Lean Government

Office of Pesticide Programs
Antimicrobial Testing Program (ATP)
Lean Event Case Study

Summary

EPA's Office of Pesticide Programs (OPP) conducted a Lean value stream mapping (VSM) event in July 2010 to improve the efficiency and effectiveness of its Antimicrobial Testing Program (ATP). EPA's ATP has been responsible for testing hospital sterilants, disinfectants, and tuberculosides since 1991 in order to ensure that these products and others in the marketplace meet stringent standards of efficacy. These products chemically disinfect hard, non-porous surfaces such as floors and tables, a process which is considered an important component of the infection control system in hospitals, food processing operations, and other places where disease-causing microorganisms may be present. In the ATP, EPA and state contract laboratories collect samples from sources, including manufacturers, and test them for efficacy. Products that fail to meet the EPA's strict standards are brought into compliance through regulatory or enforcement measures.

The goals of the Lean event were to design a process that flows without interruption, to improve the quality of the process by reducing rework to cut lead time by 50 percent, and to improve employee satisfaction with the process. Participants in the Lean event observed and sought to alleviate a number of undesirable components in the ATP process, including the following:

- Communication and data management were hampered by a lack of an adequate feedback loop, missing data, and multiple databases and tracking systems.
- The process took too long, was convoluted, and involved too much time to notify the public after a product was deemed a failure.
- There was a lack of dedicated resources and unclear roles.

During the three-day event, the team created a map of the current process and designed and mapped a new process, called an interim future state process, which the team could implement within a few months. When the interim state has been achieved, lead time will be reduced from two years to 5–6 months, and the percentage of products with passing data will increase from 60 percent to 100 percent. The team also identified a longer term strategy for working towards an ideal future state for the process, including a goal of ensuring that 100 percent of products in the marketplace are in compliance.

Results

Participants in the Lean event created a new process for the ATP that is more effective and efficient than the current process. The event cut the number of steps in the process by almost 50 percent. The following metrics reflect the results that are expected after the interim future state changes have been implemented.

Metrics	Current State	Interim Future State Expected Results
Lead Time	2 years	5–6 months
% Passing	60%	100%
Products in need of testing	365	Approximately 250
Satisfaction with process*	2–2.7/10	7.8/10

* This is based on the group's satisfaction with the process before the Lean event versus the proposed changes in future state.

Scope of the Lean Project

Project Scope: The ATP process, beginning with the generation of a sample collection list and ending with achievement of full compliance of the product.

Goals

The goals of the event included:

- Design a process that flows without interruption.
- Improve the quality of the process (reduce the number of loopbacks, rework, etc.).
- Reduce the lead time by 50 percent.
- Improve employee satisfaction throughout the process.

Process Changes and Improvements

During the event, the team of participants developed a value stream map of the current state of the ATP process, analyzed the problems with the process using information in the current state map, and decided to take a two-fold approach to implementation to address the problems, working first towards an interim future state and then towards an ideal future state. The interim future state process consisted of steps that could be taken within a few months. The team made the decision during the event that an interim future state process was necessary in order to implement changes and achieve results in the near term. The ideal future state represented the longer term goal for the process.

Interim Future State Process Improvements

The interim future process for the ATP that the team developed is more effective and efficient than the current process, and it is based upon actions that can be implemented within a few months. Characteristics of the new process include:

- Reduced number of process steps (cut by almost 50 percent), including elimination of redundant steps
- More clear responsibility and accountability (clarity of roles and responsibilities)
- Ability to track products through the process
- Standardized work provides for greater consistency and reduced chance of errors
- Ability to communicate results to the public more quickly
- More defined universe of products to be tested

Participants came up with the following key improvement actions to achieve the interim future state process:

- The Office of Compliance (OC) will **develop standard suggested guidance for how to obtain samples** when the registrant claims “no production”—a step which gets the regions involved in sample collection and communication with the registrant.
- The OC will also develop standard work that will **instruct the Regional offices in a clear, repeatable, predictable way** as to how they should find non-production products, as well as the process to get those products into the correct lab for testing.

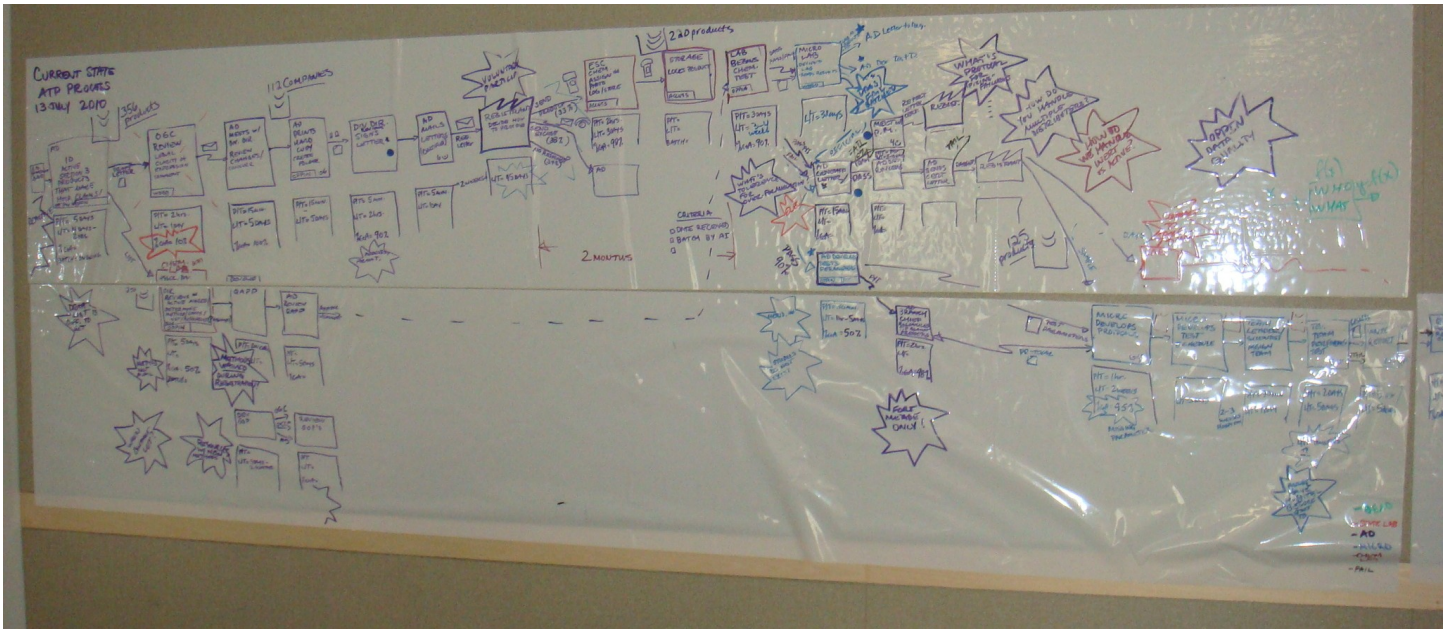

Figure 1: Current Process Map

- The event team will establish a "Blue Ribbon Team," and will charter it **to develop succinct, consistent, repeatable, predictable standards on rules of engagement for industry** to follow in order to maintain registration. The Blue Ribbon Team will specify timelines and guidance on how to handle non-response from registrants.
- The Antimicrobials Division (AD) and Biological and Economic Analysis Division (BEAD) will **develop a robust list of products** that are active in the market, have never been tested, or are in need of re-testing. BEAD has already developed a database containing information on product statuses that will now inform the team with data necessary for them to make decisions. The team will evaluate the BEAD database and incorporate the data into the new Public Health Tracking System being developed.
- The EPA labs will **change some contracts with state labs** in order to reduce lead time.
- The labs will **reduce batch size for products**, so that labs test all products from the same active ingredient class in one month instead of two months.
- Finally, the Lean event team plans to **increase the frequency of public notice** such that it will occur once per month.

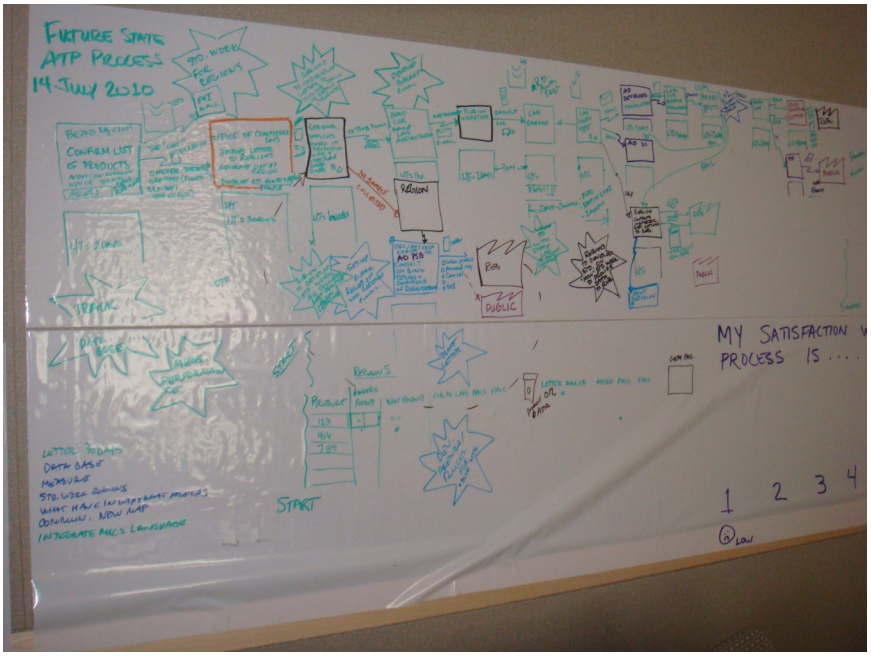

Figure 2: Interim Future State Process Map

Ideal Future State Process Improvements

The team made plans to work toward an ideal state process farther into the future; the ideal state process features a pre-registration approach as well as reliance on enforcement and regulatory actions to ensure compliance. The ideal future state will rely heavily on information gathering and data analysis that will be conducted by a "Gold Seal Team," which will draft recommendations. This ideal state has a goal of 100 percent of products in the market being in compliance. The team plans to actively implement the interim future state while simultaneously gathering data to work toward the ideal future state.

Implementation

As of February 2011, the Lean event team had met bi-weekly to follow up on action items in the implementation plan. The team has taken many steps to implement the process improvements that were identified during the event, including the following:

- Created a task order for State labs and modified the table for developing testing protocols with the goal of reducing lead time. Explored the issue of chain of custody with labs with regard to voluntary shipments.
- Identified the number of new registrations since September 30, 2009 in order to better balance workload and reduce lead time.
- Developed a letter for the Regional offices detailing standard operating procedures for collecting samples and provided a new list of samples to OECA, in order to increase consistency and provide clarity to industry by operating as a single EPA voice.
- Communicated with the Regional offices to impart an understanding of the interim future state, in order to gain buy-in on the improvements.
- Developed a communication plan for the public, in order to reduce lead time from product failure to action.
- Developed performance measures and finalized the development of an IT system to measure, manage, and monitor performance.
- Began an effort by the Blue Ribbon Team to develop consistent and repeatable standards for the rules of engagement that industry can follow.

OPP plans to continue these implementation efforts, including finishing the Blue Team's work on standards for industry, as well as launch the Gold Seal Team's efforts to develop a plan for the ideal future state.

For More Information:

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