Framework for Critical Thinking – Introducing Lean Philosophy to Statistical Programmers

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ABSTRACT

'Lean', coined by Jim Womack's team at MIT in the late 1980s, describes the Toyota Production System that aims to deliver goods and services of the highest quality at the lowest cost in the shortest lead time. We're seeing businesses in all industries including healthcare are using the 'lean' principles to guide their best practices.

Lean is based on creating a culture on how to respond to a problem rather than what tool to use. Lean approach creates a problem solving mindset. It has four main principles: customer first, trusting and respecting each other, continuous process improvement (CPI), and elimination of waste.

This paper will introduce and discuss the lean principles in the context of statistical programming in the pharmaceutical industry. Customer first is to understand what is of the highest value to the customers. Trusting and respecting people is to build the best team and create a learning-centered environment. It promotes the concept of treating every mistake as a learning opportunity. CPI is to apply rapid improvement methods of PDCA (Plan, Do, Check and Act) at all organizational levels. Waste elimination is to identify and minimize the activities that do not add value. Lean philosophy also calls for the management to create an environment that empowers the people.

In conclusion, lean is a culture and a mindset. It works when everyone in the organization is on board and follows the lean principles in their daily work.

INTRODUCTION

How many times do we face challenges such as resource constraints, working over-time, waiting for data, and cycle times that are too long? These challenges create the need to significantly improve the way we run our business. We need to improve productivity and reduce waiting time. We need to increase efficiency and reduce cycle time. At the same time, we must continue to ensure quality and be compliant. We must bring value to patients. We must be competitive. We must create a culture of continuous improvement (CI).

Lean is the response to these challenges. 'Lean', first referred to by Jim Womack and his team at MIT in the late 1980s, describes the Toyota Production System (TPS). TPS has the goal of delivering goods and services of the highest quality at the lowest cost in the shortest lead time, which means higher value for the customers.

Lean is based on creating a culture on how one responds to a problem rather than what tool one uses.

The principles of lean include:

- Customer first
- Trusting and respecting each other
- Continuous Process Improvement
- Eliminating waste

CUSTOMER FIRST

Every company needs to understand what value the customer places upon their products and service. A customer can be external or internal. Our downstream functions within the company are our customers. Customer first does not mean taking all customer input at face value. Try to understand the purpose

behind it. Know what makes our customer successful and what is of the most value to the customers. We focus our efforts on the things that add the most value for our customers. Activities that do not add value are called 'waste'. We will discuss how to identify and eliminate waste later in the paper.

In TPS, managing customers means building relationship with deep understanding and trust which can lead to a highly responsive network of goods and services. In our world of statistical programming for clinical trials, that translates into managing upstream stakeholders such as data management and downstream customers such as statisticians and medical writers for the service we do. Furthermore, we also need to manage our partners such as our Functional Service Partners (FSP) so that our deliverables (tables, listings and figures), as part of the final product, are of high quality within the set timeline.

Effective stakeholder management requires leadership and emotional intelligence. We are not in the business of simply taking orders. Much more is involved in dealing with our stakeholders, many of whom also need to manage their own customers. Statisticians need to manage the expectations of the clinical scientists. Statistical programmers need to make sure their statisticians and medical writers receive what they need for their analysis and reporting responsibilities.

Stakeholder management is a dynamic and ongoing relationship management. This is about managing communications to satisfy the needs of, and resolve issues with, project stakeholders.

Here are some questions to consider, especially for our challenging stakeholders:

- What are their short-term and long-term goals and do we have a plan to help them meet these goals?
- Are their expectations reasonable given the timeline and resources at hand?
- Who are the other stakeholders who influence them? What stakeholders do they influence?
- How do they want to receive information?
- What information will they give you? If this information is vital to the project, consider documenting this to hold your stakeholders accountable.
- What is their communication style? Formal or informal? Collaborative or authoritative?
- And finally, are they willing to take risks? For example, if you want to propose a different solution, are they open to change or set in their ways?

TRUSTING AND RESPECTING EACH OTHER

BUILD A HIGH PERFORMING TEAM

Rather than think, 'I need an A-team for this project', we should build a high performing team by enhancing knowledge and treating team members with trust. As a result everyone is of A-team caliber. We need to resist the urge to do work for others. By spending time coaching and guiding, we will get to know the strengths and limitations of the team. This will help to make smarter resourcing decisions for future projects. Another goal of coaching is to build knowledge among the programmers so they can work independently and deliver quality work. As they take on more work, it's important to monitor progress closely. As the team lead, we can create an environment that embraces and encourages innovation, particularly in ways that reduce waste and add value to our customers. The will result in actual workplace improvement.

EMPOWER THE STAFF

We need to empower the staff members to be the investigator of their own work. We need to create a safe learning environment by banishing the blame and treating every mistake as an opportunity to learn. Through learning and empowerment, teams build knowledge and enhance critical thinking skills.

People are capable of creating, learning, adapting and overcoming obstacles through problem-solving. We need to work smarter - not harder. When responding to a problem, thinking is more important than tools. Consider the 80/20 rule - 80% thinking and 20% tools.

BUILD A LEARNING-CENTERED ENVIRONMENT

Leadership's role in building a learning-centered environment:

- Help the frontline staff understand the responsibility of improving their own work.
- Provide necessary resources and guidance to enable workplace improvement.
- Encourage the staff to continually learn and contribute ideas.
- Support teamwork.

BANISHMENT OF BLAME

The foundation of trust and respect is the ability of the organization and individuals to show 'Banishment of Blame'. This leads to everyone being empowered sharing insights for learning. If we consistently do this, we will be able to build high performing teams. Within Toyota, people call TPS Toyota People System. It is focused on building better people so we can build better products and processes.

CONTINUOUS IMPROVEMENT

PDCA – CONTINUOUS IMPROVEMENT

An **improvement** process is an effort to improve products, services, or processes. These efforts can seek **"incremental"** improvements over time or one **"breakthrough"** improvement all at once. Lean methodology focuses more on the **"incremental"** improvements which start small and go through trial and error using a structured problem-solving method called "PDCA" – Plan, Do, Check and Act.

Problem Solving Process (PDCA)

The idea is to involve people who do the work so that the improvements are made closest to the place of work. The ongoing continuous process improvements cannot be done in a board room by a group of senior managers. Direct observation is a key component of this, GO LOOK, GO SEE. When we go look and go see we should understand what the expectation is (Plan or maybe even a hypothesis), we then observe actual output (DO), we compare (Check) and then we learn and adjust (ACT). If we enable this cycle to take place on a small scale you don't have to do large improvements. We manage the ecosystem continuously versus through very disruptive change. Therefore we call it continuous improvement

LEADERSHIP ROLE AND RESPONSIBILITY IN CONTINUOUS PROCESS IMPROVEMENT

- Executive leaders are the champions for improvement.
- Top management
  - Provide direction for initiative.
  - Connect to business strategy and organizational culture.
  - Provide linkage of strategic intent with day-to-day implementation.
- Upper middle management
  - Participate in project reviews.
  - Authorize resources.
  - Remove barriers for project teams.

COMMON CHALLENGES IN DEPLOYMENT OF CONTINUOUS IMPROVEMENT

When conducting or deploying an improvement solution, we need to beware of the following challenges:
- People are willing to give the tool a try but not the culture that comes along with it. Therefore it stops

- Leaders do not understand how to effectively enable Lean/ CI because it requires them to approach how they manage people and approach problems completely differently (manage down, not up + direct observation, get involved tactically)

- It takes time. We have to build the people first

- Because of the intangible nature of this approach sometimes Continuous Improvement is overtaken by automation decisions that are perceived simpler and faster. Reality often is that they end up cementing bad process in code.

ELIMINATION OF WASTE

SEVEN TYPES OF WASTE

People work on wasteful items without often realizing it. We can group most of the waste into seven types:

1) Overproduction

Overproduction is producing too many items or producing items too early. This is the worst type of waste. It drives all the other wastes.

2) Waiting

Waiting means people are idle. They cannot move on to the next task.

This is the easiest waste to resolve. All we need to do is re-allocate people to value adding tasks. This is still hard because often we don't have transparency into what tasks people are performing and what it actually takes.

3) Conveyance (or Transportation)

Conveyance or transportation involves moving materials or output unnecessarily. It can also be to move the surplus material to make room.

4) Inventory

Too much work in progress, often as a result of overproduction.

This is mostly a result of the inability to understand customer demand and aligning our processes to effectively meet that demand with minimal waste.

Not all inventory is bad! Good inventory is inventory that is justified because we understand fluctuations and or risks in demand

5) Over-Processing

Doing more than necessary within a step, this is often a result of an unclear expectation. Therefore extra 'padding' is added just in case.

6) Motion

Too much unnecessary movement of people. For example, people try to locate misplaced document or seek unnecessary approvals.

7) Correction (rework)

Correction (rework, mistake) is the seventh waste and it's the most difficult to see. It impacts directly to quality and leads to other types of waste listed above.

LINK BACK TO WHAT WE DO AS STATISTICAL PROGRAMMERS

Using programming examples, here are examples of the seven types of waste:

Waste	Programming Examples
Overproduction	Produce certain TFLs 'just in case'
Waiting	Sit on unanswered questions for weeks
Conveyance	Reformat raw data fields to SDTM variables
Inventory	Program and QC TFLs ultra-early that result in rework later because of inevitable spec changes
Over-processing	Too many levels of approvers
Motion	Staff spend long time searching for controlled documents, specs, e-mails and buttons
Correction (rework)	Mistakes and errors that must be found and corrected. This type of waste is the hardest to spot

WASTE CAN BE DIFFICULT TO SEE

- People appear to be busy.
- Sub-optimization of functional group processes vs. optimizing entire value streams.
- Comfort in legacy systems and old ways.
- The common misconception of 'more is better'.
- Staff members are not convinced if the process is good.
- Staff members do not know what the standards are.

CONCLUSION

The business environment will continue to change. We must respond to changes quickly and be flexible. Businesses in all industries and services, including healthcare and governments, are using lean principles as they conduct business.

Lean focuses on people. When businesses build a culture of lean thinking, people's ingenuity will eliminate waste and lead to better outcomes.

I'd like to conclude this paper on the note by Charles Darwin: *It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change.*

ACKNOWLEDGMENTS

RECOMMENDED READING

- *The Goal: A Process of Ongoing Improvement*

- *The Toyota Way: Fourteen Management Principles From The World's Greatest Manufacturer*

- *Learning To See: Value Stream Mapping To Add Value And Eliminate Muda*

- *Gemba Kaizen: A Commonsense Approach To A Continuous Improvement Strategy*

- *Lean Thinking: Banish Waste And Create Wealth In Your Corporation*

- *Implementing Lean Software Development: From Concept to Cash*

- *The Machine That Changed The World: The Story Of Lean Production – Toyota's Secret Weapon In The Global Car Wars That Is Now Revolutionizing World Industry*

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