

Designing Beyond Launch: Managing Design Debt in Medical Devices

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Agenda

- Understanding Design Debt
- Why It Matters in MedTech
- The Five Pillars of Managing Design Debt
 - Strategic Contextual Planning
 - Quantifying Tradeoffs
 - Lifecycle-Ready Design
 - Cross-Functional Alignment
 - Debt Resolution Planning
- Boston Engineering's Role



Introduction: Realities of Product Development

- There are always tradeoffs
- Every decision has ramifications
- Design Debt is the accumulation of those trade-offs



What is design debt?

- Broader than user experience and technical debt
- Includes regulatory, quality, manufacturability, and operational impacts
- Not a mistake – a choice made in the face of competing needs





Why Medtech is Particularly Vulnerable

Compliance complexity

Long product lifecycles

Result: Cost of post-launch changes is extremely high

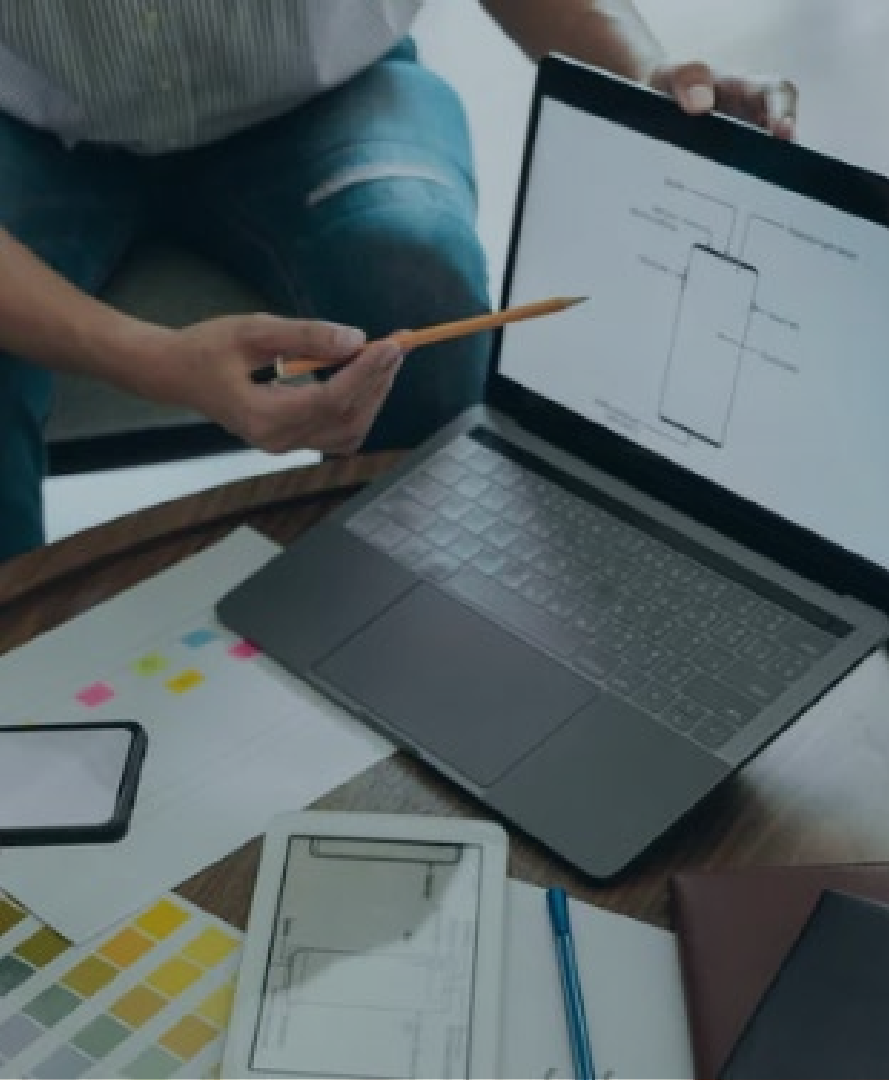
Strategic Contextual Planning



BD Alaris™ Infusion System



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Strategic Contextual Planning

Justifying the decision

Document, document,
document

Exit Strategy

Quantifying Trade-Offs

- Make cost, risk, and debt accumulation visible
- Informs business and product development leaders



Therac-25 Medical Linear Accelerator

- Cancer treatment device
- 6 recorded incidents included 3 deaths, 2 profound injuries
- Incidents occurred over 19 months
- Safety moved from hardware to software
- Human factors poorly managed

N. G. Leveson and C. S. Turner, "An investigation of the Therac-25 accidents," in Computer, vol. 26, no. 7, pp. 18-41, July 1993, doi: 10.1109/MC.1993.274940.

Lifecycle-Ready Architecture



EPIQ™ Ultrasound System



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Lifecycle-Ready Architecture

- Plan for extensions, failure investigation, and revisions
- Document deferred features
- Architect for what's next—not just what's now



Cross-Functional Alignment

- Design for Manufacturing, Service, Compliance, Quality, Reliability
- Avoid isolated optimization
- Leverage cross-disciplinary knowledge



Debt Resolution Planning

- All design debt eventually comes due
- Be ready with failure diagnostics, original design intent, and root cause analysis
- Create feedback loops for smarter next-gen design



Cumulative Business Impact of Design Debt

- Mounting redesign costs
- Delayed market entry
- Regulatory remediation
- Opportunity cost of non-responsiveness





Design Debt Should be Strategically Managed

- The goal is not avoidance, but preparedness
- Knowing when and how design debt may be used empowers performance

The Five Pillars Revisited

Strategic Contextual Planning

Quantifying Tradeoffs

Lifecycle-Ready Design

Cross-Functional Alignment

Debt Resolution Planning

What Success Looks Like

- Designs that scale and evolve
- Fewer surprises post-launch
- Delighted customers
- Faster time to next-gen products



How Boston Engineering Helps

- Not just a design partner, but a business one
- Systems-based thinking
- Proven development methodology
- Full-spectrum development—from concept through sustaining engineering
- Ability to leverage past experience, not rely on it

Closing Thoughts

- Don't treat Design Debt as taboo — it's a fact of development
- The smart teams are those who plan for it



Q&A



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