

**LEAN PRODUCT LAUNCH:
3 WAYS 3P EVENTS CAN REDUCE
WASTE, RISK, AND TIME TO MARKET**



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INTRODUCTION

Get a diverse group of smart people in a room and present them with a challenge. Brainstorm ideas and collaborate to choose the best solution. Build a mockup and simulate the process to learn as much as you can before bringing it into the real world.

Sounds like a solid foundation for a successful a product launch, right? We think so, too. In a nutshell, that's what happens during a Lean Production Preparation Process (3P) event.

For more than a decade, Viant teams have been leveraging **Lean Product Development** and **Lean Product Launch** techniques to improve product quality, lower cost, and speed time to market. We're bringing Lean to life across the product lifecycle to support our customers in expanding their product offerings, optimizing their supply chains, and managing costs on a global scale.

Both Lean Product Development and Lean Product Launch have Lean principles at their core, like identifying and reducing waste. Both use Lean tools, including cross-functional teams and set-based design. However, Lean Product Development is used *earlier* in the product lifecycle and focuses on the process of **product design**. While there is often some overlap, Lean Product Launch happens *later* in the product lifecycle and focuses on the design of the **manufacturing process**.

3P is a Lean Product Launch tool that has been particularly effective for our customers. 3P events bring stakeholders together to identify and reduce waste in every step of a process, thereby increasing efficiency, de-risking the manufacturing process, and compressing the timeline. Viant has conducted dozens of 3P events for customers ranging from tiny startups to large global corporations.

This white paper will focus on 3P as a key Lean Product Launch tool. It will explain how this tool can help accelerate time to market and take a step-by-step look at each phase of a 3P event.

1. 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.

2. Lean Product Launch (LPL): A process that uses Lean tools and methodology to develop a robust manufacturing process that enables an organization to optimize capital spend, cycle time, and manufacturing labor while ensuring device quality is inherent to the process. This approach minimizes risk by maximizing learning throughout the launch process.

3. Production Preparation Process (3P): A Lean Product Launch tool that helps teams examine how a product is designed and manufactured. It focuses on the true requirements of a process to mitigate risk and identify and eliminate waste.

3 WAYS 3P EVENTS CAN SPEED PRODUCTS TO MARKET

1. Aligning stakeholders for more efficient, effective decisions

3P events bring together a diverse team of 8-16 stakeholders that represent constituents from both Viant and the customer's organization. While engineers are key members, a balanced team is the goal. The team could comprise:

- Manufacturing, quality, and/or design engineers
- Equipment operators
- Equipment integrators
- Customer's program manager
- Leaders from both companies
- Subject matter experts in a relevant therapeutic area or manufacturing process

When you should consider a 3P

- New product development
- Capital expenditure approval
- Product design changes
- Significant changes in volume
- Manufacturing transfer

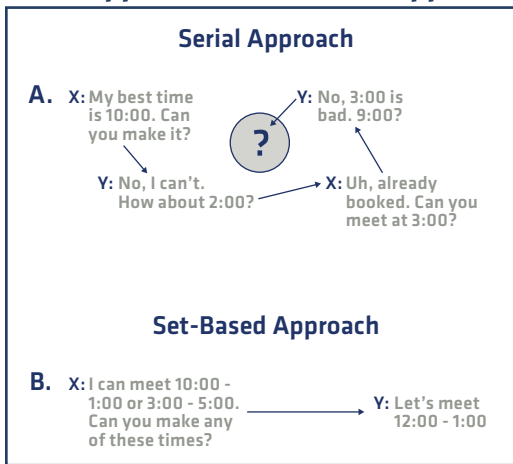
The idea is to bring all constituents to the table to evaluate a range of options together—rather than serially—to make decisions more efficiently and effectively.

In a 3P event, team members use a Lean tool called **set-based design** to identify a set of options (rather than a single concept), gather performance data for each, and eliminate choices until the best one emerges (Figure 1).

Having all stakeholders represented allows for efficient

decision-making. This approach reduces the number of serial iterations, which reduces labor and cost, and ultimately, increases the likelihood of a product launching on time.

Figure 1.
Serial approach vs set-based approach



Take a simple example of setting up a meeting. In the serial approach (A), meeting time options are considered individually. In the set-based approach (B), options are presented in sets, which quickly results in finding a mutually agreeable time. (Source: University of Michigan Integrative Systems + Design.)

2. Understanding design requirements

It's essential that team members have a common understanding of how the device functions and its intended use. In the planning stage of a 3P event, we gather as much information as possible from the customer. We evaluate the customer's drawing packages, their risk-based quality documentation, and their assembly process information. This ensures that 3P participants understand device use, the impact of improper assembly, and the effects of poor quality. This information is readily available throughout the event to ensure that quality is at the forefront of the 3P event.

We also ask the customer to bring device samples or a simulation to educate the team about the device's clinical use and its critical-to-quality characteristics (CTQs). These are the performance characteristics necessary to meet the needs of the end user and ensure patient/user safety. For example, a CTQ for a cardiovascular catheter is that it must be free from kinks or folds, as these characteristics may result in unpredictable and/or restricted fluid flow. For complex devices, the 3P team will create a large flow diagram detailing how the device is assembled, injecting CTQs at key points.

Understanding the product design and function plays a critical role in reducing risk and saving both time and cost. Without a 3P event, design engineers would have to take the time to educate process designers on the important aspects of the product. That can be time-consuming, and that communication is often less effective than having a cross-functional team working together from the beginning.

Another factor is cost of change (Figure 2). Once a manufacturing process is fabricated and built, it becomes extremely expensive to make a change, including re-machining parts, re-installing, re-validating, etc. It's much more cost effective to make changes on the front end, when we can easily modify the design in CAD. In this case, a change takes minutes rather than weeks or even months.

Real customers on 3P

“The [3P] process opens your eyes in terms of design details that need to be addressed before manufacturing.”

Clearly defining CTQs during process design can also significantly reduce the time required to validate the process after implementation. Since process designers understand what really matters in terms of form, fit, and function, they're able to design validation methodologies into the process. The result is less complex and more robust validations that can be executed more quickly than traditional validation approaches.

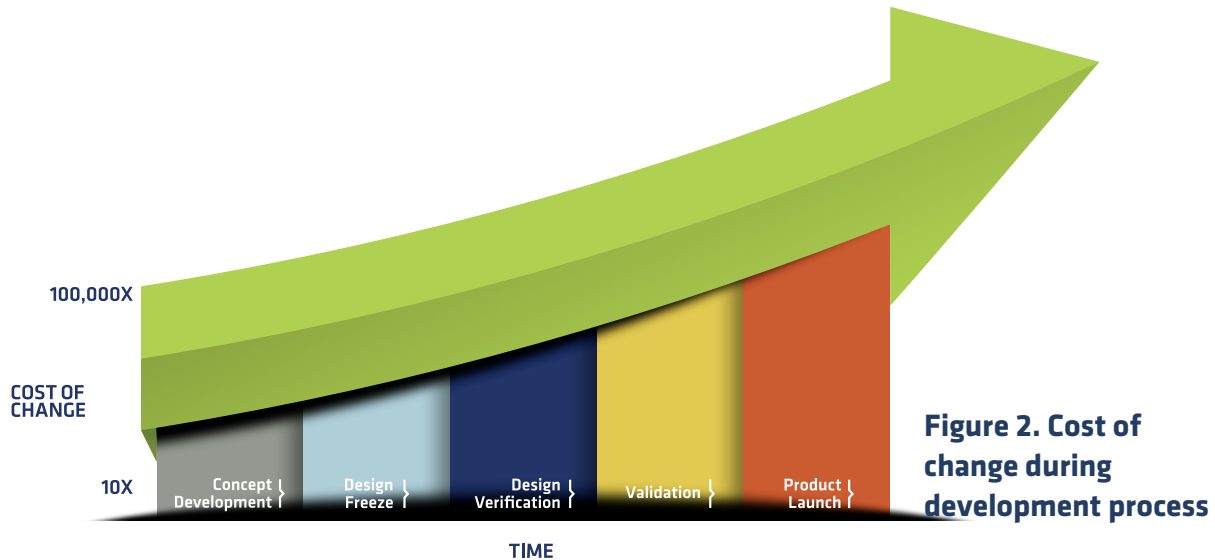


Figure 2. Cost of change during development process

3. Identifying opportunities to reduce/eliminate waste

Identifying waste is at the heart of a Lean Product Launch. However, the approach differs depending on whether we're transferring an existing manufacturing line to Viant, or designing a manufacturing process for a new product.

When we're transferring manufacturing to Viant, we always focus on the customer's definition of value and improving the process. To make improvements, the 3P event is scripted to evaluate every step of the current manufacturing process to identify and eliminate waste.

REAL-LIFE EXAMPLE

Viant was engaged to transfer a dip molding process associated with the manufacture of cardiac catheters. This process had been running at the customer's facility for more than 15 years. To prepare for the 3P event, a Viant team traveled to their facility to map the current state of the entire process. This included the cleanroom layout, equipment size and locations, component storage locations, and the movement of operators. On site and at the 3P event, the customer's manufacturing supervisor was instrumental in injecting actual shop-floor knowledge into the mapping exercise. This map served as the basis for the "spaghetti diagram" (Figure 3) that we used to identify waste in all its forms (Figure 4).

The team identified 36 forms of waste in the customer's legacy process, then broke into subteams to brainstorm waste reduction solutions. Team members were able to reorganize the manufacturing process to eliminate much of the movement of staff and materials by arranging assembly stations sequentially and creating integrated cells for discrete processes. The result was a streamlined manufacturing process that improved flow, reduced the bottleneck, and boosted efficiency.

When we're launching new products, there's no existing process from which to eliminate waste. In this situation, we have the opportunity to design a manufacturing process from the ground up, in the "least-waste way." 3P events have a "clean slate" from which to design a scalable process in an efficient way that eliminates operator waiting time or movement, reduces cycle time, and uses one-piece flow instead of batch methodology.

Figure 3. "Spaghetti diagram"

This spaghetti diagram from an actual 3P event shows the movement of staff and materials throughout the manufacturing process.

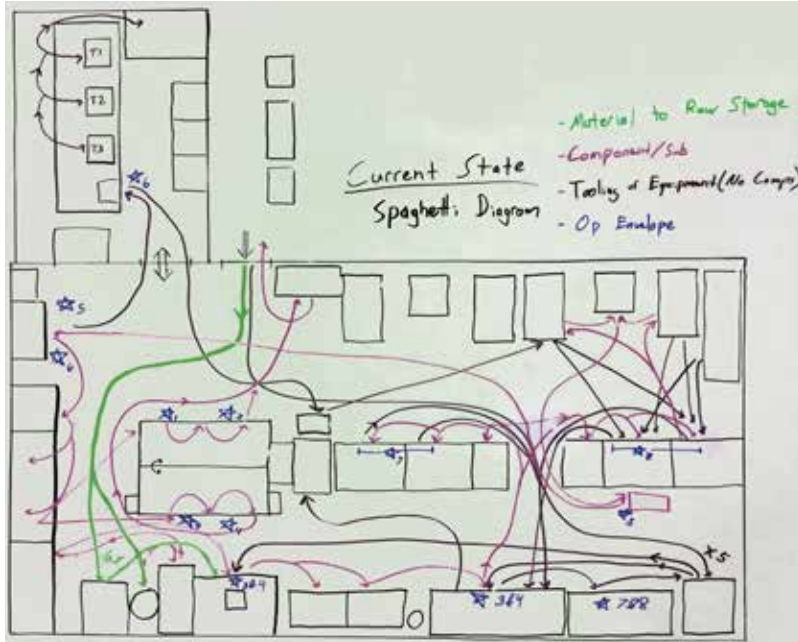


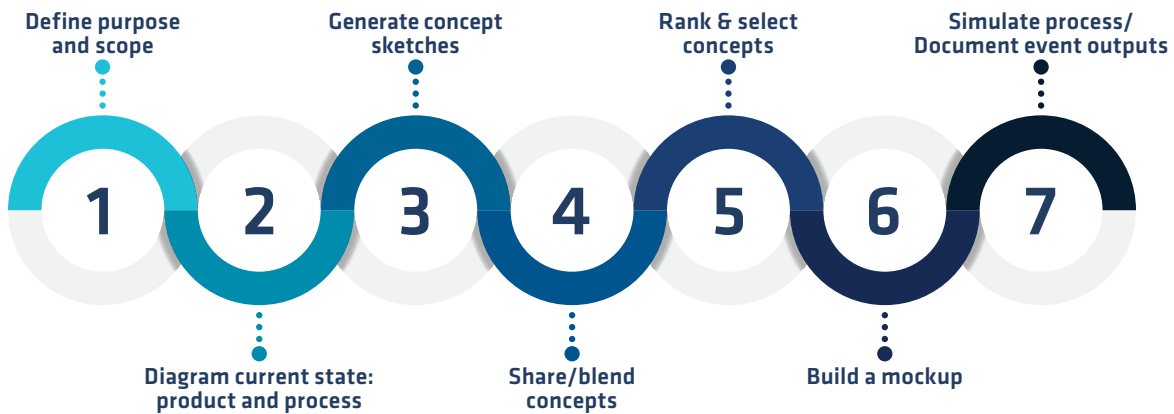
Figure 4. Forms of waste



MAPPING 3P STEPS

Let's take a look at each phase of a 3P event.

Figure 5. 3P steps



1. Define purpose and scope

First, the 3P team discusses the customer's definition of value to generate a clearly defined purpose statement. This statement is then posted in the 3P arena, where it remains visible throughout the life of the event. Next, we identify the event scope, which establishes the boundaries of the team's focus and efforts. For example, "All cleanroom assembly operations are in scope, excluding boxing or palletizing." The strategy of the 3P event is then structured around the purpose and scope; the overall business strategy associated with the product.

For example, let's say a customer is developing a product with the goal of launching in 6 months and quickly ramping up. Capital budget is less of a concern than timeline. In this case, the event may focus on automation and robotics rather than a manual process to accommodate the need for speed and rapid scale-up.

Another customer with a firm capital expenditure target may be more concerned about budget and less concerned about speed to market. We adapt the 3P strategy based on the customer's definition of value, so in this scenario, the process solution may be more manual to reduce CapEx.

Critical Event Input

- Customer forecast
- Process capacity
- Takt time
- Program budget

2. Diagram current state: product and process

In this 3P stage, we create diagrams that map the sequence of component assembly. This serves as the foundation for developing a new process or improving an existing one. The team must understand how the device is intended to be assembled, including the CTQs, before it can develop a robust manufacturing/assembly process. In the case of manufacturing transfers, we create a second diagram to map the current manufacturing process. This map includes the flow of people and materials, well as the workstation layout (Figures 3 and 6).

Since the current-state process is often at a different location than the 3P event, the team will watch videos of the process. We will also solicit input from the operators to ensure the process map accurately reflects the current-state process. After we generate the maps, the team brainstorms to identify forms of waste (Figure 4).

Figure 6. Current-state process flow diagram



3. Generate concept sketches for each station and the complete process

This is where we lay the foundation for the rest of the event. Leveraging the diagram of the current state, we spend time individually coming up with “blue sky” ideas for how to reduce waste and improve flow. The facilitator then groups team members with the objective of bringing diverse perspectives together. Each team brainstorms concepts and produces sketches to capture ideas for the overall process layout. These sketches include the operator envelopes, how materials move through the stations, and even more detailed



sketches of machine/equipment concepts. This activity results in multiple concept sketches of how team members envision the optimized process in “future state” (Figure 7).

Figure 7. Future-state process concept

4. Share/blend concepts

Often taking a full day, this step is where the magic happens! The teams share their future-state concepts with the larger group, and we discuss their strengths as well as how each could be improved (Figure 8). We then go back to our teams to further refine our concepts. Teams borrow strengths from one another and fill gaps identified during the sharing session. This is an iterative process that progressively improves concepts



by blending the diverse experience of the collective team. At the end of the day, the best ideas rise to the top and breakthrough concepts emerge. That's the magic of a 3P event.

Figure 8. Presenting a team's concept during the Sharing phase

5. Rank & select concepts

The group ranks the future-state concepts objectively against the customer's definition of value, the core problem statement, and Lean criteria such as reducing waste in all its forms. We then assign each concept a rank according to these criteria. The concept that progresses to the next phase of the event is the one that achieves the ranking criteria in the least-waste way.

Real customers on 3P

"Very well run! Worthwhile, detailed, organized & prepared. Makes you dive deep into aspects of process that you would not typically think about, especially if you're not directly involved in manufacturing."

Often, team members start to see that one solution is ideal, so the ranking process is abbreviated. It's also common to narrow the selection to two concepts that rank relatively equally. In this case, we discuss the concepts and gradually weed out less valuable ideas until we arrive at a single solution that makes the most sense based on the event's purpose statement.

6. Build a mockup

The next step is to create a physical to-scale mockup of the future-state process using cardboard boxes, duct tape, two-by-fours, and whatever else is needed to simulate the equipment (Figures 9 and 10). All participants in the event roll up their sleeves to collaboratively construct the mockup. This activity is great for team building and further challenges the team's creativity.

We retain this mockup throughout the process design lifecycle and continually revisit it to verify concepts before process approval in CAD. As shown in Figure 2, it's always less costly (in terms of both time and money) to make changes before equipment has been fabricated and procured.



Figure 9. Constructing a 3P mockup



Figure 10. Mockup of manufacturing equipment within cleanroom footprint

7. Simulate process/Document event outputs

Finally, we run assembly simulations using the mockup and actual components (Figure 11). Observing the simulation in real time reveals additional opportunities to improve the process. The team performs several iterations to further refine the process and eliminate more waste. During a simulation, we record cycle times to assess line balance, evaluate ergonomics and safety, and record video for future reference.

The Viant team may spend a week or more documenting the 3P event and the details of the simulation on Process Specification Sheets. We record details such as process steps per assembly station, component storage quantities, poka-yoke concepts, and any important criteria that a mockup can't demonstrate. We then provide this documentation package to equipment integrators to supplement equipment quoting.



The output from a 3P event can cut quote lead time in half and greatly increase the accuracy of a quote, which ultimately reduces time to market.

Figure 11. Process simulation and time studies for an adhesive bonding process

Real customers on 3P

“Labor content was **reduced by ~50%** compared with expectations, which is an incredible accomplishment.”

CONCLUSION

At Viant, we've consistently demonstrated the significant value of the 3P tool and its ability to generate winning concepts at the front end of the product launch lifecycle. A 3P event allows us to develop a robust manufacturing process with product quality at the foundation, while also embedding the customer's definition of value into the process solution. With the 3P tool we can optimize capital spend, cycle time, and manufacturing labor, resulting in increased speed to market. It also ensures Viant's product launch strategy is aligned with the customer's business objectives.

Whether we're launching a new product or transferring the manufacturing of a legacy product, the 3P tool allows us to de-risk and filter out waste throughout the Lean Product Launch process. Viant's customers have regularly voiced that an investment in 3P has reaped benefits including increased product quality and process efficiency, more aligned teams, and reduced time to market.



ABOUT TODD CLARK

Todd has more than 10 years of experience in multiphased new product

introduction (NPI) strategies and best practices in the medical device industry. He has planned and facilitated 3P events that have reduced capital, derisked projects, and increased speed to market. He has Six Sigma Black Belt training and significant experience in Lean methodologies.

ABOUT VIANT

Viant is a trusted global design and manufacturing services provider that partners and innovates with customers to provide the highest quality, life enhancing medical devices. We do this through our depth and breadth of capabilities, end-to-end integration, technical expertise, and relentless focus on customers and operational excellence. With nearly 6,000 associates across 24 locations worldwide, we offer a unique combination of small-company service and attention with big-company resources. Our customers count on us to help bring mission-critical projects to life. For more information, visit viantmedical.com or follow us on LinkedIn.