2025, FDA cleared	411113	18-7-2025	N/A	N/A
8	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 11, 2025, FDA cleared	411111	18-7-2025	N/A	N/A
9	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 05, 2025, FDA cleared	411109	18-7-2025	N/A	N/A
10	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 27, 2025, FDA cleared	411105	18-7-2025	N/A	N/A
11	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 03, 2025, FDA cleared	411098	18-7-2025	N/A	N/A
12	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 06, 2025, FDA cleared	411095	18-7-2025	N/A	N/A
13	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 27, 2025, FDA cleared	411092	18-7-2025	N/A	N/A
14	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 11, 2025, FDA cleared	411091	18-7-2025	N/A	N/A
15	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 20, 2025, FDA cleared	411089	18-7-2025	N/A	N/A
16	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 27, 2025, FDA cleared	411081	17-7-2025	N/A	N/A
17	USA	510(k)	Product Assessment	510(k) Premarket Notification K2	On June 20, 2025, FDA cleared	411078	17-7-2025	N/A	N/A

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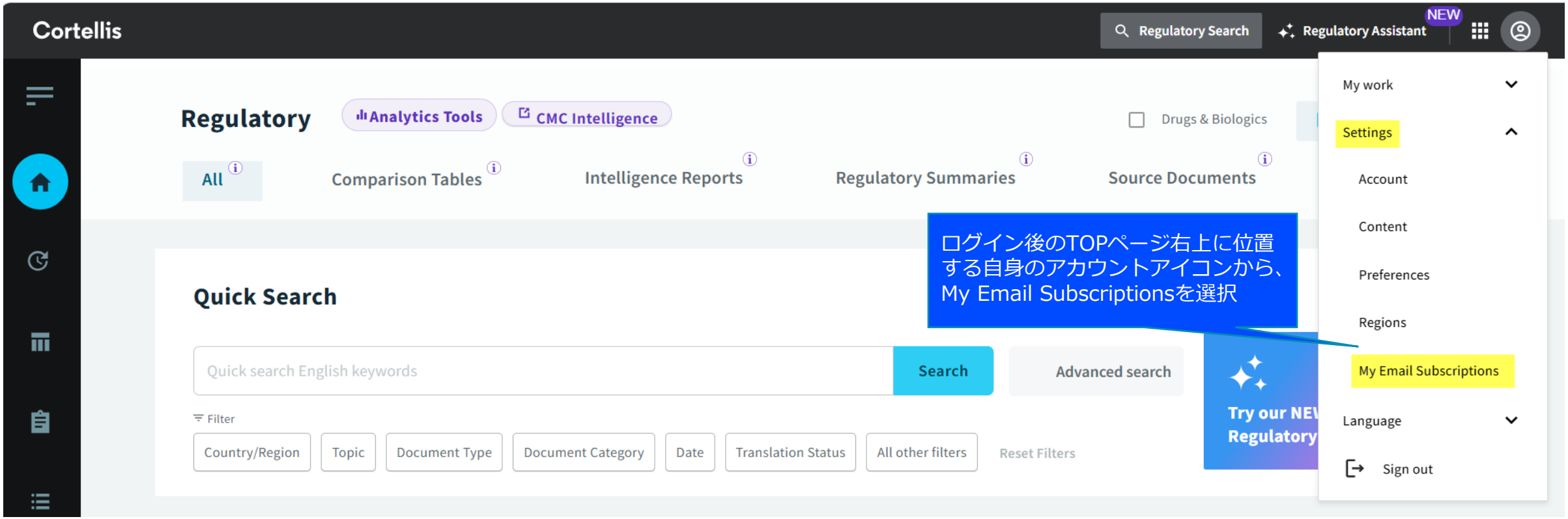
1.ウィークリーアップデートの設定



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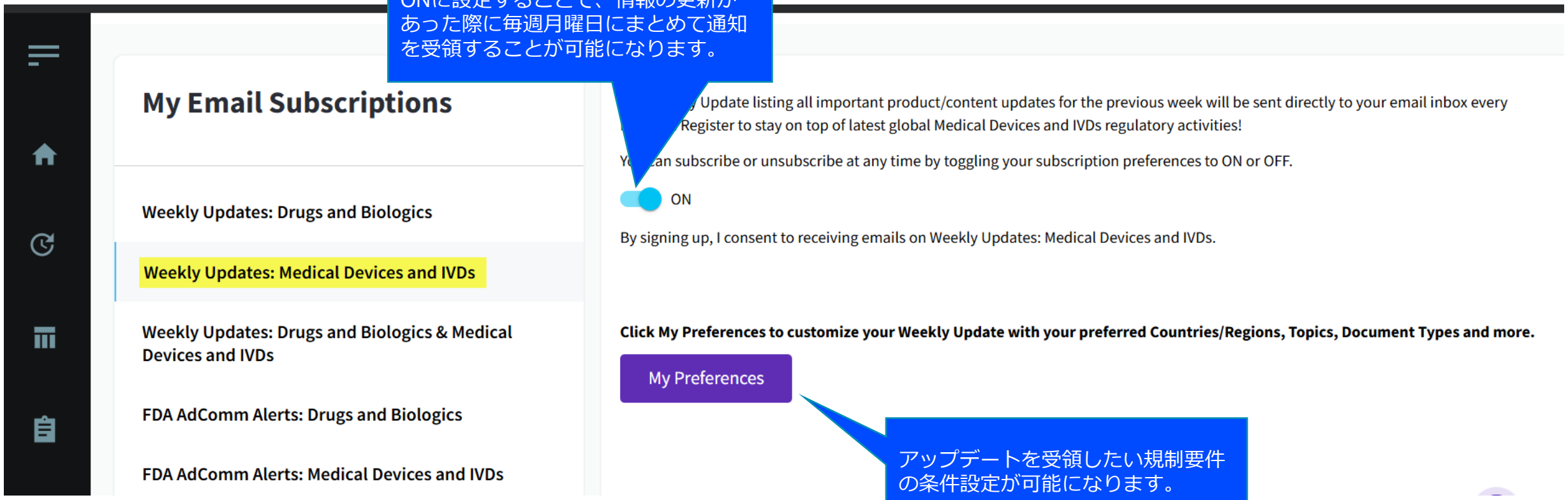
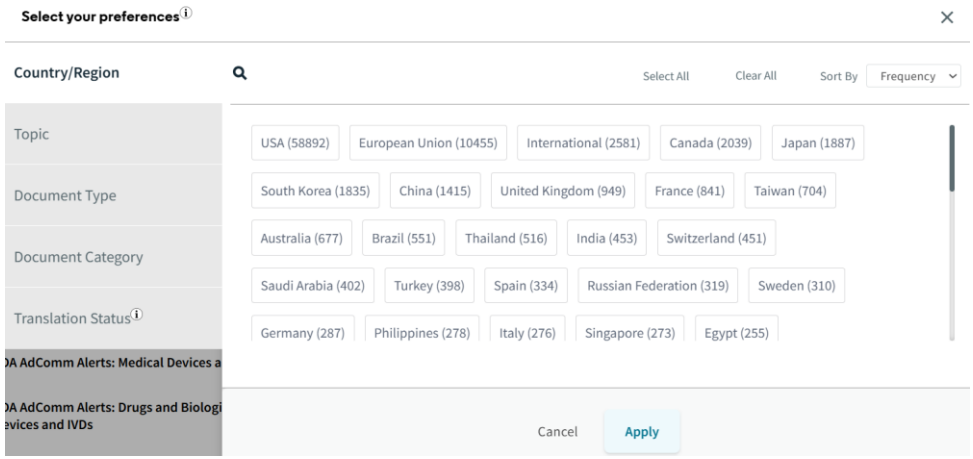
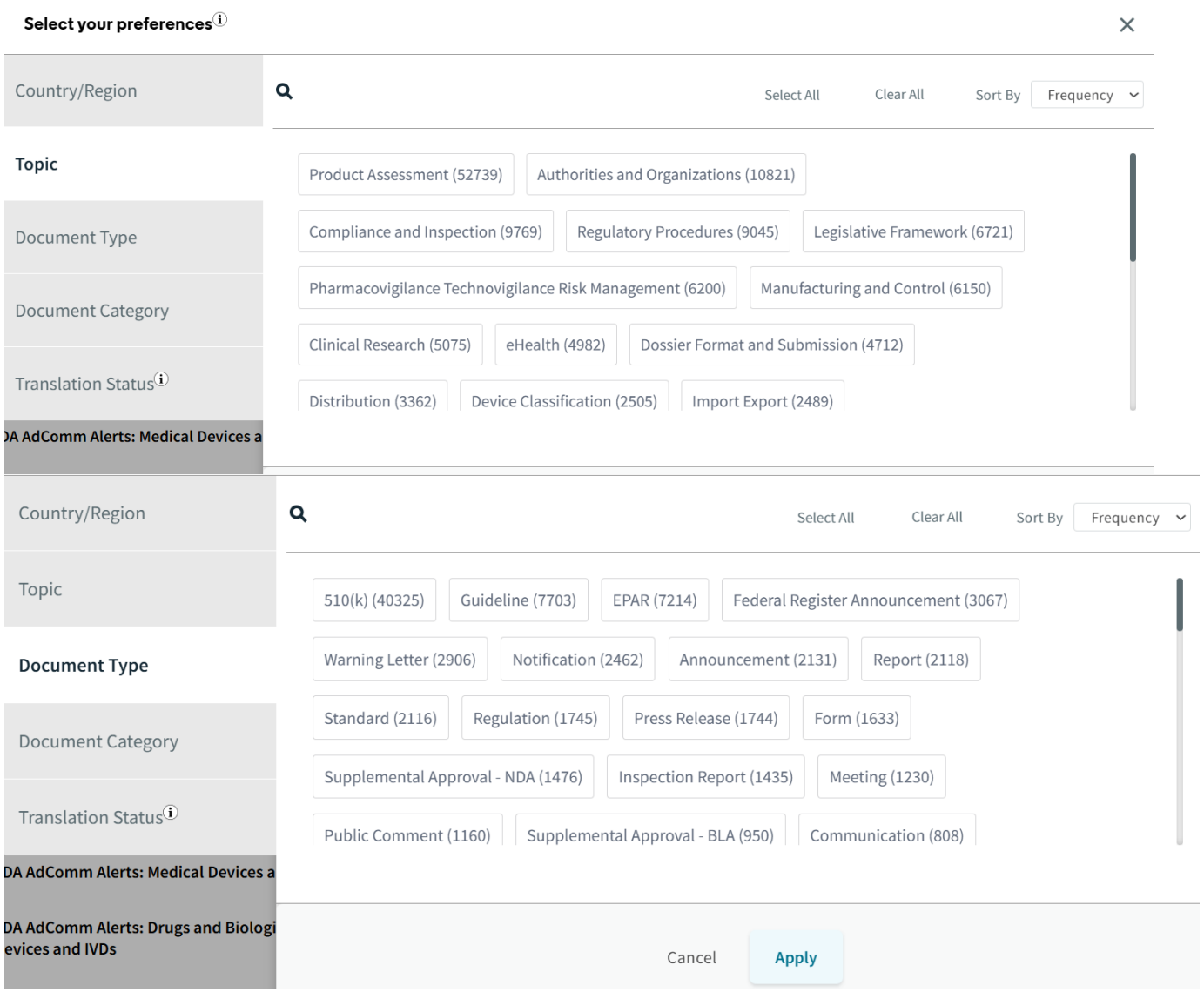
ONに設定することで、情報の更新があった際に毎週月曜日にまとめて通知を受領することが可能になります。



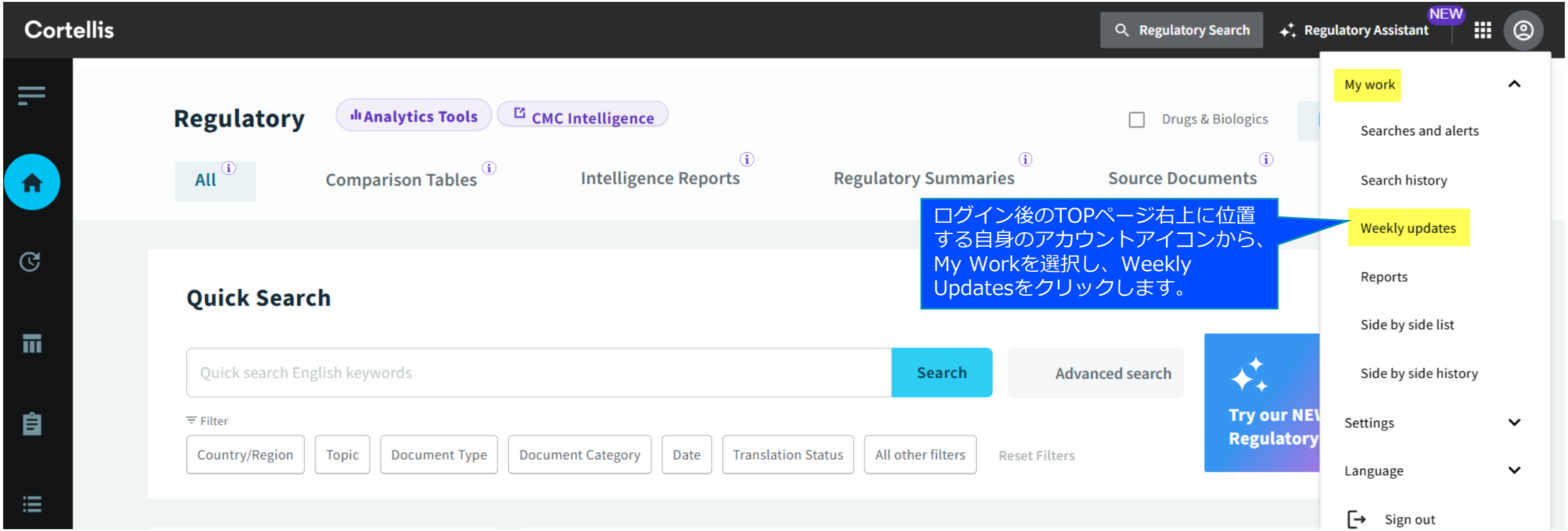
アップデートを受領したい規制要件の条件設定が可能になります。

My Preferencesの設定





ウィークリーアップデートの確認とアップデート一覧を出力する



Weekly Updates

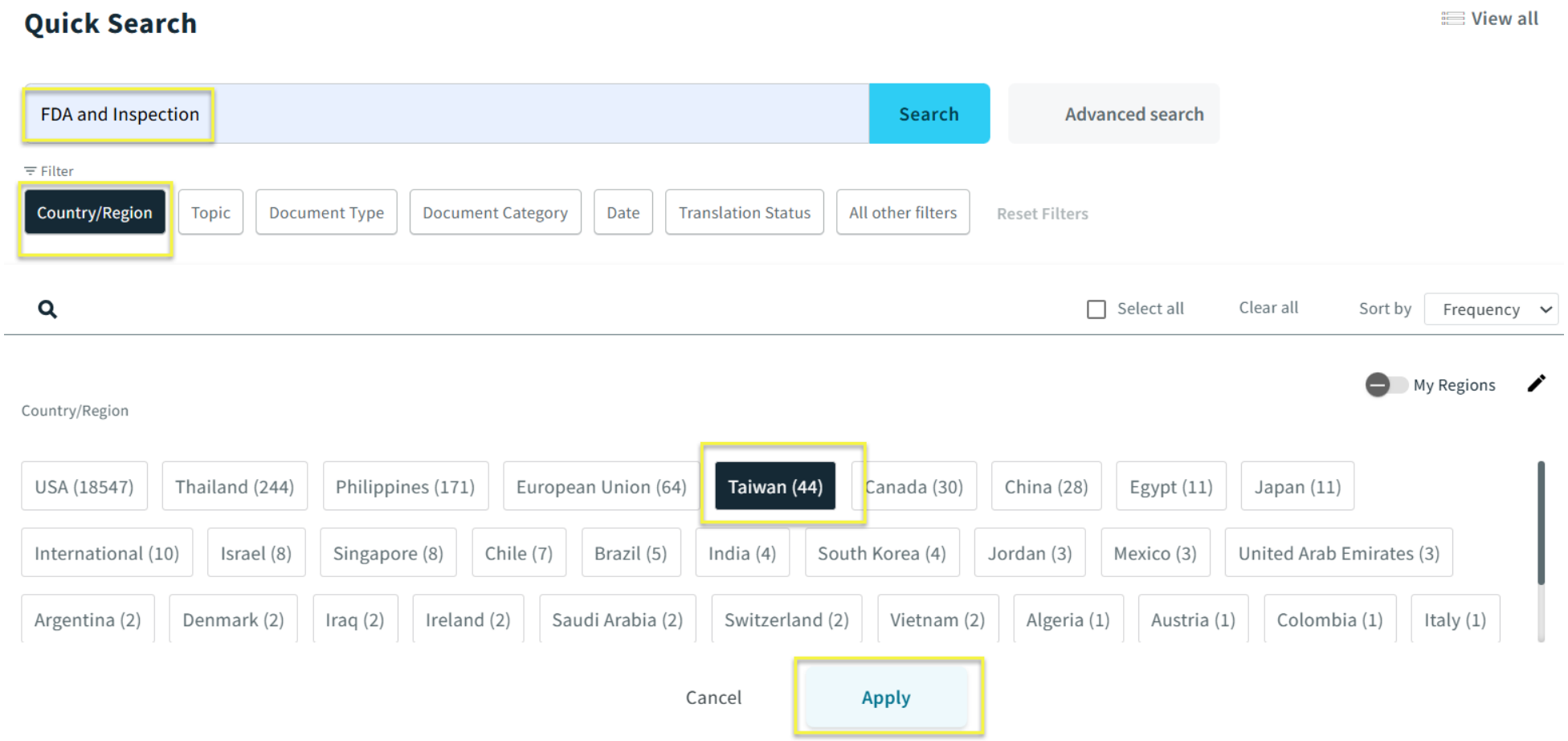
Drugs and Biologics | **Medical Devices and IVDs** | Drugs and Biologics & Medical Devices and IVDs

Volume	Date ↓	My Preferences	Actions
Volume 29	21-Jul-2025	Topic: Product Assessment Document Type: 510(k)	
Volume 28	14-Jul-2025	Topic: Product Assessment Document Type: 510(k)	

アップデート内容の確認とアップデート一覧のテーブル出力が可能です。

2. 文書検索時の検索条件に対するカスタムアラート設定（Alert on Query）

例：FDAおよびInspectionというキーワードをタイトルやアブストラクトに含む台湾の文書をモニターする。条件に合致した新規文書が収録された際には、通知がされる。



FDA and Inspection

Search

Advanced search

Filter

Country/Region | Topic | Document Type | Document Category | Date | Translation Status | All other filters | Reset Filters

Side by Side Viewer

Showing **1-10** of 26 results

Save and Alert on

Query | Reports

Customize Columns

Sorted by Relevance

Summary	Title	Abstract	Previous Version		Reaso
29-Jun-2012 V TW ZH RD	TFDA Announcements on GMP/QSD Conformity Assessment of Overseas Medical Devices: Establishment Inspection Reports (EIRs) for U.S.	According to the TFDA Announcement No.1011603436 and TFDA Announcement No. 1015030819, all the domestic and	N/A	18-Sep-2024	This s chang affecti
12-Dec-2017 V TW ZH RD	MOHW Order No.1061667279: Amendment of Enforcement Rules of Medical Care Act: Review and Inspection on Clinical Trials of New Drugs, 12-Dec-2017	This document offers the amendment of the Article 55 of Enforcement Regulations: Enforcement Rules of Medical Care Act,	N/A	23-Jan-2024	This d file of transl

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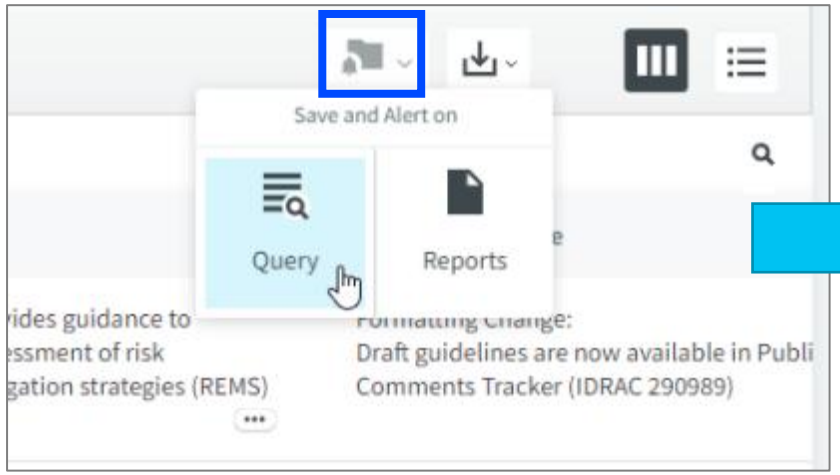
検索条件のアラート設定詳細（Alert on Query）



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

参考：アラートメールのイメージ

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11-Mar-2025

REGULATORY SEARCH ALERT

Your DAILY alert contains information that was updated on 10-Mar-2025

Name: GMP 27-Jan-2025 03:00:57
Owner:
Contact:

1 new 0 updated 1 total.

NEW - SINCE LAST ALERT View in Cortellis
1 Report was new to your results set in this time period.

Taiwan - **Guideline: Application for Changes to the Registration of Medical Device Manufacturing License and Approval Documents, 10-Mar-2025**	
Abstract	This document provides the revised version of Guideline: Checklist for Applications of Medical Device Manufacturing License and Log-in Letters for Medical Device GMP/QSD Accreditation, 01-May-2021 (IDRAC 329945), which includes the following parts: 1. Application methods. There are two application methods. Applicants are encouraged to choose one and prioritize using the Medical Device Quality Management Application Platform to submit their application, as it can help improve the efficiency of case review. 2. Application fees 3. Dossier requirements 4. Annex: Application Form. Compared to the previous version (IDRAC 329945), this document: - add the application methods for electronic and paper submission - revise item 1 of the application documents that should be attached when applying for authorization transfer of pharmaceutical importer for an approval document for QMS compliance of manufacturers of imported medical devices (Number 6) - revise the terms used in the application form without major changes in the content This document supersedes the Guideline: Checklist for Applications of Medical Device Manufacturing License and Log-in Letters for Medical Device GMP/QSD Accreditation, 01-May-2021 (IDRAC 329945).
Reason for Update	New on **11-Mar-2025**:

IDRAC Number	403467	**Document Date**	10-Mar-2025
Document Category	Reference Document		
Document Type	Guideline		
Regulatory Version	Revision	**Languages**	Chinese

UPDATED - SINCE LAST ALERT
No reports were updated in this time period for the update types you are subscribed to

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