



Cortellis Regulatory Intelligence

Medical Devices and IVDs Regulatory Summary

他国の承認情報や臨床評価により、市場アクセスの迅速化が可能になる
規制メカニズムの有無について確認する

Regulatory Summaryは医療機器や体外診断薬の開発段階～市販後までの様々な規制対応プロセスを英語で解説しています。各国で同じトピックの解説文を統一された文書構成で提供している為、以下のトピックごとに迅速な要件把握を必要とするお客様をサポートします。

- 当該国における医療機器の定義、主要な法的基盤
- 当該国の管轄規制当局・指定機関
- 医療機器の分類
- 製造業者、販売業者、輸入業者及び指定代理人に対する要件
- 品質システム要件／GMP規制／査察
- デバイス・ドシエ／技術ファイル／申請書及び提出書類
- 医療機器の承認・認可・認証・適合性評価・その他の仕組み
- 包装および表示に関する要件
- 市販後変更に関する要件
- 臨床試験の規制法令等
- 各種手続きにおける費用
- ビジランスおよびリコール
- 検査など当局の対応措置と施行規則
- 広告
- 価格設定および償還
- 貿易および当局間の協力協定
- 将来的な変更が差し迫っている規制

Regulatory Summary

Regulatory Summary
Continuously monitored and updated



Medical Devices Regulatory Framework (USA)

Reason for update	Date	Reason for update description
Content Update	2024-05-20	The regulatory summary has been updated to revise the link of Remanufacturing of Medical Devices (IDRAC 383704) only in section Q8.4 with no content change.
Content Update	2024-04-02	This revision updates SOPP 8704: Managing MDUFA User Fee Payments and Billing Activities (IDRAC 381381) in section Q11.1 with no content change.
Formatting Change	2024-02-20	This document has been revised to delete the guidance bulletins.
Formatting Change	2023-12-11	formatting change
Content Update	2023-11-08	This revision updates section Q12.4 with HL7 individual case safety reporting information. Also updates Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Final) (IDRAC 371692) in section Q 12.10 and Q18, Draft Guidance for Industry and the FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (IDRAC 371692) in section Q12.10. Guidance for Industry and Food and Drug Administration Staff: Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificates for Devices, Nov-2023 (IDRAC 373789) in section Q 4.6 and Q4.8. And Guidance for Industry and Food and Drug Administration Staff: Electronic Submission Template for Medical Device 510(k) Submissions (IDRAC 371916) (IDRAC 371916) in section Q6.6 and annex files with no content update.
		This revision, updates; Guidance for Industry: Breakthrough Devices Program (IDRAC 371144) in section Q6.8, Guidance for Industry, Tool Developers, and Food and Drug Administration Staff: Qualification of

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

Summary of Mandatory Reporting Requirements for Manufacturers and Importers

REPORTER	WHAT TO REPORT	TO WHOM	WHEN
Manufacturers	30-day reports of deaths, serious injuries and malfunctions	FDA	Within 30 calendar days of becoming aware of an event
	5-day reports for an event designated by FDA or an event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health	FDA	Within 5 work days of becoming aware of an event
Importers	Reports of deaths and serious injuries	FDA and the manufacturer	Within 30 calendar days of becoming aware of an event
	Reports of malfunctions	Manufacturer	Within 30 calendar days of becoming aware of an event

*FDA Form 3500A (or its electronic equivalent) is required for all reports in this section

Summary of Mandatory Reporting Requirements for User Facilities

REPORTER	WHAT TO REPORT	REPORT FORM #	TO WHOM	WHEN
User Facility	Device-related Death	Form FDA 3500A (IDRAC 117865)	FDA & Manufacturer	Within 10 work days of becoming aware
User Facility	Device-related Serious injury	Form FDA 3500A (IDRAC 117865)	Manufacturer. FDA only if manufacturer unknown	Within 10 work days of becoming aware
User Facility	Annual summary of death & serious injury reports	Form FDA 3419 (IDRAC 117870)	FDA	January 1 for the preceding year

See the [Guidance for Industry: Medical Device Reporting for User Facilities](#) (IDRAC 48005)

Note that [21 CFR 803.30](#) (IDRAC 46892) (User Facility Reporting Requirements) does NOT state that device user facilities are required to report device malfunctions where the malfunction would likely cause or contribute to death or serious injury if the malfunction were to recur.

Note on Combination Products: A final rule on postmarket safety reporting for combination products was issued in the Federal Register. The FDA issued several guidances noting specifics regarding the reporting requirements as well as compliance deadlines for the elements of reporting in the final rule. Refer to Q7 of [How to Market Combination Products](#) (IDRAC 48188) for more information.

ここでは市場アクセスの迅速化を可能にする規制メカニズムの有無について、国別に用意されたRegulatory Summaryの記載内容を確認していきます。下図の手順にて、国名をクリックしサマリを展開します。

The screenshot displays the Cortellis Regulatory Assistant interface. At the top, there is a navigation bar with 'Regulatory Search' and 'Regulatory Assistant' (marked as 'NEW'). Below this, the 'Regulatory' section is active, with tabs for 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents'. The 'Regulatory Summaries' tab is highlighted with a yellow box. A blue arrow points from this tab down to a list of countries under the 'Medical Devices Regulatory Framework' section. The list includes: Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, EAEU, 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, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Africa, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, USA, Ukraine, United Arab Emirates, United Kingdom, Venezuela, Vietnam.

サマリの左側に記載されたセクション一覧から、Q6.8 (Are there any country specific mechanisms available to speed the access of a medical device product to the market?) を選択し、右側の記載内容を確認します。

Q1 Definitions and Legal Basis

Q2 Competent Authorities/Notified Bodies

Q3 Medical Device Classification

Q4 Requirements for Manufacturers, Distributors, Importers and Authorised Representatives

Q5 Quality System Requirements/GMP Regulation/Inspections

Q6 Device Dossier/Technical File/Applications & Submission

Q6.1 What is the legal basis and legal definitions applicable to the device dossier/technical file/application?

Q6.2 Is there an application procedure to a regulatory authority (or notified body)?

Q6.3 What are the content requirements for the device dossier/technical file/application?

Q6.4 Are there any mandatory recognized harmonized/consensus standards?

Q6.5 Is there a specific format required for device dossier/technical file applications?

Q6.6 Is the device dossier/technical file/application to be submitted in paper or electronic format?

Q6.7 Is there a possibility to interact with the regulatory authority (or notified body) in the pre-submission/certification phase?

Q6.8 Are there any country specific mechanisms available to speed the access of a medical device product to the market?

Q6.9 What guidances are applicable to this section?

Q7 Device Approval/Clearance/Certification/Conformity Assessment/Other mechanisms

Q8 Packaging and labeling requirements

Q9 Postmarketing Device Modification Requirements

Q10 Devices Clinical Investigations

Q11 Fees

Q12 Device Vigilance and Recalls

Q13 Enforcement

Q14 Advertising

Q6.8 Are there any country specific mechanisms available to speed the access of a medical device product to the market?

Yes. There are several mechanisms in Thailand to accelerate the approval process, including the following.

i. Concise Evaluation Scheme

The Thai FDA has implemented a concise evaluation scheme for some detailed notification medical devices and/ or licensed medical devices. Additionally, the Thai FDA allows applicants to apply by referring to the existing documents, transferring documents for detailed notification medical devices (moderate to high-risk medical devices) as per [Guidelines for Referencing Existing Documents, Transferring Documents, or Other Cases in the Application for the License for Manufacturing or Importation of Detailed Notification Medical Device B.E. 2567 \(2024\)](#) (IDRAC 390672).

This scheme is available for Detailed Notification Medical Devices and/or Licensed Medical Devices that meet the two conditions below.

1. The medical device has been approved by one of the following regulatory authorities:
 - Therapeutic Goods Administration (TGA) of Australia,
 - Health Canada (HC) of Canada,
 - European Union Notified Bodies (EU NB) of European Countries,
 - Japan Ministry of Health Labour and Welfare (MHLW) of Japan,
 - US Food and Drug Administration (US FDA) of the USA, or
 - WHO Prequalification of In Vitro Diagnostic (WHO PQ IVD) of WHO

The period of obtaining approval from the authorities above must be at least one year or more, and it must not be a medical device that has been approved with an exemption from the Evaluation of Safety and Performance.

タイFDAは、特定の条件下で、申請者が既存文書を参照する方式による申請を認めている。

例：当該医療機器が以下の規制当局のいずれかにより承認されていること：オーストラリア治療製品管理局 (TGA) カナダ保健省 (HC) 欧州連合指定機関 (EU NB) 日本厚生労働省 (MHLW) 米国食品医薬品局 (US FDA) 世界保健機関体外診断用医薬品事前認証 (WHO PQ IVD) 日本の厚生労働省 (MHLW)、米国の食品医薬品局 (US FDA)、またはWHO体外診断用医薬品事前審査 (WHO PQ IVD)

参考例：タイ

2025年9月より、メキシコでは「Vía Regulatoria Abreviada」（略式規制経路）と呼ばれる国別の規制メカニズムを導入し、医療機器の市場アクセスを大幅に迅速化している。

- 参照規制当局（RRA）による事前承認の承認（IMDRFおよびMDSAPのメンバーを含む）
- WHO推奨の依存原則の適用
- 具体的なタイムライン：医療機器については30営業日
- 条件：当該機器は海外で承認されたものと同じである必要があり、通常の承認のみが認められる（緊急承認や条件付き承認は不可）

参考例：メキシコ

- ▶ Q1 Definitions and Legal Basis
- ▶ Q2 Competent Authorities/Notified Bodies
- ▶ Q3 Medical Device Classification
- ▶ Q4 Requirements for Manufacturers, Distributors, Importers and Authorised Representatives
- ▶ Q5 Quality System Requirements/GMP Regulation/Inspections
- ▶ **Q6 Device Dossier/Technical File/Applications & Submission**
 - Q6.1 What is the legal basis and legal definitions applicable to the device dossier/technical file/application?
 - Q6.2 Is there an application procedure to a regulatory authority (or notified body)?
 - Q6.3 What are the content requirements for the device dossier/technical file/application?
 - Q6.4 Are there any mandatory recognized harmonized/consensus standards?
 - Q6.5 Is there a specific format required for device dossier/technical file applications?
 - Q6.6 Is the device dossier/technical file/application to be submitted in paper or electronic format?
 - Q6.7 Is there a possibility to interact with the regulatory authority (or notified body) in the pre-submission/certification phase?
 - Q6.8 Are there any country specific mechanisms available to speed the access of a medical device product to the market?**
 - Q6.9 What guidances are applicable to this section?
- ▶ Q7 Device Approval/Clearance/Certification/Conformity Assessment/Other mechanisms
- ▶ Q8 Packaging and labeling requirements
- ▶ Q9 Postmarketing Device Modification Requirements

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Q6.8 Are there any country specific mechanisms available to speed the access of a medical device product to the market?

Since Sep-2025, Mexico has a country-specific mechanism called the “Vía Regulatoria Abreviada” (Abbreviated Regulatory Pathway), which significantly speeds up market access for medical devices. This mechanism was formalized through an [Agreement Establishing General Guidelines for the Abbreviated Regulatory Pathway for the Granting of Health Supplies Marketing Authorizations Based on Recognition of Foreign Regulatory Authorities and WHO Prequalification](#) (IDRAC 411300).

This agreement establishes:

- Recognition of prior approvals from Reference Regulatory Authorities (RRA), including members of IMDRF and MDSAP.
- Application of the WHO-recommended reliance principles.
- Specific timelines: 30 business days for medical devices.
- Conditions: The device must be identical to the one approved abroad, and only ordinary approvals are accepted (no emergency or conditional authorizations).

Q6.9 What guidances are applicable to this section?

- [Agreement Establishing Simplification of Procedures Before the COFEPRIS, 15-Aug-2025](#) (IDRAC 412989)
- [Agreement Establishing General Guidelines for the Abbreviated Regulatory Pathway for the Granting of Health Supplies Marketing Authorizations Based on Recognition of Foreign Regulatory Authorities and WHO Prequalification, 15-Jul-2025](#) (IDRAC 411300)

該当国における臨床評価のスキップについては、Q10.2（Is a clinical evaluation required for devices?）にて、関連する記載を確認可能な場合がございます。

参考例：インド

The screenshot shows a document viewer interface. On the left is a table of contents with the following items:

- ▶ Q1 Definitions and Legal Basis
- ▶ Q2 Competent Authorities/Notified Bodies
- ▶ Q3 Medical Device Classification
- ▶ Q4 Requirements for Manufacturers, Distributors, Importers and Authorised Representatives
- ▶ Q5 Quality System Requirements/GMP Regulation/Inspections
- ▶ Q6 Device Dossier/Technical File/Applications & Submission
- ▶ Q7 Device Approval/Clearance/Certification/Conformity Assessment/Other mechanisms
- ▶ Q8 Packaging and labeling requirements
- ▶ Q9 Postmarketing Device Modification Requirements
- ▼ Q10 Devices Clinical Investigations
 - Q10.1 Which laws and regulations govern clinical investigations for devices?
 - Q10.2 Is a clinical evaluation required for devices?
 - Q10.3 Is the submission of an investigational application to regulatory authorities needed?
 - Q10.4 What is the procedure for an application for clinical investigation?
 - Q10.5 Is ethics committee approval required?
 - Q10.6 What are the requirements concerning the reporting of adverse incidents during a clinical investigation?
 - Q10.7 What requirements apply to investigational devices?
 - Q10.8 Can an investigational device be used outside of the study protocol, in an emergency situation?
 - Q10.9 What guidances are applicable to this section?
- ▶ Q11 Fees
- ▶ Q12 Device Vigilance and Recalls
- ▶ Q13 Enforcement
- ▶ Q14 Advertising
- ▶ Q15 Pricing & Reimbursement
- ▶ Q16 Trade Agreements/Cooperation
- ▶ Q17 Future Developments and/or Imminent Changes to the Regulations

The main content area on the right displays the text for Q10.2, which is highlighted with a yellow border:

Q10.2 Is a clinical evaluation required for devices?

Yes, according to [Essential Principles for Safety and Performance of Medical Devices](#) (IDRAC 274540), for all medical devices, the demonstration of conformity with essential principles includes a clinical evaluation. The clinical evaluation should review clinical data in the form of any, (a) clinical investigation reports; (b) literature reports/reviews; or (c) clinical experience, to establish that a favorable benefit-risk ratio exists for the device.

The results of clinical investigation in India may not be required to be submitted where the investigational medical device is approved by the regulatory authorities of either the United Kingdom or the United States of America or Australia or Canada or Japan and the said device has been marketed for at least two years in that country and the Central Licensing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device.

As per Medical Device Rule-36 sub-rule and [Medical Devices Frequently Asked Questions No. CDSCO/FAQ/MD/01/2024 Addendum No. 2, 09-Jul-2025](#) (IDRAC 410611):

- For Class A & Class B devices, published safety and performance data or clinical investigation reports generated in the country of origin may be submitted if a Free Sale Certificate from specified countries is not available.
- For Class C & Class D devices, a clinical investigation report generated in India may be submitted if a Free Sale Certificate from specified countries is not available.

Below this, Q10.3 is also visible:

Q10.3 Is the submission of an investigational application to regulatory authorities needed?

Yes, according to the Seventh Schedule of the [Medical Device Rules](#) (IDRAC 362804). To import or manufacture an investigational medical device for conducting a clinical investigation, an application in Form MD-22 shall be made to the Central Licensing Authority along with the following data:

- (i) Design analysis data
- (ii) Bio-compatibility and Animal Performance Study
- (iii) Information shall be submitted along with Investigator's Brochure as prescribed, Clinical Investigational Plan as prescribed in Table 5, Case Report Form, Serious adverse event reported, if any, Informed Consent Form, investigator's undertaking and Ethics Committee approval, if available.
- (iv) Regulatory status in other countries, including information in respect of restrictions imposed, if any, on use of investigational medical devices in other countries, prescription-based devices, exclusion of certain age groups, warning about adverse device effects. Likewise, if the investigational medical device has been withdrawn in any country by the manufacturer or by the regulatory authority, such information shall also be furnished along with reasons and its relevance, if any. This information must continue to be submitted by the sponsor to the Central Licensing Authority during the entire duration of marketing of the said medical device in the country
- (v) Proposed instructions for use or electronic instructions for use, or directions for use and labels shall be submitted as part of the application. The drafts of the label shall comply with the provisions of the labeling rules specified in the Medical Device Rules, 2017.

対象医療機器が英国、米国、オーストラリア、カナダ、または日本の規制当局により承認され、かつ当該国において少なくとも2年間販売されており、中央認可機関が当該機器の安全性、性能、ファーマコビジランスに関するデータに満足している場合には、インドにおける臨床調査結果の提出が不要となる場合があります。



Think forward

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