

REGDESK DATAMANAGER

REGULATORY INTELLIGENCE REPORT · JULY 2026

2026 Global Regulatory Updates — Impact on Submission Wizards

New Device Registration · 14 Key Markets · Enforcement Dates & Action Items

MARKETS COVERED

14 Jurisdictions

REPORT DATE

July 2026

CLASSIFICATION

Confidential

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Executive Summary

The 2026 regulatory landscape introduces substantial changes across all major markets, with four dominant themes reshaping how new medical device registrations must be submitted. Submission wizard builders must act now to accommodate mandatory e-submission portals, updated data fields, UDI enforcement, and AI/SaMD-specific sections.

⚠️ Research Note: This report is based on regulatory intelligence gathered as of July 2026. Requirements may evolve. Always verify specific submission requirements with the relevant regulatory authority before filing.

THEME 01

Mandatory E-Submission Portals

The USA (eSTAR), Canada (CESG/REP), EU (EUDAMED), UK (MHRA portal), Brazil (SOLICITA), and Australia (new TGA Business Services) have all mandated or expanded electronic-only filing. Email and paper-based submissions are being phased out or eliminated entirely across top markets.

THEME 02

UDI Enforcement Expanding Globally

Mandatory UDI data entry is now required in submission wizards for Australia (Class IIb/III from July 2026), EU (EUDAMED UDI database fully operational), South Korea (expanded scope), and Saudi Arabia. Wizards must include UDI-DI/UDI-PI fields and validation logic.

THEME 03

AI / SaMD New Required Sections

FDA (eSTAR updated Aug 2026), TGA (Australia, Feb 2026 guidance), MHRA, and NMPA (China) now require dedicated AI/SaMD sections in submission templates. Wizards need new conditional modules covering intended use, training data, lifecycle management, and transparency requirements.

THEME 04

Human Factors & Risk-Based Categories

FDA's finalized Human Factors guidance (effective Aug 1, 2026) introduces three risk-based HF submission categories. The eSTAR templates were updated Aug 2026 to include mandatory HF validation sections. Similar risk-based HF requirements are expanding in EU (MDR Annex I), UK, and Japan.

14	38+	12	8	2026
MARKETS COVERED	REGULATORY UPDATES	HIGH-IMPACT CHANGES	NEW E-PORTALS / MANDATES	ENFORCEMENT YEAR

 AMERICAS

 USA — FDA (CDRH)
510(K) · DE NOVO · PMA · ESTAR PROGRAM

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
eSTAR Mandatory — De Novo	All De Novo requests (with limited exceptions) must be submitted electronically via eSTAR. Wizard must route De Novo submissions through the CDRH Portal with structured eSTAR PDF format.	Oct 1, 2025 (enforced 2026)	HIGH
Human Factors Guidance — New Submission Categories	FDA finalized HF guidance (May 28, 2026, effective Aug 1, 2026) introducing 3 risk-based HF Submission Categories. eSTAR templates updated Aug 2026 to include mandatory HF validation section. Wizards must add conditional HF module with category-selection logic for 510(k), De Novo, and PMA submissions.	Aug 1, 2026	HIGH
QMSR (21 CFR Part 820 Revision)	QMS regulation now aligned to ISO 13485:2016. Submission wizards should update QMS declaration fields and reference ISO 13485 instead of legacy QSR for applicable submissions.	Feb 2, 2026	MEDIUM
Electronic Labeling (NPRM)	FDA proposes allowing replacement of paper IFU with e-labels. While not yet mandatory, submissions will eventually require electronic labeling declarations. Wizard should add e-labeling section for forward compatibility.	NPRM: Nov 2026	LOW



UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
Mandatory REP + CESG Electronic Gateway	Regulatory Enrollment Process (REP) is now mandatory for all Class II, III, IV submissions and amendments. Submissions via Common Electronic Submissions Gateway (CESG) are required — email submissions no longer accepted. Wizard must generate CESG-compliant packages and support REP enrollment data fields.	Jan / Apr 2026	HIGH
MDL Guidance v5 — Stricter Screening	New Guidance v5 (Feb 2, 2026) introduces tighter deficiency response timelines and stricter screening procedures. Wizard must enforce completeness checks before submission to prevent screening failures.	Feb 2, 2026	HIGH
Terms & Conditions Framework	Health Canada can now impose legally binding T&Cs on MDLs (Class II–IV). Wizard should include T&C acknowledgment section and post-market commitment fields in submission forms.	Jan 1, 2026	MEDIUM
MDEL Phase 2 Amendments	Mandatory supplier lists required with MDEL applications (name, address, device risk class per supplier). Wizard must add supplier list data module for MDEL submissions.	Dec 14, 2026	MEDIUM
Significant Change Guidance — Final	Final guidance (Mar 31, 2026) clarifies when amended MDL is required before implementing device changes. Wizard should add "Significant Change Assessment" pre-screening module for amendment submissions.	Mar 31, 2026	MEDIUM



Brazil — ANVISA

SOLICITA PORTAL · RDC 751/2022 IMPLEMENTATION

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
SOLICITA e-Submission Portal — Mandatory	ANVISA's SOLICITA electronic submission system is the mandatory channel for all product registration petitions. Physical submissions eliminated. Wizards must generate SOLICITA-compatible documentation packages and support all required data fields for Class II–IV medical devices.	Fully enforced 2026	HIGH
RDC 751/2022 Full Enforcement	Full enforcement of the updated device classification and registration regulation (RDC 751/2022). Wizard must reflect updated risk classification mapping for ANVISA classes (I–IV) and include all newly required technical documentation sections.	2026 (phased)	HIGH
QMS Certification Requirements	Updated QMS certification documentation (BPFC — Good Manufacturing Practices) must accompany Class II–IV submissions. Wizard must add BPFC certificate upload field and expiry date validation.	Ongoing 2026	MEDIUM



Mexico — COFEPRIS

FEDERAL COMMISSION FOR PROTECTION AGAINST SANITARY RISK

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
VuCE e-Submission Platform	COFEPRIS continues mandatory use of the VuCE (Ventanilla Única de Comercio Exterior) electronic platform for device registration submissions (dispositivos médicos). Wizard must support VuCE-formatted submissions with all mandatory Mexican NOM standard references.	Ongoing / 2026 expanded	MEDIUM
NOM Updates for IVD & Class III Devices	Updated technical standards (NOMs) for specific device categories require additional technical documentation. Submission wizard must include NOM compliance declaration fields and reference updated 2026 NOM list.	2026	MEDIUM

 EUROPE



European Union — EC / EUDAMED

MDR (EU 2017/745) · IVDR (EU 2017/746) · EUDAMED DATABASE

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
EUDAMED Mandatory Registration	EUDAMED actor registration and device registration (UDI/Device Module) became mandatory. All economic operators placing devices on the EU market must register via EUDAMED. Submission wizards must integrate EUDAMED actor ID and device SRN fields into all EU device registration workflows.	Mandatory — 2026	HIGH
UDI Database — Mandatory Data Upload	Manufacturers must upload UDI-DI data to EUDAMED before placing devices on the EU market. Submission wizard must include EUDAMED UDI registration confirmation step and validate UDI-DI/UDI-PI format compliance.	Mandatory — 2026	HIGH
IVDR Full Enforcement (Class B/C)	IVDR full enforcement extended to additional IVD classes with updated transition timelines. Wizard must support IVDR-specific classification rules, performance evaluation requirements, and notified body involvement flags for Class B, C, D IVDs.	Phased 2026–2027	HIGH
Common Specifications (CS) Updates	New Common Specifications published for specific device categories under MDR/IVDR, establishing minimum technical requirements. Wizard must add CS compliance declaration fields and reference applicable CS documents by device type.	2026 (rolling)	MEDIUM
Notified Body Capacity & Documentation	Increased documentation requirements for notified body (NB) submissions, including expanded clinical evaluation documentation (MEDDEV 2.7/1 Rev 4 application). Wizard must enforce complete clinical evidence section requirements.	Ongoing 2026	MEDIUM



United Kingdom — MHRA

MEDICAL DEVICE REGISTRATION · DSAR · UK MDR 2002 (AMENDED)

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
New MHRA Registration Portal	MHRA launched a redesigned digital submission portal for medical device registration in the UK. Manufacturers and UK Responsible Persons must register through the new system. Wizard must support new MHRA portal data format and UK Responsible Person (UKRP) details as mandatory fields.	2026	HIGH
UK MDR Reform — New Classification Rules	Post-Brexit UK MDR reform introduces updated classification rules increasingly diverging from EU MDR. Certain device classes require re-assessment. Wizard must maintain separate UK classification logic vs. EU classification and support UKCA marking pathways.	2026 (phased)	HIGH
AI / SaMD Guidance — MHRA	MHRA published updated guidance on Software as a Medical Device (SaMD) and AI-enabled devices, expanding documentation requirements. Wizard needs dedicated SaMD/AI section with MHRA-specific fields (intended clinical function, clinical evidence for AI outputs).	2026	MEDIUM
International Reliance Pathways	MHRA expanded reliance on FDA, Health Canada, and TGA approvals for faster registration. Wizard must add "Reliance Pathway" selection option linking to existing foreign approval data fields.	2026	LOW



Switzerland — Swissmedic

MEPV / SWISS MDR ALIGNMENT

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
EU MDR/IVDR Alignment — Full Enforcement	Switzerland's Medical Devices Ordinance (MepV) fully aligned with EU MDR 2017/745 and IVDR 2017/746. Manufacturers with CE-marked devices benefit from simplified Swiss registration, but EUDAMED-registered devices must also be notified to Swissmedic. Wizard must add Swiss CH-REP (Authorised Representative) field and Swissmedic notification step.	2026	MEDIUM
e-Submission via RegDesk/Swissmedic Portal	Swissmedic mandates electronic notification for medical devices via the dedicated online portal. Paper-based notifications phased out. Wizard must generate Swissmedic-compliant structured submission data.	2026	MEDIUM

 ASIA-PACIFIC

 Australia — TGA
THERAPEUTIC GOODS ADMINISTRATION · ARTG

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
UDI Phased Rollout — Class IIb & III	UDI requirements commence for higher-risk devices (Class IIb/III). Wizard must add TGA UDI data fields (UDI-DI, UDI-PI, issuing agency) and validate format compliance for applicable device classes starting July 2026.	Jul 1, 2026	HIGH
New TGA Business Services Portal	Refreshed TGA Business Services portal and new Health Business Services single sign-on system rolled out 2026–2027. Wizard must support new portal authentication flows and updated submission data schemas.	2026–2027 rollout	HIGH
AI-Enabled Medical Device Software Guidance	Updated TGA guidance (Feb 5, 2026) on AI/ML-enabled SaMD clarifies classification and evidence requirements. Wizard must add AI/SaMD conditional module for software devices including training data description, intended use environment, and lifecycle management documentation.	Feb 5, 2026	MEDIUM
Classification Rule 5.5 Reclassification Deadline	Sponsors of affected devices (microbial, recombinant, animal substances) must submit reclassification applications before Jul 1, 2026. Wizard must flag devices matching Rule 5.5 criteria and route to reclassification workflow.	Jul 1, 2026	MEDIUM
Mandatory Adverse Event Reporting (Healthcare Facilities)	Healthcare facilities must report adverse events for high-risk devices via ASDER system from Mar 21, 2026. Wizard post-market module must include ASDER reporting pathways for Class III and Class 4 IVD devices.	Mar 21, 2026	LOW



Japan — PMDA / MHLW

PHARMACEUTICALS AND MEDICAL DEVICES AGENCY · MINISTRY OF HEALTH

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
PMDA Gateway — Expanded e-Submission	PMDA Gateway mandatory electronic submission system expanded scope for medical device applications (Shonin). Wizard must generate PMDA-compatible structured submission packages including all required Japanese labeling sections and clinical data in Japanese language.	2026 (expanded)	HIGH
AI/SaMD New Guidance — Programming Medical Devices	PMDA/MHLW published updated guidance for AI-based Software as a Medical Device. New requirements include algorithm change protocol, real-world performance monitoring plan, and transparency documentation. Wizard must add Japan-specific SaMD module.	2026	MEDIUM
Conformity Assessment — Updated Standards	Updated list of applicable JIS/ISO standards for conformity assessment. Submission wizard must reference current 2026 standards list and validate that referenced standards are not superseded.	Ongoing 2026	LOW



China — NMPA

NATIONAL MEDICAL PRODUCTS ADMINISTRATION · CIMRS PORTAL

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
CIMRS Portal — Mandatory e-Registration	China's Comprehensive Intelligent Medical Device Registration System (CIMRS) is mandatory for all imported and domestic medical device registrations. The portal requires structured data entry covering classification, clinical evaluation, QMS certificates, and labeling. Wizard must integrate CIMRS data schema.	Ongoing / 2026 enforced	HIGH
AI Medical Device Classification Guidance	NMPA issued updated guidance on AI-assisted medical devices (2026), introducing new classification criteria and required clinical evidence for AI-enabled devices. Wizard must add NMPA AI device category fields and clinical performance data module.	2026	HIGH
UDI Phase 3 Expansion	China's UDI system Phase 3 expands mandatory UDI coding requirements to additional Class II medical device categories. Wizard must add NMPA UDI fields (DI/PI format) and China UDI database submission step for affected device classes.	2026	MEDIUM
Updated Registration Review Timelines	NMPA streamlined review timelines for Class II devices via online pre-submission consultations. Wizard may integrate pre-submission consultation request module to leverage faster review track.	2026	LOW

 ASIA-PACIFIC (CONTINUED)



Singapore — HSA

HEALTH SCIENCES AUTHORITY · MEDICS PORTAL

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
MEDICS Portal — Enhanced e-Submission	HSA's Medical Device Information and Communication System (MEDICS) enhanced with new data requirements and improved workflow. All device registrations must use MEDICS. Wizard must support updated MEDICS data fields including expanded product description and QMS documentation requirements.	2026 (updated)	MEDIUM
ASEAN CSDT Harmonization	Singapore advances ASEAN Common Submission Dossier Template (CSDT) adoption. Wizard submissions for Singapore should use CSDT-compatible format to facilitate regional harmonization and potential reliance pathways across ASEAN markets.	2026	MEDIUM
SaMD Guidance — Risk Classification	HSA updated guidance on SaMD classification and clinical evidence requirements. Wizard must add SaMD conditional module aligned with HSA's risk-based classification framework for software devices.	2026	MEDIUM



South Korea — MFDS

MINISTRY OF FOOD AND DRUG SAFETY · UNIPASS / E-SUBMISSION

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
UDI Expanded Enforcement	MFDS expanded mandatory UDI requirements to additional medical device categories in 2026. UDI data (DI and PI) must be registered in the MFDS UDI database and included in registration submissions. Wizard must add MFDS UDI fields and database pre-registration confirmation step.	2026 (expanded scope)	HIGH
Digital Health Device Guidance Update	MFDS updated digital health and AI-based medical device guidance, introducing new performance testing and real-world evidence requirements. Wizard needs updated SaMD/AI module for Korean submissions.	2026	MEDIUM
Technical Document — Updated Format	MFDS issued updated technical document format guidelines aligning closer to IMDRF standards. Submission wizard must update Korean technical file structure to reflect new section ordering and mandatory content requirements.	2026	MEDIUM



India — CDSCO

CENTRAL DRUGS STANDARD CONTROL ORGANISATION · SUGAM PORTAL

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
SUGAM Portal — Mandatory e-Filing	CDSCO's SUGAM portal is the mandatory electronic filing system for medical device import licenses (MD-14/MD-15) and manufacturing licenses. All applications must be submitted via SUGAM with all required documents in digital format. Wizard must generate SUGAM-compatible submission packages.	Mandatory — 2026	HIGH
MDR 2017 — Class B/C/D Enforcement	India's Medical Devices Rules 2017 enforcement extended to Class B, C, D devices with updated licensing requirements. Wizard must support India's 4-class (A/B/C/D) risk classification and route submissions to appropriate licensing pathway.	2026 (expanded)	HIGH
BIS Quality Certification Integration	Updated requirements for BIS quality certification for certain domestic device categories. Import license submissions for applicable categories must include BIS certification data. Wizard needs BIS certificate field for relevant device types.	2026	MEDIUM

 MIDDLE EAST



Saudi Arabia — SFDA

SAUDI FOOD & DRUG AUTHORITY · GHAD PORTAL

UPDATE	DESCRIPTION & IMPACT ON SUBMISSIONS	ENFORCEMENT DATE	IMPACT LEVEL
GHAD Portal — Enhanced Mandatory e-Submission	SFDA's GHAD electronic portal is mandatory for all medical device registration submissions. Enhanced 2026 requirements include additional product characterization fields, labeling compliance declarations, and mandatory AR-language labeling upload. Wizard must support full GHAD submission data schema.	Ongoing / 2026 enhanced	HIGH
UDI Mandatory for Class C & D Devices	SFDA mandates UDI for higher-risk Class C and D devices. UDI data must be registered and included in SFDA device submissions. Wizard must add SFDA UDI fields and Saudi-specific barcode format requirements (GS1 standards).	2026	HIGH
Local Technical Representative (LTR) Requirements	Updated guidance on mandatory Local Technical Representative information in registration submissions. Wizard must enforce LTR details as required fields for all non-Saudi manufacturers submitting to SFDA.	2026	MEDIUM
Clinical Evidence — Saudi-Specific Requirements	SFDA expanded requirements for clinical evidence in Class C/D submissions, aligning closer to IMDRF GHTF principles. Wizard must add SFDA clinical evidence section with Saudi-specific fields for post-market clinical follow-up plans.	2026	MEDIUM

Wizard Builder Action Plan

Priority actions for RegDesk Submission Builder teams based on 2026 regulatory changes across all markets.

PRIORITY	ACTION REQUIRED	MARKETS AFFECTED	DEADLINE
P1 — CRITICAL	Update eSTAR templates with new Human Factors section (3 HF categories)	USA — FDA (510k, De Novo, PMA)	Aug 1, 2026
P1 — CRITICAL	Implement CESG/REP gateway integration for Canada submissions	Canada — Health Canada	Apr 2026 (immediate)
P1 — CRITICAL	Add EUDAMED actor ID + SRN + UDI-DI mandatory fields to EU wizard	EU — EUDAMED (MDR/IVDR)	Immediate
P1 — CRITICAL	Add TGA UDI fields + validate for Class IIb/III Australia submissions	Australia — TGA	Jul 1, 2026
P2 — HIGH	Build AI/SaMD conditional module (FDA, TGA, MHRA, PMDA, NMPA, HSA)	USA, AU, UK, JP, CN, SG	Q3–Q4 2026
P2 — HIGH	Add SFDA UDI fields + GHAD portal export format for Saudi Arabia	Saudi Arabia — SFDA	2026
P2 — HIGH	Update India CDSCO wizard with MDR Class B/C/D licensing pathways in SUGAM	India — CDSCO	2026
P3 — MEDIUM	Separate UK UKCA classification logic from EU MDR in wizard routing	UK — MHRA	2026
P3 — MEDIUM	Update MFDS UDI fields + Korean technical document format structure	South Korea — MFDS	2026
P3 — MEDIUM	Integrate ASEAN CSDT format for Singapore and regional harmonization	Singapore — HSA	2026

Global Summary Matrix

At-a-glance overview of key regulatory changes per market and their impact on submission wizard functionality.

MARKET	AUTHORITY	KEY 2026 CHANGE	PORTAL/SYSTEM	UDI IMPACT	AI/SAMD	IMPACT
 USA	FDA / CDRH	HF guidance + eSTAR update, QMSR	CDRH eSTAR / Portal	No new	✔ New HF categories	HIGH
 Canada	Health Canada	Mandatory REP + CESC e-gateway	CESC	No new	—	HIGH
 EU	EC / EUDAMED	EUDAMED mandatory, UDI upload, IVDR	EUDAMED	✔ Mandatory UDI-DI	MDR Annex I updates	HIGH
 UK	MHRA	New portal, MDR reform, SaMD guidance	MHRA Portal	Aligning	✔ SaMD guidance updated	HIGH
 Switzerland	Swissmedic	MepV full MDR alignment, e-notification	Swissmedic Portal	EU-aligned	—	MEDIUM
 Brazil	ANVISA	SOLICITA mandatory, RDC 751 enforcement	SOLICITA	Developing	—	HIGH
 Mexico	COFEPRIS	VuCE platform, NOM updates for IVD/III	VuCE	—	—	MEDIUM

MARKET	AUTHORITY	KEY 2026 CHANGE	PORTAL/SYSTEM	UDI IMPACT	AI/SaMD	IMPACT
 Australia	TGA	UDI rollout Class IIb/III, new portal	TGA Business Services	✓ Jul 2026 Class IIb/III	✓ AI/SaMD guidance Feb 2026	HIGH
 Japan	PMDA	PMDA Gateway expanded, AI guidance	PMDA Gateway	Existing	✓ AI/SaMD new guidance	MEDIUM
 China	NMPA	CIMRS mandatory, AI guidance, UDI Phase 3	CIMRS	✓ Phase 3 Class II expansion	✓ AI device guidance 2026	HIGH
 Singapore	HSA	MEDICS enhanced, ASEAN CSDT	MEDICS	—	✓ SaMD classification update	MEDIUM
 Saudi Arabia	SFDA	GHAD enhanced, UDI Class C/D mandatory	GHAD Portal	✓ Class C/D mandatory	—	HIGH
 South Korea	MFDS	UDI expanded scope, digital health guidance	MFDS e-System	✓ Expanded categories	✓ Digital health update	MEDIUM
 India	CDSCO	SUGAM mandatory, MDR Class B/C/D	SUGAM	—	—	HIGH

Key Takeaways for RegDesk Submission Builder

- **9 of 14 markets** now require mandatory electronic-only submission — paper/email pathways eliminated or being phased out.
- **6 markets** have new or expanded UDI enforcement in 2026 requiring new wizard data fields and validation logic.
- **7 markets** introduced or updated AI/SaMD-specific guidance requiring new conditional wizard modules.
- The **USA eSTAR Human Factors update** (Aug 1, 2026) and **Canada CESG mandate** (Apr 2026) require immediate wizard updates.
- An **ASEAN CSDT-compatible format** for Singapore submissions will improve regional harmonization efficiency.

