Adding Value with Lean Quality

By Tsvika Bublitsky, Pete Caldwell and Rotem Greener

1. Background

The lean revolution began back in the 1990s, spawned by the quality revolution of the 1980s. What made it uniquely fresh for many manufacturers was that the lean philosophy redefined 'quality' as 'value', thereby revealing to companies that their customers wanted more than reliable manufacturing processes that could deliver a product 'to specification'. They also needed delivery reliability, flexibility and speed at optimum cost, plus all the other facets that we expect from goods and services today.

The pharmaceutical sector started to go lean in the late 90s, and the following years saw most companies embarking on large-scale lean transformations. Paradoxically however, "quality" itself was initially exempt from these programs. One likely reason for this was the misconception that lean meant cutting corners by removing any operations which did not add value (e.g. quality testing), thereby increasing risks. This misunderstanding reduced the actual scale of improvements achievable through lean measures in the pharmaceutical supply chain. Since this sector typically includes numerous QC steps along its value stream, the act of removing QC from the value-stream and making it an external department like Finance, makes it impossible to maintain an end-to-end line-of-sight to the customer, this being one of the corner-stones of lean processes.

During the 2000s, companies began to scrutinize quality operations as an untapped source of efficiency improvements and a hindrance to product flow. Many quality functions reacted to this by starting their own lean initiatives, defining the

customer as the next step in the process (packaging, dispatch, planning, etc). The fundamentals of lean (specifying and maximizing value, flowing and pulling product through the process and continuously improving) were directly applicable in QC labs, and programs delivered results such as halving lead-times, boosting reliability to near 100%, and dramatically increasing throughput per analyst (by 35% in many cases).

However, since these quality programs were often functionally driven with the Head of Quality as the sponsor, the very ethos of lean – the chain-long, multi-functional and team-based approach to product flow from A to Z throughout the plant, the zero waste ideal and no delay in the delivery of single orders to customers – became an unachievable target. The very nature of a functional program in some cases even reinforced the interface barriers between internal suppliers and customers. In order to make QC efficient, counter-productive practices such as 'over-campaigning', were employed, leading to a situation where the QC department acted as the brake and manufacturing as the accelerator.

2. The new generation of "Lean Quality"

In the last few years, most pharmaceutical organizations have taken a more holistic approach. Quality is now frequently included in Operational Excellence transformations. A more multi-functional approach to improvement has been taken, and improvement engineers within quality functions have found themselves dealing with projects that are more focused on value streams and are less insular, thereby achieving increasingly greater scope.

Recent quality operations improvement projects seem to be sharing a common approach from which two main characteristics have emerged; the purpose of the program and its scope.

- The purpose: to strive for the 'perfect' end-to-end state, where value and responsiveness to the customer are maximized, and waste and delays are eradicated throughout the entire value chain.
- The scope: the boundaries of the lean program – whether it focuses on the quality testing process alone or has a wider application.

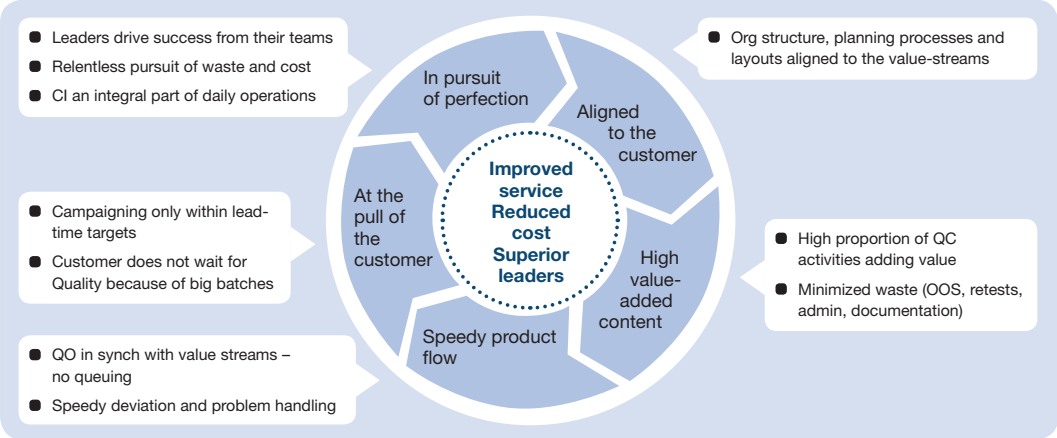
3. Purpose: the philosophy of lean quality

1. Take an end-to-end approach to fully understand what your customers value about you, your position and role in the chain, and how you can help to achieve customer fulfillment. In the case of pharmaceutical companies, the real customers are the patients. Within the end-to-end philosophy, any other 'customers' (payers, regulatory authorities, planning departments) are not customers, though they do have a stake in the performance of the value chain. Like you, they are contributors or representatives in your mutual ambition to supply safe, effective, timely, cost-effective products to end-users. Although they are not customers, crucially, they may be able to specify customers' needs more accurately and powerfully than the patients themselves. As stakeholders, they all have a say, and translating their needs into operational goals may involve some tricky prioritization – lower cost, faster delivery and higher quality do not always go hand-in-hand. Certain trade-offs (famously, utilization versus flexibility) will need to be quantified and ranked.

2. Identify the extent to which you are really satisfying your customers, and whether you are performing activities that add no value (but will still raise costs). Under the lean philosophy, testing a product does not add value. The product must be transformed to add value while testing merely checks whether the value has been created properly. However, since quality control is a vital link in the chain, and the process cannot proceed until the checks have been made, testing and recording results accurately and on time remains a valuable activity.

3. Optimize 'flow' and 'pull' to suit the work rate and rhythm requirements of your subsequent process step. Specifically, 'flow' means eliminating the delays caused by bottlenecks, while 'pull' means responding immediately to the trigger of the subsequent process – producing results when and only when needed. QC operations should synchronize their organization and operation with production, to pull the product right through the entire value chain. Although the tendency to batch produce is attractive, this desire should be counter-acted by minimizing setup times and process queues. There should always be enough trained analysts available to run labor-intensive and complex tests and adequate equipment capacity for longer, automatic runs (preventing wait times). Tests should also be synchronized in parallel so that the longest test determines the lead-time through the department.

4. Strive for perfection: the principles of lean leadership should be applied in the labs – organizational structure and processes should be designed to encourage continuous improvement, for example, standard management routines, clear accountability for improvement, visible leadership on the lab floor, clear KPIs, etc.



4. The scope of lean quality

Once you have decided that the lean philosophy is right for your quality organisation, it is time to decide on the scope. There are a variety of strategic decisions and operational practices which can impact on value-stream performance. Many organizations concentrate their lean efforts initially at the lab-floor level, minimizing wasteful activities in the process of adding value to the product. However there are many more hidden opportunities to enhance value which will also improve customer satisfaction. Tefen's lean quality program includes eight elements, spread between two main themes: strategic and operational:

Strategic

1. Quality philosophy: define your quality assurance approach. Choose whether to apply inline testing and error-proofing during manufacture, post-production testing or a combination of both. Do you want suppliers to provide pre-certified raw materials or is goods-in testing enough?
2. Organizational structure: define whether quality operations should report to manufacturing or to an external quality function. To what extent should the quality assurance structure mirror the value-streams? Specify decision-making empowerment levels and a culture for improvement.
3. Layout: at the macro level, should the quality operation be in close proximity to the point of manufacture? Within the quality operation, is a functional layout appropriate, or a value-stream, product-based layout? At the micro level, can cellular and 5S concepts be deployed?
4. Technology: to what extent can the quality operation use state-of-the-art testing methods and IT solutions such as automated data entry and LIMS?

Operational (based on the plan-do-check-act cycle)

1. Planning and scheduling: are the trade-offs between the operation's utilization and flexibility understood? Are its time standards accurate enough for robust capacity modeling? Do you have processes in place to build and communicate mid-term plans and short-term schedules to maximize resource utilization and value stream flexibility?
2. Doing the core testing operations: Do you have efficient procedures for sample management, preparing and running tests, analyses and compiling documentation? Ensure that the deviation management systems are robust and efficient enough to correct and prevent errors in the manufacturing, documentation and analysis processes.
3. Checking and managing performance: Do you have the data needed to measure operational performance in the required timeframe, including lagging metrics (such as throughput, delivery reliability, historical lead-time and quality) and leading metrics (such as bottleneck loading, skills flexibility, dynamic lead-time and supplier delivery performance)?
4. Acting on learnings and continuously improving: Are improvement processes embedded into the culture to reveal opportunities and initiate projects,capture benefits and give staff real ownership of these improvements?

5. Diagnostic benchmarking

Lean philosophy is based on a cultural cycle of learning and improving. One way for labs to learn is by using benchmarks, which can be broadly divided into three categories:

- Metric benchmarking (focus on outputs and results with little emphasis on the enablers to poor performance).
- Diagnostic benchmarking (assessing priorities, practices and performance - allowing customized recommendations for the specific objectives and constraints of each company under review).
- Process benchmarking (typically unstructured but highly detailed, giving deep insight into specific areas of potential improvement).

Generally speaking, the cost and effort required for metric benchmarking is low and it may well provide a valuable trigger for improvement. However, it does not aid in understanding root causes or potential solutions. At the other extreme, process benchmarking is most useful when a specific problem is known and different solutions are being considered. In most cases, diagnostic benchmarking provides the best trade-off between effort and benefit, as the process is generally structured and efficient, while still providing great insights, particularly if the three cornerstones of priorities, performance and practice are all scrutinized. When this is the case, companies can gain valuable insight into what others facing the same problems have done to combat specific areas of low performance.

The diagnostic benchmarking knowledge amassed by now in the industry includes leading and lagging performance figures throughout the entire lean framework, including performance metrics financials, value-streams, internal processes and organizational matters. There is also plenty of good practice data spanning the entire strategic and operational scope of a holistic lean quality program as described above.
By using a multi-level and holistic diagnosis, companies are able to drill down into specific performance issues that are hampering their objectives, pinpoint root causes, compare practices against others in a similar situation, design new practices based on third party experience and predict the impact on future performance.

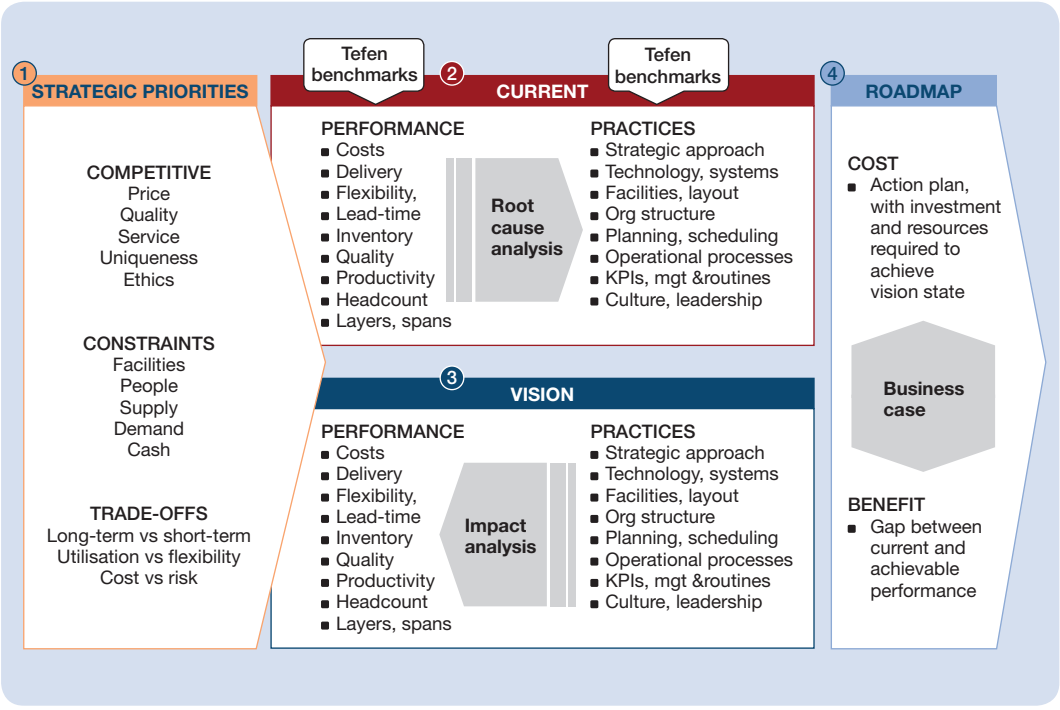
Over the last ten years, Tefen has been involved in almost one hundred QC operational improvement programs and has used the diagnostic benchmarking approach widely across this timeframe. This type of experience and data can be a valuable tool, not only in short-circuiting the errors made by others, but also in building a viable, compelling and less risky case for change.

CASE STUDY

Introduction

During 2011, a global pharmaceutical company, facing a shortage of products in the market and decreasing customer satisfaction, started a concerted effort to transform its supply chain speed and cost base. One of the main factors seen to contribute towards the perceived poor performance was the QC Operations, where release lead-time was increasing and labor productivity had been steadily declining, causing a primary bottleneck across the entire supply chain. This was partially due to a recent increase in regulatory requirements, coupled with a need for more robust deviation management.

Tefen was asked to apply its lean quality solution to the problem, to quantify root causes, set up a vision, and support the transformation program. Tefen began with an in-depth analysis and vision-building process, as shown below:



Strategic priorities

A structured priority-ranking approach revealed a management situation that was focused on short-term symptom-solving rather than a joint collaboration towards strategic goals. A culture of fire-fighting and trial-and-error was prevalent, resulting in wasted effort and unresolved problems.

Workshops were executed to design a new set of strategic priorities to overcome the immediate market shortages, while also improving supply-chain speed and cost, aligned to the site's 2012-13 objectives. The priorities agreed were:

- Increasing lab's throughput (batches and tests) as first priority.
- Improving service level and reducing back orders for internal and external customers.
- Setting a management infrastructure to support consistency of performance through:
  - Improving planning processes and delivery alignment mindset.
  - Implementing continuous improvement processes.
  - Optimizing and aligning the organizational structure.

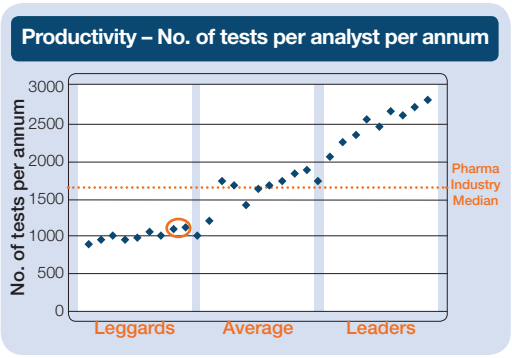
Diagnosing the status quo

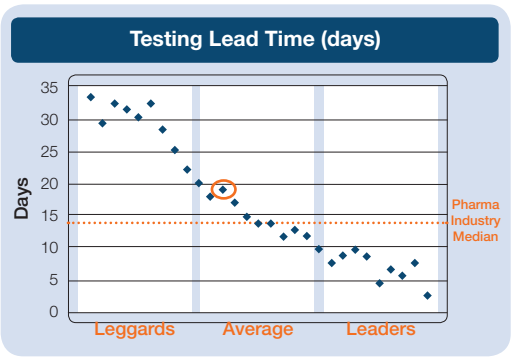
The current state was assessed using Tefen's 8 lean quality elements described above. Benchmarks from similar QC operations were also used to support and challenge performance levels and working practices.

Current performance summary

Data analysis of historical performance and comparison with benchmarks showed that the labs were not performing at a high operational level. The productivity (number of tests per analyst per year) was near the lowest level found in the benchmark, and the lead-time was higher than the industry median. This was reinforced by the deviation rate which was also higher than average, and contributed to low productivity and long lead-times.

Although the basic lab infrastructure of work processes, IT and professional skills existed, there were a number of short-comings observed that contributed to these declining levels of performance:





Major findings - strategic elements

1. Quality approach

a. Quality assurance and control were subject to major revisions of their testing and documentation procedures, following new regulatory requirements. This resulted in a higher workload in the lab.

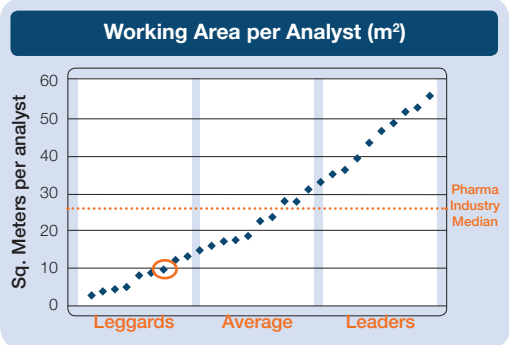
2. QC organizational structure

a. Testing and batch releasing activities were not segregated from the R&D support group. On top of this, analysts also had to handle logistics activities as part of their roles. This mixture of operations within each team created confusion and hemmed the development of expertise, resulting in time-consuming operations and capacity losses.

b. The management structure was sub-optimal, with too many analysts assigned to each team leader. This caused high workloads for the team leaders, reducing their availability to support the analysts on routine testing activities, and therefore, analysts had to wait for team leader support.

3. Layout

From observations and benchmark comparison, it was clear there was not enough room for all lab activities to take place conveniently. Crowded surroundings resulted in queuing, waiting and interference, therefore low productivity.



Major findings - operational elements

1. Planning and scheduling

a. Poor planning and management infrastructure meant that lab planners spent more time expediting samples than prioritizing work to reduce bottlenecks and lead-time.

b. 35% of samples did not arrive on time due to unreliable sampling process. The result of these delays was a poor visibility of work causing many urgent changes, that created a chaotic and sub-optimized sequencing of work (according to benchmarks, 20% of urgent samples is considered as “chaotic”).

c. The campaigning (batching) policy was not defined or optimized. As a result, time was wasted on excessive system setups and management of equipment utilization was lacking.

2. Testing and deviation management:

a. Analyst roles were not optimized. During their daily routines, analysts were seen wasting 20% of time performing non-value-adding activities (walking, waiting for sample or idle) and another 25% of time performing low-skilled activities such as cleaning, printing work procedures or searching for reagents.

b. The wide span of responsibility for each team leader prevented them from providing adequate support to analysts, leading to high levels of lab errors and lack of work prioritization.

3. Measuring & monitoring:

a. The only KPIs reviewed were the ones related to lab output and productivity; lead-time and delivery performance were not measured.

b. The KPIs were not communicated regularly to team leaders and analysts and therefore were not used as a means to drive lab performance.

4. **Continuous improvement**
   a. There was an absence of a continuous improvement infrastructure and of visual management tools. Standard work procedures and management routines were also lacking, all resulting in an inability to escape the short-term fire-fighting cycle.

Designing the vision

An operational vision must be based on the status quo. It should stretch performance but remain viable. According to Tefen's Lab Evolution Model, we should not expect an operation to move from 'basic' to 'predictable' in one leap.

With the QC operation in question, the basic infrastructure was in place, but the managerial structure (planning & scheduling, management routines, KPIs) was not. The 6-month vision was to reach 'managed' status within 6-12 months, 'standardized' within 18 months, and 'predictable' in 2 years. The vision for year 1 is comprised of five pillars:

1. **Robust planning & scheduling** processes to steer the operation
   a. Collect requirements from internal customers.
   b. Clearly prioritize work.
   c. Design a weekly work plan based on standard testing times and predefined constraints (analysts' skills, equipment compatibility, availability etc.).

2. **Effective and efficient work processes** to maximize throughput
   a. Introduce a replenishment process based on a pull system with clear visual management of lab stock.

3. **Aligned organizational structure and roles** to improve flexibility and focus
   a. Commercial release testing segregated from all other non-production work (validations, R&D support and lab logistics & administration).
   b. New continuous improvement roles built into the operation with responsibility for developing and implementing change projects.
   c. Low skilled tasks (e.g. preparation of documentation, weighing samples, standard solution preparation) reallocated to lower skilled employees.
   d. Improved discipline e.g. reinforcement of strict break hours.

4. **Measurement & control systems** to drive improvements
   a. The team was focused on defining a performance management infrastructure – KPIs, visual management tools and management routines.
   b. Simple, compelling KPIs, aligned to value-stream performance (throughput, productivity, lead-time, plan vs. actual, percentage of deviations).

5. **Culture**
   a. Standard work in place including a daily 10-minute 'stand-up' meeting, to review the previous day's performance by each analyst, raise operational issues to be resolved (equipment malfunctions, missing reagents etc), and make new plans accordingly.
   b. Visual boards installed per team, to support communication of KPIs and plan execution progress.
   c. People more involved in lab performance, routinely raising improvement ideas.

Roadmap for implementation

In any lean transformation, as well as implementing the content-based work streams, it is also critical to manage the change process itself, both from the perspective of an organization and on an individual level.

The main change management tools used in this project were:

1. Stakeholder management – this activity was more important than usual due to the high seniority of employees, increasing the level of resistance to change. Major department managers, team leaders and key analysts were analyzed for their level of influence on others and their attitude towards the change. An action plan was designed accordingly in order to "recruit" the potential resistors and increase the chances for success.

2. On-going communication to all levels:
   a. Communication of project progress to analysts was conducted mainly through the daily and weekly meetings. The fact that each employee in the lab felt part of the change made the process a lot smoother.
   b. Plant management was informed about the progress on a weekly basis during the management meetings.

3. Brainstorming with analysts became a key empowerment tool in this project. Team leaders and analysts were involved in the design of processes and management routines, thus making them a lot easier to implement.

Benefits

Performance

1. Lab output was increased by 20% within the first two months.
2. A steady, continuous improvement in productivity was achieved in the 6 months following the initial implementation.

Other benefits

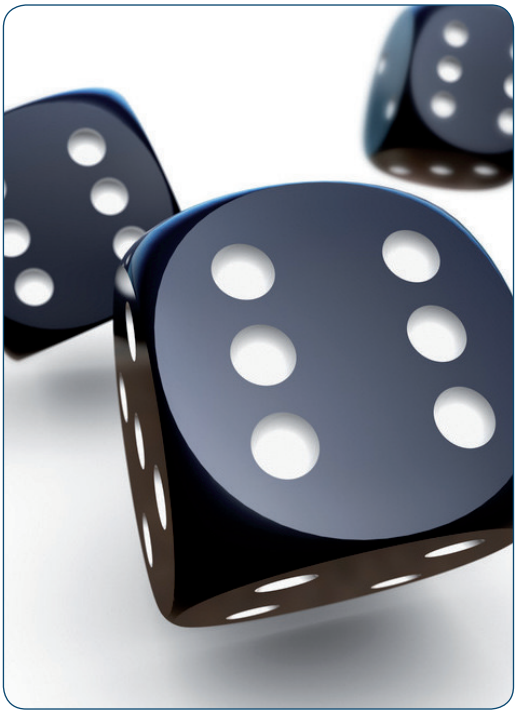
1. Proactive culture instead of fire-fighting – employees feel part of the change and lead improvement teams.
2. Higher job satisfaction levels, mainly for analysts.
3. Improved interface between the lab and the production & planning departments.

Lessons learnt from Tefen's lean quality program

The Key Success Factors for a well established change in operation are:

- Management commitment and involvement.
- Buy in from team leaders and analysts.
- Tight support in the initial stages of the implementation.
- Creating robust management routines and KPIs and ensuring sustainability of those routines.

The move toward applying operational excellence in QC labs is not a stand-alone project; it is a journey. As with all operational excellence efforts, continuous improvement opportunities for the new processes should be explored and performance managed using appropriate performance indicators.



Tsvika Bublitsky, Partner, Tefen Israel
Pete Caldwell, Managing Director, Tefen UK
Rotem Greener, Director, Tefen Israel