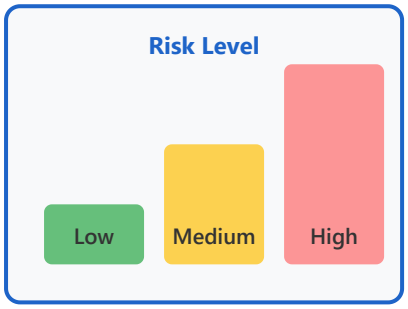
Global Perspectives

Key Regulatory Principles

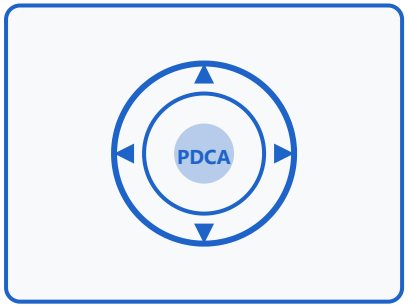
1 Risk-Based Classification



Medical devices are classified based on their intended use and associated risks to patients. Higher-risk devices require more stringent regulatory oversight and clinical evidence.

- **Class I:** Low risk (e.g., bandages, examination gloves)
- **Class II:** Moderate risk (e.g., infusion pumps, surgical instruments)
- **Class III:** High risk (e.g., implantable devices, life-supporting equipment)

2 Quality Management System (QMS)



ISO 13485 provides the foundation for medical device quality management. It ensures consistent design, development, production, and post-market surveillance processes.

- **Plan:** Establish objectives and processes
- **Do:** Implement the processes
- **Check:** Monitor and measure against objectives
- **Act:** Take corrective and preventive actions

Global Regulatory Pathways

Market Authorization Process

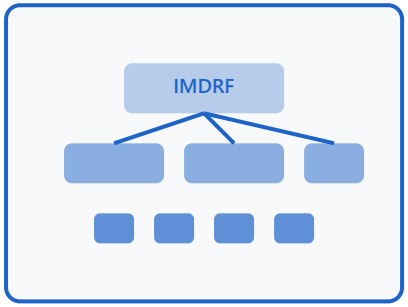
Pre-Market	Submission	Approval	Post-Market
Documentation & Testing	Regulatory Review	Market Entry	Surveillance

Region	Primary Pathway	Key Requirements	Timeline
FDA (US)	510(k), PMA, De Novo	Substantial equivalence or clinical trials	3-12 months
EU (MDR)	CE Marking via Notified Body	Technical documentation, clinical evaluation	6-18 months
PMDA (Japan)	Shonin approval	Clinical data, GCP compliance	12-24 months
NMPA (China)	Registration Certificate	Local testing, clinical trials	12-36 months

Strategic Consideration: Companies often pursue parallel submissions to major markets while leveraging international standards (ISO 13485, IEC 62304) to streamline the approval process and reduce redundant testing.

International Harmonization

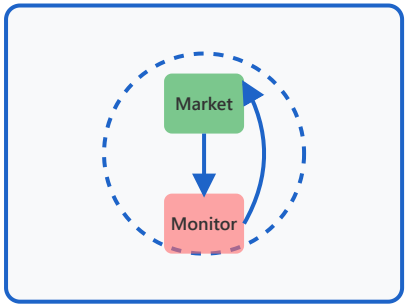
3 IMDRF Framework



The International Medical Device Regulators Forum (IMDRF) promotes global harmonization through shared guidelines and standards, reducing regulatory burden for manufacturers.

- Unified nomenclature and classification systems
- Common clinical evaluation requirements
- Standardized adverse event reporting
- Mutual recognition agreements between jurisdictions

4 Post-Market Surveillance

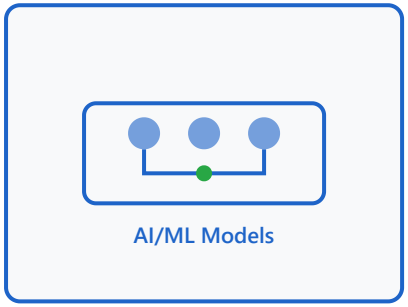


Continuous monitoring of device performance in real-world settings is mandatory across all major markets to ensure ongoing safety and effectiveness.

- Adverse event reporting (MDR/MAUDE databases)
- Periodic safety update reports (PSUR)
- Post-market clinical follow-up (PMCF)
- Field safety corrective actions when needed

Emerging Global Trends

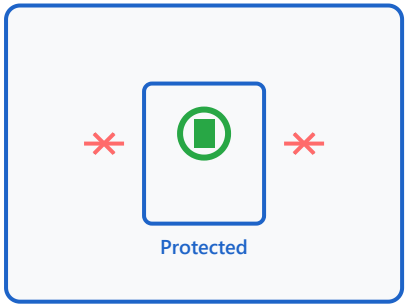
5 Digital Health & AI Regulation



Regulators worldwide are developing frameworks for software as a medical device (SaMD) and artificial intelligence/machine learning (AI/ML) technologies.

- FDA's AI/ML-based SaMD Action Plan
- EU's AI Act and MDR integration
- Adaptive algorithms and continuous learning challenges
- Real-world performance monitoring requirements

6 Cybersecurity Requirements



Growing emphasis on cybersecurity for connected medical devices across all regulatory jurisdictions to protect patient data and device integrity.

- Secure by design principles mandatory
- Software bill of materials (SBOM) requirements
- Vulnerability disclosure and patching protocols
- Risk management throughout product lifecycle