Compliance-First Approach and Quality Silos are Obstacles to Improving Product Quality

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Axendia recently completed a research study on "Quality Management System Trends in Life Sciences". The study identified the state of current Quality Management System (QMS) implementations across Life Sciences and their impact on product quality, regulatory risk and adverse event exposure.

We will be sharing key insights and conclusions from the "Quality Management System Trends in Life Sciences" research study in a series of briefings, webinars and articles.

In this Research Alert, we focus on three key findings from this QMS research:

1. The use of QMS to author quality records and document compliance with regulatory requirements.
2. The need to create a consistent QMS infrastructure which provides global visibility from multiple sites and across functional areas.
3. The lack of QMS integration has created another "silo"

## Don't Just Create Quality Records - Improve Product Quality.

The survey shows that over 95% of Life-Science Companies have implemented some QMS functionality. Respondents reported the use of QMS to manage the following functions:

- 69% Document Management
- 64% Calibration
- 63% Complaints/Adverse Events
- 58% CAPA
- 54% Training
- 53% Maintenance

The challenge is that in most cases, a QMS is primarily used to author quality records and document compliance with regulatory requirements.

Although, 70% of respondents stated that "Higher product quality and more consistent processes" were key reasons for implementing a QMS, 67% listed "Regulatory Requirements" as a close second.

Our analysis shows that in the vast majority of Life-Science Organizations, "Higher product quality and more consistent processes" is **not** one of the actual benefits achieved:
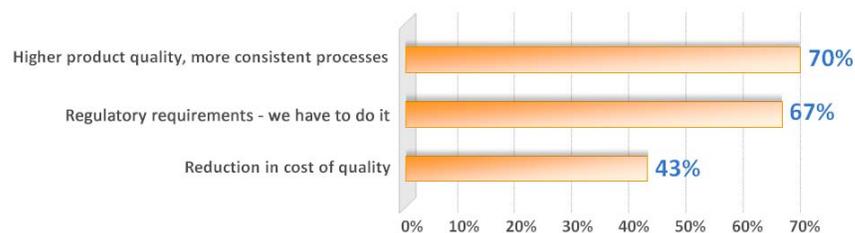
- Only 33% experienced a reduction in number of CAPAs since the implementation of QMS.
- 3% of organizations use their QMS as a tool to "Predict" Quality Issues a majority of the time.

QMS, "The New Silo"?

Data shows that in a vast majority of implementations, QM Systems were installed as silos with little integration to operational systems. This approach creates islands of information.   When asked about current integration point for QMS,

- 37% have integrated QMS with Enterprise Resource Planning (ERP)
- 27% have integrated QMS with Manufacturing Execution Systems (MES)
- 25% have integrated QMS with Supply Change Management (SCM)

When asked about desired integration points,

- 31% would like to integrate with their MES
- 29% would like to integrate with their SCM
- 28% would like to integrate with their PLM or LIMS

This silo approach makes the QMS system unable to manage the containment, enforcement, and disposition of product to address a CAPA. Furthermore, it makes it difficult to prevent the same issue from recurring. This is evident by the fact that **93%** of respondents reported the reoccurrence of issues after a CAPA has been closed in their QMS.

Fragmented View of QMS

According to the survey, QMS implementations in most Life-Science organizations are fragmented. While typical QMS implementations provide visibility at the local level, they fall short to deliver global visibility. This is especially significant, given that 75% of respondents belong to multi-site organizations.

For those companies that have multiple sites our survey shows that:

- Only 34% can roll up QMS data from multiple locations in real time
- 37% need to aggregate the data from multiple locations
- 29% say it is not possible to rollup data from multiple locations

The business impact of fragmented QMS is aggravated by the "Modus Operandi" companies employ to manage non-conformances and product disposition today (or in the worst-case scenario of a recall).

Need to Aggregate Data **37%**

Not Possible **29%**

Yes, in real time *Only* **34%**

In most organizations, the affected lot or batch is quarantined until the non-conformance is addressed. If the source of the non-conformance is shared across multiple locations (like in the case of a raw material or component supplied to multiple sites) organizations tend to cast a wide net over potentially affected product.

In the worst case scenario of a recall, the lack of global visibility makes it difficult to quickly and definitively identify affected product.

The ability to analyze real-time QMS data across multiple sites, locations and organizational functional areas is a key a requirement, ***not a luxury***.

This methodology will yield:

- A coherent approach to data collection and analysis
- The ability to identify patterns and trends across multiple facilities before they become non-conformances and CAPAs
- Reliable action plans that meet regulatory requirements and improved product quality.
- A consistent platform to provide a global and uniform QMS language.
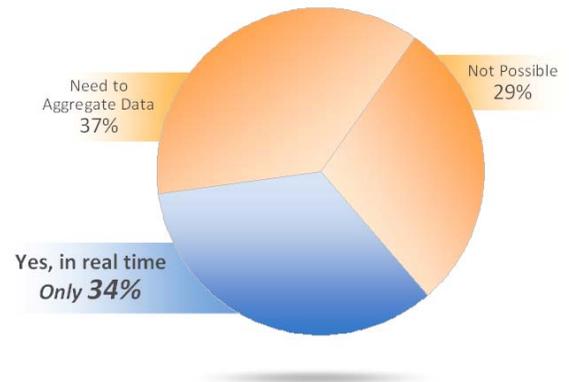
Conclusions

Although Life-Science Companies have been implementing QMS since the
adverse events reported to the agency. http://www.fda.gov/Cder/aers/st

Despite the FDA's focus on QMS (especially CAPA), at present, there
seems to be no positive correlation between the wide spread use of
these systems and the quality the product reaching the public.

Enabling QMS to positively impact product quality requires Life-
Science organizations to:

△ Shift QMS's primary function from "Documenting" quality and
regulatory events to "Managing and Preventing Quality Issues"

△ Correct QMS fragmentation by employing systems that provide global visibility in real-time. This would allow identification of
patterns and trends across multiple facilities to address them before they become non-conformances and CAPAs.

△ Implement open architectures that enable and support integration of multiple systems to provide global visibility from multiple
sites and across organizational boundaries.

△ Integrate QMS with operational systems (like ERP, MES and PLM). Thus enabling containment, enforcement and disposition of
product to facilitate CAPA implementation and prevent recurrence.

This model to QMS implementation will enable Life-Science organizations to improve product quality and financial performance, while
continuing to meet regulatory requirements.
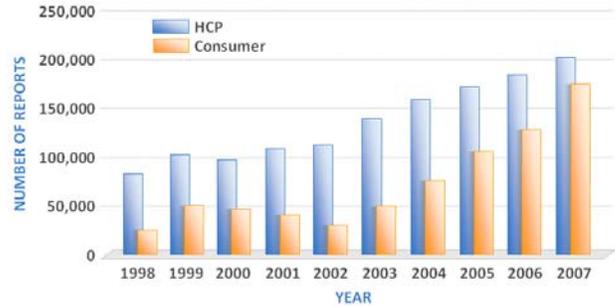
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