Lean in Regulatory Operations

Dr. Alan P. Maloney and Dr. Gary Ryan, BSM Ireland Ltd.

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Introduction

BSM have been pioneering applied research into the utilization of "Real Lean" methodologies to solve problems and generate efficiencies in Regulatory Affairs Operations (Reg Ops) in large life science companies. Operations from a Regulatory perspective encompasses the standard activities that accompany the filing of Regulatory submissions such as Labelling, Publishing, Production, Archiving etc. "Real Lean" is the term used to describe BSM's approach to implementing Lean in a wide variety of industrial settings. We use this term to distinguish our approach from generic Lean implementations which primarily focus on elimination of the seven wastes. "Real Lean" has at its core a commitment to incorporate the key principles of Levelling, Flow and Standard Work as a basic operating system.

BSM have demonstrated that the concepts of "Real Lean" are equally applicable and effective in Regulatory Affairs Operations and have developed a skill set capable of transforming Reg Ops groups into highly efficient, high quality, highly compliant and low cost operators.

Key challenges for Regulatory Operations

A. Process Harmonisation

Many large multinational life science companies have evolved as a result of multiple mergers and takeovers of smaller organizations. When a small company is assimilated into a larger organization, the Regulatory Affairs (RA) department will often remain *in situ* as a satellite office retaining the support function for the products that the parent once produced. This coupled with poor harmonization of processes can result in the same basic activities/functions being executed very differently within the same company, a potential compliance issue. It can also create "tribal knowledge" which may easily be lost through employees leaving the company. "Tribal knowledge" of specific products also makes work sharing and levelling of workload across sites virtually impossible. Thus, standardizing of processes and generating associated standard work is highly desirable and a key feature of any solution in Reg Ops.

B. Workload Volatility

The submission profile for any large life science multinational is likely to be inherently volatile. This volatility is present at a number of levels, each causing difficulties from an operational perspective. Firstly, the submission profile is a volatile data set, with overall numbers of submissions varying significantly from week-to-week/ month-to-month. Secondly, there is high variability in the mix of work. In other words the submission types can vary from week-to-week/month-to-month. Thirdly, there is volatility in the volume of work. Consider two different weeks that appear to have identical numbers and types of submissions due. The overall work content associated with the submissions from Week 1 could potentially be double that of Week 2. This is down to the fact that by and large each single submission is unique, and the work content is determined by the trigger for the submission, not the submission type.

The causes of the volatility can be both internal and external. Examples of external volatility sources are *ad hoc* requests and directives from Health Authorities which can have a considerable impact on

the overall workload, particularly if they coincide with a period of intense activity on large applications. There is nothing that can be done to "level" external sources of volatility as they are outside the control of the company.

Measures can readily be taken to address the internal sources of workload volatility and significant improvements can be made provided you have the support of all process stakeholders. The main sources of internal volatility are;

A. Unanticipated moving of submission dates
B. Unlevel loading of new product launches
C. Rework (caused by lack of built in quality)
D. Personnel dedication

In our experience, most Reg Ops departments are significantly over-resourced in order to cope with the volatility in their process (see **Fig. 1** below). We term this the Volatility Penalty, and unless specific measures to reduce the impact of volatility are taken, the company will be shouldering this considerable cost burden for a very long time.

C. Lack of Flow

Submission building is a considerable undertaking, involving the coordination of input from many groups/departments, a single submission potentially containing many hundred documents. Delays and inefficiencies (lack of Flow) throughout the R&D value stream and in the submission building process accumulate and manifest at the end of the Regulatory value stream (*i.e.* Reg Ops). Submission deadlines cannot be missed, therefore a constant flow of urgent submissions leads to significant Work-Life Balance issues for employees as stress levels increase proportionally with the urgency level.

D. Lack of Appropriate Metrics

Reg Ops managers will be able to tell you how many submissions they process per year, but they are unlikely to have accurate data on Cycle Time, Lead Time, Touch Time, Number of Defects, First Pass Acceptance Rate etc. This is largely a cultural issue as historically there has been much focus on Compliance and little focus on Operational Excellence. Data collection is seen as a burdensome activity and to many the value of collecting information routinely is not clear.

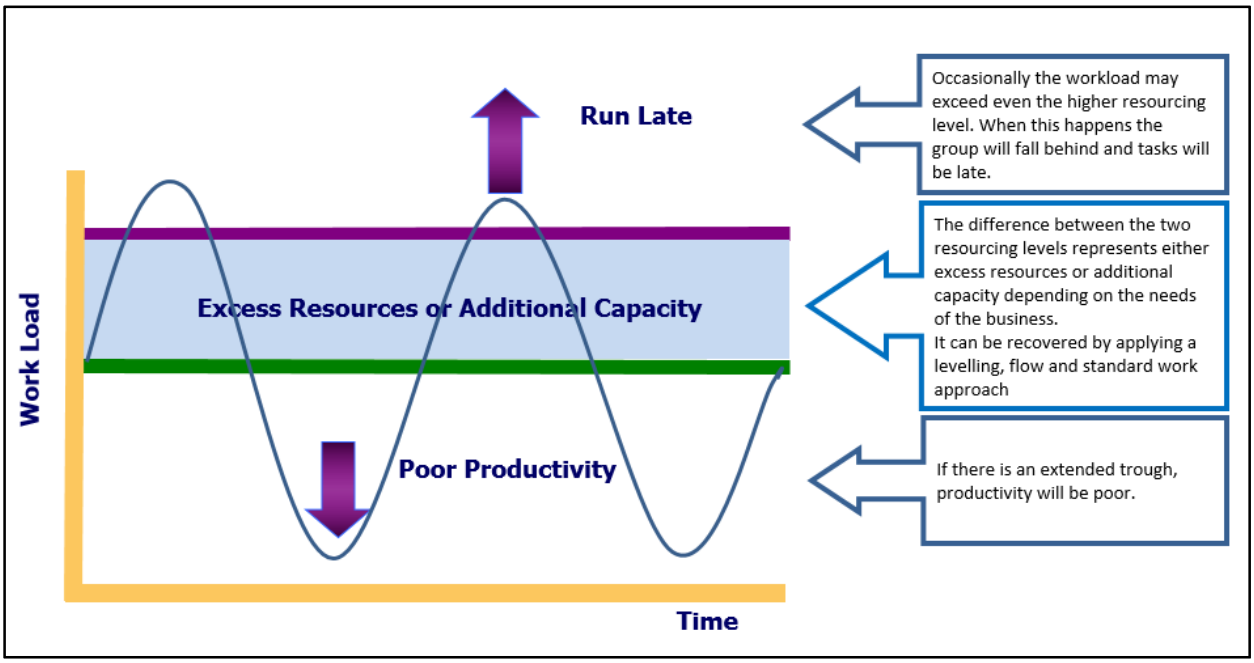

Fig. 1. Workload Volatility Graph.

This graph displays the impact of volatility in the workload. The hypothetical sine wave profile represents a workload that is highly variable and consequently difficult to resource efficiently. BSM find that most groups that are subject to significant volatility will inevitably be over-resourced to enable them to cope with the peaks. The purple line represents the typical level of resource required to manage a volatile workload. Levelling is the process by which we address the volatility and attempt to work to the "levelled demand rate" as indicated by the green line above thereby recovering some/ all of the excess cost.

Countermeasures

We have discussed the many issues that a Lean Project Team is likely to encounter in the Regulatory environment. Key elements of BSM's "Real Lean" solution to address these issues are:

A. Visualise the Workload

The key to visualising the workload is to set up centralised workload queues where ALL tasks required of the group are assessed simultaneously. Another very important but challenging element of this approach is to estimate the work content or size of each task. The combination of the task description, due date and work content in a centralised queue allows the manager to make decisions on who has the skill set and capacity to take on tasks prior to assigning thus avoiding overburden or under utilization. It also allows managers to make decisions on which tasks are priority for the business during periods of conflict caused by workload peaks.

B. Move to "Task Experts" model

Certain elements of the submission building process are better served by task experts rather than product/country/region experts. By instigating a cultural paradigm shift towards the task expert model, significant improvements in standards and quality can be made in a short space of time. This

has a knock on effect on Productivity and Speed as it is no longer necessary to resolve the same issues over and over again at different sites.

C. Level-Load through Workload Sharing

Once the workload is visualised and quantified, and the task expert ethos has been established, it is now possible to distribute the workload evenly throughout the team and work close to the levelled demand rate. Workload sharing reduces volatility by distributing workload peaks throughout the team thus limiting overburden.

D. Isolate Routine Tasks and Introduce Flow

Even though many submissions and submission related tasks have a highly variable content, many repetitive tasks also occur throughout a product's lifecycle (safety reports, marketing promotional updates *etc)*. We have successfully demonstrated that isolation of routine tasks and development of a system for processing those tasks to the levelled demand rate in a managed workflow can provide significant productivity improvements.

E. Flexible Capacity (Outsourcing)

Our experience is that a model of well managed, flexible outsourcing is very effective in Reg Ops whereby the business decides to what level an activity can be handled efficiently in-house, with anything above that threshold being outsourced on a pay-per-task basis. This system is an efficient, cost-effective levelling tool and is a systematic way of dealing with workload peaks in a volatile workload.

F. Frequent Huddles

Core to a BSM "Real Lean" solution in the QC/QA/R&D/Manufacturing environment is the concept of daily "huddles". These are 10 minute meetings where the manager assembles the team in the functional area and uses visual aids to assign the daily workload, resolve any issues and review performance metrics. The same principle should apply in the Reg Ops environment although the execution is slightly more challenging due to the fact that managers and team members often operate across different locations and time zones. Video conferencing in conjunction with a visually effective, shared workload queue is an important tool to utilise in order to engage all team members in the discussion.

G. Data Collection As Standard (DCAS) and Metrics

The main focus of existing Reg Ops metrics is likely to be Quality and Compliance and there are few metrics that focus on the operational performance of the group. Discipline in recording details such as touch time, cycle time and defects are vital to providing an accurate overview of the real process and enabling the development of meaningful performance metrics. The potential return for the business far outweighs the negatives as Data Collection As Standard (DCAS) enables setting a baseline from which all Continuous Improvement initiatives can be assessed.

H. Effective Project Management and Project Planning

Effective project management is highly beneficial in coordinating large, complex projects or groups of projects that have a downstream impact on the Reg Ops group thus ensuring a more consistent flow

of activity. Project Planners in Labelling Operations for instance, have responsibility for planning and prioritising labelling updates according to the due dates of each project and they also manage the interface between the Project Lead and the Labelling Operations Group. Each "Planner" has responsibility for a subset of the product portfolio and regular Planning Team meetings enable prioritisation of important projects at peak times. They also ensure that the labelling expertise is focused earlier in the process and therefore enforce standards in the quality of inputs into the Labelling group.

Benefits of Lean in Reg Ops

The potential benefits of a Lean Implementation in Reg Ops include;

- Productivity - Improvements of 400% have recently been achieved
- Quality - >2 fold reduction in quality defects achieved
- Compliance - Improved project management and workload visibility can reduce audit observations (e.g. implementation of safety updates in labelling)
- Speed – Introducing Flow and reducing Waste reduces task cycle times
- Work Life Balance Improvements
- Continuous improvement Opportunities become apparent
- Provision of additional services- Freed up resources can be used to provide new services according to the business needs.

Over the past few years, BSM have proven that the benefits of a "Real Lean" transformation in the Regulatory Environment are truly astonishing. To our mind it is no longer a question of whether or not Lean theory applies to RA, this has been proven beyond reasonable doubt. The only question is when are **you** going to use Lean to revitalise and reenergise your Regulatory Affairs Operations groups and gain the competitive advantage that Lean performance brings?

For more information, please contact BSM at:

Ireland
Parkmore Business Park West, Galway
T: + 353 (0) 91 746900 W: www.bsm.ie E: info@bsm.ie

USA

c/o Katz Abosch, 9690 Deereco Rd., St 500, Timonium, MD 21093
T: + 1 410 833 7213 W: www.bsm-usa.com E: info@bsm-usa.com