MedTech Market Uncertainty Playbook

Building Regulatory Resilience:
2026 Strategy Guide for MedTech Leaders

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Navigating an Unpredictable Regulatory Landscape

Medical device innovators are facing one of the most fluid regulatory environments in recent memory.

Over the past 18 months the U.S. Food and Drug Administration (FDA) has implemented new user-fee commitments, dealt with staff reductions and leadership turnover, and introduced new digital submission tools.

While 2024 showed a decrease in review times and PMA decisions, in Q1 2025, FDA approvals for high-risk devices fell to a ten-year low, with only nine approvals despite more applications.

The drop follows the loss of over 220 employees at CDRH in February and broader HHS cuts in April, with industry warning of slower reviews and eroding confidence while 2025 510(k) and PMA averages remain unpublished.

De Novo review times and outcomes vary widely, and anecdotal reports suggest some AI-related software moves faster than traditional devices, underscoring renewed strain from staffing losses, rising volumes, and shifting priorities.

Compounding this uncertainty are global shifts such as the EU's Medical Device Regulation (MDR) and separate UK regulations. A recent survey highlighted in AlvaMed's newsletter found that more than half of medtech leaders now view Europe as more challenging than the United States, and **23%** of respondents with CE-marked products are pursuing Japanese or Chinese registration before entering the EU.

Such unpredictability underscores the need for executives to treat regulatory strategy as a core business discipline rather than a checkbox exercise.

This guide synthesizes FDA guidance, best-practice design-control principles and recent market data to help senior leaders model regulatory risk and maintain investor confidence.

> "In today's environment, regulatory strategy isn't just about compliance; it's about setting expectations and building resilience into your timeline."
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> **Eric Bannon**
> SVP of Regulatory and Clinical Affairs, AlvaMed

Shifting FDA Timelines & Their Impact on Strategy

Shifting FDA Timelines and their impact on What They Mean for Strategy

Although parts of 2024 showed promising review time improvements, Q2 2025 data reveal a sharp downturn. Recent reports attribute this reversal to FDA workforce attrition, with nearly **14%** staffing cuts impacting review speed.

Anecdotal industry observations indicate that 510(k) approvals have slowed significantly with increasing incidence of holds for additional information and PMA review times are rising. This volatility reinforces the need for medtech teams to prepare for wide timeline swings and adjust regulatory strategies accordingly.

The agency's own guidance on the Q-Submission (Q-Sub) program offers clues.

Early interaction with FDA reviewers "may improve the quality of subsequent submissions, **shorten total review times** and facilitate the development process". The Q-Sub program includes Pre-Submissions (Pre-Subs), Submission Issue Requests, study-risk determinations and informational meetings.

Pre-Subs allow a company to receive written feedback within roughly 70 days and hold a meeting around days 70-75. Study-risk determinations and informational meetings have longer 90-day targets. These timeframes, while not guaranteed, provide anchors for scenario planning.

> **By aligning product-development milestones to these windows and adding buffer time for reviewer reassignments or clarification requests, leaders can better predict cash needs and investor communications.**

Companies should also monitor global regulatory shifts; the EU MDR introduces new requirements for unique device identification, stricter clinical evidence and post-market surveillance with little transparency from Notified Bodies . These changes have made Europe less attractive for first launch, leading many firms to prioritize the U.S. or other markets.

The Power of Early Engagement: Leveraging the Q-Sub Program

The FDA's 2025 Q-Sub guidance emphasizes that the program is voluntary but highly advantageous. It notes that early interaction on non-clinical and clinical studies can "improve the quality of subsequent submissions" and **streamline the regulatory process.**

A well-structured Pre-Sub should include a succinct background package, clear specific questions and no more than three or four substantial topics to maximize the depth of feedback.

Table 1 of the guidance summarizes target timelines, with written feedback typically provided within 70 days. Sponsors can request a meeting in addition to written feedback, with scheduling based on mutual agreement. These interactions are not binding, but they illuminate FDA expectations and help teams spot gaps in data or predicate selection.

For example, AlvaMed's case study on a lidocaine delivery device illustrates how Pre-Sub engagement and a 10-day Q-Sub meeting clarified regulatory expectations, enabling the team to incorporate last-minute FDA changes.

> **Without this proactive dialogue, companies risk receiving deficiency letters late in the review cycle, leading to costly redesigns or resubmissions.**

The takeaway for executives is very clear: allocate resources to prepare Pre-Subs early in development, assign cross-functional subject-matter experts to engage in meetings and treat FDA feedback as a strategic asset rather than a bureaucratic hurdle.

Aligning your project timeline with Q-Sub milestones can help maintain investor confidence by demonstrating that contingencies have been mapped and that regulatory surprises are less likely.

Design Controls and Risk Management: Building Quality Into the Timeline

Regulatory resilience starts with a robust design-control program. The FDA's design-control requirements (21 CFR 820.30) mandate that manufacturers establish documented procedures for design planning, inputs, outputs, verification, validation and changes.

A foundational element is **risk analysis,** which the agency notes should almost always be performed and should begin during design inputs. The intent is to identify hazards, including use errors, calculate risk under normal and fault conditions, determine risk acceptability and reduce unacceptable risks to acceptable levels.

Risk analysis must encompass software validation and human factors, as these are leading causes of recalls. The same FDA design-control guidance emphasizes that cross-functional teams are critical for design controls and that design activities should be documented, reviewed, approved and updated as changes evolve.

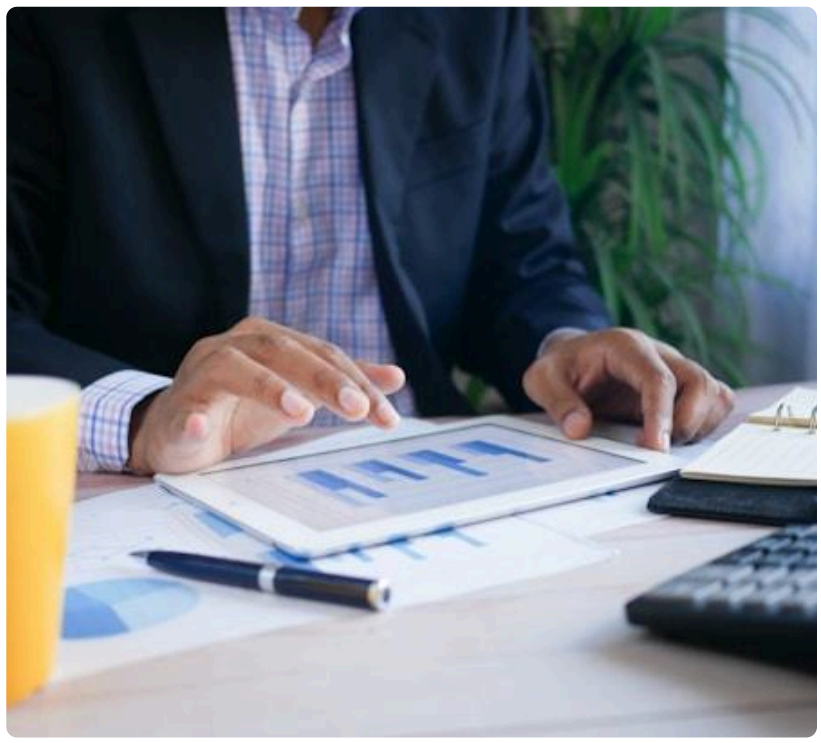
In practice, this means involving regulatory affairs, quality engineering, clinical specialists and user-experience experts early in the development process so that potential pitfalls are identified before testing. By aligning design-control milestones with regulatory timelines, such as completing verification and risk analysis before submitting a Pre-Sub, companies can provide FDA reviewers with coherent, well-structured dossiers that invite fewer questions.

Executives should adopt a culture in which design controls are not just compliance tasks but strategic tools for de-risking the timeline. They should also ensure that risk-analysis documentation is scalable; as highlighted in AlvaMed's newsletter on use-related risk analysis, the current FDA guidance can be burdensome, requiring exhaustive documentation of every potential use scenario.

> **Advocating for streamlined risk analysis is important, but companies must still invest the resources to demonstrate that user risks have been thoughtfully identified and mitigated.**

Use-Related Risk Analysis: Balancing Safety and Innovation

Use-related risk analysis (URRA) assesses how device design and user interactions could lead to errors or adverse events. A recent AlvaMed newsletter explains that industry groups have called for revisions to the FDA's URRA guidance, arguing that its **scope is excessively broad,** leading to extensive documentation and resource burdens.



Manufacturers are concerned about **regulatory uncertainty** (especially where different reviewers interpret the guidance inconsistently) which can delay approvals. There is also fear that current requirements may **stifle innovation,** particularly for smaller firms with limited resources.

Industry coalitions propose several changes:

1. **Streamlining the process** by focusing on high-risk scenarios and minimizing documentation for low-risk elements
2. **Clarifying expectations** through detailed examples and standardized criteria
3. **Balancing innovation with safety** by aligning risk analysis requirements with the level of novelty and
4. **Supporting smaller manufacturers** through tailored guidance or assistance.

The FDA has acknowledged these concerns and is engaging with stakeholders. In the meantime, executives should ensure their design-control processes comprehensively address use-related risks and allocate sufficient resources for human-factors engineering.

They should also monitor emerging guidance changes and be prepared to adjust internal procedures. Taking a proactive stance on URRA can help prevent costly redesigns and maintain investor confidence by demonstrating a commitment to patient safety.

Learning From Experience: A Case Study in Regulatory Persistence

AlvaMed's 2024 case study offers a compelling example of how expert guidance can turn a faltering submission into a success. The client, a company developing an aerosolized lidocaine delivery device, received an FDA Additional Information Needed (AIN) letter listing **108 deficiencies,** including predicate justification, biocompatibility testing and comprehensive hazard analysis.

The FDA granted a 360-day response window that included an additional 180-day extension due to COVID-19, but unforeseen test equipment failure led to an incomplete response and the submission withdrawal.

When AlvaMed took over the project, they conducted a detailed gap analysis, updated testing and documentation, particularly completing ISO 18562 gas-pathway testing, and reformatted the submission to the FDA's new eSTAR template.

Crucially, they leveraged a Submission Issue Request Q-Sub meeting to clarify FDA requests and negotiated last-minute changes. The resubmission process spanned **1,163 days** and six FDA interactions, yet the second resubmission received only **four** follow-up questions. The experience highlights several strategic lessons:

Implementation Guidance

1. **Expert regulatory guidance matters.** A comprehensive gap assessment and knowledge of evolving standards (e.g., ISO 18562) can dramatically reduce deficiencies.
2. **Adaptability is critical.** Transitioning to new templates and updated standards prevents avoidable delays.
3. **Proactive communication pays off.** Structured meetings and simplified responses foster collaborative review.
4. **Comprehensive preparation keeps projects on track.** Thoroughly addressing all requests and ensuring complete documentation avoids withdrawal and resubmission.

For executives, the case study demonstrates that regulatory setbacks are not fatal if addressed strategically. It also underscores the importance of building slack into project schedules for equipment issues or data collection challenges. Using scenario planning to map out potential failure points and mitigation actions can prevent similar delays.

Global Market Entry: Why Many Firms Now Prioritize the U.S.

The regulatory landscape is global, and decisions about where to launch can affect timelines and investor confidence. AlvaMed's newsletter notes that the **U.S. has become the favored geography for market entry** after surveys of medtech executives revealed dramatic shifts.

In 2020, Europe and U.S. were considered the least challenging regions, but by March 2022 more than half of survey respondents considered the **EU much more challenging** than the U.S. Nearly a quarter of respondents with CE-marked products were seeking Japanese or Chinese registration before EU clearance.

The primary catalyst is the EU MDR, which introduce requirements for unique device identification, strengthened clinical evaluation, post-market surveillance and rigorous risk management.

Additional complications stem from Brexit: the UK now requires a UKCA mark and the appointment of a UK Responsible Person, and manufacturers must navigate separate notified bodies and registration systems.

These changes impose significant costs and create uncertainty about future trade negotiations. In contrast, 79% of respondents in a March 2022 study agreed that the FDA is responding well to advances in medical technology. Programs such as the Q-Sub process, Breakthrough Device Designation and De Novo classification provide predictable pathways for novel devices.

Nonetheless, smaller companies continue to struggle with regulatory efficiency; many have only months of cash on hand and cannot absorb lengthy review cycles.

For executive teams deciding where to invest, these insights highlight the relative predictability of the U.S. pathway but also **underscore the need for robust scenario planning and investor communication regardless of geography.**

Scenario-Planning Worksheet: Modeling Regulatory Risk

Building resilience into regulatory timelines requires more than intuition; it demands structured scenario planning. The following worksheet framework can help leadership teams model various regulatory outcomes and communicate plan-B strategies to investors:

Industry coalitions propose several changes:

1. **Define key regulatory milestones.** Identify submission types (Pre-Sub, 510(k), De Novo, PMA) and key interactions such as Pre-Sub meetings, RTA checks and panel reviews. Use FDA guidance to map expected timeframes.
2. **Create three timeline scenarios.** Build **best-case, expected** and **contingency** timelines for each milestone. For example, the best case might assume FDA meets its user-fee goals, the expected case might mirror current averages, and the contingency case might add 25–50% to account for staff changes or clarifications.
3. **Assign buffer periods.** Include buffer time between milestones for completing additional testing or addressing deficiency letters. The AlvaMed case study shows that failing to complete one test led to a months-long withdrawal; building slack prevents cascading delays.
4. **Map resource requirements.** Allocate internal resources—regulatory, quality, clinical and engineering—for each scenario. Identify which roles are critical for engagement with FDA (e.g., lead reviewers, clinical experts) and ensure availability.
5. **Identify external risk events.** Consider factors such as FDA staffing changes, global regulatory shifts, supply-chain disruptions or equipment failures. Use risk-analysis principles to assign likelihood and impact and design mitigation actions.
6. **Develop investor communication plans.** For each scenario, prepare talking points that explain timeline assumptions, contingency measures and financial impact. Emphasize proactive engagement strategies, like the Q-Sub process, to reassure investors that the team is managing uncertainties.

Teams should update this worksheet quarterly or when major regulatory announcements occur. Sharing the model internally fosters alignment across departments and ensures that everyone understands how regulatory decisions influence budgets and launch dates.

With a transparent plan, companies can demonstrate to investors that they are prepared for different outcomes and are actively managing risk.

Building Resilience Into Regulatory Strategy

Regulatory resilience comes from embedding flexibility into every layer of product development.

First, adopt a **regulatory-aligned design process:** align design-control milestones with regulatory milestones, initiate risk analysis during design inputs and engage human-factors experts early.

Second, prioritize early FDA engagement through the Q-Sub program and informational meetings; these interactions shorten review times and clarify expectations.

Third, study the global landscape and decide where to launch based on predictability and resource availability; the U.S. currently offers more structured pathways than the EU.

Fourth, advocate for regulatory improvements, such as streamlined use-related risk analysis, while ensuring compliance with current guidance.

Finally, **institutionalize scenario planning** by integrating the worksheet framework into program management.

Executives should view regulatory strategy as a dynamic component of business planning. The quote from Eric Bannon underscores this mindset: resilience is not a defensive posture but an active strategy to ensure that innovation reaches patients despite regulatory fluctuations.

> By building disciplined processes, investing in cross-functional teams and engaging proactively with regulators, medtech leaders can turn unpredictability into a strategic advantage.

Executive Summary

- **FDA review timelines are once again in flux.** Q2 2025 analysis reflects a continued slowdown in device approvals, with total counts still well below 2024 levels. The FDA has not yet published official averages for 510(k) or PMA decisions, but industry observers report prolonged review timelines across all submission types with increased number of additional information holds. De Novo and panel-track approvals remain inconsistent, though some AI-related software is reportedly advancing more quickly. The overall pace underscores the lingering effects of staffing cuts, increased application volume, and shifting regulatory priorities.
- **Early engagement reduces risk.** The FDA's Q-Submission program allows companies to obtain written feedback within ~70 days and schedule meetings around day 70–75. Guidance notes that early interactions can improve submission quality and shorten review times.
- **Robust design controls and risk analysis are essential**. The FDA expects manufacturers to perform risk analysis during design inputs and to address use-related hazards, software validation and human factors. Cross-functional teams and documented design controls help reduce recalls and regulatory delays.
- **Real-world experience demonstrates the value of strategic guidance.** In an AlvaMed case study, addressing 108 FDA deficiencies and resubmitting via the eSTAR template, with proactive, strategic Q-Sub engagement, reduced follow-up questions from 108 to **four.** The process underscores the importance of comprehensive preparation and adaptability.
- **Global dynamics favor U.S. market entry but demand vigilance.** Surveys show a shift from Europe to the U.S. as the preferred launch market due to EU MDR complexity and Brexit, with 23% of CE-marked companies pursuing Asian markets first. The U.S. offers structured pathways like Breakthrough Device Designation and De Novo classification, yet smaller firms still grapple with cash-flow risks.
- **Industry is pushing for more practical risk-analysis guidance.** Stakeholders argue that the current use-related risk analysis guidance is overly burdensome and propose streamlining requirements, clarifying expectations and tailoring support for smaller manufacturers.
- **Scenario planning is crucial.** A worksheet approach that defines milestones, builds best-case and contingency timelines, assigns buffer periods and maps resources helps teams anticipate delays and communicate effectively with investors. Integrating this planning with design controls and Q-Sub milestones enables medtech leaders to build resilience into their regulatory strategies.

Sources

FDA Workforce Cuts Lead to Historic Drop in Medical Device Approvals
https://trial.medpath.com/news/eed758e5831cfe32/fda-workforce-cuts-lead-to-historic-drop-in-medical-device-approvals

Us Favored Over EU For Medical Device Market Entry - Alvamed
https://alvamed.com/newsletter/us-favored-over-eu-for-medical-device-market-entry/

Case Study: Navigating Regulatory Challenges to Achieve FDA Clearance - Alvamed
https://alvamed.com/case-studies/case-study-navigating-regulatory-challenges-to-achieve-fda-clearance/

The Status of Use-Related Risk Analysis - Alvamed

https://alvamed.com/newsletter/the-status-of-use-related-risk-analysis/

Final-Q-SubGuidance-2025
https://www.fda.gov/media/114034/download

FDA Design Controls
https://www.fda.gov/media/116762/download

FDA's novel medical device clearances slow to a crawl
https://www.fiercebiotech.com/medtech/fdas-novel-medical-device-clearances-slow-crawl

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