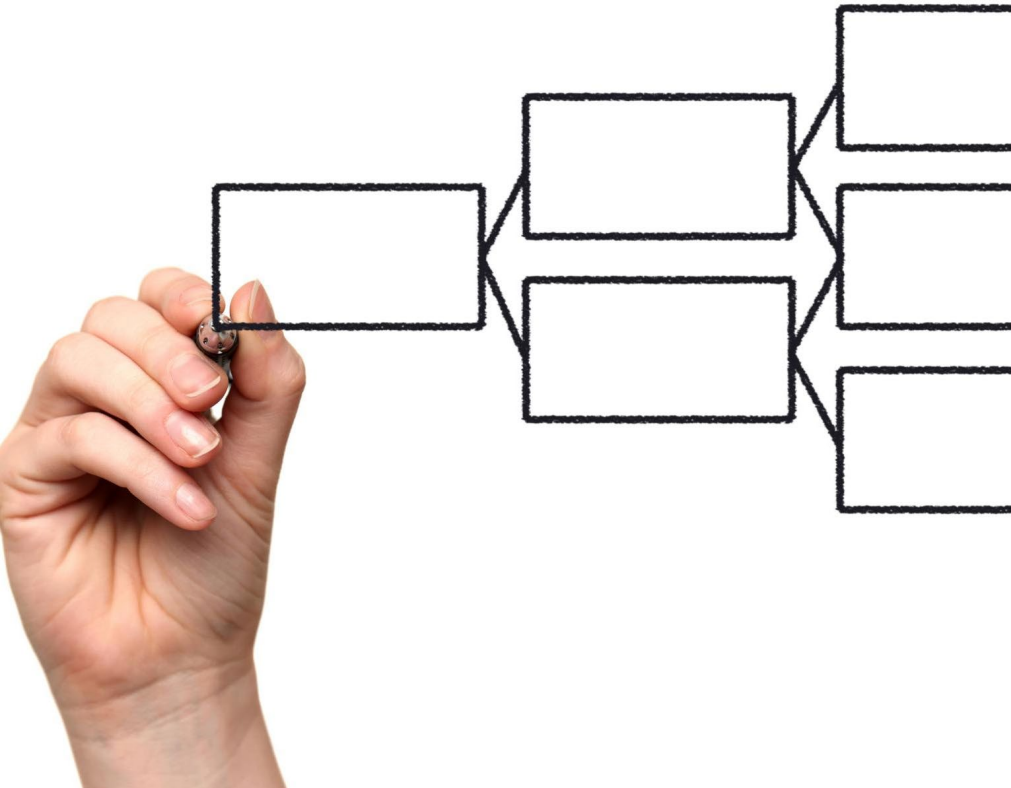


US Medical Device Regulation – FDA Masterclass

Understanding regulatory pathways for
medical devices

Introduction to US Medical Device Regulation

Claims and Classification



Why Claims Matter in the United States

Claims Define Device Classification

Manufacturer claims determine if a product is a medical device and its regulatory classification in the US.

FDA Holistic Claims Evaluation

FDA reviews all product claims including marketing, manuals, and websites to assess regulatory pathways.

Strategic Impact of Claims

Claim wording impacts regulatory risk, development timelines, costs, and market access speed significantly.

Aligning Ambitions and Compliance

Organizations must align commercial goals with regulatory requirements to avoid burdensome escalations.



US Device Classification in Practice

FDA Risk-Based Classes

FDA classifies devices into Class I, II, and III based on increasing patient risk and device complexity.

Comparison with EU Classification

US classification has three classes compared to Europe's four, sometimes resulting in different regulatory paths.

Examples of Device Classes

Surgical gloves are low risk; infusion pumps differ; pacemakers represent the highest risk class in both systems.

Regulatory Impact

Classification affects evidence requirements and regulatory pathways, emphasizing patient safety and risk consequences.

Routes to Market



Understanding US Market Access Pathways

FDA Regulatory Pathways

The FDA offers 510(k), De Novo, and PMA pathways reflecting different device risks and novelty levels.

Clearance vs Approval

510(k) and De Novo pathways result in FDA clearance, while PMA leads to FDA approval after intensive review.

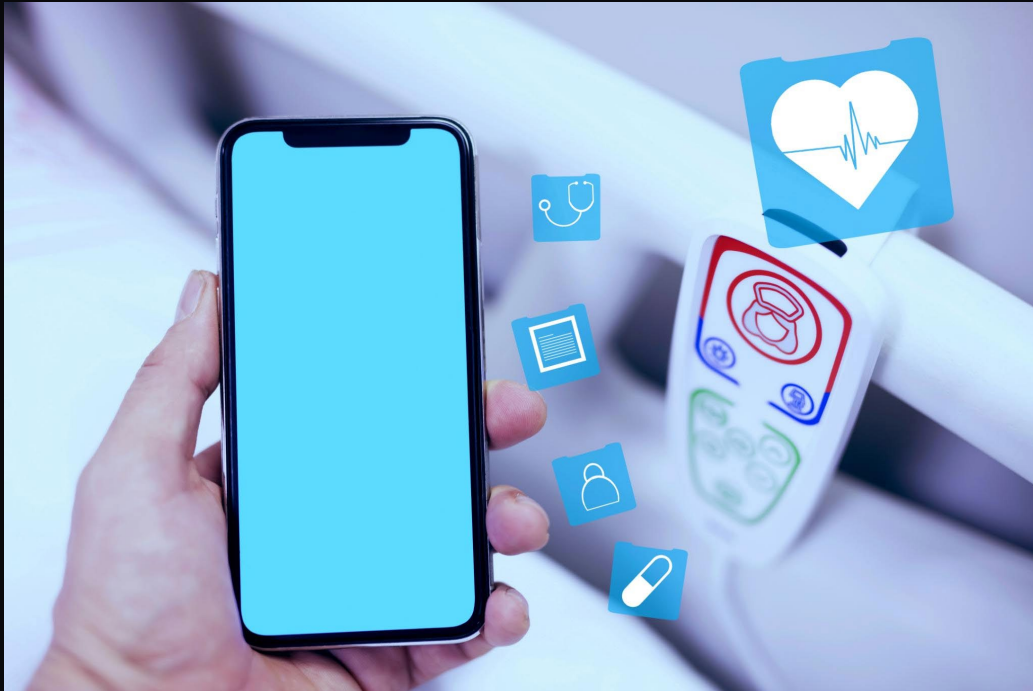
Strategic Pathway Selection

Choosing the right regulatory path affects development cost, evidence needs, time-to-market, and competitive strategy.

Risks of Incorrect Assumptions

Wrong assumptions about pathways can cause delays, rework, and lost commercial opportunities in market access.

510(k) and De Novo Pathways Explained



•510(k) Pathway Overview

- The 510(k) pathway requires showing substantial equivalence to an existing legally marketed device in use and technology.

•De Novo Pathway Purpose

- The De Novo pathway is for novel low to moderate risk devices lacking a predicate, creating new classifications.

•Clinical Data Requirements

- 510(k) often does not require clinical data unless safety questions arise; De Novo submissions typically include focused clinical evidence.

•Strategic Regulatory Choices

- Understanding these pathways helps organizations set realistic regulatory strategies and manage expectations with stakeholders.

Quality Systems and Oversight



Quality Management System Regulation (QMSR)

Alignment with ISO 13485

QMSR aligns US device quality requirements with ISO 13485, simplifying compliance for manufacturers globally.

FDA Authority and Inspections

FDA retains enforcement authority, continuing statutory inspections of quality systems throughout product lifecycle.

Importance of Executive Oversight

Sustained executive commitment and resource allocation is critical to preventing quality system deficiencies and regulatory actions.



The Role of MDSAP

Single Audit for Multiple Regulators

MDSAP enables one audit to meet the quality system requirements of several regulators, including FDA.

Voluntary Participation and FDA Acceptance

Participation in MDSAP is voluntary, but FDA may accept audit reports instead of routine inspections.

Alignment with FDA Expectations

MDSAP aligns closely with FDA's Quality Management System Regulation but does not replace all inspections.

Strategic Efficiency for Boards

For Boards, MDSAP offers audit burden reduction and raises expectations for quality system maturity.

Cybersecurity and Patient Safety

Cybersecurity as a Regulatory Requirement



Regulatory Mandate for Cybersecurity

US law requires manufacturers of software-enabled medical devices to provide cybersecurity evidence in premarket submissions.



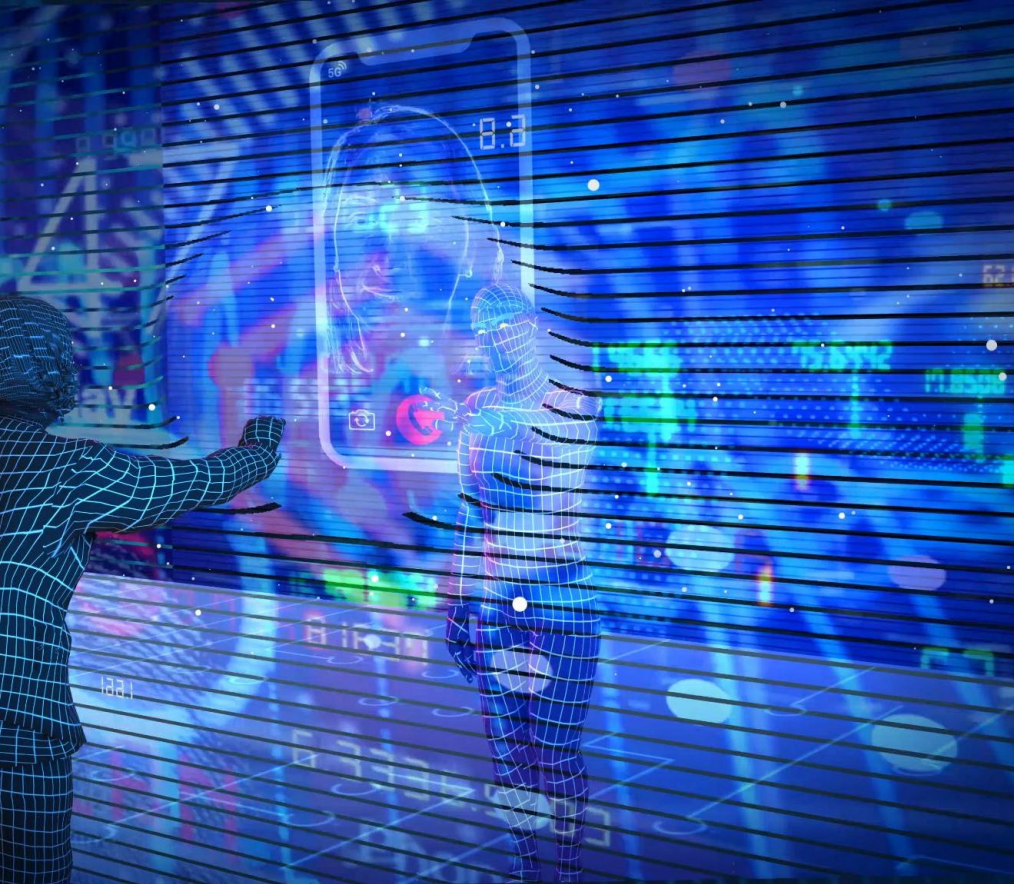
Patient Safety and Cyber Risks

The FDA evaluates cybersecurity risks as part of patient safety, recognizing cyber vulnerabilities can cause direct harm.



Secure Product Development

Manufacturers must apply threat modeling, justify security controls, and maintain transparency with Software Bills of Materials (SBOMs).



Lifecycle Cybersecurity Obligations

Continuous Vulnerability Monitoring

Manufacturers must continuously monitor emerging cybersecurity vulnerabilities throughout the device lifecycle to ensure patient safety.

Safe Patch Deployment

Deploying patches safely is critical to mitigate risks without disrupting device functionality or patient care.

Regulatory and Commercial Impact

Inadequate cybersecurity can delay market access, result in post-market actions, and damage reputation and revenue.

Operational and Financial Commitment

Senior leadership must integrate cybersecurity as an ongoing operational and financial priority in planning.

Strategic Takeaways for Leadership



Board-Level Conclusions

Regulatory and Commercial Strategy

Regulatory strategy is closely linked to commercial strategy, affecting time-to-market and development costs.

Board Responsibilities

Boards must ensure clear regulatory pathways, aligned claims, quality systems, and cybersecurity plans are in place.

US Market Distinctions

The US regulatory path is distinct and requires early FDA engagement and thorough preparation.

Goal: Patient Access

The ultimate goal is patient access to safe and effective devices across jurisdictions.