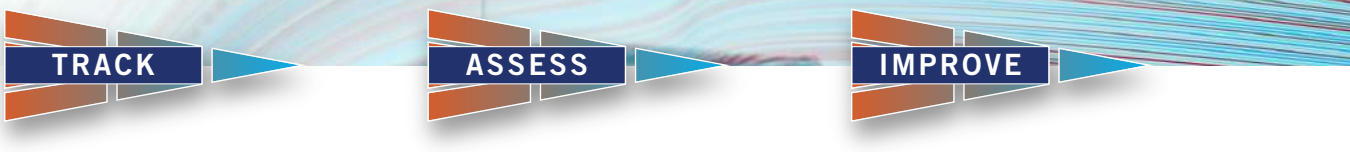
EFESO CONSULTING
PHARMA & LABS PRACTICE

MANAGEMENT BRIEFING

Metrics Methodology

A Lean Lab Approach Aligned to New FDA Guidelines on Metrics for Pharma



On the application of structured performance metrics to Lean Labs projects to monitor and improve lab performance. With application to FDA guidelines on metrics for quality operations to assist in risk based surveillance inspection planning currently in development.

BSM

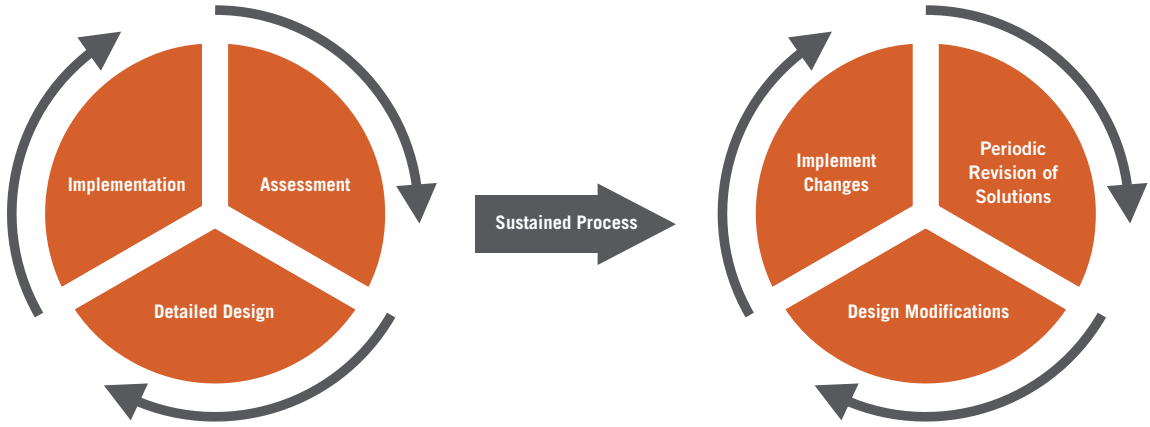
BSM is the global leader in the provision of Real Lean Transformation Services to Pharmaceutical and Life Sciences companies. We are a team of highly motivated consultants with a passion for improving processes and performance and have an unrivalled track record in the achievement of significant and 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 quality and R&D functions need step changes in performance in 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:

- Significantly Increased productivity
- Reduced lead-times and adherence to customer schedules
- More consistent & predictable performance
- A greater understanding of capacity and resource utilization
- 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

Metrics Methodology

A Lean Lab Approach

Performance metrics are a critical part of any effective Lean Lab solution, helping to identify issues and directing and driving performance improvements.

As part of every BSM Lean Lab or Lean R&D project, metrics are developed with these concepts in mind. This briefing will describe our Lean Lab approach to performance metrics, demonstrate specific examples and highlight the applications of the approach to include visual displays, reduction of metric data gathering workload and applicability to the FDA's guidance on metrics to facilitate risk based assessments.

Best practice metrics are typically structured on a tiered basis with; (i) customer facing metrics, (ii) leading lab internal metrics and (iii) pareto type analysis of causes of poor performance (cause analysis).

The tiered metrics are designed to clearly speak to the intended target audience. For example a customer facing metric (tier 1) for lead time adherence may quote the lab's overall adherence to the supply chain target, whereas a leading lab internal metric (tier 2) may break this down into testing and review targets by lab group. A tier 3 metric may pareto chart any problem products or tests that are causing missed targets. It is important that all metrics are clear to the intended audience and set against sensible, well-thought-out targets. See blog titled *'Understanding Service Level Agreements in Lean Projects'* https://bsm.ie/blog

Tier 1 ***Customer Facing Metrics***	High level metrics showing performance of the lab in key areas critical to success of the business and associated adherance to targets
Tier 2 ***Leading Lab Internal Metrics***	Mid-level metrics showing internal lab targets specific to performance monitoring and targeted improvement
Tier 3 ***Pareto of Poor Performance***	Identification of problem areas allowing for root cause analysis of poor performance and targeted continuous improvement actions

Key Metric Examples

Metrics are generally customized based on each individual lab's requirements. However, there are some common metrics often incorporated in a Lean Lab project; Customer Schedule Adherence (or lead lime adherence), Standard Work Roles Completed on Time, Productivity and Right First Time percentage (RFT). Each of these metrics are important for the lab to monitor and maintain a balance between Quality, Speed and Value and ensure it does not get pulled in one direction while compromising another.

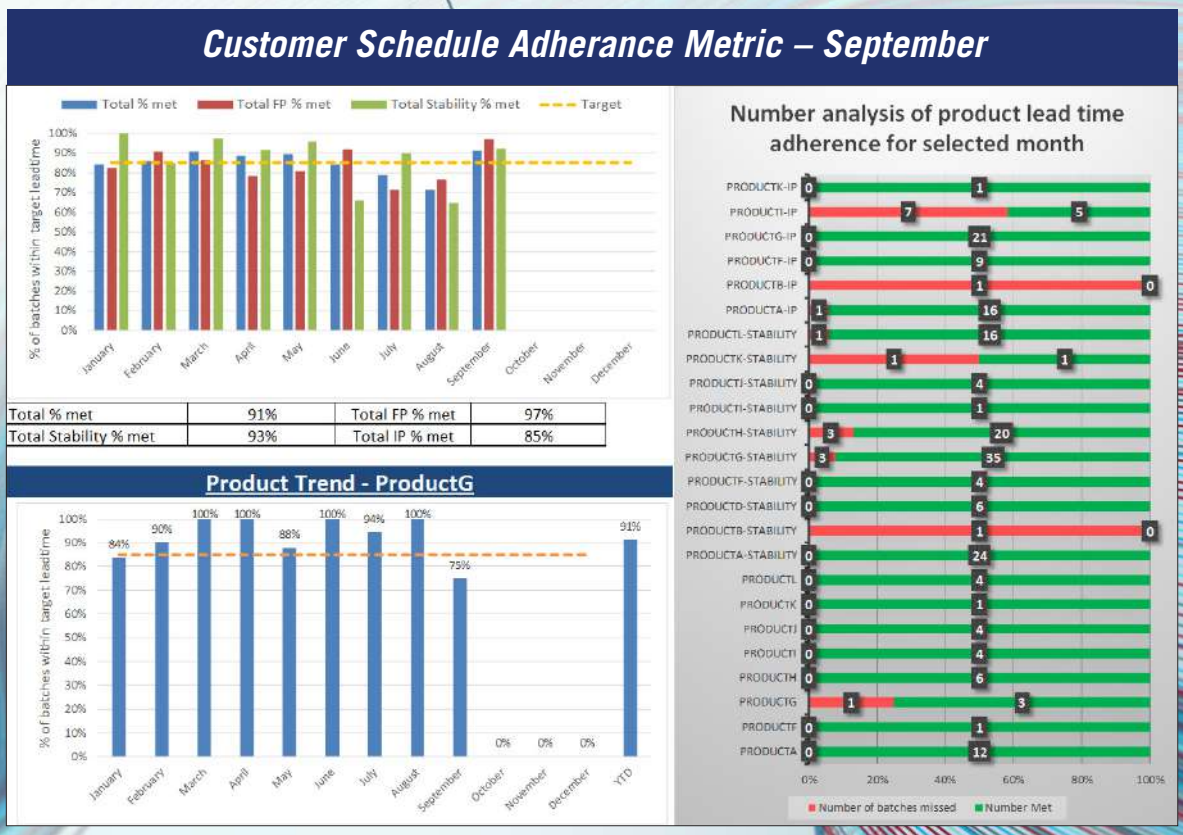
A brief explanation of each is given below.

Delivery Metrics

Customer Schedule Adherence

Shown in the example below is a Customer Schedule Adherence metric (or adherence to lead time). In this specific example the 3 tiers are combined into a single metric reporting sheet.

- Top left is the tier 1 overall customer facing metric of lead time adherence for each work-stream and target indicator.
- Bottom left is a tier 2 internal lab metric for tracking the performance of a specific product (this can also be used to monitor continuous improvement actions).
- The graph on the right is a tier 3 metric showing the performance of all products for a particular time period (in this case monthly but weekly is also a common time interval used). In this example it identifies products that have missed their lead time targets for cause analysis.



Example of Customer Schedule Adherence Metric with combined 3 tiered approach

Standard Work Roles Completed on Time

This tier 2 metric is a metric unique to Lean Lab projects. It monitors the labs standard work roles (developed during the Lean Lab project) completed on time. This combined with a tier 3 metric addition allows the lab to identify poor performing roles where remedial action can be taken. Additional daily tracked lab metrics are frequently added to this metric such as number of investigations opened etc.

Productivity

Productivity is a key lean laboratory metric. It is also one of the most misunderstood and/or miss calculated metrics we encounter during projects. Common problems we find in lab's assessing of productivity (especially by senior management) are;

- Only evaluating 'value add' work, i.e. judging a labs productivity based solely on finished batch release often ignoring (or giving little attention to) other activities such as stability testing, in process controls, special studies, non-test tasks and new product introduction (NPI) based work, all of which can make up significant percentages of a lab's responsibilities.
- Over simplified calculations. Judging a lab based on for example the number of batches tested, without giving any weighting to the different amount of work required to release different products or materials (e.g. single active versus double active products or API testing versus excipient testing).
- Having an ill-defined or inconsistent measure of person effort.

The keys to measuring productivity are to know what is the most feasibly productive way to perform each test and to know what resources the lab used to perform completed work. Knowing this information in a given time period allows us to calculate the lab's productivity. Typically a tier 1 metric, it can also measure internal lab productivity targets designed as tier 2 metrics.

Right First Time (RFT)

The RFT metric is structured using the 3 tiered approach similar to the customer adherence schedule metric described above and designed to focus on measuring quality and error reduction/prevention. This type of metric can be adapted to assist in the requirements of the reporting of lab quality metrics to the Office of Quality Metrics as part of the FDAs plans to facilitate risk based assessments on FDA regulated sites (outlined in 'FDA pharmaceutical quality oversight', L.X. Yu, J. Woodcock / International Journal of Pharmaceutics 491 (2015) 2–7). Specifically 'Invalidated OOS Rate Data (IOOSR)' metrics which relate more directly to lab activities. IOOSR metrics (as outlined in 'Submission of Quality Metrics Data - Guidance for Industry (November 2016)') are not straight forward to gather and require a level of detail in the source data to break the metrics into the required metric sub-sets. For example the requirement to segregate out accelerated stability testing, include retests of lots in the recording of quality events and counting of the total number of tests performed.

Gathering and filtering of the data required for these metrics typically requires significant manual effort and reference to multiple lab data sources. However, as demonstrated in the tier 3 metrics displayed in the customer adherence schedule example, BSM Lean Lab metrics break down tier 1 metrics into detail to allow for greater analysis. The same methodology can readily be applied to the IOOSR metrics required by the FDA (currently reported on a voluntary basis) to ease the burden of producing these metrics (see section on metric gathering for more detail).

Summary Table

METRIC	GATHERING AND DISSEMINATION METHODOLOGY
Customer Schedule Adherance	Generated using data from LIMS, this metric tracks the lab's adherence to service level agreements within the organization. Structured using the 3 tiered approach as shown in the example.
Standard Work Roles Completed on Time	Daily tracking of Standard Work Roles (developed during a Lean Lab project) assigned and completed each work day. Typically recorded at daily huddle meetings on a visual board and information logged into a spreadsheet for graphing.
Productivity	Accurate test times based on most productive method of testing are calculated during a Lean Lab project. This information leveraged together with knowledge of the number/type of tests performed and what resources the lab used (typically on an FTE basis known from the roles completed metric) over a given time period. The output is designed to be understood and relevant to the management team or lab group.
Right First Time	This metric is typically generated using data from Trackwise and LIMS. It is disseminated in a similar manner as to that shown in the customer adherence schedule example. A tier 1 over all RFT% on a per test and/or per batch basis. Lower tiered metrics typically focus on a particular product or test method root cause analysis identifying error type such as analyst error, equipment error, documentation etc.

Metric Gathering (Reducing the manual effort in metric production)

One of the issues BSM often encounters in labs is a large amount of manual work involved in generating metrics. This usually involves manually tracking batches while in the lab to assess lead time adherence, counting via manual tables to quantify workload and performing basic monitoring of error rates. This workload will increase with the introduction of FDA mandated quality metrics which are currently being developed.

Through BSM's extensive experience in working with labs we have developed methods to reduce the workload in gathering data for metrics. Using resources such as LIMS and Trackwise and taking advantage of internal records routinely kept by the lab, simple tools, using excel for example, can be developed whereby standard reports exported from software systems can be copied into standardized excel tools and the metrics automatically produced with minimal effort.

Another advantage to using resources such as LIMS and Trackwise is that the information used to produce the metrics is automated and not as open to manipulation or errors as compared to manually generated metrics where information is input by hand.

Visual Boards and Weekly Huddles

BSM's Lean Lab approach utilizes visual display boards where metrics are organized and displayed. Below is an example of how such a board may be structured, keeping in mind that each lab will have a tailored board suitable to their Lean Lab solution and any key metrics the lab may wish to track.

Example of a Visual Display board designed for metrics communication and weekly huddle meeting focus

During a Lean Lab project BSM will encourage the lab leadership team to meet weekly at this type of board to go over the metrics using tier 3 metrics to identify problem areas, tier 2 metrics to monitor effectiveness of improvement actions highlighted from tier 3 and ultimately seeing improvement in tier 1 level metrics. Unique and specialized metrics such as 5S audits and a training matrix review can also be incorporated here.

Conclusions

The metric examples demonstrated in this document provide a good cross section of what is deployed in a Lean Lab project. Additional tailored metrics can be developed depending on the lab's objectives. Alignment to current FDA quality metrics will enable the lab to produce quality internal metrics alongside those currently requested by the FDA resulting in a reduction in excessive effort involved in metric data gathering and duplication of effort where common source data for metrics overlaps.

While metrics are a powerful tool in any Lean system, they are only as good as the methodology behind them. The best metrics are truly effective in driving good behavior and performance improvement. BSM , through experience in implementing Lean in labs across the globe and in various quality environments, is uniquely qualified to deliver effective tailored metrics that will enable the lab to maintain a continuous improvement culture and build on a performance step change achieved during a Lean Lab project.

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 QC, QA, 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.

To discuss any aspect of this paper

or how BSM can benefit your organisation please contact:

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