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NSF Health Sciences Pharma Biotech Consulting

The importance of COPQ for the pharmaceutical industry

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Introduction

As any senior executive within an organisation knows, the reduction of waste and, more importantly, the cost associated with that waste can have a major effect on any business. Whilst some waste is unavoidable, an executive can begin to implement principals to eliminate this additional "cost of poor quality" (COPQ) by considering which costs would be eliminated if every system, process and product in the business were run at maximum optimisation. In the pharmaceutical industry, it is not uncommon for such costs to range between 25 and 40 percent of total sales revenue[1] and yet reducing the COPQ is not a well understood or implemented practice.

WHAT is COPQ

Ever since Feigenbaum[2] first suggested the concept of "quality costs" as a means to quantify the total cost of quality-related efforts and deficiencies in 1956, one common misconception has been that a good quality product is automatically more expensive to produce than a lower quality product. As such, Harrington[3] adopted the term "poor quality costs" in order to emphasise the fact that investment in the detection and prevention of failures is more than compensated by the savings made by reductions in product failures.

As a basic example, **Figure 1** shows that the cost of ensuring a good quality product increases exponentially with higher quality products.

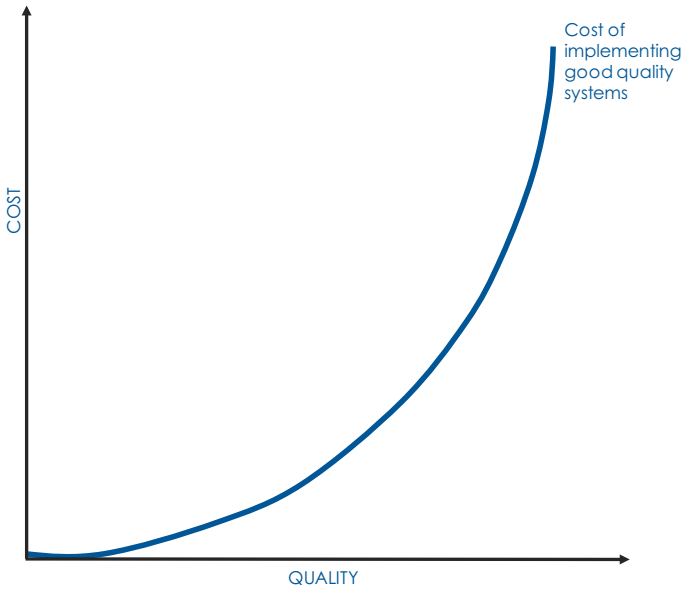

FIGURE 1: THE COST OF IMPLEMENTING QUALITY

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Conversely, **Figure 2** shows that the cost of rectifying errors reduces exponentially for higher quality products.

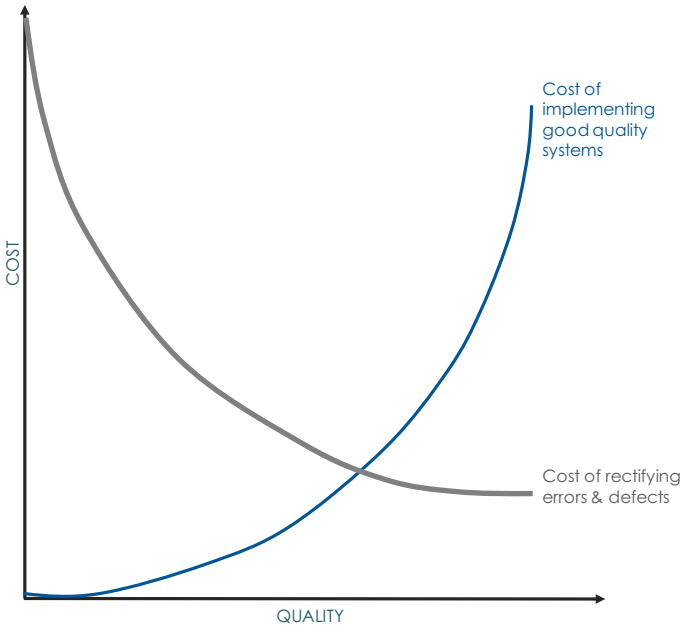

FIGURE 2: THE COST OF ERRORS

Both the increased costs of a good quality product and the potential savings of having fewer errors to rectify demonstrate Harrington's point.

COPQ is increasingly valuable for the pharmaceutical and medical device industries, where maximising product quality is paramount and defect reduction has an additional knock-on effect that can in turn reduce design and development time, the number of validation processes, changes during manufacture, wastage and the number of tests and inspections required. These combine to bring the grey line in Figure 2 even lower.

Calculating COPQ

There are four key areas where the cost of material and labour must be identified in order to calculate COPQ:

- Prevention
- Appraisal
- Internal failures
- External failures

Calculating the costs associated with each of these four key areas can be done via a large number of processes, each of which will contribute to the quality improvement. Naturally, there are many means by which these costs can be calculated, and **Figure 3** suggests some common processes that a manufacturer can implement.

Prevention

- Surveys
- Voice-of-customer analysis
- Prototyping
- Automated design & testing tools
- Quality training
- Review checklists
- Defensive design

Appraisal

- Inspection costs
- Quality system
- Development defect costs
- Production defect costs

Internal Failures

- Poor testing
- Addressing development defects
- Poor validation
- Addressing production defects
- Design defects
- Requirements
- Inspection issues

External Failures

- Servicing
- User-identified defects
- Complaints
- Correction filling and addressing
- Field corrective actions

FIGURE 3: COMMON METHODS TO ESTABLISH THE COST OF COPQ

In addition to the cost calculations carried out for the four key areas, manufacturers should also consider additional costs arising from corrective actions, subsequent quality assurance and control activities, and corrective actions for failures.

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What to do with COPQ data

The primary goal of COPQ calculation is to define preventative actions that, as well as optimising overall product quality, reduce defects and in turn costs.

How NSF Health Sciences can help you with COPQ

It is important to remember that COPQ is not without its limitations, and has associated costs that can be difficult to quantify. Yet the realities of increased time to market, poor product reputation or wasted storage facility space make it essential to understand as much as possible about an organisation's product production in order to apply COPQ and reduce costs overall. Whilst this paper provides a brief introduction to the topic, learning from an experienced individual could benefit an organisation hugely. John Johnson, FRSC CChem MIQA, a Corporate Quality Assurance Specialist with nearly 20 years of international senior quality experience, is a great advocate for applying the COPQ model to the pharmaceutical industry.

NSF Health Sciences Pharma Biotech Consulting offers a training course that aims to provide the tools required for developing a strategy that drives organisational change, business excellence and cost reduction whilst maintaining cGMP and product quality. This course is also available on-site.

> " It's possible to make significant savings to product production via the implementation of COPQ. In one example, I was able to implement changes that lead to 43 percent bottom-line saving, to the value of £957,000 over a relatively brief [30-month] period. "[1]
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References

1 Johnson, J: **2015**. *Personal correspondence.*

2 Feigenbaum, AV: **1956**. Total Quality Control. *Harvard Business Review*, **34**(6).

3 Harrington, JH: **1987**. Poor-Quality Cost. *American Society for Quality*, **ISBN 978-0-8247-7743-2**.

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