Lean Thinking for Laboratories

Introduction to Lean in the Laboratory

While it might sound like some sort of fad diet, "Lean" in the context of business improvement refers to a specific methodology which originated in the Japanese motor industry towards the end of the 1980s. Over the decades, this lean philosophy has been successfully adopted by many companies across a broad spectrum of industries and more recently, lean thinking has filtered into laboratories. The focus of a lean laboratory is to test samples in the most efficient way possible in terms of cost, or speed, or both. Although most of the key principles of generic lean apply in labs, the specific challenges facing laboratories require significant adaptation of standard Lean 'tools'.

Laboratories are typically faced with more volatility and variation in the type and volume of work they are required to perform than manufacturing operations. The life science industry is faced with the additional layer of GMP and GLP complexity. In this context, attention to efficiency and productivity is often secondary. However, there is in fact no inherent conflict between efficiency and compliance. Lean processes in a laboratory achieve regulatory compliance in the most efficient and productive manner possible. A lean lab welcomes auditors and delights in the opportunity to showcase their process improvement achievements along with their capacity to satisfy not just regulators, but customers (internal and external) too.

The Factors Affecting Laboratory Performance

Performance in today's laboratories tends to be negatively affected by a number of issues. These include:

Volatile incoming workload
Most labs experience a volatile incoming workload and with significant peaks and troughs. This results in low productivity (during troughs) and/or poor lead time performance (during peaks). Understanding laboratory capacity and resource requirements and leveling workloads in a meaningful way is the crux of 'leaning' a laboratory. ***The surest way to fail is to put more work into the lab than it can handle!***

High levels of WIP (Work in Progress)
Samples do not "flow". While laboratory analysts may progress speedily through testing, haphazard scheduling due to cross-training deficiencies and instrument conflicts means lots of samples are partially tested, but few fully completed. Lean in the laboratory means performing the right test at the right time to minimize WIP.

Long and variable lead times

In an attempt to be more productive, many laboratories build up queues of samples for tests with long set up times, e.g. HPLC or GC. While some grouping of samples is often a good idea this is usually overdone and needs to be controlled in order to avoid long and variable lead times, equipment conflicts and imbalance in daily analyst workloads.

Ineffective 'Fast Track' systems

Labs often attempt to address the unpredictability associated with long and variable lead times by developing a "fast track" system to allow for urgent samples to be dealt with separately. Typically, however, the proportion of "fast track" samples increases over time to the point of being unmanageable. In designing a lean solution, laboratories can increase the velocity of every sample, eliminating the need to prioritize. This may sound impossible but it can and should be done. If done correctly, the amount of analyst effort required per sample does not change; samples simply spend less time in queues.

Lack of Cross-Skilling

Training gaps are sometimes attributed to high analyst turnover; however lack of cross skilling is often as much of an issue in laboratories with low turnover where staff members have become subject matter experts and are de-facto dedicated to specific tests or activities. Labs tend to operate at extreme ends of a spectrum, whereby they are either mimicking Henry Ford style mass production, with analysts repetitively carrying out the same tasks day in day out, or they are like 'craft producers', taking a sample through its full testing schedule whether it is productive to do so or not. In most cases, the optimum resourcing will be in the middle with each analyst having the capability of doing all of the testing, but carrying out defined combinations of tests which uses their time well and reproducibly meets demand in the most productive way.

Muda, Mura, Muri….The Lean Laboratory Pitfalls

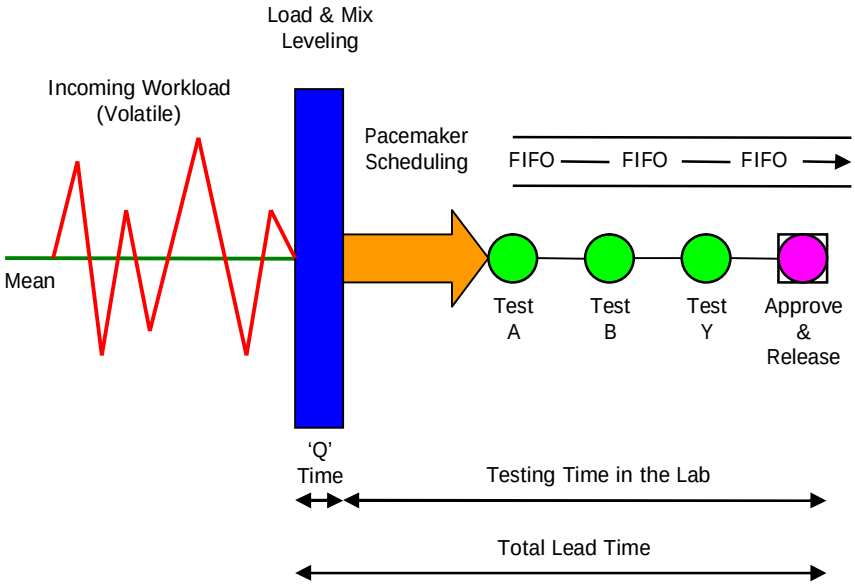
The focus of many lean laboratory projects is almost totally on waste reduction (or Muda, to give it its Japanese term). Significant time is spent on value stream mapping to highlight new "wastes" to work on and while some improvements are made, these are often not converted into meaningful overall performance improvement.

This is no surprise; waste is easy to see and understand whereas the more challenging wastes of "Mura" i.e. the waste of 'unevenness' (volatile workloads) and "Muri" i.e. the waste of 'overburden' (imbalance in daily analyst workloads) are often ignored. These are more difficult to understand but effectively dealing with them will deliver significantly greater productivity improvement than tackling waste alone and indeed will provide a context in which to 'spend' the benefits of waste reduction.

The Recipe for Success

The most successful lean laboratory projects tackle the "levelling" and "standard work" aspects first. Analysis of historical data and forecasts to understand exactly what the levelled demand rate of testing is and resourcing to adequately meet this levelled demand rate provides the best foundation for a lean laboratory. Successfully leveling a

volatile load and mix will significantly improve productivity and/or lead time. The productivity improvement can be used to provide additional capacity or converted into a cost reduction.



Routine testing can be levelled via "Rhythm Wheel" or "Trains", depending on the volatility of the laboratory in question.

A Rhythm Wheel is a repeating cycle of tests with fixed quantities of sample per test. The numbers of samples to be tested is calculated to meet the 'levelled' demand rate, and every test is carried out at a defined interval. This type of solution is best where incoming volatility is low and sample volume is high.

When volatility is high, and sample volume low, a "Trains" solution is employed. This involves defining a pattern of tests to optimise the throughput time of a group of samples, with a "levelling queue" being used to allow samples to build up before being moved very quickly through the sequence of testing.

Often, due to the complex mix of samples and tests, laboratories are required to construct creative hybrids of "Rhythm Wheels" and "Trains" to configure a best fit solution.

Four Key Components

1. Level the load and mix into the Lab using a leveling 'Q' or other Heijunka device.
2. Apply 'Pacemaker' scheduling to the 1st process step downstream from the Heijunka.
3. Create Standard Work and analyst's roles that ensures FIFO after the Pacemaker (i.e. once a sample is launched into the Lab do not let it stop or 'Q' again).
4. Short interval performance management (i.e. review performance daily and correct if necessary.

When the optimal testing sequences have been defined, "Standard Work" roles ensure that analysts execute their tasks in the same order, with the same number of samples on the defined days to reproducibly meet the demand rate.

With the mura and muri under control, muda can be addressed to further enhance the solution. Laboratories have great scope for waste elimination, starting with the housekeeping aspect via 5S, and moving on to improving training systems (to increase the velocity with which a new analyst becomes fully productive) and documentation (via lean test documentation and “Excellent SOPs”).

The Lean Journey

The design of the new Lean lab process is only the first part of the journey. A clean easy transfer from the existing process to the new one is not always possible or practical (manufacturing must not be impeded), operation of a dual system (for a period) may be necessary. Focused management is required to ensure that the old system is phased out without impacting manufacturing.

The temptation to revert to old habits at the first hurdle…and the second…and the third must be avoided. Tenacity is required, as well as frequent communication about the benefits of change.

It is important for all concerned to realise that lean in the laboratory is about more than a one off project. The motivation to continually improve how the new process works must be maintained and performance must be managed and monitored using appropriate KPIs (key performance indicators).

The Results

Depending on the focus of the lean intiative results will be seen in productivity improvement, or increased testing speed…but often results will be seen in both areas.

KPI / Metric	Focus	Before	After	% Improvement
Lab Lead Time	Speed	15 days	5 days	67 %
Testing Right First Time (RFT)	Quality	49 %	90 %	84 %
Batch Approval to Target Time	Speed	43 %	98 %	128 %
Earned Hours (measure of productivity)	Productivity	3.43 Hrs	5.29 Hrs	52 %
Samples per Analyst	Productivity	17	37	118 %

These measurable improvements (from laboratories that have recently completed lean projects) demonstrate what can be achieved.

Labs are not the same as manufacturing but Lean thinking can and should be applied in the laboratory environment.

BSM is a leading life science 'Lean and Operational Excellence' consulting company with offices in the US, Ireland and the UK. We have developed Lean methodologies and solutions specific to the Lab environment which substantially improve lead-time productivity.

For further information please contact Tom Reynolds, Operations Practice Director at tom.reynolds@bsm-usa.com or check out www.bsm-usa.com