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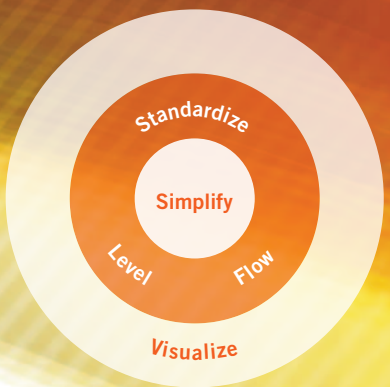
MANAGEMENT BRIEFING

REAL LEAN

IN QUALITY ASSURANCE



Transforming operational performance and consistency in QA functions

BSM

In pharmaceutical companies, the Quality Assurance (QA) function is usually directly on the critical path for the release of product and is often a significant cost center in its own right. QA functions are complex areas with volatile, short interval workloads and often suffer from poor or inconsistent performance.

While it is not obvious how the principles of lean and operational excellence can be applied to such areas, **BSM** have developed methodologies and tools based on the 'Real Lean' principles of leveling, flow and standard work that enable QA functions to significantly improve operational performance and consistency.

Incoming workloads for QA groups come from many sources and are often inherently volatile. For example, the number, type and mix of batch records received daily/weekly into the batch disposition process will vary, resulting in a variable amount of review and disposition work to be completed. This variability is also true of other QA workstreams, e.g. change control, investigations, CAPA, etc. This volatility causes periods of overburden of resources and also periods of underutilization. This effect is often compounded by unwieldy, slow and punitive correction processes, driven by poor Right First Time (RFT), multiple delay/queue/sign-off points, and non-value adding effort expended in prioritization due to long turnaround times. In order to avoid running late, QA functions are often resourced close to their peak workload. This results in productivity losses during slower times.

Principles of Real Lean

Real Lean in QA is based on the key principles of leveling, flow and standard work, supported by visual management and controls. Applying these principles effectively will significantly reduce the waste from short interval volatility.

In fact leveling short interval volatility in workload is typically the single biggest improvement opportunity in QA processes. However, many archetypal "lean" programs seem to completely ignore this opportunity.

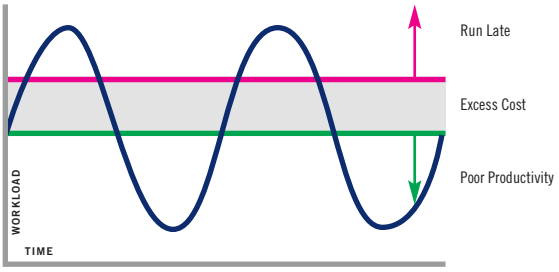


Figure 1. *The effect of volatile workloads*

Real Lean in QA shifts the focus of improvement initiatives from individual wastes or activities to the leveling of workloads and the creation of flow through all the QA workstreams.

A 'Real Lean' approach includes active leveling of short interval workloads and generates flow by creating 'defined work sequences' that move items quickly through all required activities and reviews. QA activities are then combined into balanced, productive, repeatable roles that use people's time well.

This approach transforms the organization and the QA processes and generates significant productivity and lead time improvements, as well as improving RFT and compliance.

In this paper we describe the Real Lean concepts that can be used to address the process and volatility issues described above and create robust, fast processes supported by visual management that allow QA groups to consistently meet target release dates in the most productive way possible.

KEY CONCEPTS

CONCEPT ONE: Leveling Volatile Workloads

When incoming workload exceeds capacity, the individual or group will fall behind and either batches will be released late or deadlines will be missed on other workstreams. Because it is usually considered worse to be late than expensive, QA processes often carry more resources than strictly required to process the mean workload. However, even with some excess resources, QA functions will still fall behind during the highest workload peaks, and conversely suffer from poor productivity during extended periods of low incoming workload. The difference between the staffing required for the mean workload and the actual staffing level, represents either excess cost or additional capacity and is recoverable if you can level the workload and distribute it among the group (or between groups) as appropriate (*Figure 1*).

The simplest leveling strategy is to create the ability to process QA workloads at the 'leveled demand rate' quickly (via flow). This is achieved by developing repeating sequences of operation that move the work 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 agreed service levels.

While in the queue, work can be prioritized or re-prioritized according to customer requirement using a system of 'must start dates'. But when released into the QA process as part of a level daily workload, it is processed in FIFO order.

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

These repeating work sequences are carefully designed to meet the overall QA workload and consistently achieve the lead times required by the business.

Mixing Workstreams that are difficult to level in their own right

The overall QA workload comes from various sources and is likely to be inherently volatile in the short interval (i.e. day to day or week to week). For example, in client sites we often find significant variability in the weekly volume (and mix) of batch records received for disposition. The same is true for the volume and types of change controls and deviations, etc. that need to be processed.

This inherent volatility can often be exacerbated, by dedication of resources to specific workstreams (e.g. batch record review, raw material review, investigations). Creating subject matter experts often seems like a good way to get tasks accomplished quickly, however these individual workstreams will typically have higher volatility in incoming volume, compared to the overall workload.

In *Figure 2*, the individual resources for a QA group were dedicated to three different workstreams. The volatility, as described by the COV (Coefficient of Variation) is higher for each of the individual work streams than for the combined overall workload. This is quite typical and represents an opportunity for leveling the individual people resources by distributing work flexibly across the group.

HOURS WORK	WORKSTREAM A	WORKSTREAM B	WORKSTREAM C	COMBINED
AVERAGE	43.82	39.94	68.22	151.99
COV	0.35	0.26	0.19	0.18

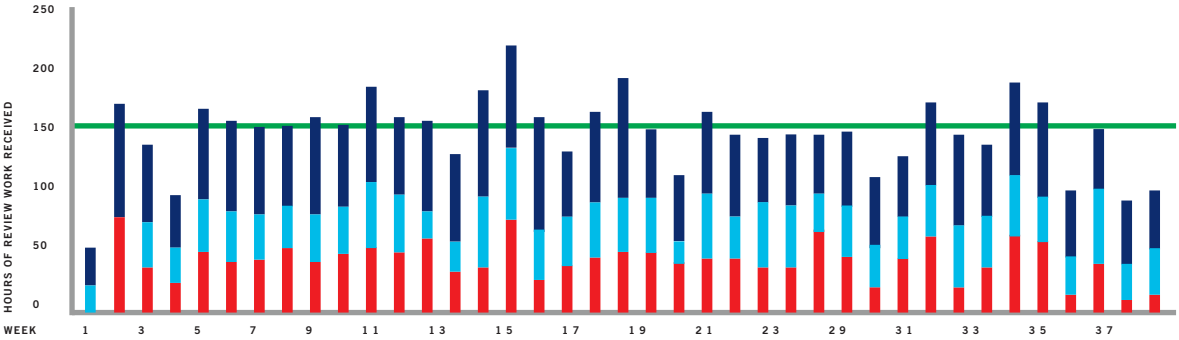


Figure 2. *Combining volatile workstreams usually creates a more stable and manageable workload*

CONCEPT TWO: Visual Queuing

To simplify short interval management of workloads i.e. releasing the leveled demand amount of work into the QA group each day, we normally use visually managed queues. Obviously there will be days when we receive more work than we will complete in a day. These batch records (or other work) need to be queued in a planned, organized manner so that we always know which items to work on next. We accomplish this by using the visual queues, see *Figure 3*.

Where possible the physical batch record (or other relevant document) is used to create the queue. When this is not possible 'T-cards', magnets or other place holders can be used instead. When a batch record is received it is assigned a 'Must Start Date' (MSD). This is the last day we can start working on the document and still release/complete on time. The batch record is then inserted into the relevant place in the queue based on the MSD. Each day, when releasing the leveled demand amount of work from the queue, items with the earliest MSD are taken first. In the example in *Figure 3*, the leveled demand amount of work is 13 hours.

The assignment of a MSD is important because it helps ensure that we are never late. Each day enough items are picked from the queue (in MSD order) to reach 13 hours of work content. On any day the review work can consist of a different mix of records but will consistently represent 13 hours of work. All items which have a MSD of today, must be started today, even if that exceeds the leveled demand amount. However, if the leveled demand rate has been calculated correctly this will almost never happen.

While in the queue, individual batches can be prioritized or re-prioritized according to customer requirements by adjusting the MSD. But when released into the process, they are processed in strict FIFO order. In this way we do not "stop-start", or pick up and drop work, which is an inherent waste in itself that the system is designed to avoid.

This type of queue is also very useful for visualizing and quantifying the amount of work that is 'in' our group at any one time.

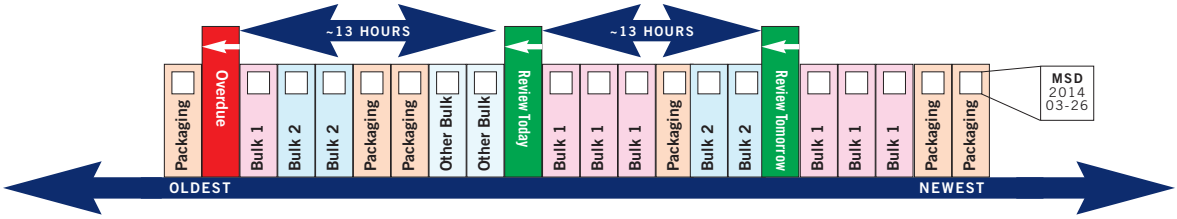


Figure 3. *A visual queue of batch records used to manage the daily workload*

CONCEPT THREE: Standard Work & Role Cards

When daily workloads are leveled in this way, it becomes possible to design Standard Work that enables the work to be completed in a productive manner. Some people are naturally good 'time and task' managers and will organize and sequence their work in a logical and productive manner. However, many people are not!

We can use a Standard Work approach to develop repeatable roles (possible because we are controlling the workload and the mix) that make good use of people's time – i.e. "solve the problem once" and keep using the solution. Also, because Standard Work combines tasks and uses people's time well, it delivers a significant productivity gain in itself. Standard work is typically organized into 'Role Cards' that eliminate the need for elaborate short term planning and scheduling and balance the work between different days and among group members, ensuring everyone is given a fair day's work every day.

The role cards have clear short interval targets during the day that link with visual management displays and help visualize and manage short-term performance. They also provide a focus for a daily huddle where issues with completing the roles are discussed.

			MON	TUE	WED	THU	FRI	HOURS
ROLE A	Real Time Review	AM						30.0
	Release	PM	3.0	3.0	3.0	3.0	3.0	
ROLE B	Queued Review	AM	3.0	3.0	3.0	3.0	3.0	30.0
	Waters		3.0	3.0	3.0	3.0		
	Real Time Review	PM					3.0	
ROLE C	Sterilization Review	AM	3.0	3.0	3.0	3.0	3.0	30.0
	Deviations/Other	PM	3.0	3.0	3.0	3.0	3.0	
ROLE D	Queued Review	AM	3.0	3.0	3.0	3.0	3.0	30.0
	Sterilization Review	PM	3.0	3.0	3.0	3.0	3.0	
ROLE E	Deviations/Other	AM	3.0	3.0	3.0	3.0	3.0	30.0
	Queued Review	PM	3.0	3.0	3.0	3.0	3.0	
ROLE E	Deviations/Other	AM	3.0	3.0	3.0	3.0	3.0	30.0
	Queued Review	PM	3.0	3.0	3.0	3.0	3.0	
ROLE E	Deviations/Other	AM	3.0	3.0	3.0	3.0	3.0	30.0
	Queued Review	PM	3.0	3.0	3.0	3.0	3.0	
	Total Hours		42	42	42	42	42	210

ROLE E

AM	1. Clear Queues of Priorities from "Other" Queues (e.g. Masters Approvals, Calculations, Samples) 2. Complete Deviation Priorities
	LUNCH
PM	1. Check/Clear any new "Other" priorities 2. Clear 3hrs-worth of work from Batch Review Queue(s)

The role card guides the reviewer through the day's priorities — often by directing them to the relevant visual queue

Figure 4. *QA role cards: the card provides a high level outline of the day's work*

CONCEPT FOUR: Batch Record Simplification and Re-design to improve Productivity and RFT

Poor layout and design of the batch record document can significantly increase the propensity for errors.

Common issues include:

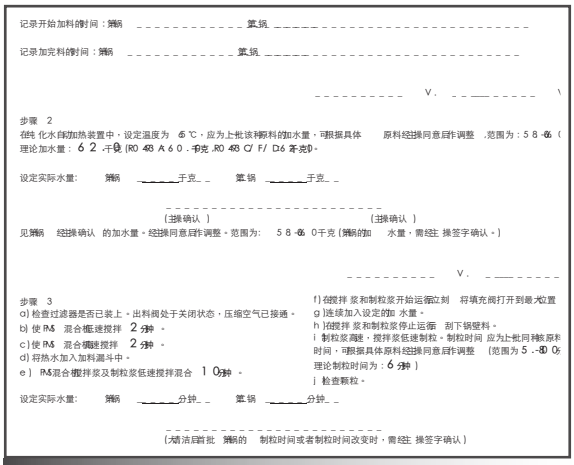
- Data entry points not aligned or standardized throughout the document making 'errors of omission' more common and causing problems for both data-entry and review personnel.
- Poor sequencing of data entry requiring moving backwards and forwards in the document to input (or transcribe) data.
- A large number of unnecessary entries including transcription from (already validated) systems or printed reports.

The batch record should be critically reviewed and the value of each entry evaluated. Unnecessary entries should be removed and the amount of transcription reduced. It is common to achieve a 40-50% reduction in the number of entries by re-engineering the batch record in this way.

The remaining entries should be sequenced to closely match the actual process. Shading and 'Data Masks' can be used to prompt entry of the correct data and to reduce 'errors of omission'.

Pareto Analysis of the types (and locations) of errors found by QA reviewers should be used in the re-design process. The re-design should involve representatives from both manufacturing and QA and any other people who directly interact with the records. It also provides an opportunity to design the record for ease of review, by highlighting critical entries and review requirements.

Figure 5 shows a before and after document from a BSM-led project. A well designed batch record visually stands out from its poor relation – no matter what the language!



BEFORE (DATA ALL OVER THE PAGE)

AFTER

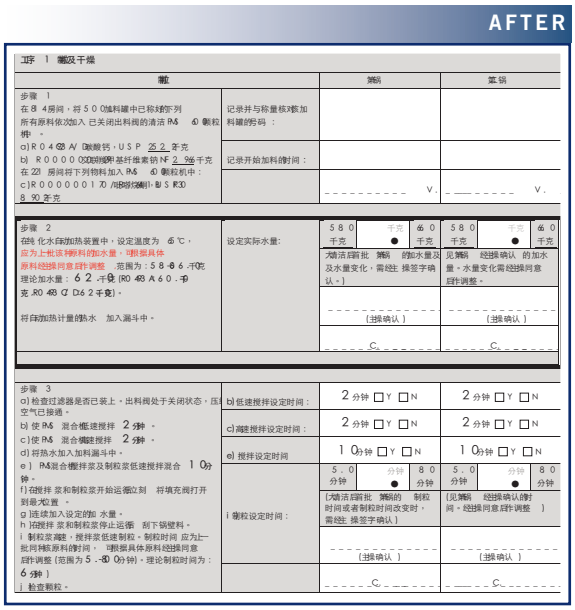


Figure 5. *Batch record simplification - before and after*

Real Lean and Electronic Records

There is a commonly held view, that electronic batch records can fix all the problems associated with poor RFT and 'on time release'. While there are clear benefits to the introduction of electronic records, it is important to re-engineer the documents themselves prior to implementing the new system. Directly transferring a poor paper process to an electronic format will result in sub-optimal benefits.

The process of improving the batch record documents (described above) is an important precursor to moving to an electronic batch record system. By analyzing and improving the paper process prior to the transfer, greater benefits can be realized. All the concepts described in this paper, including leveling and queuing, work equally well when applied to paper based or electronic batch record processes.

CONCEPT FIVE: Improving Batch Record flow using 'Standardized Review', performed in Real Time or Incrementally

When the batch record process is mapped, it is common to find that the majority of the 'turn around' time is spent queuing. In the example in *Figure 6*, over 95% of the overall lead time was spent in queues. By designing and implementing a robust document flow, the time spent at these delay points can be reduced or eliminated.

One method of improving batch record flow is to introduce 'real time' or 'incremental' review of the record as it moves through the manufacturing process rather than waiting until the batch record is complete. In this approach the batch record is reviewed by manufacturing and QA personnel at fixed points or times while the batch record is still on the shop floor. This allows for corrections to be made in real time and reduces the need for elaborate correction processes and the delays often associated with waiting for operators to be 'back on shift'. Also, as the corrections are made in a face-to-face interaction between QA personnel and operators there is less opportunity for misunderstanding of what correction or change is required.

Most entries can usually be reviewed in real time, however others can only be reviewed when the batch record is completed. As part of the batch record re-design this type of entry can be highlighted in the record. Obviously having the bulk of the review completed before the record leaves the shop floor means that the final review is much shorter.

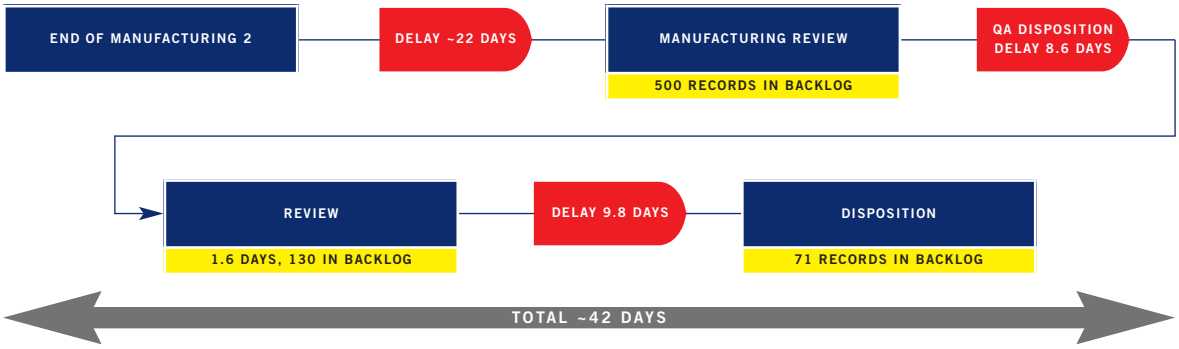


Figure 6. *Example of delays in a batch record disposition process*

CONCEPT SIX: Standardizing Reviews & Corrections

Within any QA review group it is not unusual to find variation in the interpretation of requirements for corrections or comments and/or the need to return the batch record for further clarification. This is not to suggest that some people are reviewing to a higher standard or are being more diligent, rather that individual reviewers often have different expectations and ideas of what a comment or correction should entail.

This can cause uncertainty, confusion and also frustration for the operator filling in and correcting the batch record. There is often a perception on the operators' side of seemingly arbitrary returning of batch records; while there is also frustration on the part of the reviewer because "I told them how to fix this last time".

One of the ways to address this is to get QA reviewers to agree a set of standard comments and corrections that operators are trained on. It is often useful to generate work aids detailing these standard comments or correction methods.

When reviewers and operators are working to a shared common understanding of the batch record requirements there will usually be a significant reduction in the number of batch records that require correction. This decreases the overall effort required per batch record, reduces throughput times and decreases frustration for both operators and reviewers!

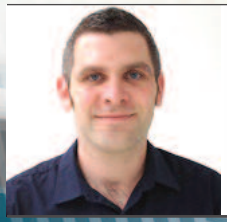
BSM is the global leader in the provision of Real Lean transformation services to life science companies. We have an extensive track record of successful implementations in quality functions. We are now part of EFESO Consulting, extending our global reach and our ability to provide local language support.

Benefits

QA projects led by BSM, always address short interval volatility in workloads, as this is by far the biggest lean opportunity. Successfully leveling a volatile workload will deliver significantly greater benefits than waste elimination alone and will typically generate improvements in productivity ranging in previous projects from 25% to 80%. This can be converted into unit cost reduction and/or used to reduce lead-times (by up to 90% in some cases). Annual returns are typically 3 to 5 times the cost of the projects.

The Author

Dr. Adrian Fegan is a Senior Manager with BSM prior to which he completed his Ph.D. and postdoctoral research in chemical biology. Adrian has led Lean Laboratory, Lean in Quality Assurance & Lean in R&D projects with Mylan, BMS, Pfizer, Warner Chilcott (now Actavis) and Abbott Nutrition.



To discuss any aspect of this briefing or your own Quality Assurance organization and opportunities for improvement please contact:

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