COULD LEAN PRODUCT DEVELOPMENT GET YOU TO MARKET FASTER?

3 KEY QUESTIONS TO FIND OUT

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Every manufacturing engineer is familiar with *The Machine That Changed the World: The Story of Lean Production.* First published in 1990, this classic book was the first to detail the Toyota Production System from which the principles of Lean Production were derived. The authors predicted that Lean Production would become the gold standard not only in the auto industry, but in every industry worldwide, including healthcare.

However, the medical device industry has been slow to adopt Lean systems and techniques. While some contract manufacturers currently apply Lean tools to specific processes or areas, Viant stands out for its systematic use of Lean principles throughout the product lifecycle, from Lean Product Development to Lean Product Launch. For more than a decade, our teams have been applying these techniques to improve product quality, lower cost, and speed time to market.

Is Lean Product Development (LPD) for you? When I talk with OEM customers, I ask them 3 key questions to help them assess whether LPD could benefit their organization.

This white paper will reveal those key questions, explain how LPD can mitigate risk in each phase of the product development process, and share examples of how Lean Product Development has transformed the way Viant brings products to market.

Lean Product Development (LPD):
An organized system of understanding what you know and don't know about a product throughout its development. LPD uses an efficient, systematic approach to drive design-based decisions to mitigate risk as a design progresses through development.

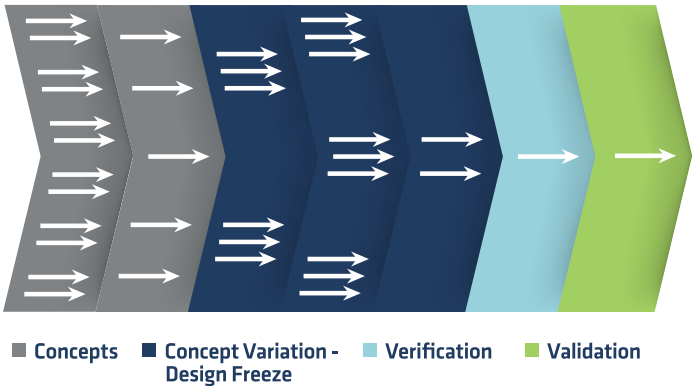
3 KEY QUESTIONS

#1: HOW MANY OF YOUR PROJECTS LAUNCH ON TIME?

If you find that actual launch dates differ significantly from the original targets, it's a sign that your project teams are not making data-based decisions on key design elements to minimize risk.

A Lean, knowledge-based approach uses a **set-based design methodology** to select critical design features based on quantifiable performance, which greatly increases the likelihood of launching on time. Set-based design keeps component specifications fluid as long as possible. Rather than pursuing a single concept, you identify a set of options, gather system-level performance data for each, and eliminate choices until the best one emerges. This approach reduces the number of serial iterations and saves time.

Figure 1. Set-Based Design



Testing multiple potential solutions in parallel up front lowers the risk of late-stage problems.

#2: HOW MANY TIMES DID YOU *THINK* YOU HAD A PRODUCT THAT WORKED, ONLY TO SEE IT RUN INTO PROBLEMS IN THE VALIDATION PHASE?

If you uncover product issues in the validation phase—despite your team's best efforts—it's a sign that the design process did not adequately explore the component variation that typically impacts product performance.

It's also possible that the variability of the full range of production processes was not tested—even in small batches—early enough in the development process.

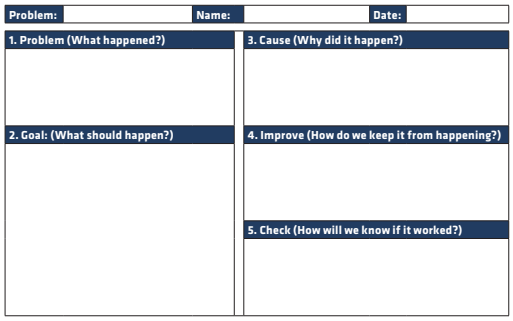
A Lean, data-driven approach develops performance data across a set of solutions to determine the manufacturing tolerances. This ensures that components are manufacturable and that a design meets product performance requirements within real-world variation.

#3: HOW MANY PROJECTS HAD TEAMS ASSIGNED TO RESOLVE ISSUES DISCOVERED *AFTER* THE LAUNCH?

If you discover issues only *after* the product has launched, it can be a sign that the team did not use proper root-cause analysis during the product development cycle.

Every product design progresses through a series of discovery steps in which the design does not perform to the requirements. A Lean, knowledge-based approach will use a structured **A3 problem-solving method** to identify an issue and implement a fix. This prevents problems from reoccurring, enables faster problem resolution through knowledge sharing, and allows the team to make data-based decisions.

Figure 2. A3 Problem-Solving Method



The A3 problem-solving method is a simple, structured approach to guide problem-solving. It typically uses a single sheet of A3 paper, which is the source of its name.

MAPPING THE LEAN PRODUCT DEVELOPMENT PROCESS

Figure 3. Product development process

Every ISO 13485, GMP-compliant organization follows a process from identifying user needs to validating that the manufacturing process is repeatable. You can leverage LPD tools in each phase.

A key part of the LPD methodology is deconstructing a device into manageable subsystems, focusing on each subsystem to understand the critical drivers, and iterating solutions to make it work, then integrating the subsystems to understand how they work together as a system. If issues arise at that point, you already know how each subsystem works, so you can make data-driven decisions to rapidly solve system-level problems without going back to the drawing board.

LPD is not rocket science. In many cases, it's just structured common sense.

LPD is not rocket science. In many cases, it's just structured common sense. But it takes patience, discipline, and attention to detail that not every organization has. Taking this systematic approach allows you to make design decisions that will help you optimize the project timeline as well as product cost and product performance.

Let's take a look at what LPD looks like in each product development phase.

Concept Development/Evaluation

- Break design concept into subsystems
- Develop set-based solutions for each subsystem to obtain data
  - Subsystem knowledge allows you to optimize cost, quality, and performance
- Begin events to identify issues that arise from integrating the subsystems

REAL-LIFE EXAMPLE

Lean Product Development Accelerates Time to Market for Laparoscopic Device

A large surgical technology company needed to accelerate the market release of a novel flexible monopolar scissors for a new laparoscopic surgical system. The Viant team used **set-based design** to optimize cutting (one of 4 priorities identified).

Team members evaluated design inputs and isolated 2 key variables: form (curve) of blades and squeeze force. They then developed a set-based design of experiments (DOE) to efficiently evaluate the impact of squeeze force on various form factors.

Leveraging Lean Product Development:

- Increased cut cycle performance
- Launched novel product in 1 year
- Beat customer's internal launch time by 50%
- Hit budget and cost targets
- Accelerated time to FDA submission

Design Freeze

- Develop data to optimize design concept details: materials, tolerances, assembly techniques, etc.
- Continue integration events that bring subsystems together to identify issues at a device system level

REAL-LIFE EXAMPLE

Innovative Design & End-to-End Capabilities Help Reduce Complexity & Boost Efficiency for Orthopedic Instrument System

A large, market-leading orthopedic company turned to Viant for help in developing instruments for an integrated joint replacement system. A key surgeon complaint was that the device markings were hard to read.

The customer specified that the high-contrast marking be done manually with ink from syringe dispensers. But the team quickly determined that permanent markings were needed to last through the cleaning and sterilization cycles for this reusable device.

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REAL-LIFE EXAMPLE

Using **set-based design,** the team concurrently evaluated 5 different overmolding options for the text itself and for the feeder system to deliver the melt to the text. The team then moved the high-confidence design into production tooling. Selecting one of the text configurations that didn't work would have wasted $75,000 in production tooling.

Applying Lean Product Development tools for this project:

- Improved surgeon experience
- Saved > 1 year in development time
- Saved hundreds of thousands of dollars

Design Verification

- Develop robust test plan leveraging data collected
- Test product against performance specifications
  - If issues arise, subsystem data from Design Freeze help you quickly isolate, identify, and solve problem

REAL-LIFE EXAMPLE

Design, Manufacturing & Supply Chain Expertise Fuels Stability and Growth of Arthroscopic Product Line

A large orthopedic device supplier obtained an established arthroscopic product line as part of an acquisition. The line of shavers and burrs was marred by inconsistent field performance, an incomplete design history file (DHF), and an unstable supply chain. Viant successfully transferred product manufacturing using facilities in the US and low-cost geographies. The team also redesigned the product for improved performance and launched new devices with an updated DHF.

During Design Verification testing, the team discovered a problem with metal particulate from the blades (shedding). Team members leveraged data from the **set-based design** from the Design Freeze stage and used **root-cause analysis** to rapidly diagnose the problem. Although the blades were in spec, the assembly process was positioning the hub onto the inner blade, which created interference with the outer blade and generated metal particulate. The team was able to implement a robust and simple correction–adjusting the blade on the assembly fixture–with minimal time lost.

Applying Lean Product Development tools for this project led to:

- 80% decrease in COGS
- More reliable device performance
- Reduced customer complaints
- Solid yearly volume growth

Validation

- Design validation
  - Devise simulated clinical use to ensure product meets user needs and intended uses
- Process validation
  - Develop data to prove that product is working within normal variation of manufacturing process and that the process is repeatable
- If issues arise, process tolerance data from Design Freeze help you understand windows for adjusting design or process to successfully pass validation

REAL-LIFE EXAMPLE

Lean Product Launch with 3P Event Reduces Risk & Compresses Timeline for Energy-Based Device

A small startup needed help scaling up a system to treat the symptoms of benign prostatic hyperplasia (BPH). The system included an RF generator and a complex, handheld, energy-based delivery device requiring sophisticated assembly technology.

The team held a cross-functional **Production Preparation Process (3P)** event that brought stakeholders together to identify and reduce waste in every step. Four teams worked independently then collaborated to mock up and simulate production on a 20-station lean assembly cell.

The 3P event led to a more robust validation, due to 2 drivers. First, the alignment of stakeholders—engineering, operations, quality, and customer representatives—led to a better understanding of product use and acceptance criteria. Second, the risk-based approach of the 3P event drove a very solid understanding of the process and associated risk, enabling a more sound PFMEA and risk assessment.

As a result of the Lean 3P process, the team was able to:

- Decrease cycle time by 10% of quoted target
- Decrease net labor by 48% of quoted target
- Balance the line within +/- 4%
- Achieve necessary capacity with no additional CapEx

CONCLUSION

The medical device industry has been slow to adopt Lean tools and techniques. One reason is that we operate in a highly regulated environment. Another reason might be a mindset that methods for designing cars are not appropriate for designing medical devices.

But whether you're building a car or a cutting device, many of the Lean product development tools that transformed Toyota can successfully be used in the medical device industry to improve product quality, cost, and time to market.

Figure 4. LPD vs Traditional Product Development

Figure 4 compares Lean Product Development with traditional product development. In this simulation, Design Freeze took slightly longer in the LPD model than in the traditional model. However, the end result is that LPD shaved 4 months off the product development timeline.

LPD can also bring benefits that are harder to measure, such as creativity. Using set-based design, for example, expands your thinking and stimulates creativity by challenging you to develop a set of possible solutions instead of one single solution.

At Viant, our Lean2Life initiative is transforming end-to-end manufacturing. Leveraging our broad capabilities and global resources, we're applying Lean principles across the product lifecycle to deliver optimal cost of ownership with uncompromised quality and reliability.

Successfully implementing the principles of Lean is about much more than how you manufacture products. It's best implemented in a culture of continuous improvement, operational excellence, and relentlessly upholding the customer's reputation for delivering high-quality, high-value devices.

Don Welling has 20+ years of experience developing and launching new products. He has lead Lean Manufacturing and Lean Product Development projects that have reduced WIP by 50%, decreased cycle time by 6X, launched new products with a 50% reduction in time to market, and decreased product costs by 80%. He holds a BS in Mechanical Engineering from Pennsylvania State University.

ABOUT VIANT

Viant is a global strategic manufacturing partner that helps medical device OEMs bring complex medical devices and components to market. Our deep materials expertise, combined with our experience in design, manufacturing, assembly, and packaging, allow us to bring our customers' medical technology solutions to life. With nearly 6,000 associates across 24 locations worldwide, we are a unique combination of big-company scale and small-company attention. For more information, visit www.viantmedical.com.

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