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Key Risks in Medical Device Development

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Medical innovation is an exciting field, driven by the potential to save lives and improve healthcare outcomes for an ageing global population. However, bringing a new medical device to market in the modern era is a complex undertaking, often likened to navigating a minefield. The process is fraught with inherent technical, regulatory, and clinical risks that require meticulous planning, rigorous testing, and vigilant management throughout the entire product lifecycle. Addressing these risks is essential for ensuring the safety and efficacy of devices for both patients and healthcare providers.



The Role of Regulatory Classification

The foundation of any medical device development project is understanding its regulatory classification. This classification determines the level of regulatory control required and dictates the degree of scrutiny applied to design, manufacturing, and testing. While classification systems vary globally, the US Food and Drug Administration (FDA) system is commonly referenced and uses three main classes:

- **Class I (Low-to-Moderate Risk):** These are simple devices, such as bandages or handheld surgical instruments, that pose minimal risk and are subject to the least regulatory control.
- **Class II (Moderate-to-High Risk):** More complex devices like infusion pumps or diagnostic tools fall into this category. They require more stringent controls, including special labeling and post-market surveillance.
- **Class III (High-Risk):** Life-sustaining or innovative devices, such as pacemakers or heart valves, face the highest level of oversight, including mandatory pre-market approval.

Accurately determining a device's class early is critical; misclassification can lead to incorrect submission pathways and significant data gaps.

Requirements Development and Management: The Critical Pillar

Perhaps the most vital aspect of development is the systematic definition and control of a device's specifications. Failure to rigorously track requirements often leads to technical, commercial, and regulatory failure.

- **Discovery and Documentation:** Stakeholders—including clinicians, engineers, and end users—must identify unmet needs without bias. At this stage, the objective is to understand the problem the device is intended to solve and the outcomes it should achieve. Care should be taken not to bias prospective users toward a particular solution during the discovery process. These user needs must then be translated into detailed technical requirements that development teams can execute.
- **Verification and Validation:** Verification confirms that the device design complies with its specified requirements, while validation ensures the final product meets its intended purpose for the user. Verification testing plays a critical role in demonstrating that the device functions as intended and complies with applicable standards, providing objective evidence that requirements have been met.
- **Traceability:** A robust traceability matrix is essential to link every requirement to specific design, verification, and validation activities. This provides the necessary evidentiary foundation for regulatory submissions.

A traceability matrix helps to ensure each requirement is addressed during the development process and provides a basis for regulatory submissions. Maintaining this documentation throughout the development process can save significant time and effort during later stages of commercialisation.

- **Change and Risk Control:** As insights evolve, formal change control processes maintain development integrity. Concurrently, using a "risk register" allows teams to analytically address the highest-risk elements early in the process.

Requirements management is not a one-time exercise but an iterative process that continues throughout the device lifecycle as new information, user feedback, and regulatory considerations emerge. Effective requirements management also supports the broader design controls process, helping manufacturers maintain a structured and traceable approach to device development.

The Hurdle of Regulatory Compliance

Regulatory risk involves the uncertainty of obtaining approvals and complying with evolving laws and standards, such as ISO 13485 or the European Medical Device Regulation.

- **Data Sufficiency:** Insufficient preclinical or clinical data can result in rejected submissions or requests for additional, costly studies.
- **Quality Management Systems (QMS):** A robust QMS is critical to avoid non-compliance findings during audits. It also facilitates the creation of a Design History File (DHF), which serves as a permanent record of all design control activities.
- **Evolving Requirements:** Regulatory requirements and expectations continue to evolve, requiring manufacturers to remain vigilant throughout the development process. In addition, differing regional frameworks can influence development plans and market access strategies, making early regulatory planning essential.
- **Post-Market and Human Factors:** Compliance extends beyond the product launch. Manufacturers must establish systems for post-market surveillance to monitor adverse events. Additionally, neglecting human factors and usability can lead to use errors, regulatory findings, and potential recalls.

Financial and Temporal Pressures

Managing the "business" of medical innovation is as critical as the engineering itself. Developers must navigate both cost and schedule risks to ensure project viability.

Cost Risks

Multiple factors can inflate production expenses:

- **Material and Supply Chain:** Fluctuations in raw material prices, geopolitical disruptions, and dependency on specific suppliers introduce significant financial uncertainty.
- **Labour and Compliance:** Investment in research, specialised testing, certification, and skilled labour are primary cost drivers. Manufacturers may adopt approaches such as lean manufacturing practices, continuous improvement initiatives, and close supplier collaboration to optimise these costs.

Schedule Risks

In a competitive industry, speed to market is paramount. However, timelines are often dictated by "gating factors" that cannot be expedited, such as biocompatibility testing, accelerated life testing, or lengthy regulatory review periods.

An example schedule is often riddled with interdependencies and gating factors that cannot be expedited (e.g. regulatory submissions, biocompatibility testing, accelerated life testing, etc.). Without careful oversight and planning, the project team could experience delays or periods of limited resource utilisation while certain pacing items occur.

- **Interdependencies:** Delays in one area, such as a supplier bottleneck or a late-stage change in technical scope, can invalidate completed tasks and derail the entire project schedule.
- **Proactive Management:** Effective schedule management depends on detailed project plans with clear milestones and open communication among stakeholders to quickly resolve roadblocks. Identifying high-risk activities early and developing contingency plans can help teams respond more effectively when delays occur.

Leveraging Strategic Partnerships

Given these multi-layered complexities, many manufacturers choose to partner with third-party organisations. An ideal partner should mirror the manufacturer's own capabilities, possessing a deep understanding of the medical industry, a dedicated project management team, and a rigorous QMS to ensure requirements are properly translated into the necessary technical scope. Strong project management and clear communication become particularly important when development activities are shared across multiple organisations.

By addressing these technical, regulatory, and financial risks with a disciplined and iterative approach, manufacturers can successfully navigate the development lifecycle and bring safe and effective products to market.

Travis Schneider, Business Development Manager, Aerotech