



# Finding the Ideal Balance – “Where Risk and Cost of Quality Meet”

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What is the answer to improve value for customers and reducing overall costs? Part of the answer resides within the functional activities of risk and cost of quality management. These critical processes are needed to reach and maintain the optimum operating space, and provide the value customers seek. Common challenges to effectively pull these two processes together are similar in most organizations, but the strategies implemented to identify and mitigate these challenges is somewhat unique to every organization and often is not fully realized. Thoughtful evaluation of risks facing a program enables appropriate identification of impending threats. Such a process of risk assessment works as an offensive discipline that helps to create a robust risk mitigation framework. Efficient implementation of a risk-based mitigation strategy creates a competitive cost of quality advantage that optimizes the value for both the customer and contract manufacturer. On the other hand, poor implementation and execution of risk and quality cost management can result in direct financial loss. This represents opportunities.

## **Cost of Quality (COQ) – “Landing on the sweet spot”**

The total cost of quality is a financial model of the costs incurred to operate and maintain the function of quality in a business. Typically, in contract manufacturing, tracking and maintaining visibility of these costs regularly is critical. The cost of quality model takes into account all of the quality assurance activities a typical company would perform in providing goods and services to its customers. It is a process that measures and determines where and how resources are utilized in the overall product assurance scheme. On the top of page 2 is a high-level illustration of the cost of quality categories.

The competitive pressures facing firms in today's environment have led to a desire for extremely high outgoing quality levels. As a result, the cost of quality footprint is created broad and wide, and the outputs of risk management help justify and direct those costs. The total costs of quality have been estimated

by Kent (2005) at 5-15 percent for companies in Great Britain, by Crosby (1984) at 20-35 percent of sales for manufacturing and service companies in the USA, and by Feigenbaum (2001) at 10 percent of revenues. Even the most conservative of these estimates might exceed a company's net profit and highlights the potential importance of COQ. In recent years, the importance of the quality-related costs has been closely managed because they represent a considerable proportion of a company's total costs and sales.

## **A diligent risk assessment process represents opportunities:**

- Avoiding unchallenged risks and customer dissatisfactions
- Identifying potential problems at early stages
- Utilizing risk mapping to gain future business benefits through innovation and growth

## Basic Cost of Quality Breakdown

### Cost of Good Quality

(Realized due to preventative measures)

#### Appraisal Costs

- Inspection (All)
- Calibration
- Auditing – Internal/Supplier
- Registrations/Certifications

#### Prevention Costs

- Risk Management – Process FMEA
- Advance Quality Planning (AQP)
- Capability Studies/Design for Manufacturability (DFM)
- Training

### Cost of Poor Quality

(Realized due to failures and escapes)

#### Internal Failure Costs

- Rework
- Scrap
- Supplier Corrective Actions
- Material Review Boards (MRB)

#### External Failure Costs

- Product Returns
- Customer Complaints
- Corrective/Preventive Actions
- Recalls

### Several factors help drive commitment and action to find that balance:

1. Overall costs that the organization incurs while trying to achieve and maintain acceptable outgoing quality levels can impact margins supporting a positive bottom line
2. Deploying the cost of quality helps to derive a competitive advantage
3. Investing in the cost of quality and itemizing risk appropriately, we ensure that potential failures are reduced and defects eliminated
4. Seeking the balance between risk and costs can help eliminate waste and make operations more efficient

### Risk Management – “The Critical Analysis”

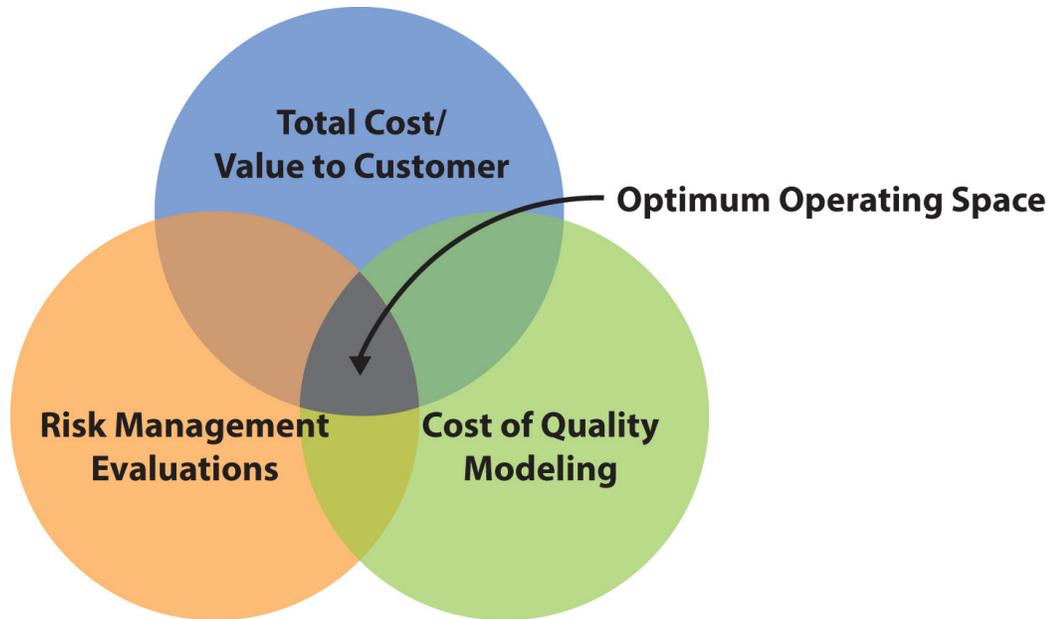
Risk Management is the identification, evaluation and prioritization of risks (defined in ISO 14971) followed by coordinated and economical application of resources to minimize, monitor and control the probability or impact of unfortunate events or to maximize the realization of overall customer satisfaction. In contract manufacturing, partnering with customers to identify and systematically score product specifications will ultimately identify process risk appropriately. This critical breakdown of risk(s) generally starts with a review of the final products Clinical Effects Analysis (CEA) which defines the critical impacts of use of the product in the clinical environment. Customers will typically use this information to help construct their products Design Failure Modes and Effects Analysis

(DFMEA) or similar product risk analysis tool. Using that input in partnership with the customer, allows development of the associated Process Failure Modes and Effects Analysis (PFMEA). Once these tools are assembled, it is imperative to find a balance between the required risk activities/controls, and the costs required to implement and maintain the levels of desired quality. This level of interaction, balancing, and transparency is needed throughout the product life cycle.

### In contract manufacturing, six key considerations are needed when aligning risk to costs:

1. **Obtain the complete picture in terms of both clinical and product design risk early** - Getting a late start on risk management is a mistake, no matter the reason. Failure to identify and mitigate appropriately could delay product launch or cause companies to select suboptimal risk mitigation strategies in haste.
2. **Review identified Critical to Quality (CTQ's) and do not over or under specify** - Having more CTQ's than necessary can drive unnecessary activities and costs, while not including a critical risk can result in unintended consequences and become a cost of quality driver.

## Model of Optimum Quality Costs



3. **Use upstream process source controls when possible, in lieu of post-production verification controls (Inspection), and use validation work strategically to justify final control plans** –
  - a. It decreases the risk of defect costs
  - b. It decreases the risk of additional appraisal costs
  - c. A fully validated process may require less in-process controls and end product testing
4. **Eliminate human and manual controls where possible** – Being able to eliminate human error and provide a platform for repeatability will better support COQ management.
5. **Use design for manufacturability and capability studies to help bracket risk and remove quality control costs** – Making products easier to manufacture and understanding process capability/variability can play a significant role.
6. **Make advance quality planning an essential part of product risk planning** - Understanding customer needs, obtaining proactive feedback and reviewing similar post corrective actions, designing within process capabilities, analyzing and mitigating failure modes, performing verification and validation, conducting design reviews, and controlling special/critical characteristics are essential in specifying overall risk and the associated costs of quality.

### Conclusion

In contract manufacturing, as in most businesses, cost, quality, and time are key components around many decisions. It is imperative that we take the inputs from advance quality planning, and apply a robust risk management process to build a cost of quality model that takes advantage of all mitigation opportunities. The lack of performing these activities can certainly drive costs, reduce margins and erode customer value. Analyzing and improving this process is part of an ongoing journey towards improved quality and efficiency that ultimately contributes to profit. It's a process of continuous improvement, and every business has room for at least some improvement.



**JD Williams**  
Vice President Quality and  
Regulatory

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715.247.3500  
jimmy.williams@smcltd.com

**SMC<sup>®</sup> Ltd.**

330 SMC Drive  
Somerset, WI 54025  
715.247.3500  
inquiry@smcltd.com  
www.smcltd.com