

# 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               |
|----|----------------|----------------|-----------------------------|----------------------------------|-------------------------------|------------------------|-------------------|-------------------------------|-----------------|
| 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 | <a href="#">411138</a> | 18-7-2025         | N/A                           | N/A             |
| 3  | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 13, 2025, FDA cleared | <a href="#">411134</a> | 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 | <a href="#">411131</a> | 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 | <a href="#">411123</a> | 18-7-2025         | N/A                           | N/A             |
| 6  | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 03, 2025, FDA cleared | <a href="#">411115</a> | 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 | <a href="#">411113</a> | 18-7-2025         | N/A                           | N/A             |
| 8  | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 11, 2025, FDA cleared | <a href="#">411111</a> | 18-7-2025         | N/A                           | N/A             |
| 9  | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 05, 2025, FDA cleared | <a href="#">411109</a> | 18-7-2025         | N/A                           | N/A             |
| 10 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 27, 2025, FDA cleared | <a href="#">411105</a> | 18-7-2025         | N/A                           | N/A             |
| 11 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 03, 2025, FDA cleared | <a href="#">411098</a> | 18-7-2025         | N/A                           | N/A             |
| 12 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 06, 2025, FDA cleared | <a href="#">411095</a> | 18-7-2025         | N/A                           | N/A             |
| 13 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 27, 2025, FDA cleared | <a href="#">411092</a> | 18-7-2025         | N/A                           | N/A             |
| 14 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 11, 2025, FDA cleared | <a href="#">411091</a> | 18-7-2025         | N/A                           | N/A             |
| 15 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 20, 2025, FDA cleared | <a href="#">411089</a> | 18-7-2025         | N/A                           | N/A             |
| 16 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 27, 2025, FDA cleared | <a href="#">411081</a> | 17-7-2025         | N/A                           | N/A             |
| 17 | USA            | 510(k)         | Product Assessment          | 510(k) Premarket Notification K2 | On June 20, 2025, FDA cleared | <a href="#">411078</a> | 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 shows the Cortellis Regulatory Search interface. The top navigation bar includes the Cortellis logo, a search bar labeled 'Regulatory Search', and a 'Regulatory Assistant' button with a 'NEW' badge. A user profile icon in the top right corner has a dropdown menu open, listing options: 'My work', 'Settings', 'Account', 'Content', 'Preferences', 'Regions', 'My Email Subscriptions', 'Language', and 'Sign out'. The 'Settings' and 'My Email Subscriptions' options are highlighted in yellow. 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' (Select My Email Subscriptions from your account icon in the top right corner of the TOP page after login). The main content area features a 'Regulatory' section with tabs for 'Analytics Tools' and 'CMC Intelligence'. Below these are tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. A 'Quick Search' section contains a search input field 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. A blue banner at the bottom right says '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

Weekly Update listing all important product/content updates for the previous week will be sent directly to your email inbox every week. 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.

ON

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

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

Select your preferences ⓘ

×

Country/Region

🔍

Select AllClear AllSort ByFrequency ▾

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

ces and IVDs

Cancel

Apply

Select your preferences ⓘ

×

Country/Region

🔍

Select AllClear AllSort ByFrequency ▾

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

Country/Region

🔍

Select AllClear AllSort ByFrequency ▾

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

ces 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 shows the Cortellis Regulatory search interface. The top navigation bar includes the Cortellis logo, a search bar with 'Regulatory Search', and a 'Regulatory Assistant' button with a 'NEW' badge. A user profile icon is in the top right corner. The main content area has tabs for 'Regulatory', 'Analytics Tools', and 'CMC Intelligence'. Under 'Regulatory', there are sub-tabs: 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. A 'Quick Search' section features a text input field 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. A blue callout box points to the user profile icon in the top right, 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。'. The user menu is open, showing options: 'My work', 'Searches and alerts', 'Search history', 'Weekly updates', 'Reports', 'Side by side list', 'Side by side history', 'Settings', 'Language', and 'Sign out'. A 'Try our NEW Regulatory' button is also visible.

Cortellis

Regulatory Search

Regulatory Assistant

NEW

Regulatory

Analytics Tools

CMC Intelligence

Drugs & Biologics

All

Comparison Tables

Intelligence Reports

Regulatory Summaries

Source Documents

Quick Search

Quick search English keywords

Search

Advanced search

Filter

Country/Region

Topic

Document Type

Document Category

Date

Translation Status

All other filters

Reset Filters

Try our NEW Regulatory

My work

Searches and alerts

Search history

Weekly updates

Reports

Side by side list

Side by side history

Settings

Language

Sign out

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。

# 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<br>Document Type: 510(k) |   |
| Volume 28 | 14-Jul-2025 | Topic: Product Assessment<br>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

Search

Advanced search

Filter

Country/Region

Topic

Document Type

Document Category

Date

Translation Status

All other filters

Reset Filters



☐ Select all

Clear all

Sort by

Frequency

Country/Region

My Regions

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)

Cancel

Apply



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

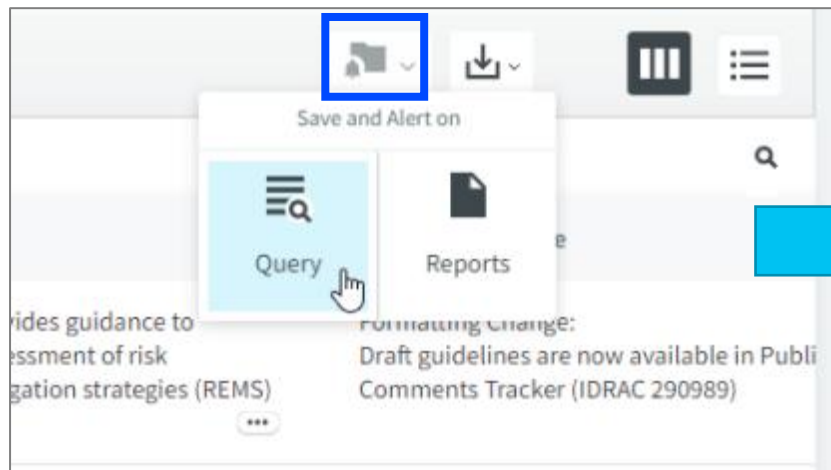
| <input checked="" type="checkbox"/> | Summary                                                                       |  | Title                                                                                                                                            | Abstract                                                                                                                | Previous Version | Reason                       |
|-------------------------------------|-------------------------------------------------------------------------------|--|--------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------------|------------------------------|
| <input checked="" type="checkbox"/> | <div>29-Jun-2012</div> <div>ZH</div> <div>RD</div> <div>V</div> <div>TW</div> |  | 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              | This s<br>chang<br>affecti   |
| <input checked="" type="checkbox"/> | <div>12-Dec-2017</div> <div>ZH</div> <div>RD</div> <div>V</div> <div>TW</div> |  | 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              | This d<br>file of<br>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

**Save Search Query**

Title "risk management plan" 30-Nov-2020 06:14:10

Details

Query "risk management plan"

Content Set Regulatory

Filters 4 Filters Applied

☒ Create Alert ^

Format

HTML Text

Frequency

Daily

Daily Weekly Monthly

Share

training.japan21@clarivate.com X Add more

Cancel Save

任意のアラート名称を設定できます

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

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

Frequency  
アラートの頻度をDaily, Weekly, Monthlyの3つから選択できます

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

"Save"で  
設定完了

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

1 Report was new to your results set in this time period.

[View in Cortellis](#)

|                                                                                                                                                             |                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Taiwan - <a href="#">Guideline: Application for Changes to the Registration of Medical Device Manufacturing License and Approval Documents, 10-Mar-2025</a> |                                                                                                                                                                                                                                                                       |
| 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:<br><br>- add the application methods for electronic and paper submission<br>- 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)<br>- revise the terms used in the application form without major changes in the content<br><br>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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