

Lean principles: transforming analytical laboratory services

Dr. Vikki Renwick, Tepnel Pharma Services, Livingston, Scotland.

Lean leads the way

The arguments for lean are compelling: reduce waste, raise efficiency, increase productivity and drive competitiveness. Vikki Renwick describes how lean principles can transform laboratory services.

The concept of 'lean' was first developed by the car manufacturer Toyota soon after the end of the Second World War. Adopting an overriding principle to eliminate waste and maximise value, the so-called Toyota Production System systematically touched every part of the business.

Toyota's ethos was brought to the attention of the western world by MIT in the 1980s. Now dubbed 'lean manufacturing', the framework redefines waste as "anything that does not add value" – not only unused materials, like offcuts and defective products, but any action or process for which a customer is unwilling to pay.

Viewed this way, you quickly grasp why a lean approach is also powerful in a quality orientated, highly regulated business. You systematically remove waste to deliver exactly what your customers need: a simplified, customer-focused service with high quality assurance and a compelling promise to deliver on time.

The house of lean

The lean model is often described as a house, built with a foundation, pillars and a roof. First, you need an underlying culture of participation driven by strong leadership with a vision for change and a willingness to adapt continually to customer needs, employees and the environment.

With this foundation in place, a business can raise the 'pillars' – tools and methodologies for systematic analysis and modelling which will identify and remove waste and add customer value. The simplification of operational processes is an example of how the pillar of continuous improvement (known as 'kaizen') is applied. Kaizen is often implemented in tandem with 'just in time' manufacturing, 'customer pull' (where manufacturing is governed by customer demand rather than internal operational factors) and 'value stream mapping'.

Finally you attach your roof to the house. This represents the outcomes from

your lean programmes, for example shorter turnaround times, simplicity or "unconscious competency" which all help to create a sustained performance culture.¹ With the roof in place your house is built; you have a business constantly striving for excellence.

Benefits of lean for service companies

- Simplicity
- Right first time
- Rapid turnaround time
- Error prevention
- Customer responsiveness
- Increased productivity
- High efficiency
- Best practice
- Consistency
- Improved quality
- Team empowerment
- Operational excellence

Mapping and problem solving

Among the key tools for lean implementation are value stream mapping and "Plan, Do, Check, Act" (PDCA) problem solving.

Value stream mapping helps a business analyse its processes end to end; maps identify where value can be delivered to customers, for example by reducing the lead time from when the laboratory receives a sample to when it issues a

Certificate of Analysis. Faster turnaround supports the client's own just-in-time manufacturing, hence adding value to the analytical service. Value stream mapping can highlight both quick wins and areas requiring more strategic programmes, for example to deliver economies of time.

Wherever a value stream map identifies waste, PDCA problem solving finds ways to reduce or eliminate it. PDCA is a four-step, iterative cycle ideal for practical kaizen. First described by Shewhart¹ and adapted by Deming², the model shows how a business can continuously scrutinise its processes and seek to improve customer value.

PDCA hones in on details. It helps you to improve a process, either a single step or a longer value chain. The key steps in PDCA problem solving are:

- Theme/background – where does this process fit within the business and its strategy?
- Problem definition – what exactly is wrong with your current process or why does it underperform?
- Goal/target state – what do you want your improvements to achieve?
- Root cause analysis – what exactly is stopping you from making this process deliver maximum value?
- Containment measures – how will you stop this process leading to underperformance elsewhere in the business?

- **Proposed countermeasure(s) – what specific changes will you make to meet your goal?**
- **Action plan – how will you implement these changes?**
- **Impact check – how are your changes affecting the process or the business?**
- **Next actions – what will you do next to improve this process even more?**

Lean in the service industry

The incredible success of lean across the globe has made it the new paradigm for all manufacturing businesses.

Within the pharmaceutical sector, for example, the stringent requirements for regulatory compliance (product quality, quality management, data integrity, etc.) encourage drug manufacturers to adopt lean principles. Lean supports compliance whilst helping a business be cost effective, reduce development times and minimise the potential of any drug supply shortage.

Pharmaceutical service companies can benefit too. Lean principles can boost their productivity, maintain service quality and improve communication and customer relations. Although the lean approach is really common sense, it is surprising how many service providers fail to apply it, partly because so much waste is hidden. Early adopters could find they stand out in a crowded marketplace.

It starts at the top

If you want your business to 'go lean' you first need full backing and commitment from the management team. Lean is more than a business model; it is a work ethic, a philosophy that every employee must embrace.

For many businesses, the move to a lean approach requires a radical change to the work culture. Instead of a top-down, "need-to-know" management style, lean embraces participation; it values the expert insights of each employee on their specific activities. Managers must accept that the people most involved in a process are in the best position to analyse them and improve them.

For the past 12-18 months Tepnel has been transforming its business through the implementation of lean principles. One of the biggest areas of investment has been the training of the company's leadership.

An external specialist has supported senior managers to define their new operational culture and identify all the

values and tools they need to create sustainable, long-term growth. They have received coaching and mentoring for leadership skills so they can "live out" Tepnel's core values and effectively drive the cultural change.

Project managers have also participated in training on how to achieve significant service improvements, business growth and focus on the voice of the customer – through lean approaches. Indeed, all employees, including laboratory analysts and administrative staff, have been involved in skills training and coaching to embed this new mind set: a culture of continuous improvement and active participation in customer engagement.

Challenging employees to run a business for the day, tutors coached teams to explore and apply a variety of different lean concepts and principles including excellence, kaizen and poka yoke (error-proofing).

The business simulations included:

- Running the 'business' – four to six rounds (each representing a working week)
- 'Weekly' meetings – time to reflect on outcomes and work in cross-functional teams to improve the business
- Identifying "flash bangs" – mission critical problems with quick-win solutions – using value stream mapping and PDCA problem solving
- New knowledge – introduction to tools and insights on lean

Implementation

In consultation with customers, Tepnel has developed systematic analysis tools and has already identified aspects of its services that clients value most. They include:

- Efficient working practices
- Faster turnaround
- Short lead time (customer demand driven)
- Rapid response
- Open channels of communication

Teams of employees have used value stream mapping to understand all the steps, workflows and processes involved in a particular service. This has helped the company understand how each activity affects value for the customer.

Armed with these maps, Tepnel is using the PDCA approach to optimise its systems to reduce waste and maximise customer engagement. All changes are controlled by the Pharmaceutical Quality System which allows them to be monitored,

reviewed and refined in a process of ongoing and continuous improvement.

Value stream mapping highlights importance of inventory control

A Tepnel taskforce identified all the critical materials and inventory its laboratory required to meet a customer's goal of a 10-day turnaround time for batch release testing. Value stream mapping revealed minimum stock levels, trigger points and potential improvements to the management of critical materials.

Tepnel has now introduced an active stock management process which prevents any potential delays from waiting for suppliers or carrying an excess of critical material. This monitoring and control makes the customer pull effective and efficient.

Key wins:

- Quicker response times
- Greater productivity
- Customer pull as the trigger point

Customer pull: clients in control

Giving the customer maximum control over the service adds real value. For batch release testing, as soon as the customer calls to say samples are on their way, the clock is ticking.

Using the "Plan Do Check-Adjust" (PDCA) approach to problem solving, a Tepnel team developed a new product-specific template for Total Viable Counts and Absence of Pathogens testing. The new template optimises and simplifies testing to a single form whilst maintaining quality compliance through process simplification.

Key wins:

- Organisational learning
- Standard form for one or multiple samples
- Increased efficiency and consistency

The value of communication

Within the service industry it is sometimes difficult to grasp how lean principles deliver value to customers. In manufacturing, if you can reduce the level of scrap fivefold, say, it is easy to appreciate how everyone benefits. But how does phoning a customer once a week or arranging quarterly appointments add value to your service?

It might be near impossible to express the value of open communication in financial terms, but regular, clear communication is possibly the one element of a service that clients appreciate the most. If you have a lean business you will focus on customer experience i.e. working to improve what your customer gets, not what you think you give. Without doubt, open dialogue builds good working relationships and enhances customer engagement; it helps to avert potential problems, respond to crises, and keep processes flowing smoothly and efficiently.

Tepnel views its pharmaceutical clients as relationships. The company seeks to integrate so seamlessly with its clients' operations that its facilities and services are more like an extension of the pharmaceutical company rather than a distinct contractor. Tepnel always agrees a communication plan for every project; it sets out communication pathways and timetables, the frequency of progress reports and who needs to talk to whom. Although Tepnel's sales team leads core contract negotiations, technical staff are also involved to build trust, respect and confidence between operational teams even before the contract is signed.

Striving for perfection: delivering exactly what the customer wants, exactly when they want it

A dramatic shift in Tepnel's operational culture alongside adjustments to business processes and laboratory practices have generated some impressive gains in turnaround times and other key performance indicators.

By focusing on continuous improvement, Tepnel has embraced the true spirit of kaizen: a constant and critical analysis of activity that empowers employees to improve what they do, which ultimately adds value to all processes and procedures and drives customer loyalty.

Kaizen is now part of every employee's culture as they all participate in monthly cross-functional kaizen meetings. Tepnel people submit ideas as they encounter waste or see opportunities to add value to a service. Every idea is 'ragged': green for immediate action, amber for further consideration, red for discussion with senior management.

Today the opinions of all employees and all clients count; Tepnel has shifted away from a "command and control" management style to more open dialogue among peers.

PDCA for error prevention

Before running high pressure liquid chromatography (HPLC) assays, laboratory analysts have to calibrate the equipment with standardised reagents. A value stream mapping exercise discovered this can be a time consuming process. A team implemented standardisation to the training programme which built error prevention steps into workflows and improved the user interface.

Key wins:

- Time savings
- Less instrument downtime
- Greater analytical capacity
- Increased efficiency and consistency

In summary

- The implementation of lean approaches is relatively underdeveloped in analytical laboratory facilities
- Lean principles can systematically improve turnaround times and raise the consistency and quality of analytical services
- Operational excellence results in customer engagement and loyalty
- A cultural shift embeds lean approaches and puts continuous improvement in place at all levels of the company

Minimise mistakes

Sometimes raising quality means eliminating errors (a form of waste). A Tepnel laboratory analyst realised that the process of repetitive pipetting of a large number of samples could introduce potential mistakes. They designed a simple colour coding system (poka yoke) as a simple, visual way to eliminate potential sources of error and to make procedures more robust.

Right first time

The pharmacopeia is extremely complicated and it is easy for people inexperienced with its layout to inadvertently misinterpret methodology. A cross-functional team identified this as a potential source of error and designed a new pharmacopeial template so users could consistently capture all the critical information and calculations they would need for their assays. This pro-active approach introduced quality by design.

Key wins:

- Increased productivity
- Quality by design
- Higher throughput
- Time and cost savings.

References

1. Shewhart, W. A. 1939. Statistical Method from the Viewpoint of Quality Control
2. Deming, W.E. 1950. Elementary Principles of the Statistical Control of Quality
3. Tepnel White Paper. Batch release testing: get ready for new requirements. 2015.