

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



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

1.ウィークリーアップデートの設定

The screenshot displays the Cortellis Regulatory Assistant interface. At the top, the 'Cortellis' logo is on the left, and 'Regulatory Search' and 'Regulatory Assistant' (with a 'NEW' badge) are on the right. Below the header, there are tabs for 'Regulatory', 'Analytics Tools', and 'CMC Intelligence'. A navigation bar includes 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The main content area features a 'Quick Search' section with a search input field, a 'Search' button, and an 'Advanced search' button. Below the search field are filter buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters', along with a 'Reset Filters' button. On the right side, a user profile menu is open, listing options: 'My work', 'Settings', 'Account', 'Content', 'Preferences', 'Regions', 'My Email Subscriptions', 'Language', and 'Sign out'. A blue callout box with white text points to the 'My Email Subscriptions' option, stating: 'ログイン後のTOPページ右上に位置する自身のアカウントアイコンから、My Email Subscriptionsを選択'. Another blue callout box with white text and a star icon points to the 'Try our NEW Regulatory' button, stating: 'Try our NEW Regulatory'.



My Email Subscriptions

Weekly Updates: Drugs and Biologics

Weekly Updates: Medical Devices and IVDs

Weekly Updates: Drugs and Biologics & Medical Devices and IVDs

FDA AdComm Alerts: Drugs and Biologics

FDA AdComm Alerts: Medical Devices and IVDs

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。

Weekly Update listing all important product/content updates for the previous week will be sent directly to your email inbox every Monday. Register to stay on top of latest global Medical Devices and IVDs regulatory activities!

You can subscribe or unsubscribe at any time by toggling your subscription preferences to ON or OFF.



By signing up, I consent to receiving emails on Weekly Updates: Medical Devices and IVDs.

Click My Preferences to customize your Weekly Update with your preferred Countries/Regions, Topics, Document Types and more.

My Preferences

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

Select your preferences ⓘ

Country/Region Select All Clear All Sort By Frequency

Topic
USA (58892) European Union (10455) International (2581) Canada (2039) Japan (1887)

Document Type
South Korea (1835) China (1415) United Kingdom (949) France (841) Taiwan (704)

Document Category
Australia (677) Brazil (551) Thailand (516) India (453) Switzerland (451)

Translation Status ⓘ
Saudi Arabia (402) Turkey (398) Spain (334) Russian Federation (319) Sweden (310)

Germany (287) Philippines (278) Italy (276) Singapore (273) Egypt (255)

DA AdComm Alerts: Medical Devices a

DA AdComm Alerts: Drugs and Biologi
vices and IVDS

Cancel Apply

Select your preferences ⓘ

Country/Region Select All Clear All Sort By Frequency

Topic
Product Assessment (52739) Authorities and Organizations (10821)

Document Type
Compliance and Inspection (9769) Regulatory Procedures (9045) Legislative Framework (6721)

Document Category
Pharmacovigilance Technovigilance Risk Management (6200) Manufacturing and Control (6150)

Translation Status ⓘ
Clinical Research (5075) eHealth (4982) Dossier Format and Submission (4712)

Distribution (3362) Device Classification (2505) Import Export (2489)

DA AdComm Alerts: Medical Devices a

Select your preferences ⓘ

Country/Region Select All Clear All Sort By Frequency

Topic
510(k) (40325) Guideline (7703) EPAR (7214) Federal Register Announcement (3067)

Document Type
Warning Letter (2906) Notification (2462) Announcement (2131) Report (2118)

Document Category
Standard (2116) Regulation (1745) Press Release (1744) Form (1633)

Translation Status ⓘ
Supplemental Approval - NDA (1476) Inspection Report (1435) Meeting (1230)

Public Comment (1160) Supplemental Approval - BLA (950) Communication (808)

DA AdComm Alerts: Medical Devices a

DA AdComm Alerts: Drugs and Biologi
vices and IVDS

Cancel Apply

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





The screenshot displays the Cortellis Regulatory Assistant interface. At the top, the 'Cortellis' logo is on the left, and search and user options are on the right. The main navigation area includes 'Regulatory' with sub-tabs for 'Analytics Tools' and 'CMC Intelligence'. Below this are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. A 'Quick Search' section features a search bar with the placeholder 'Quick search English keywords', a 'Search' button, and an 'Advanced search' button. Below the search bar are filter buttons for 'Country/Region', 'Topic', 'Document Type', 'Document Category', 'Date', 'Translation Status', and 'All other filters', along with a 'Reset Filters' button. On the right side, a user profile dropdown menu is open, showing options like 'My work', 'Searches and alerts', 'Search history', 'Weekly updates', 'Reports', 'Side by side list', 'Side by side history', 'Settings', 'Language', and 'Sign out'. A blue callout box points to the 'Weekly updates' option in the menu, containing the text: 'ログイン後のTOPページ右上に位置する自身のアカウントアイコンから、My Workを選択し、Weekly Updatesをクリックします。' (After logging in, click on your account icon in the top right corner of the main page, select My Work, and click on Weekly Updates.)

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。


Quick Search

 View all

FDA and Inspection

 Filter

Select all Sort by 

My Regions 

Country/Region

USA (18547)	Thailand (244)	Philippines (171)	European Union (64)	Taiwan (44)	Canada (30)	China (28)	Egypt (11)	Japan (11)		
International (10)	Israel (8)	Singapore (8)	Chile (7)	Brazil (5)	India (4)	South Korea (4)	Jordan (3)	Mexico (3)	United Arab Emirates (3)	
Argentina (2)	Denmark (2)	Iraq (2)	Ireland (2)	Saudi Arabia (2)	Switzerland (2)	Vietnam (2)	Algeria (1)	Austria (1)	Colombia (1)	Italy (1)

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

Customize Columns

Sorted by Relevance



Summary

Title

Abstract

Previous Version

Reason



29-Jun-2012



TW

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

ZH

RD



12-Dec-2017



TW

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

ZH

RD



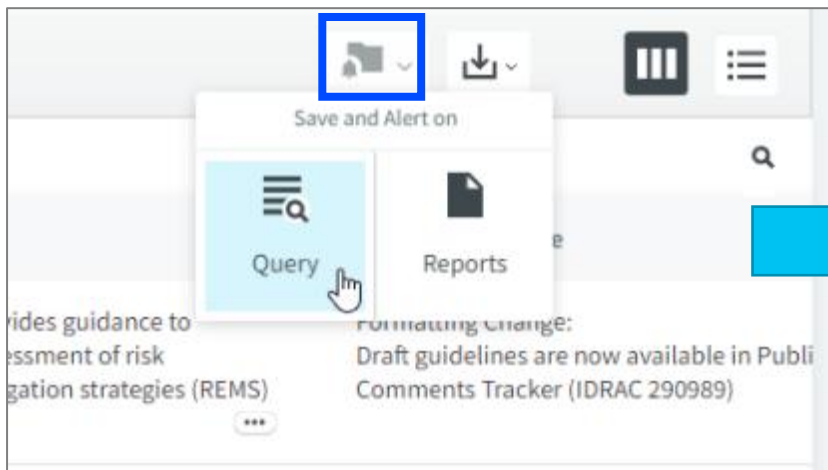
This d file of transl.

Save and Alert on

Query

Reports

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

A detailed view of the 'Save Search Query' dialog box. The dialog has a title bar with a close button and the text 'Save Search Query'. Below the title bar, there is a 'Title' field containing '"risk management plan" 30-Nov-2020 06:14:10'. To the right of this field is a blue callout box: '任意のアラート名称を設定できます'. Below the title bar, there is a 'Details' section with the following information: 'Query: "risk management plan"', 'Content Set: Regulatory', and 'Filters: 4 Filters Applied'. Below the details, there is a 'Create Alert' checkbox which is checked, with a blue callout box: 'このチェックを外すとアラート設定せずに検索条件の保存だけを行います'. To the right of the 'Create Alert' checkbox is a small upward-pointing arrow icon, with a blue callout box: 'アラート頻度などの詳細設定をするには"Create Alert"の右隣の矢印アイコンをクリックします'. Below the 'Create Alert' checkbox, there is a 'Format' section with 'HTML' selected and 'Text' as an option. Below that is a 'Share' section with an email address 'training.japan21@clarivate.com' and an 'Add more' button. To the right of the 'Share' section, there is a 'Frequency' dropdown menu with 'Daily' selected, and a blue callout box: 'Frequency アラートの頻度をDaily, Weekly, Monthlyの3つから選択できます'. At the bottom of the dialog, there are 'Cancel' and 'Save' buttons. A blue callout box points to the 'Save' button: '"Save"で設定完了'.

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

参考：アラートメールのイメージ

Cortellis™



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	<p>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:</p> <ol style="list-style-type: none"> 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.

	<p>Compared to the previous version (IDRAC 329945), this document:</p> <ul style="list-style-type: none"> - 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 <p>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).</p>		
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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