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Slow Down to Speed Up

Product development best practices in medical devices

Use the Brakes Early in Development to Fast-Track Product Launches

In the 1970's, the American automotive industry was caught off guard by the dramatic success of Toyota and other Japanese car manufacturers. Since then, Toyota has become the world's largest automaker, and only trails Ford in the U.S.

The company's success is largely attributed to its Toyota Production System (TPS), which emphasizes eliminating waste and enhancing performance. This philosophy is rooted in Dr. Edwards Deming's research and application of statistics to improve quality and business processes.

The application of TPS to product development enables Toyota to bring new products to market twice as fast as its U.S. competitors[1]. Toyota's average of 150 engineers per new car project is only one-quarter of the engineering staff that Chrysler and other American automotive companies typically devote to creating new models.

At a high level, car brands and medical device companies are both focused on outmaneuvering their competitors through innovation, cost advantages, and rapid time to market. Understanding how Toyota's new product development engine operates can provide medical device executives with ways to improve their own innovation processes.

Front-load the Development Process

Toyota takes great effort to identify and resolve all potential problems early in the product development process, which takes time due to the ambiguity of some product requirements. The company typically builds consensus by having cross-functional product development teams work methodically to understand product requirements.

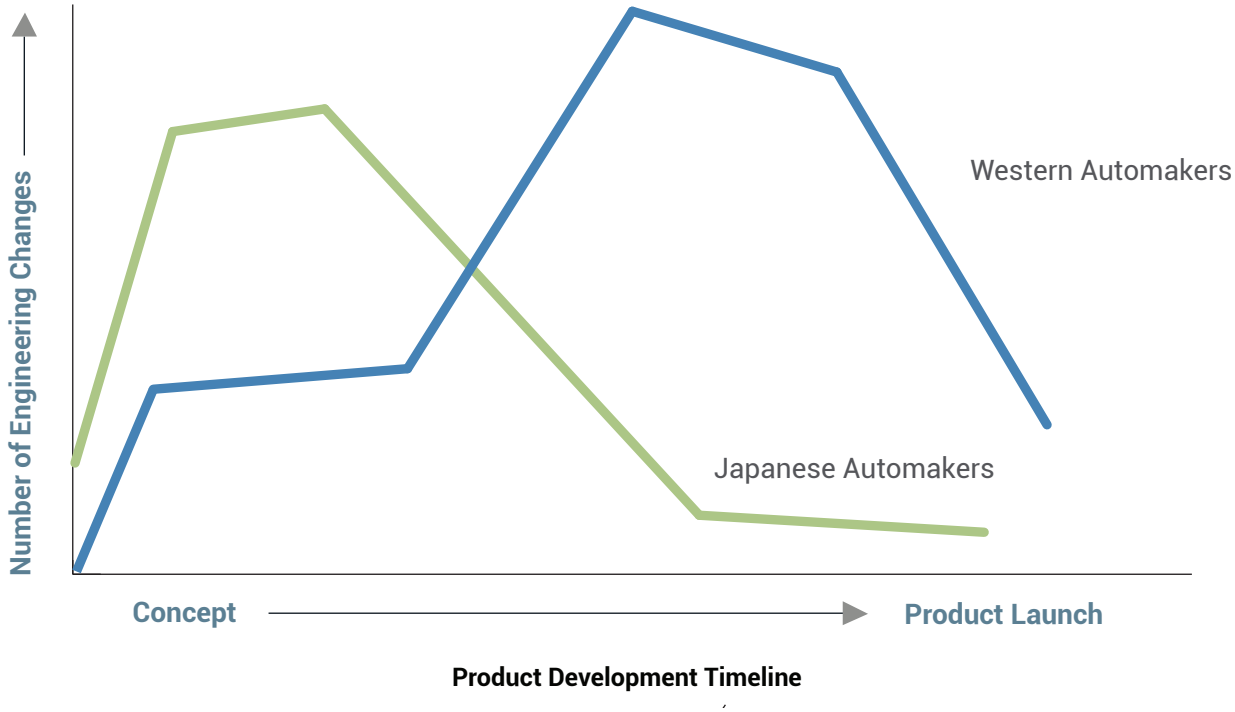
Toyota's product development framework, along with the company's overarching focus on customer needs, helps to guide the process. Toyota manufacturing engineers produce a detailed checklist of what they can achieve within the project scope. This broadly defines the design space and gives designers room for creativity. The checklist also serves as the basis for communication and negotiation among marketing, product development, and production.

Speed Through the Engineering and Testing Phases

Confident that its early-phase work is accurate, Toyota limits engineering changes later in the product development process (Figure 1).

A Toyota Camry platform project manager took this philosophy a step further by implementing a "Zero Engineering Changes" approach, which prohibits additional engineering revisions once production drawings are released. This change, and the extensive use of advanced simulation, reduced Toyota's development cycle from 36 to 26 months[2].

Figure 1: Japanese and Western Engineering Activity Throughout the Automotive Development Process



Source: Boston Engineering Corporation

Quantify the Cost of Late-Stage Medical Device Changes

The cost of changes increases by an order of magnitude at each successive development stage (Figure 2). Unlike the automotive or other industries, medical device product changes also require revalidation.

If a medical device manufacturer incorporates significant updates after the product is cleared, the Food and Drug Administration (FDA) often requires a new submission. The FDA's average time to review and clear a 510(k) is 166 days — nearly six months[3]. In addition, required testing — such as EN 60601, ISTA, and UL — must be completed and compiled before a company can submit a 510(k). This testing, usually conducted by external laboratories, can take weeks or months.

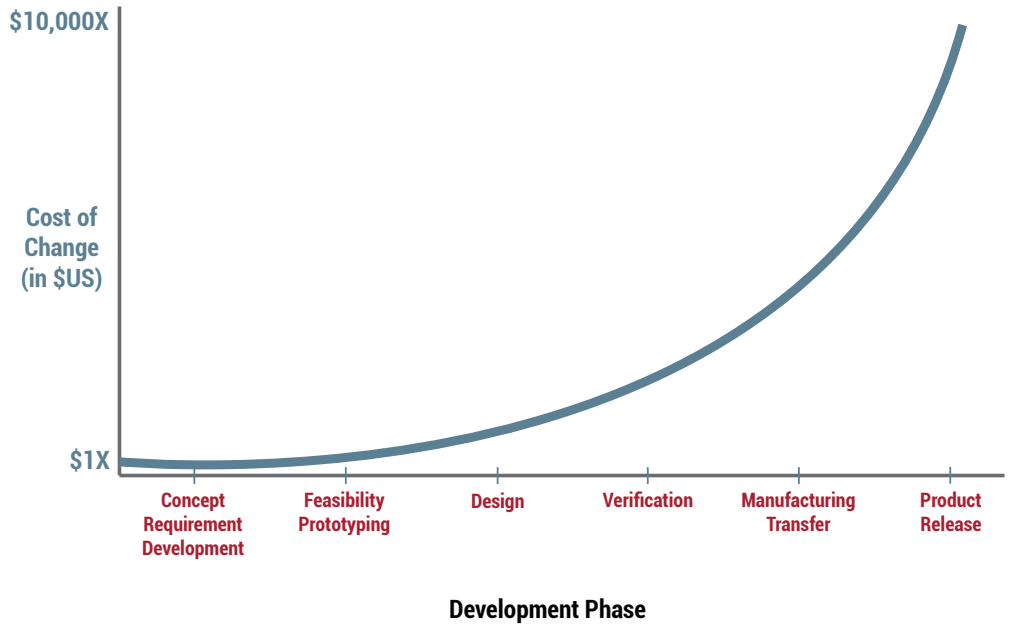
While all manufacturers understand the cost, delays, and disruption of late engineering changes, few have learned to limit them.

Applying TPS to Medical Device Innovation

Time to market is critical for any company. For start-ups, longer development times equate to higher costs and the need to raise additional funding, which dilutes company ownership for the original investors. For large companies, new product delays cause lost sales and missed market opportunities.

A common challenge that executives face is balancing time to market with requirements to resolve product features, process risk, and manage regulatory requirements. When the product development schedule slips, relationships among stakeholders often become adversarial. Product marketing complains that engineering takes too long to develop new products. Engineering retorts that product scope changes keep projects stalled. This finger pointing often continues while the projects move forward.

Figure 2: The Exponential Cost of Late-Stage Design Changes

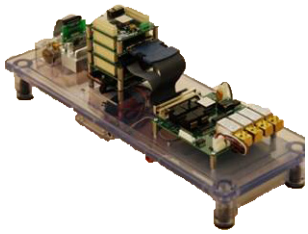
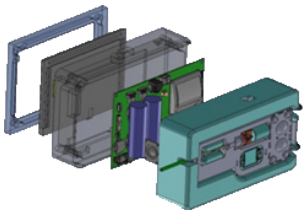


Source: Boston Engineering Corporation

To mitigate these challenges, medical device companies need to follow their phase-gate product development process vigilantly. The phase-gate process in Figure 3 complies with ISO and FDA design control requirements for medical devices. Regulatory requirements such as the FDA's Quality Systems Regulation (21 CFR Part 820) play a substantive role in shaping activities and decisions in the process.

Applying Toyota's blueprint for success to the medical device phase-gate process requires additional analysis and time dedicated to the first two phases: Initiate and Formulate. This includes conducting a detailed usability assessment and developing a comprehensive product specification. In effect, taking the time during the first and second phases to reach consensus on product specifications applies TPS principles to the phase-gate process.

Figure 3: ISO 13485 Medical Device Stage Gate Product Development Process

Gate 1 - Initiate	Gate 2 - Formulate	Gate 3 - Develop and Verify	Gate 4 - Manufacture and Validation Support
Device is ready to transfer from concept to active project status	The device's technical feasibility is proven and product development can begin	Design outputs satisfy design inputs and have acceptable design risk levels	Validation testing confirms design outputs satisfy design inputs - user needs are met
			
Gate 1 Deliverables • Early stage technical risk and design inputs (preliminary uFMEA, PRD/DI) • Preliminary product/ software design specifications (PDS, SDS) • Human factors/usability assessment	**Gate 2 Deliverables** • Project charter/timeline • Refined design inputs (DI) • Design inputs complete (PDS, SDS) • Preliminary traceability matrix (TM) • Verification test plan • Hazard analysis/FMEAs • DFM • Initiate design history file (DHF) • Comprehensive concept defined - technical hurdles conquered	**Gate 3 Deliverables** • Device master record (DMR) • Verification and validation (V&V) test matrix • Device verification (DV) test methods • DV test analysis, results, and report • Process validation plan • Select suppliers	**Gate 4 Deliverables** • Design validation • V&V matrix complete • Manufacturing process plan and pFMEA • Risk management plan • Supplier qualification • DHF complete • Regulatory submission(s)

Source: Boston Engineering Corporation "Quality Manual Product Development Procedure"

Resist Pressure to Try Short Cuts

In the business world, where time and dollars spent have significant ramifications, every product development program faces growing pressure to meet its milestones, especially when closing in on the launch date. That “top down" pressure from senior management affects everyone associated with the program.

If this pressure begins early in the program, truncating the initial stages and starting the “real” work of design and making parts may seem attractive because quantifiable activity is often viewed as a clear sign of progress. But relief from internal pressure is short-lived and only postpones the need to make hard decisions.

For example, an incomplete product specification may omit the needs to support a foreign market. As a result, a power source may be selected to help satisfy a cost requirement, but may not meet a multinational distribution requirement.

If this difference is not resolved until the prototype or verification stages, then replacing that power source will cause delays and additional costs (redesigning, prototyping, and testing the new configuration).

Recalibrate Your Innovation Process

Lean techniques are as applicable to the product realization process as they are to manufacturing, and the results are equally impressive. To realize these gains, incorporate TPS elements and consider augmenting your existing process to include the following steps:

1. Define the market requirement and the features required to address market needs
2. Perform usability assessments to understand the needs of all stakeholders: patients, healthcare providers, insurers, etc.
3. Innovate based on a product specification that incorporates usability assessment findings
4. Eliminate ideas that introduce unacceptable risks for the current product version
5. Use an honest corporate self-assessment to understand and communicate organizational skills and capabilities
6. Take the time early in the process to eliminate ambiguity or contradictions among user needs, marketing requirements, and product specifications. Ensure that user needs receive the highest priority
7. Prioritize product specifications based on documented user needs
8. Gain the capabilities to satisfy user needs by developing new processes and/or by utilizing outside product/process development support
9. Negotiate specific user needs only after determining that it's not possible to develop or acquire a required capability cost effectively

Added due diligence at the beginning of a project ultimately reduces the time and the cost of new product development. In short, slow down to speed up.

About the Author: David Jacobs is the director of Boston Engineering's Medical Devices practice. Previously, Jacobs served as chief operating officer at Scion Medical Technologies, and held senior leadership positions at Interlace Medical, Intact Medical, and ACT Medical.

Endnotes:

1. "Lean Development", *Business Strategy Review*, Freddy Balle' and Michael Balle', Aug. 1, 2005
2. "Toyota Pursues the Elusive Triple WOW", *Automotive Design & Production*, Kermit Whitfield, Sept. 1, 2001
3. "How Long Does it Take for a 510(k) Submission to be Cleared by the US FDA?", Emergo Group, Chris Schorre, Feb. 1, 2014

About Boston Engineering

Boston Engineering improves the way that people work and live through innovative product design and novel engineering. We manage the entire product development process — from ideation to supply chain development. Certified for ISO 9001 and ISO 13485, our industry expertise includes consumer products, defense & security, medical devices, robotics, and industrial & commercial products. Boston Engineering is also the Northeast's largest PTC software reseller.

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