

A Lean Version Of Lean

Successful deployment of Lean at Amgen

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If I were an internal consultant within the automotive industry or in semiconductors, rolling out a Lean initiative would be easy. In fact, I led operational excellence efforts in the semiconductors industry for a few years and encountered only ordinary change-curve resistance. It's easier in old, mechanical industries because all of the business processes have settled and the major barnacles have been removed.

I'm not in semiconductors anymore; I'm in biotech and when I was offered a position to lead the deployment of Lean Thinking at Amgen, I knew I'd have my hands full. Prior to joining Amgen, I worked across industries in 15 countries providing various consulting services, and the lesson I learned on the outside is just as applicable on the inside: You must start where the client is. For me, this means that we must research not only what tools are best, but also what is the best way to deploy those tools within a particular organization.

Before I provide a detailed look at how to deploy Lean, I should explain why biotech in general and Amgen in particular would be interested in Lean principles.

Amgen is interested in being more efficient and effective because we can. We know that our pace of growth has created business processes improvement opportunities. We know we have some Non-Value Adding (NVA) activities in the system and we should get them out. We're also aware that now is the right time to look at efficiency and effectiveness. Other industries—semiconductors included—would love to go back to the days when they didn't have to do Lean in order to survive. They'd love to deploy Lean in a steady-state environment for a while, instead of working with a stopwatch around their collective neck and a trap-door under their feet like they do now. In Biotech, we still have the opportunity to improve efficiency and effectiveness because it's the right thing to do. Then, when cost pressure intensifies down the road, we'll already be leaner and we'll already be versed in the tools. When the market pulls further improvements we'll be able to go directly to implementation without having to ramp-up our learning from square one.

Having addressed why biotech is interested in Lean, we can move to the issue of how best to deploy it. I consider three things when determining a deployment approach:

- 1) Industry maturity
- 2) Company Culture and
- 3) Best Practices.

Maturity

The first one was easy to address—for Biotech. We are a very young industry. The impact of youth has to do with the level of business process maturity in your organization. In young industries, many mistakes are being made for what seems like the first time. In semiconductors, whatever improvement you're planning can be researched in some similar cases, because the industry is about 50 years old. Biotech is about half that. Do a search for operational excellence in Biotech and you'll probably end up with lists of documents relating to work done in other industries. The reason it hasn't been done on a large scale in our field is because cost hasn't pulled it yet.

In my experience in semiconductors, we arrived at the point of profit margin competition where air travel was shut down for almost everyone, food service was scaled back, and the holiday gathering became a biennial event. More importantly, we ranked and rated employees for termination potential on a continuous basis. No one wanted to eliminate staff, so we wrenched every last drop of savings out of our business processes. A mature industry is likely to have experienced the necessity to address efficiency at some point in its history. In biotech, the margins have thus far muted the improvement call of costs. So, the conclusion from the first consideration is that Biotech is a young industry that experienced rapid growth and therefore there is likely NVA in major business processes.

Culture

The second consideration is the company culture. In semiconductors I worked for an organization that had been in existence since the beginning and knew its way around continuous improvement activities. This organization knew that its processes were controllable (completely controllable). The industry has been around long enough to have boiled most problems down beyond the novel solution. Everyone in the industry is doing the fundamentals the same way, so speed at problem solving and continuous improvement innovation differentiate the players. In terms of yield, the grade range was as follows: 100% = A, 94% = F. The scores in between were tolerated but not celebrated. With this type of expectation, the staff in this company were driving for every yield point they could get and they didn't care where it came from. As an internal expert in improvement, my first days on the job were frightening. Not because they didn't listen to me, but because they did. The engineers listened extremely closely to everything I said, trying to find something that they could try. When they heard something that made sense, they tried it, and if it worked they came back for more. The main focus was information sharing and getting the right answer as quickly as possible.

Amgen's culture is different due primarily to the fact that much of what we do was invented here. This is a function of the industry's maturity and Amgen's involvement at the very beginning. Not everyone is doing the fundamentals exactly the same way in biotech, so one size cannot fit all in this industry. Information on deployment from elsewhere in the industry is relevant, but not nearly completely persuasive. Information on deployment that comes from outside the industry is borderline irrelevant. Acknowledging this cultural component meant that an approach to deployment that started small and generated convincing data inside Amgen would be best.

The potential problem of rolling Lean out this way is that you fragment work and end up pushing NVA among work groups. Though this may be great job security for an internal consultant (kidding), it's not best for the company. I was willing to take the risk of fragmentation because of the importance of momentum. The youth of the industry told me there was likely plenty of efficiency opportunity, and the culture at Amgen told me that I would need some quick wins and some internal data. I know all external consultants are squirming at the thought, but considering industry maturity, culture, and best practices means accepting some trade-offs. I knew I could mitigate the risk by getting as much cross-functional participation as possible for certain projects and by including senior management in crucial report-outs.

Best Practices

The third consideration is best practices. This involves asking, "What have I learned from past deployment that is relevant to the current situation?" My best practices are to deploy in a grassroots fashion and generate measurable results as quickly as possible to build interest and momentum. Since this mapped well to the industry maturity and company culture discussions, I knew how I was going to deploy. Other best practices are "Never call anything a pilot" and "Keep it simple." So, with no bells, whistles, or parades, we deployed a Lean version of Lean at Amgen.

We built our Lean version of Lean to provide just-in-time training, identify NVA, and eliminate NVA by focusing on the customer pull. We delivered a two-day Lean Event with a simple agenda:

- Training: 90 minutes
- As-is process confirmation: 3 hours
- To-be process creation: 2-6 hours
- Actions and owners: 1 hour

The front-end process, before the two-day event, involved mapping the as-is process with a small core group from the hosting organization. The back-end process—lasting for 60 days following the two-day event—included a telecom once per week to maintain momentum and ensure closeout.

This process is as simple as it looks, with two exceptions. The first is that we prohibit teams from assigning themselves actions that will take more than 60 days to complete. The intention is to keep us from identifying a lot of major system overhauls that will take many months—if not years—to implement and will have to run through layers of review even to gain approval. We wanted quick elimination of NVA that would result in a measurable gain. We would then take that gain and justify additional work in this area, possibly to include any necessary system overhauls.

The second area where the agenda was slightly more complex than it appears was the training. We covered basic

concepts of Lean and showed a slide depicting a classical Lean event involving one of our distribution centers. The slide showed an assembly line that had been shortened from 400+ feet to less than 100. In the training, we explain that this is what most people think of when they think of Lean and that much of our work will not look like this. The point, within a quality organization, is to integrate the basic operating principles that Lean provides into areas that more closely resemble the service industry. The purpose of the slide is to acknowledge the fact that some folks have had exposure to traditional Lean and to set up our work in a less tangible area. We wanted our customers in biotech to hear us say that we knew upfront that their area would need to be different. If they didn't hear us say that, we wouldn't get out of the starting gate. As I mentioned above, semiconductors was an industry of engineers, so we needed to treat our biotech industry of scientists differently (at least at the outset).

The agenda for the training also included a simulation. The simulation took up 60 minutes of the 90 we allotted for training, so it was where most of the lessons were imparted.

Folderol

The simulation is a basic paper airplane assembly. It's been around for a while, but bear with it.

Our initial step is to identify six volunteers. The first four are operators and each is assigned a different operation. The sum total of the operations is a paper airplane. The two remaining volunteers are a materials handler and a supervisor. The materials handler is the only person that is allowed to move material (paper) among the operators. A stack of blank paper is placed next to the first operator and she is told to pull material as needed.

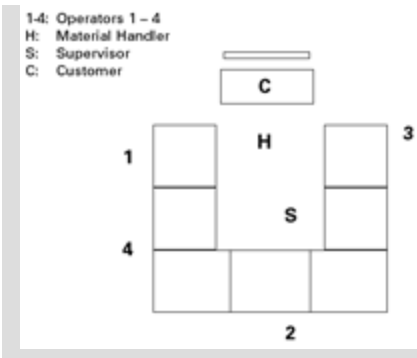
When setting up the simulation, I make sure the volunteers are positioned so that the operators are far apart. This sets up the illustration of layout. The traditional version of this activity then moves directly into the making of paper airplanes. I customize the activity for biotech by adding a number of verification steps. Operators are told that they have to sign off on the quality of the material as it arrives to them. I explain that our airplane company added these steps because of a contamination that happened previously. I then tell the supervisor that she must sign off after operations number 2 and 4. I explain that one of the operators missed something previously so we wanted the supervisor to double-check. Operators are told to sign along the bottom of the plane and everyone is told to sign next to the person before them.

Before starting the clock, the group is told that they can only move product in batches of three. The workers are told that we batch because a consultant told us that batching would be more efficient. When they have completed a batch, they call over the materials handler to move the material to the next station. Operators 2 and 4 have the additional requirement of calling over the supervisor for signatures. Everyone without a direct job is told to watch the process for improvement opportunities. They are asked to note these rather than inject them along the way.

All of the instructions are given in a hurried, completely verbal fashion so we're sure there will be difficulty once the simulation starts.

A person assisting me acts as the customer and separates incoming finished product into two piles, good product and rejects. The customer/assistant is told to reject planes with folds that don't have sharp angles and any plane missing signatures or with signatures in the wrong place.

Simulation Set-up



The manufacturing process begins and, eventually, planes begin to appear at the customer station. Once the line is fed, I insert a piece of paper marked RUN #1 at the top of the pile of raw materials. When this paper reaches the customer, I call time and capture data.

Round #1 shows a number of problems. First, defects/NCs will be high. Most of the problems come from misplaced signatures, so we discuss the fact that our own so-called quality controls have impeded our ability to release a quality product. The numbers in the table will also show that our productivity is in the .3 - .6 range, meaning we're getting about a half a person in output from each person on the job. We highlight this point and discuss what it was like to work in this company during round #1. We capture some of the comments under "quality of life." The comments usual surround topics like stress and chaos.

I ask the observers and the team what they would change going into Run #2. This is a critical component of the simulation. A full array of suggestions emerges and they all are based on the apparent bottlenecks. In the simulation, we have the final operator complete two folds while the rest of the team has one fold. Therefore, the final position in the line is a major bottleneck. However, the signatures are muddying the water in Run #1 and we always get a pile of work in progress (WIP) before operator #2. This causes the observers and participants to dive right in and begin suggesting fold combinations earlier in the line than necessary. The facilitation of this discussion eventually guides the group to a small number of changes and I suggest that some of the others would be good for a theoretical Run #3. We don't do a third run in the simulation, but by citing it we make a point about continuous improvement.

	Run #1	Run#2	Run #3
Lot Size	3		
WIP			
Total Run Time			
Throughput (Lead) Time			
Total Output			
Total staff	6		
Productivity			
Defects or Non-conformances			
Quality of life			

The first fix we accept for Run #2 is to straighten the line. Someone invariably suggests putting the operations in a line. I place them around one table.

I also take the suggestion of about removing batching. Then I remind everyone of the concept of kanban (or pull) that we discussed in the introduction and I place kanban squares between every operation and one in front of the customer. The operators are told not to process anything unless the square to their right is empty.

Everyone sees how this is going to improve the operation and is eager to get started; I ask first what we should do with our handler. He or she invariably gets promoted (they say fired; I translated). I then ask about what we should do with the signatures. I remind them that we're making paper airplanes here and recommend that they get aggressive about efficiency for the simulation. They remove the signatures. I ask them what the supervisor should do and everyone is stumped. I remind them that the original inception of the supervisor position did not involve pure administration. At that point they say that they want the supervisor to observe the process for future improvements and to make sure staff are getting what they need. This is adopted as the supervisor's role.

Output doubles for the second run (right). The staff feel like working in this organization was more fun. They

experienced less stress and were also aware of their increased productivity. This brought more job satisfaction.

The debrief for this run affirms the improved productivity and decreased WIP, cost, and defects. The most important point, however, returns to the bottleneck issue. Now that the line is straight and the redundant signatures have been removed, staff can see how the process actually runs. This is reinforced with a quick step-mapping of the process at the flipchart. They call out every step, including things like calling the materials handler and waiting for the handler. All of the steps are listed and then we cross out the ones that the customer doesn't value. At the end, the list is reduced by 80% and all that remains are the steps to pull in the raw materials and the individual folds. Run #2 eliminated the Non Value-Adding activity and allowed staff to see the actual operational process clearly. They then are able to identify that the bottleneck is at operation #4, because of an unbalanced workload. In the theoretical Run #3, they could begin to work on balancing the line.

The point that is impossible to miss is that we must first chip off the barnacles before we start applying varnish! Getting too cute with Lean too quickly is itself wasteful.

We delivered 10 Lean Events at Amgen in 2005 and generated several million dollars in savings while reducing complexity in targeted areas. Based on our results, I was offered additional headcount and expanded responsibility. We now have Metrics and Analysis coupled with continuous improvement and we're raising our Lean Events up to the global cross-functional level. Without building the momentum of year one, there would not have been a year two.

Biotech will continue to explore efficiency gains and we can anticipate a developing Lean enterprise. Specifically, organizations that serve biotech companies will need to offer business processes that mirror our streamlined ones. Industries that have already followed this timeline have seen individual organizations develop Lean approaches and follow NVA all the way to their suppliers. The suppliers in turn are forced to go Lean in order to keep from losing business and they must call on their suppliers to help them improve efficiency. We're still in the early stages in biotech but in the years to come the entire value stream will be impacted.