Global Postmarket Surveillance Requirements

Top 12 Medical Device Markets

INTRODUCTION

- This guide compares manufacturer-facing postmarket surveillance obligations after commercialization.
- Focuses on vigilance/incident reporting, periodic review, field actions, and local-language/local-agent issues.
- Covers the top 12 medical device markets by sales.
- Practical training aid for RA and QA teams — not legal advice.

AT-A-GLANCE COMPARISON MATRIX

Country	Regulator	Core vigilance reporting	Periodic PMS output	FSCA / recall expectations	Local actor / language	Key watch-out
United States	FDA	30-day MDR; 5-day urgent reports	No PSUR equivalent; complaints/CAPA trending	21 CFR 806 corrections/ removals	Manufacturer, importer; English	Strong complaint-file discipline; 522 studies possible.
China	NMPA + provincial AE monitoring	Event reporting and reevaluation; severity-based timelines, often 15–30 days	Risk review may be required for higher-risk/ special products	Field actions coordinated via local agent and NMPA pathway	Local agent; Chinese	Class, clinical data, and local agent strategy strongly affect PMS execution.
Japan	MHLW/ PMDA	MAH adverse event reporting; typically 15 or 30 days depending on case type	Re-examination/ use-result survey may apply	Recall and safety actions reported promptly	MAH/D-MAH; Japanese	Approval conditions may drive added surveillance.
Germany	BfArM / PEI	EU MDR Art. 87: 2/10/15 days	PMS report (Class I); PSUR IIa every 2 yrs; IIb/III annually	FSCA/FSN without delay	EU AR; German	EUDAMED plus national authority coordination.
United Kingdom	MHRA	Manufacturer vigilance via MORE; seriousness-based timelines often aligned to 2/10/15-day model	PMS/trend review expected; no EU MDR PSUR framework in same form	FSCA coordination with MHRA	UKRP for non-UK firms; English	Great Britain vs Northern Ireland pathway nuance.
France	ANSM	EU MDR Art. 87: 2/10/15 days	PMS report / PSUR per MDR class rules	FSCA/FSN without delay	EU AR; French	Language and ANSM communication matter.
Italy	Ministry of Health	EU MDR Art. 87: 2/10/15 days	PMS report / PSUR per MDR class rules	FSCA/FSN without delay	EU AR; Italian	Local authority interactions and language readiness help.
India	CDSCO + MvPI	Materiovigilance and adverse event reporting; timelines can be case-dependent	No single EU-style PSUR model; active complaint trending important	FSCA/recall coordination through CDSCO channels	Indian Authorized Agent/importer; English widely used	Framework continues to mature; execution discipline matters.
Brazil	ANVISA	Tecnovigilance reporting of adverse events and technical complaints; category-based timelines	No EU-style PSUR; trend/risk review important	Field actions and recalls reported through ANVISA/ Notivisa pathways	Brazilian Registration Holder; Portuguese	Local BRH is central to PMS and FSCA management.
Canada	Health Canada	Mandatory problem reporting: 10 days death/serious deterioration; 30 days near-miss recurrence risk	No EU-style PSUR; complaint trending expected	Recall/problem reporting to Health Canada	Importer/ distributor; English/French	Bilingual considerations and mandatory problem reporting rules.
South Korea	MFDS	Adverse event and defect reporting through local license holder/importer	Re-examination or PMS activities may apply to some products	Recall reporting required	Local license holder/importer; Korean	KGMP and local license holder coordination are important.
Spain	AEMPS	EU MDR Art. 87: 2/10/15 days	PMS report / PSUR per MDR class rules	FSCA/FSN without delay	EU AR; Spanish	RECOPS/local commercialization records and Spanish communications can matter.

MDR = Medical Device Report/ Medical Device Regulation depending context | **PSUR** = Periodic Safety Update Report | **FSCA** = Field Safety Corrective Action | **FSN** = Field Safety Notice | **AR** = Authorized Representative | **UKRP** = UK Responsible Person | **MAH** = Marketing Authorization Holder **D-MAH** = Designated MAH

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Reporting Timeline Visual

Typical manufacturer-facing reporting clocks. Exact triggers vary by event facts, device type, and local law; verify before submission.

A REPORTING TIMELINE VISUAL

Country	Urgent public-health escalation	Death / serious injury	Other serious incident / malfunction	FSCA / recall / action reporting
United States	5 workdays urgent remedial/public-health events	30 calendar days MDR	—	10 working days for corrections/removals report under 21 CFR 806
China	severity-based reporting	often 15–30 days	local investigation and reevaluation expected	—
Japan	—	typically 15 or 30 days depending on case type	—	prompt recall/safety action reporting
Germany	EU MDR Art. 87: 2 days public-health threat	10 days death/ unanticipated serious deterioration	15 days other serious incidents	FSCA/FSN without delay
United Kingdom	manufacturer vigilance via MORE	seriousness-based timelines commonly aligned to 2/10/15-day logic	seriousness-based timelines commonly aligned to 2/10/15-day logic	FSCA coordination with MHRA
France	EU MDR Art. 87: 2 days public-health threat	10 days death/ unanticipated serious deterioration	15 days other serious incidents	FSCA/FSN without delay
Italy	EU MDR Art. 87: 2 days public-health threat	10 days death/ unanticipated serious deterioration	15 days other serious incidents	FSCA/FSN without delay
India	case-dependent timelines	—	—	rapid escalation of serious events and recalls through CDSCO/ MvPI channels
Brazil	category-based technovigilance timelines	—	—	prompt serious-event and field-action reporting through ANVISA pathways
Canada	—	10 days death/ serious deterioration	30 days if recurrence could cause death/serious deterioration	recall/problem reporting to Health Canada
South Korea	severity-based event/defect reporting via local license holder/importer	—	—	recall reporting required
Spain	EU MDR Art. 87: 2 days public-health threat	10 days death/ unanticipated serious deterioration	15 days other serious incidents	FSCA/FSN without delay

B AT-A-GLANCE TRIGGER DEFINITIONS

Serious public-health threat
Event with reasonable probability of causing serious harm to public health; requires immediate escalation.

Death / serious injury
Death or a serious deterioration in health, or serious injury attributable or possibly attributable to the device.

Other serious incident / malfunction
Any malfunction or deterioration in characteristics or performance that could have led to, or might lead to, serious harm.

Field safety corrective action (FSCA)
Action to eliminate or mitigate a risk related to a device already placed on the market.

C PRACTICAL TIMING REMINDERS

1. Day-0 starts when the manufacturer becomes aware.
Awareness triggers the clock — not confirmation.

2. Local representatives/ importers may have parallel duties.
Obligations can exist in addition to manufacturer duties.

3. Follow-up reports are expected when new facts emerge.
Update authorities and records as information changes.

4. Recalls and FSNs often require authority coordination and customer communication.
Plan communications and logistics early to avoid delay.

Timelines shown as planning ranges and common statutory windows, not substitutes for country-specific legal review.

DETAILS

Global Postmarket Surveillance Requirements

Requirements That May Change by Device Type

A REQUIREMENTS THAT MAY CHANGE DEPENDING ON DEVICE TYPE

1 **Low-risk / general devices**	• Complaint handling, trend review, CAPA. • Reportability evaluation (complaints, incidents, FSCA triggers). • Basic field-action readiness and customer communication.
2 **High-risk / implantable / life-supporting**	• Stronger signal review and analytical expectations. • More active PMS with defined cadence and broader data sources. • Periodic safety output more likely. • Registry/clinical follow-up emphasis. • Faster escalation sensitivity for serious events and trends.
3 **Sterile / reusable / reprocessed**	• Heightened focus on sterility and infection-related complaints. • Packaging integrity, barrier failure, and transport conditions. • Reprocessing/cleaning validation oversight. • Shelf-life stability and supplier-control focus.
4 **Active / electrical / software-enabled**	• Service data trending and failure mode analysis. • EMC/electrical safety complaints and event capture. • Cybersecurity monitoring and software-correction workflows. • Usability and use-error analysis.
5 **AI / SaMD / connected devices**	• Version control and change-impact evaluation. • Cyber monitoring and vulnerability management. • Real-world performance drift and bias monitoring. • Algorithm changes and retraining controls. • Cloud/vendor issue management and data-privacy considerations.
6 **Products with special standards or special pathways**	• Radiation, MRI, and other modality interactions. • Combination products and cross-regulatory obligations. • Pediatric and other special populations considerations. • Country-specific post-approval commitments may apply.

B COUNTRY-SPECIFIC WATCH-OUTS

United States
Do not miss 21 CFR 806 corrections/removals or 522-study risk.

China
Local agent, Chinese-language execution, and class-specific pathways heavily influence PMS.

Japan
MAH/D-MAH structure and approval conditions can create extra surveillance tasks.

Germany
EU MDR rules apply, but national authority interactions still matter.

United Kingdom
Great Britain and Northern Ireland are not operationally identical.

France
French-language communications and ANSM coordination can drive execution detail.

Italy
Local authority interfaces and language readiness help smooth field actions.

India
Importer/authorized-agent accountability must be crystal clear.

Brazil
Brazilian Registration Holder is central to vigilance and field actions.

Canada
Bilingual execution and mandatory problem-reporting rules are easy to underestimate.

South Korea
Local license holder/importer coordination and KGMP discipline matter.

Spain
AEMPS processes and Spanish communications may affect rollout of FSNs and records.

C REGULATORY READINESS CHECKLIST

- ☐ Intended use is frozen and documented.
- ☐ Product classification rationale is documented.
- ☐ Complaint and vigilance SOPs are live.
- ☐ Local actor responsibilities are clearly assigned.
- ☐ Field action (FSN) templates are ready and tested.
- ☐ Labeling and language strategy is ready.
- ☐ Service/software escalation path is defined.
- ☐ PMS review cadence is assigned.

The heaviest PMS burden usually appears when risk, implantability, software complexity, or special post-approval conditions increase.

SOURCES

Global Postmarket Surveillance Requirements

Resources / References

Primary regulator sources used for this training aid.
Use current official websites, guidance, and law for execution decisions.

A PRIMARY RESOURCES USED

United States
FDA
- fda.gov/medical-devices
- eCFR 21 CFR 803
- eCFR 21 CFR 806

China
NMPA
- nmpa.gov.cn
- national/provincial adverse-event monitoring resources
- recall and reevaluation notices

Japan
MHLW / PMDA
- pmda.go.jp
- mhlw.go.jp
- postmarketing safety / recall resources

Germany
BfArM / PEI
- bfarm.de
- pei.de
- EUR-Lex MDR Article 83–92 / 87

United Kingdom
MHRA
- gov.uk/mhra
- MORE portal
- Yellow Card medical device reporting

France
ANSM
- ansm.sante.fr
- EUR-Lex MDR Article 83–92 / 87

Italy
Ministry of Health
- salute.gov.it
- EUR-Lex MDR Article 83–92 / 87

India
CDSCO / MvPI / IPC
- cdsco.gov.in
- ipc.gov.in
- materiovigilance resources

Brazil
ANVISA
- gov.br/anvisa
- Notivisa / tecnovigilancia resources
- field action notices

Canada
Health Canada
- canada.ca/medical-devices
- mandatory problem reporting
- recalls and safety alerts

South Korea
MFDS
- mfds.go.kr
- medical device adverse event / recall resources

Spain
AEMPS
- aemps.gob.es
- vigilance resources
- RECOPS / commercialization records

B HOW TO USE THIS GUIDE

1. Identify the country and product type.
2. Confirm who reports locally.
3. Check the trigger and statutory clock.
4. Align the FSCA/recall and customer communication plan.
5. Document the PMS review and follow-up actions.

C KEY ABBREVIATIONS

PMS *Postmarket Surveillance*	**PSUR** *Pericodic Safety Update Report*
FSCA *Field Safety Corrective Action*	**FSN** *Field Safety Notice*
CAPA *Corrective and Preventive Action*	**MAH** *Marketing Authorization Holder*
D-MAH *Designated Marketing Authorization Holder*	**UKRP** *UK Responsible Person*
AR *Authorized Representative*	**MvPI** *Materiovigilance Program of India*

D IMPORTANT LIMITS

- Product-specific laws can alter the route.
- Local language and local representative duties matter.
- *Timelines can change when serious public-health threats exist.*
- Always verify current rules before action.

Accuracy review basis: official regulator websites and legal framework summaries reviewed Aug 2026.
Training aid only — not legal advice.