Keith Matthews, Director, Quality Systems

Developing a Quality System on a Managed Budget

Insights on driving value from staffing, automation & continuous improvement

Developing a quality system is the foundation for ensuring the organization's products or services are safe, effective and controlled to deliver customer satisfaction. Throughout the organization's lifecycle, from start-up through maturity, the quality needs of the firm, along with its budget constraints, are continually evolving. Maintaining compliance with regulations while controlling costs represents a challenging balancing act we encounter in our life science consultancy. The most successful firms apply critical assessment of their needs and gaps at present and in the future, and deploy a risk-based approach to their quality system.

Upfront Planning Avoids Costly Surprises

Before establishing a quality system, it's critical to identify the quality standards, regulations and/or requirements surrounding the company's products, service and business needs. The checklist in Table 1 provides some common areas to consider.

If your organization already has a quality system, perform a gap analysis against your identified standards/requirements per Table 1. If your quality team could benefit from an external assessment, consider hiring an experienced consultant or firm to provide expertise in the gap analysis.

If your organization is or will be manufacturing or distributing internationally, global considerations will add complexity to your quality system. For example, the following considerations can greatly impact the complexity of the quality system; European Union, ISO 13485, Canadian Medical Devices Regulations, Brazilian GMP, and Japanese Ordinance #169, and others.

Phased Enhancements: Spread the Spend Over Time

Adopting a phased approach allows firms to meet the basic requirements for the quality management system (QMS), see Table 2, with the expectation of continuous improvement from periodic assessments and modification. Some firms plan on annual or other milestones to analyze and implement upgrades to the QMS. With this phased approach, companies are better equipped to finance upgrades, often requiring more people and/or resources, to continuously improve the quality system.

Maximizing Value from Staffing

Typically human resources represent the largest line item in the quality department budget. Firms typically hire employees, contractors or specialized consultants to perform the needs of the quality function. Some considerations:

- Quality System Leader – The organization requires a competent and knowledgeable individual as the quality system leader(s) who may implement the QMS, keep the system compliant, and seek ongoing improvement.
    - Based on the lifecycle of the organization, the Quality System Leader may be tasked with implementing the QMS or just maintaining the QMS going forward. This could be two different skill sets.
    - Tip: Early stage companies can benefit from outsourcing development of the QMS to highly experienced quality consultants and then transition maintenance of the QMS to less expensive in-house personnel.
- Skill Assessment – By analyzing the skill sets of in-house quality personnel against needs, firms can identify gaps and develop solutions. A few considerations:
    - Can current staff be trained? Training represents an upfront cost but offers long term payoff.
    - If training cannot close the gaps, consider whether the needed skill set is temporary or long term. Temporary gaps can be closed cost effectively through hiring of contractors or consultants to provide specialized knowledge without paying for a full-time employee. Such expertise can be used for:
        - Internal and external Audits
        - Training of key topics or necessary regulations
        - Medical liaison for complaints, clinical, etc.
        - Other complaint handling needs
        - High demand activities like remediation, CAPA, FDA audit, medical knowledge, project management
        - Inspectors and inspection processes

If skill gaps are long term and full-time, consider hiring qualified employees.

Maximizing Value from Automation

QMS Manual – Various ISO standards and FDA QSR's require a QMS manual which outlines the various policies and procedures used in the company to produce quality outcomes. Some firms minimize cost of developing the QMS manual by purchasing templates and customizing to their needs. In carve outs or subsidiaries, we've seen the new company save money by adopting a modified QMS of the parent company. While adopting a QMS from the parent company can jump-start development of the manual, we've also seen the new companies struggle to right-size the manual to their needs.

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Electronic Systems – Quality systems are often controlled manually, electronically, or with a hybrid combination of the two. Any of these approaches can drive compliance and offer cost-savings, depending on the scale, complexity, and needs of the organization's quality system.

We've worked with a myriad of firms across their lifecycle and budget constraints, and can offer some pros/cons of the various approaches in Table 3. Below are some general guidelines for maximizing value through automation.

- Start-up or early stage organizations can benefit from basic manual systems or hybrid systems that automate some of the more labor-intensive quality functions such as document control.

- Mid market organizations can benefit from increased automation through hybrid or enterprise QMS systems that address multiple quality needs such as document control, deviations control, non-conformance, equipment calibration, equipment maintenance orders, audit, CAPA, change control, training and functions that control product outputs.
- Large organizations can benefit from enterprise QMS systems and integrating those systems with their ERP systems for even greater interoperability.

In working with digital systems, our clients have found web-based options can require less IT support than network or client-server systems. These web-based systems can encounter less organizational push back than networked systems, especially from companies experiencing IT fatigue from automating other non-quality functions.

Generally automation projects are cost-justified on their labor savings, and this is typically the case with automating quality systems. However, the automation offers greater value by enabling organizations to focus more on driving quality than reacting or reporting metrics. For example, many digital systems provide automated scorecards and dashboards that highlight quality trouble spots, monitor cost of compliance, and provide deeper visibility into the supplier quality. With these insights, organizations can leverage more opportunities to improve strategic quality management.

Don't under-estimate the change management for staff in adopting electronic systems, especially if the company has been using non automated systems for an extended period of time. Consider investing in training and change management services from experienced consultants familiar with your digital system to ease the learning curve.

Maximizing Value from Continuous Improvement

Once your quality system has been developed and managed through your budget process, it is important the entire system is audited to assure your systems and resources fully meet the level of compliance against the company's standards and regulations. Typically the initial audit should be planned at 3-6 months after implementing the QMS to give the organization time to get up to speed.

In this first true test of the quality system, companies need to make sure the quality system is compliant, complete and meets the planned budget. There are trade-offs of internally conducting the audit versus outsourcing the audit to a well-qualified quality consultancy. It's less expensive to conduct internal audits with a competent internal auditor than an external expert. Table 4 outlines the considerations.

Continual improvements to the quality system allow the organization ongoing opportunity to assess and enhance the system based on feedback from a number of different areas which typically include:

- Internal and external Audits program
- Complaints
- Customer feedback

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- CAPA system
- Product or process non-conformances
- Processing data
- Enforcement activity such as a FDA 483 or Warning Letter
- Costs relative to the budget

Companies often adopt a risk based approach in evaluating and implementing improvements to maximize value and minimize risk of noncompliance.

Budget Maximizing Tips

Regardless of careful planning and prudent management of the quality function, quality leaders are sometimes required to trim their budgets. A few short-term areas to consider:

- Travel
  - Limiting travel by employees and choosing local contractors or consultants to minimize this expense.

- For organizations with multiple locations, consider leveraging the geography of the company's quality personnel. For example, if facility A has an out-of-state supplier located near sister facility B, then facility A might be able to tap into the facility B personnel to perform the supplier audit. The travel savings could offset the cost to quality facility B personnel on the QMS audit.

- Training
  - Delaying training can minimize this expense. Although it can be less expensive in the long run to raise the skill set of your employees in areas such as internal audits, some companies trim budgets by foregoing to deferring training.
  - Group training is another possibility to minimize training expense. By training all your employees at once, companies can negotiate reduced training fees and may possibly eliminate department travel by having a trainer come on-site to the company.
    - Delaying supplier audits – Sometimes audits can be scheduled to the next quarter or early next year to save expense based on the acceptable risk exposure.
    - Group Input – The quality team is the cornerstone of the QMS. Engaging these internal experts can identify creative opportunities to trim expenses while minimizing risk.

Today's Quality leaders are responsible for managing the organization's compliance and cost of quality, while driving customer satisfaction and maximizing their department budgets. Careful planning and judicious use of human capital and other resources are critical in deploying a risk-based strategy that delivers organizational results.

About the Author: *Keith Matthews is Director of Quality Systems at Regulatory Compliance Associates® Inc. He brings over 25 years of medical device industry experience in various quality management roles. Keith can be reached at k.matthews@rcainc.com or at (262) 288-6300.*

TABLE 1

Planning Checklist for Quality System Development
Geography – in which countries does the company manufacture, distribute or conduct business?
Type of product or service such as medical device, pharmaceutical, combination product, cosmetic, nutraceutical, service, or other?
Use setting – is the product used at home and/or institutional settings?
Regulatory Agencies – Registration with FDA, EPA, etc.
Standards – Certify to an international standard (i.e. ISO 9001, 13485 or other) Is there a competitive advantage/or required to be register?
Manufacture in-house or outsource to another manufacturer?

TABLE 2

Main Elements of a Quality System
Management responsibility and commitment to the QMS, ensuring ongoing communication to and support from the organization to follow the quality system
Resource management – ensuring the right people are doing the right things
Employee competence against their job requirements
Product realization – how is the product or service developed, transferred to manufacturing, and delivered to the customer while providing safety and efficacy
Evaluation – Metrics from the quality system to assure compliant product, customer satisfaction, and drive continuous improvement

TABLE 3

Insights on Various Quality System Automation Types

Type	Pros	Cons
Manual, paper-based	Low cost Easily changeable	Time consuming Cumbersome as data grows
Stand-alone systems-typically one or a few functions such as CAPA or Document Control	Relatively low cost Effective for key single systems Generally requires minimal configuration, works right out-of-the box	Minimal adaptability No integration with other quality functions
Enterprise Quality Systems	Automates the entire quality function Modules are integrated Some systems integrate with the company's ERP system	Costly More resources/expertise to implement and maintain

TABLE 4

Internal versus External Auditing

Audit Resource Type*	Pros	Cons
Internal	Minimal additional cost More flexible scheduling	Staff diverted from other responsibilities Not objective discovery
External	Objective Brings Industry perspective Well versed in audit process	Cost Timing not as flexible

*Assuming both types are qualified and competent