EFESO CONSULTING
PHARMA & LABS PRACTICE

MANAGEMENT BRIEFING

Lab Excellence in R&D

Applying Real Lean to free up capacity, increase quality and accelerate time to project & program completion

BSM

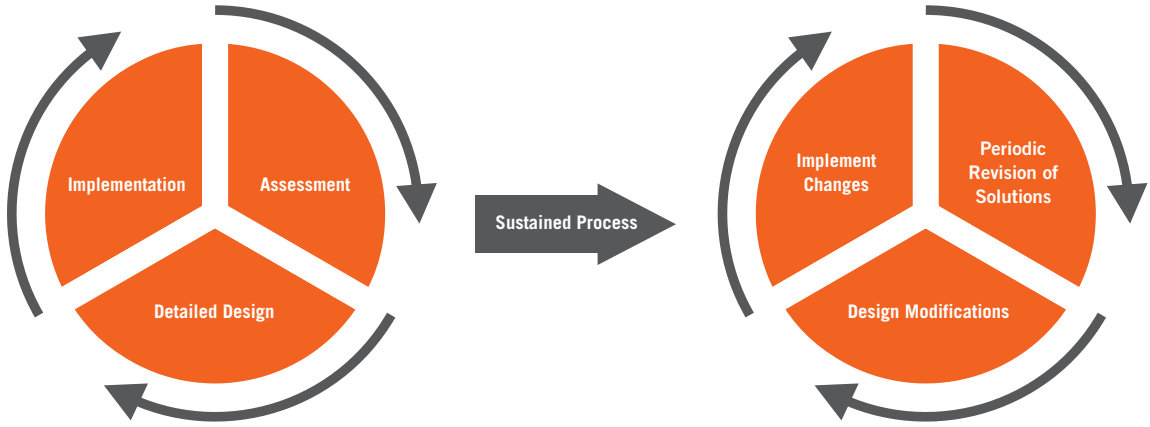
BSM is the global leader in the provision of Real Lean Transformation Services to Pharmaceutical and Life Sciences companies. We are a highly motivated team of consultants with a passion for improving processes and performance and have an unrivalled track record in the achievement of significant and sustained improvements.

We are now part of EFESO Consulting, extending our global reach and our ability to provide local language support, from offices in 26 countries.

Our clients seek our assistance when their R&D functions need step changes in performance on a scale which generic Lean / Six Sigma techniques cannot deliver. We specialize in the implementation of 'Real Lean' techniques, specifically workload levelling, flow and standard work, which often receive insufficient attention in Operational Excellence programs.

The benefits of our approach include:

- Reduced lead-times and adherence to project / program timelines
- More consistent & predictable performance
- A greater understanding of capacity and resource utilization
- Significantly Increased productivity
- Greater empowerment of personnel
- Reduced levels of WIP & inventory
- Reduced space/equipment requirements
- A culture of pro-active performance management and continuous improvement



SUSTAINED SOLUTIONS

Lean in R&D

In pharmaceutical R&D value streams there are significant differences in focus and activity between labs at different stages of the development process.

Labs in the earlier part of the process (example Discovery) have significantly different work profiles to labs that are later in the process (such as development and analytical labs). Nevertheless, the work profile in each lab will consist of a combination of (somewhat) routine activity & analysis and more creative & interpretative type tasks (e.g. report writing, interpretation of data and results, design of follow on experiments, project and portfolio management tasks, knowledge management tasks…etc.). The ratio of the 'routine' to the 'creative' will vary from lab to lab and the significant 'wastes' can be different. In some areas the real 'value adding' element is information, knowledge or a decision rather than test results. This rightly has an impact on the application of lean in that area.

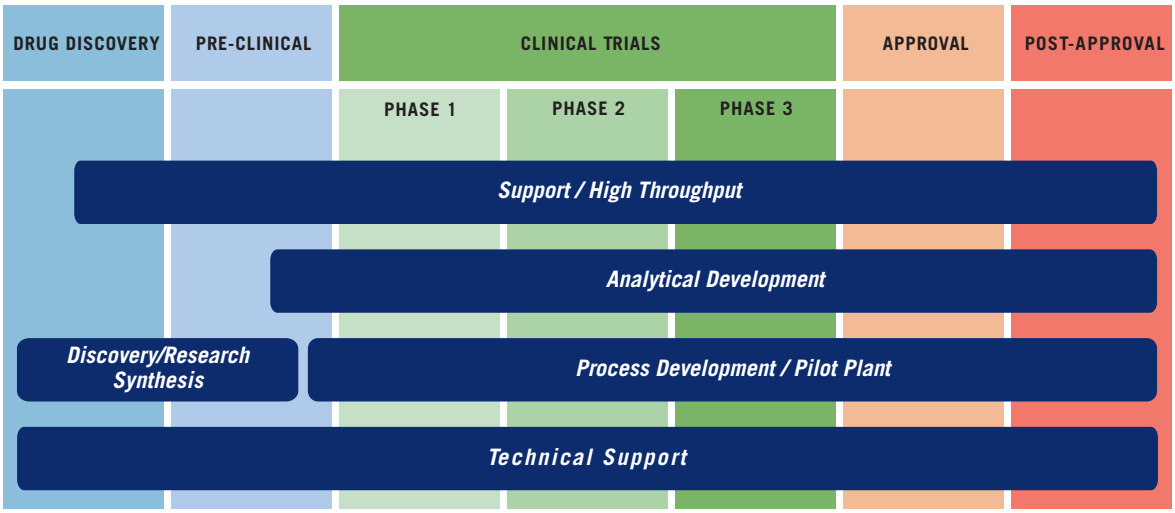


Figure 1 shows a high level representation of the overall development process. BSM tends to think in terms of the type of activity performed in a lab rather than the stage of development they operate at. As such the most common lab types we encounter are:

- ***Support / High Throughput*** – support an R&D function by deploying existing test methods to provide a test result.
- ***Analytical Development*** – develop new test methods or make refinements to existing methods.
- ***Discovery / Research Synthesis*** – synthesize new target molecules.
- ***Process Development / Pilot Plant*** – develop new manufacturing processes and pilot them at a small scale.
- ***Technical Support*** – deploy a specific technique e.g. mass spectrometry for impurity identification.

BSM has developed methodologies and tools based on the 'Real Lean' principles of levelling, flow and standard work that address the unique challenges faced by each of these laboratory types.

What we find in R&D functions

R&D labs do vary significantly one to the other, however, a number of common practices and opportunities exist, which BSM sets to resolve during a typical project.

Below is a summary of the issues typically identified during a BSM assessment

Workload

- Project Based work leading to intense peaks and dips in workload depending on the project stage or cycle
- Resources dedicated by project or program – meaning volatile project workloads are imported directly onto scientists
- Constant changes in priorities leading to stop-start-stop projects, frustration for scientists and extremely long lead times
- No Flow

Organization

- No understanding of how lab operates by decision makers
- Labs operating largely as independent silos – minimal flow of people or information between groups
- Under utilization, duplication and personal ownership of equipment and bench space
- Management structure unsuitable for issue escalation

Planning

- Poor or no resource or capacity management – meaning when one project peaks a scientist can be overwhelmed while a colleague is almost unoccupied
- Long and variable negotiated target lead times (often 10x the throughput time)
- No visibility on overall workload
- No visibility on day to day individual resource workload
- No understanding of what the true capacity of the area is
- Most activities regarded as non-routine due to regular issues
- Too many “Planners” and multiple layers of planning

Quality

- Inconsistent application of Quality by Design Principles
- No metrics or performance goals
- Delays around report writing
- No common format for data reporting
- Limited time available for true innovation because most time is spent tracking, finding, communicating, prioritizing, planning and testing common samples

Solutions

Leveling

In most labs there is short term volatility in the incoming workload with significant 'peaks' and 'troughs'. Levelling means releasing the same amount of work into the Lab each day or each week. Depending on the work profile in a particular lab there are different mechanisms by which this can be achieved.

The simplest leveling strategy is to create the ability to process workloads at the 'leveled demand rate' quickly (via flow). This is achieved by developing repeating sequence/s of operation that move the workload through all the required steps and reviews quickly. This reduces the 'throughput' time and incoming work can then be held in a 'leveling queue' at the start of the process and released into the process in a leveled way without affecting overall lead-time or program deadlines.

While in the queue, work can be prioritized or re-prioritized according to customer requirements using a system of 'must start dates'. However, when released into the lab as part of a leveled workload, it is processed in FIFO order.

To make this approach simple to manage and control we develop Heijunka devices know as Rhythm Wheels. For higher levels of volatility, we use a somewhat different Heijunka device know as 'Trains'.

In a number of situations in the R&D environment this highly structured type of solution may not be possible and flow is ensured by using interim milestone management in which projects are divided into pieces of work of the order of days. *Table 1* lists the common lab types and the solutions that most commonly apply in them.

Table 1 R&D lab types and associated lean solutions

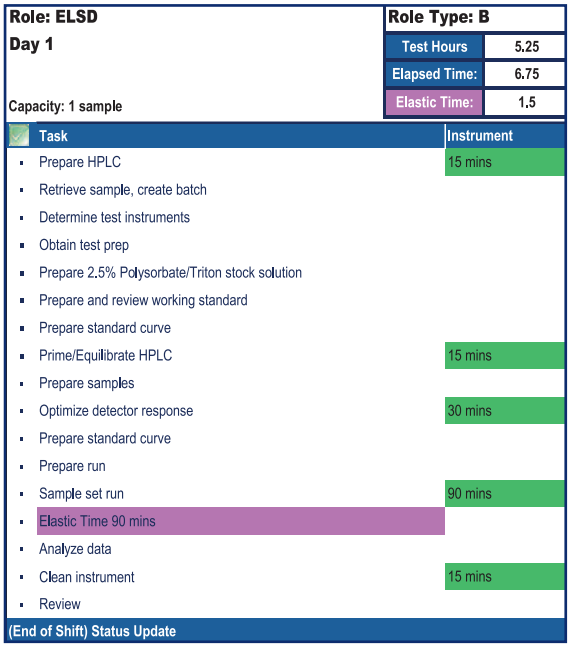
LAB TYPE	COMMENTS
Support / High Throughput	Most similar to routine commercial labs in which structured queueing and Rhythm Wheel or Train flow devices may be used. Analyst roles based on detailed standard work in addition to visual management are also important elements.
Analytical Development	Most of the opportunities here will center on structured project management and milestone based planning supported by visual management.
Discovery / Research Synthesis	Similar to a manufacturing environment and most opportunities will be centered around structured queuing, flow and standard work again supported by visual management.
Process Development / Pilot Plant	Similar to a manufacturing environment and most opportunities will be centered around structured queuing, flow and standard work again supported by visual management.
Technical Support	Most of the opportunities here will center on structured project management and milestone based planning supported by visual management.

Standard work

Some people are naturally good 'time and task' managers and will organize and sequence their work in a logical and productive manner but some people are not. Standard work is a way to capture the 'best method' and support everybody in following that method. In Lean lab, we use a Standard Work approach to develop balanced, productive, repeatable analyst roles (this is only possible because we are controlling the workload and the mix via the levelling & defined sequences of testing).

In an R&D context this can be very detailed (down to 15 minute increments) in the case of a Support lab to much higher (in day or even week increments) in the case of a more project based lab such as Analytical Development. Standard work is typically presented in role card format (shown in *Figure 2*) which shows the sequence of activities and details some Short Interval Control points during the course of completing the role. Role cards provide a focus for the daily huddle where issues with their completion are discussed.

Figure 2. Role card example

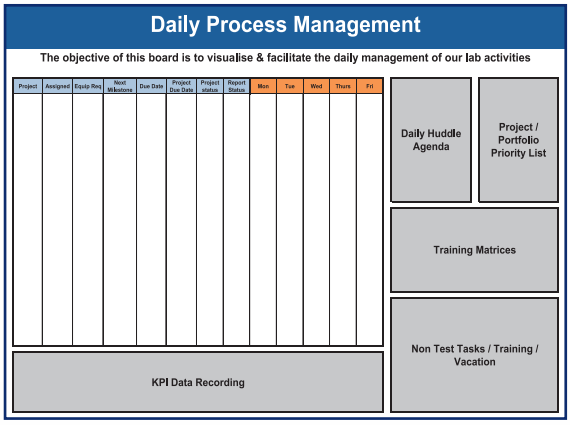


Visual management

Visual management is an approach to managing operations that uses visually presented information, signals and controls to direct activities, communicate progress and highlight issues.

Strong visual management is critical to embedding and sustaining lean within R&D labs and many other environments. Visual management in the form of a physical or virtual whiteboard is the focal point for the daily huddle (Huddles are short, frequent stand-up meetings at which progress is discussed and issues identified. The are the key means of interaction with the visual management system). Some standard visual board elements are presented in *Fig 3*.

Figure 3. Role card example



Lean Best Practice Benchmarking

Different R&D labs will be at varying levels of maturity in terms of being operationally excellent.

Where the initial focus for improvement should be will not be the same across the R&D organization of a large multi-national Life-Science company or even across the groups within a single department. Assessment and benchmarking of lean best practice is a good means to gain a clear understanding of this and determine where improvement efforts should focus.

An example of such a best practice assessment is *shown below* the scoring of which comes from a combination of data analysis, observation and interviewing of key lab personnel. Sample detail is show for the Short Interval Control & Performance Management Section.

R&D Lab Best Practice Scoring

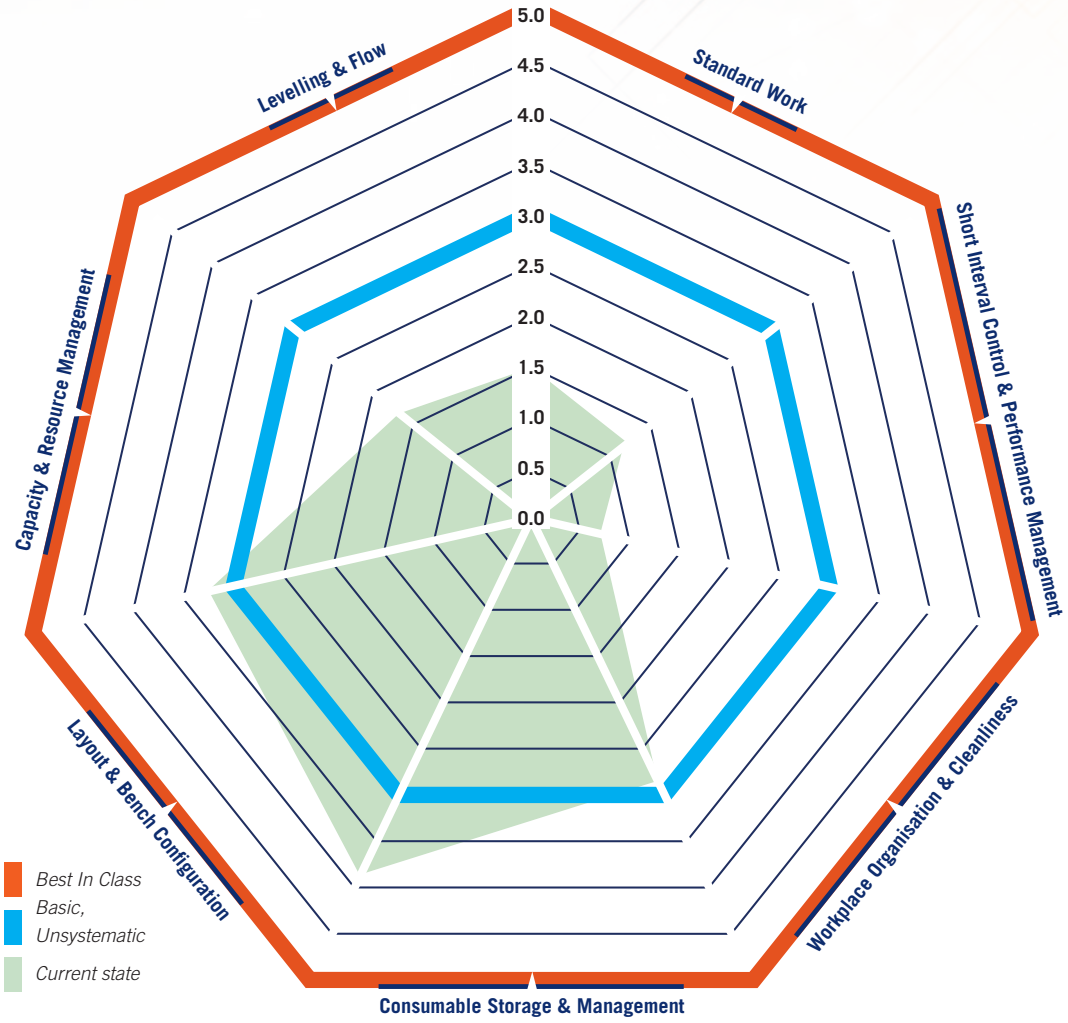


Table 2 Example Scoring Guide

	CAPACITY AND RESOURCE MANAGEMENT	OVERALL SCORE
a	Accurate measured standard times are available for all major tests, tasks, projects to balance individual workloads	4.0
b	Standard times take account of test run set-up and individual sample effort	2.0
c	Standard times are updated regularly e.g. run size, method change, retest rates, etc.	2.0
d	The calculation of routine workload is based on sound mathematical calculations	3.0
e	Non routine workload has been separately quantified / estimated	1.0
f	Realistic allowances for absence from work are included e.g. holidays, sick leave, snow days etc	4.0
g	Equipment & space capacity are addressed and understood	1.0
h	Cross training is measured and ongoing cross training plans exist	5.0
i	Lab capacity is well understood and used to make commitments / decisions	1.0
		2.56

0 No evidence of activity or understanding in this area
1 Basic understanding but little evidence of activity in this area
2 Some evidence of activity in this area
3 Examples of good activity, but not systematic or sustained
4 Strong evidence of activity, and efforts made to sustain
5 Evidence of comprehensive, sustained performance.

BSM is the global leader in the provision of Real Lean transformation services to life science companies. We support companies to deliver significant measureable improvement within their R&D and Regulatory Affairs processes. We develop innovative solutions via the application of best practice lean, re-engineering and change management techniques, and we have an extensive track record of successful implementations.

We are now part of EFESO Consulting, extending our global reach and our ability to provide local language support.

To discuss any aspect of this briefing or your own R&D organisation and opportunities for improvement please contact:

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