



Lean Concepts & Pharmacy

A How-to Guide for using Lean Pharmacy concepts to make the case for expanded automation in the Pharmacy department

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INTRODUCTION

Lean process improvement is an industry-wide initiative to achieve operational excellence. The lean process approach facilitates improvement of process efficiency and quality while delivering faster service and cost reductions. Originating with the Toyota Production System (TPS) soon after World War II, the concepts of lean implementation are no longer confined to manufacturing. They have been successfully applied to service and administrative processes. Many excellent reference resources on the subject provide the progressive Pharmacy Executive with good background information. For a brief overview, Dennis Tribble et.al have authored a Baxa technical paperⁱ specifically for the pharmacy space and is a solid resource on the subject. For a more comprehensive look at translating the TPS to healthcare, read Mark Graban's *Lean Hospitals*.ⁱⁱ

The industry-wide acceptance of Lean Principles has given rise to their expanded use outside of manufacturing and directly into healthcare applications. This thinking has led to the desire in some facilities to integrate Lean concepts with available automation as a way to advance safety in pharmacy practice especially in the area of compounded sterile preparations (CSPs).

Before discussing the selection and implementation of automation in the Pharmacy, a review of the Lean concepts at use is in order. We have attempted to condense the core Lean concepts in order to advance the discussion into more of a "how-to" guide. This guide points out some useful available resources to enable pharmacy managers to justify the expanded use of automation in the preparation of compounded sterile preparations (CSPs).

THE LEAN PHARMACY CONCEPT

There are five basic steps in developing a Lean process improvement strategy in any business:

1. Assess the Current State
2. Determine the Future State Workflow
3. Identify the Future State Organizational Structure
4. Identify Priorities
5. Develop the Plans

ASSESS THE CURRENT STATE

Map the current operational process and collect actual process data. While gathering data, take careful notes on both information and material flow. Review the data to make sure all necessary information has been collected before continuing. The completed current state "map" should allow you to see where workflow overlaps and where bottlenecks may exist in how information, personnel and material flow over the course of time in completing their tasks.

DETERMINE THE FUTURE STATE WORKFLOW

Efficient workflow is dependent on product and process layout. For most organizations, workflow is the best place to start a Lean transformation.

Carefully review the layout and arrangement of the pharmacy or office. Using your current state map as a guide, it should be easy to identify sources of extra work, such as where personnel must backtrack or revisit work stations or where certain equipment is overused or interrupts the “flow” of activity. Identify where new equipment or relocating existing equipment will streamline portions of a complex workflow. Try the new configuration to see where that experiment takes you.

In service processes, creating efficient workflow is not as easy because office processes tend to be invisible. First you will need to make these processes visible in order to intelligently adapt Lean principles to create better flow.

DETERMINE FUTURE STATE ORGANIZATIONAL STRUCTURE

Infrastructure consists of the sustaining elements in an organization. While they may not add value in the eyes of your patients, they facilitate or assist your processes. Infrastructure includes scheduling, training, culture, organizational structure, quality methods, utility systems, costing systems, investment policies and many other elements. Some of these elements are ingrained in attitudes, habits and culture rather than explicit in specific policies and procedures. Your “future state” map should address those elements that reduce waste, eliminate process inconsistencies and eliminating steps that do not add value.

IDENTIFY YOUR OWN LEAN TOOLS AND TECHNIQUES

Based on your vision of the future state of your pharmacy, pick the appropriate tools and principles of Lean process improvement to implement. Once you have begun to embrace the Lean pharmacy concept, you may identify other process improvement techniques that are not on the usual list of Lean tools. Don't be afraid to incorporate these new ideas if they have measurable impact.

IDENTIFY PRIORITIES

Next, identify priorities and precedents. Precedence may require the use of certain principles to make other principles practical. Priorities depend partly on precedence but they are influenced also by on return on investment. By giving priority to those Lean improvements, products and activities that promise the fastest and largest returns for your pharmacy and facility, the Lean transformation becomes self-financing. You can use focused-improvement tools to get immediate gains and payback for your investment. The potential difference between Lean and non-Lean facilities is not 5-10 percent; it is significant greater in terms of quality, cost, delivery and profits.

Another factor in setting your project priorities is the quick wins or "low-hanging fruit" principle. For many reasons, it may be very quick and easy to implement one or more of your

selected Lean improvements. It makes sense to give such improvements a high priority in order to get some visible project success as a way to build team confidence and gain support for Lean process thinking in your organization.

DEVELOP THE PLANS

With a broad overview of the situation and a vision of the future and knowledge of precedents and priorities, you can begin to plan your course of action.

There are eight steps for implementing and sustaining Lean improvements:

1. Gain Management Commitment
2. Train employees in the Lean concepts
3. Identify the key process or value stream to be addressed
4. Map the Current State of the process or value stream
5. Identify the metrics that best suit your organization in terms of impact and success measurement
6. Map the Future State of the process or value stream
7. Perform a gap analysis, then develop Project plans to achieve the Future State
8. Implement the Future State plans

YOUR PHARMACY IS UNIQUE

A quick Internet or published literature search provides many good examples of Lean Pharmacy success stories. Several hospital trade groups have been helping their hospital members explore and implement Six-Sigma techniques for healthcare performance improvement in order to reduce costs as well as improve operations in supply-chain, clinical, operational, and financial areas. These existing relationships are a good starting point to gather information on Six Sigma if it is a new concept to your organization. However, one concern is many organizations have tried to succeed at the Lean process by copying the solutions that other organizations have found, either through benchmarking, or out of an article or book. Your facility is unique and will likely have some unique problems and constraints. Therefore, you need to customize Lean thinking to fit your organization and find your own answers.

That is why your Lean tool box must be unique to your organization and developed with your organization in mind.

Virginia Mason Medical Center in Seattle is renowned as a US health system that has fully embraced the Toyota Lean Production System. They designed a system-wide program – the Virginia Mason Production System – to achieve greater efficiency and improve care delivery. Charles Kenney tells their story in *Transforming Health Care*, beginning with CEO Dr. Gary Kaplan and his senior team’s visit to Japan to learn the process first-hand.

PRACTICAL TOOLS FOR THE MODERN LEAN PHARMACY

Mapping of the future state of your pharmacy operation has undoubtedly led to the discussion of automating one of the last manual processes in the pharmacy department – compounding injectables in the cleanroom.

The cleanroom in any modern pharmacy will have varying degrees of existing automation depending upon the size and scope of the practice, as well as the vision of its pharmacy leadership. The automation of the pharmacy department most likely began with the introduction of the hospital’s information system (HIS), and continued forward from there perhaps adding components to the operational model such as bar-coded labeling and robotic dispensing. In some cases, the pharmacy organization will have automated parts of their operation as way of maximizing the available human resources. This may or may not have been done in a holistic manner. More often than not, because Lean principles were not in use, these elements are disjointed and inefficient from a workflow and management perspective.

With the advent of USP General Chapter <797>, pharmacies encountered economic burdens that accompanied their compliance efforts, as well as operational and implementation challenges. In a national survey for ASHP, Candy, Schneider and Pendersen described the effects on resource allocation in two key areas when speaking about USP General Chapter <797> compliance: budgetary spending, and labor spending.¹ Similarly, in an article that appeared in the *American Journal of Health-System Pharmacy (AJHP)*, Eric Kastango predicted that measurable increases in addressing the quality domains of USP General Chapter <797> would occur in eight key areas, requiring additional spending for the average hospital pharmacy.²

With the re-engineering of the modern pharmacy department toward a more efficient model of service, the application of modern business principles and strategies long accepted in other business sectors must be considered. The decision process begins with an examination of the facility’s practice philosophy. The fundamental question health systems need to answer is; “What do you intend to do once this re-engineering is complete?” More often than not, the impetus for questioning current practice in any organization is either a budgetary review or some negative quality indicators relating to service.

If budgetary review is the case, a careful review of the figures is in order. It is not satisfactory, nor prudent, to re-engineer a process as complex as the compounding of sterile drugs for human use by simply comparing the drug and the diluent price tag against the pricing of the outsourcing vendor or contract compounder. A clear understanding of all of the costs impacting the provision of each CSP to the organization is key to determining the true “return-on-investment” (ROI) an organization will realized by changing the CSP procurement process. Calculation of these “realistic-ROIs” (r-ROIs) can be done only with a clear understanding of all of the costs involved in the provision of a finished CSP dose to a patient.

Beyond the simple drug and diluent costs, health systems need to factor in the labor cost (both pharmacist and technician) to compound, check, label, package, store and deliver the CSPs.

¹ Candy, Schneider, Pendersen- Impact of USP Chapter <797>; Results of a National Survey, JASHP 2006

² E Kastango – Blueprint for Implementing USP <797> for compounding sterile preparations in pharmacy JASHP 2005

Pharmacy managers must explore innovative solutions to maximize the most expensive resource in the Pharmacy Department – its personnel. Any product that can improve accuracy, enhance workflow or maximize productivity must be considered. Application of these “new tools” will help your organization reach that “future-state organizational structure” that is key to the success of a reengineering project of this kind.

An example of a product offering that can improve the accuracy and traceability, enhance the workflow and maximize productivity for CSPs is the Baxa DoseEdge Pharmacy Workflow Manager. This software program improves accuracy by introducing bar coding to the CSP workflow. With DoseEdge, individual CSP ingredients are verified before compounding. Verification is performed on the expiry date for each ingredient and documented via imaging. The DoseEdge System tracks the status of each individual CSP in the daily process flow. This tracking ability provides traceability of each individual CSP so that doses are not lost or remade. The DoseEdge system enhances workflow by prioritizing which doses need to be prepared, preventing short-expiry doses from being prepared too early, preventing unchecked doses from leaving the pharmacy, and allowing the pharmacist to check doses without gowning up and going into the IV Room. Pharmacy productivity is maximized by providing a real-time, graphical representation of CSP doses, providing the means for managing production on a real-time basis. DoseEdge supports the Lean process in the pharmacy with significant advantages.

Health systems must also examine their current ability to assign meaningful Beyond-Use Dates (BUDs) to the preparations they are compounding, as opposed to the extended BUDs they may have from an outsourcing vendor; the testing costs when and if extended BUDs are necessary; the CSP expiry waste; the batch quantity needed of the CSP; the overhead costs including compounding supplies and materials; and the efficient utilization of the pharmacy’s scarce resources to provide clinical and cognitive services for direct patient care.

SUMMARY

Fundamentally, the right processes produce the right results – whether in manufacturing or in health-system pharmacies. For healthcare providers, the right “results” are providing safe patient doses at the right time and in the most efficient manner possible.

Increased financial constraints in healthcare are fueling the interest in the Lean Process application in the pharmacy. Careful assessment of each individual situation needs to be performed in order to determine the course of action to improve your pharmacy process. Any process improvement that increases the pharmacists’ interaction with patients and decreases their need for direct supervision of pharmacy personnel will greatly enhance the impact of pharmacy in the healthcare facility.

There are several new and innovative workflow applications that allow the modern cleanroom manager to focus upon the clinical operations of the cleanroom, while assisting in the documentation, and quality management efforts seamlessly. The Baxa DoseEdge Pharmacy Workflow Manager is one such advance. Lean Pharmacy process improvement has value in pharmacy practice. Utilizing the Lean process tools will allow reengineering of the CSP compounding process to reduce human errors.

ABOUT THE AUTHORS

Lou Diorio, RPh and Dave Thomas, RPh, MBA are the Principals of LDT Health Solutions, Inc. LDT Health Solutions Inc. (LDT) is a nationwide total quality management firm, specializing in controlled process and quality management strategies for the pharmacy community. LDT is a leader in USP <795> and <797> compliance consulting as well as developing regional compounding service models, including hazardous drug compounding, nuclear medicine and automated compounding devices (ACDs). Visit LDT at www.LDTRx.com.

LDT has over three decades of experience in extemporaneous Pharmacy compounding, cGMP manufacturing, homecare product preparation and hospital cleanroom applications. LDT is a leader in regulatory affairs and compliance, and has developed regional compounding models for many of its clients. Lou and Dave can be reached at lsdiorio@ldtrx.com and dthomas@ldtrx.com, respectively.

¹ Tribble, Dennis, vanEngen, Steven and Harvey, Eric. *Lean Pharmacy Technical Paper*– Using time tested manufacturing process tools to achieve efficiencies in pharmacy operations. BaxaCorporation. 2010.

² Graban, Mark. *Lean Hospitals – Improving Quality, Patient Safety and Employee Satisfaction*. Productivity Press. 2009.