Lean in Medical Device Manufacturing

Technology Engineering for Medical Devices – A Lean Manufacturing Plan Viewpoint

- Medical device software must meet **strict FDA/IEC 62304 regulations**, making development slow and rigid.

- Lean was applied not to cut corners but to **remove bureaucracy that added no safety or quality value**.

- MedTech's case shows Lean can **balance compliance with efficiency**, reframing regulation as a partner in improvement rather than a barrier.

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Why Lean Matters

Safety-critical

Compliance–heavy

Rigid SDLC

The Lean Perspective

Lean Software Development =

waste reduction, collaboration, efficiency
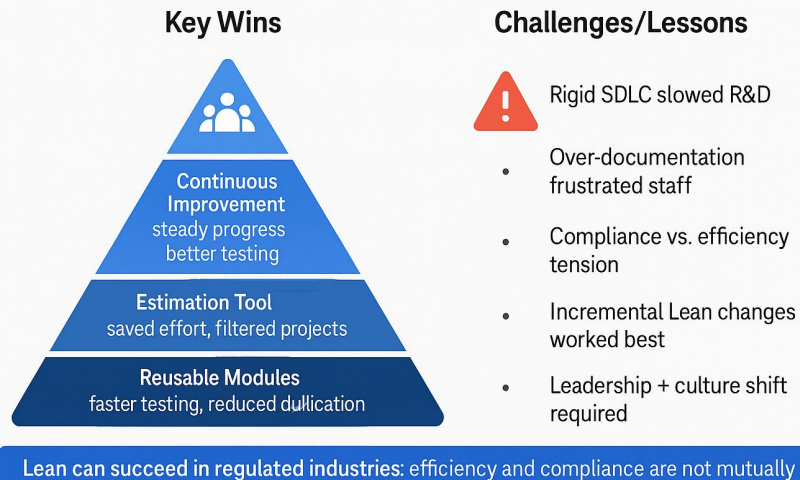
Nuance in Practice

Efficiency vs. Compliance

Remove bureaucracy, not quality

Efficiency vs. Compliance

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- MedTech achieved progress through **practical, incremental steps** — reusable modules, cross-trained teams, and smarter decision tools.

- These wins built momentum toward a culture of **continuous improvement and innovation**.

- At the same time, **rigid SDLC processes and documentation burdens** created friction, showing that Lean success depends on **leadership support and cultural change**.

- The key lesson: **efficiency and compliance are not mutually exclusive — Lean can deliver both.**

MedTech Case Study: Key Wins & Lessons

Key Wins

Continuous Improvement
steady progress
better testing

Estimation Tool
saved effort, filtered projects

Reusable Modules
faster testing, reduced dullication

Challenges/Lessons

⚠ Rigid SDLC slowed R&D

- Over-documentation frustrated staff
- Compliance vs. efficiency tension
- Incremental Lean changes worked best
- Leadership + culture shift required

Lean can succeed in regulated industries: efficiency and compliance are not mutually exc

Failure of Lean in Medical Device Manufacturing

Lean has delivered tremendous value in industries like automotive, where production is high-volume and repetitive. But when we move into the medical device industry, Lean meets a very different reality — one defined by **low-volume, high-mix production and strict regulatory oversight.**

This infographic highlights the key ways in which Lean often struggles when applied directly to MedTech.

The lesson is not that Lean fails, but that **'vanilla Lean' doesn't fit this industry.**

Success comes from a **Medical Device Lean** approach that integrates compliance, prioritizes patient safety, and targets only true inefficiencies.