BPM in Europe

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Integrated Compliance, Quality and Process Management System

Introduction

A piecemeal and fragmented approach to Quality, Compliance and Process improvement causes contention for scarce resources, creates new silos and in some cases parallel management systems. This limits the scale and scope of the benefits to be derived from these programs and equally importantly, the sustainability of initial benefits.

In response to this situation, increasing numbers of organizations are implementing their integrated quality, compliance and process improvement projects / programs under a single enterprise-wide Business Process Management System (BPMS) umbrella.   This approach provides a single, consolidated view of the organization for employees, with transparent links to process governance, risk ratings, and visibility of internal and external quality and compliance requirements.

Could your organization benefit from this approach?

The Current Situation in most Organizations

It is fair to say that today we live in the age of compliance. Companies are faced with a daunting compliance agenda that regulates most operational activities including: Safety, Health and Environment, Financial Information, Privacy, product and sector regulations.   Each of these discrete agendas needs formal and sometimes sizable management programs with specialist internal and external compliance resources to achieve compliance with new and changing regulations. In addition, frequently there are multiple concurrent compliance programs being implemented at any one time, employing different management structures and methodologies – thus Finance manages fiscal compliance, QC manages product compliance, SHE manages Safety, Health and Environment and IT manages information Life Cycle and security, with Marketing and Sales possibly responsible for compliance with privacy legislation. In addition, the complexity of the compliance burden is increased for those with global operations as they need to comply with different regulations in different jurisdictions, resulting in hundreds and sometimes thousands of compliance requirements applying to the enterprise as a whole.

This is the so-called compliance treadmill, with certain higher risk sectors (e.g. civil aviation, life sciences) being subject to more regulation than others. Furthermore, these compliance programs are expensive – the introduction of the Sarbanes Oxley Act was estimated to cost $1M for every $1B of turnover and the on-going cost of compliance in Pharmaceutical manufacturing is estimated at 25% of operational cost.   And there is a seemingly inexorable increasing appetite for even more regulation. Faced with this ever growing compliance burden, organizations are seeking out strategies to manage the compliance agenda and reduce the cost of compliance.

Figure 1. The Corporate Compliance Agenda

Quality Management Systems

In addition to mandatory compliance programs, most organizations have adopted a formal quality accreditation to a Quality Management System (QMS) or Quality Management Framework. These programs provide an internal focus on quality programs and an outward display of the organization's commitment to quality. ISO9001:2008 is, today, the world's most popular quality management framework with hundreds of thousands of organizations accredited to the standard. As an alternative, some European organizations choose to opt for the European Foundation Quality Management (EFQM) and many US organizations embrace the Baldridge Award. Mid-size and larger organizations will choose to adopt more than one framework, standard or methodology (e.g. ITIL for IT and Lean for business operations), creating a complex mosaic of quality initiatives. Few, however implement an overarching governance mechanism for all of these frameworks. Thus it is not that unusual to find that compliance processes in one function differ from that of the same function in a different business unit of the same enterprise.

All of these quality programs require a serious management commitment, they are expensive to implement and maintain and many organizations create a parallel organization to manage the quality management system. Over time, many of these programs become stale, with the quality artifacts being reduced to "shelf-ware" (unused). Some organizations freely admit that their QMS is out of date. Fearing a backlash for abandoning their formal QMS accreditation, they dust off and update the QMS annually - just in time for the standard necessary to pass the annual QMS accreditation renewal inspection. The main reason cited by Quality Managers for the erosion of the QMS is that they cannot meet the sizable challenge of maintaining the currency of the quality system artifacts. Most of the documentation is static, written in archaic language as Standard Operation Procedures (SOPs) or Work Instructions that are buried in content management systems and managed by cumbersome, semi-automated or manual change control processes. To demonstrate their understanding of process – a requirement of ISO 9001:2008 -- many organizations have simply appended a flowchart or process map to the relevant SOPs. Frequently, process maps are unstructured, they are written to different standards and they are not linked or linkable to each other to create an end-to-end view of the process, thus failing to show where the process belongs in the value chain or the organizational process architecture.

Most QMS are implemented and managed locally, even where activities are common to more than one location. In a recent exercise at a large Life Science organization, fourteen separate IT quality management systems were found to exist in the US and European locations.   Further

analysis uncovered eighty-two percent (82%) duplication in these systems, leading one manager to name the ITQMS "the eighth cause of waste" (Lean systems defines waste as "non-value-add" and it identifies seven categories of waste).

BPM / OPEX and Transformation Programs

Then there are the Operational Excellence and Transformation programs. These programs tend to be enterprise-wide, strategic in nature and are in situ for 5-7 years.   They are typically driven by "Head Office" and managed outside of the quality and compliance organizational structures. These programs attract a large on-going investment; require specialist internal and external resources (BPM, Lean and Six Sigma, Project Management), business process management infrastructure and extensive training.   The linkages between these enterprise programs and other change initiatives such as compliance and quality are often unclear and they are sometimes intentionally set up outside of the usual management structures to free them from 'old thinking'.

Discrete Product, Quality and Process Improvement Projects

Finally, in addition to these quality and compliance programs, organizations also manage a plethora of discrete or narrowly focused quality or process improvement projects. These can include incremental improvement, the introduction of industry standards such as the CE mark for a new or existing product, CMMI within an IT function to improve software development outcomes, or a discrete ISO standard such as ISO15489 (Records Management).

The Process Governance Gap

In most organizations, the governance of business processes is immature resulting in sub-optimal control and unnecessary noise and interference within the organization which can also hamper good decision making.   Business processes, like other enterprise assets, should be the subject of comprehensive governance, with individual and group roles and responsibilities documented according to the RACI (Responsible, Accountable, Consulted, Informed) model.

Deficiencies of this Approach

Each of these programs and projects is important in its own right. Maintaining the linkages and understanding the inter-dependencies among these initiatives is currently beyond achieving for most organizations, adding unnecessary risk and possible confusion within the organization. Specifically, a piecemeal approach to Quality and Business Process Improvement:

- o   Creates contention for scarce resources

- o   Creates parallel management systems

- o   Creates additional silos (compliance, quality, Business Process Improvement programs)

- o   Causes duplication of effort in extended enterprises

- o   Limits the scale and scope of the benefits, and equally important - the longer term sustainability of initial benefits.

- o   Waste, which when translated into Euros, affects the bottom line.

The way forward: an Integrated Compliance, Quality and Business Process Management System

Recognizing that each improvement project / program follows a similar change cycle and that process is at the heart of all of these initiatives, there is a small but growing trend towards the development and management of a comprehensive compliance, quality and process improvement projects/ programs achieved by the implementation of an integrated BPMS.   In these management systems, the process architecture is documented: each organizational process is described; ownership is assigned; it is visible and available to all authorized parties; individual processes and process steps are linked to specific regulatory statements, quality framework statements and other artifacts ('how-to' documents, measures etc), as appropriate.

Using this methodology, local variants (process, regulatory and quality) are easily identified where local conditions demand a specific and unique response.

Steps to Adopting an Integrated QMS

There are three main steps required to adopt an integrated QMS:

1. Understand the quality and compliance environment

This task involves the identification of all of the Regulations and Quality Management Frameworks that apply to the organization.   Note that this is not a trivial task in large and/or complex organizations.

Enter *current* versions of all of the compliance and quality statements into the BPMS as controlled artifacts.

Enter current Process Improvement Projects to provide visibility of change projects occurring across the process architecture.

2. Document the enterprise process architecture

Commencing at the very highest level, document the process architecture to level 3 and assign owners to each process and each process step.

3. Link Processes with Compliance, Quality and Process Improvement Programs and projects

Create a link between individual processes / process steps and the relevant compliance and quality standard (where a specific requirement is stated), or the relevant process improvement project, as appropriate. This will enable users and managers of the process instant visibility of activity that is subject to regulation and change.

Assumption

The chosen BPMS is capable of supporting these requirements (most are).

Benefits

Organizations adopting an integrated approach cite the following benefits: reduced cost of compliance; reduction in compliance risk; improved speed of adoption of new regulations and changes to existing regulations; better collaboration and sharing of improved and best practices across the enterprise; removal of duplication of effort across functions, business units, divisions and jurisdictions provide substantial cost savings; it is easier to conduct Process Failure Mode Effects Analysis (PFMEA) and prioritize remediation and improvement initiatives; overlaps between initiatives are visible and easily resolved; the sustainability of improvements is easier for management.

Author

Dee Carri, is an accomplished process and change management executive with over 20 years business experience. Dee is passionate about quality and performance. By enabling others to realize their potential through process and quality methods she has developed a reputation for delivering real value through process-based methods, models and designs.   Dee offers professional services as a consultant, facilitator, speaker and coach. Torque Management is a partner of BPTrends Associates, providing their curriculum in Europe.

During her career Dee has held a number of senior management positions: Gartner UK as Consulting Director PA Consulting Group as e-business development Director, Elan Corporation plc as Vice President Information Technology, and board member Elan Pharma Ltd.

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