WHAT DOES POOR QUALITY COST?

by Jesse Ahrendt

The cost of quality. A simple statement and yet few companies in the pharmaceutical manufacturing industry are paying close enough attention to this concept. Corporate focus, and rightly so at times, is for the most part focused on compliance and meeting regulatory requirements to sell products across the globe. Those compliance regulations require companies to perform at a prescribed level and maintain certain required systems.

Some of those quality systems include familiar functions such as incoming inspections, preventative maintenance and calibrations, complaints and returns, recalls, inspection and CAPA teams, environmental monitoring, rework and reprocessing. These are supportive systems that every company must have to maintain its overall compliance with industry expectations, but they come with their own internal costs. These are generally highly visible, obvious items and are easily shown on financial statements, often with a simple calculation of the total number of employees, their time allocated to these tasks and their respective fully-loaded salaries for each system or group. There are however a significant amount of hidden and less obvious costs that come along with those systems. These costs can be very large, depending directly on the level of quality in each respective area. When these costs are high, they are directly tied to the concept of poor quality.

THE REALITY OF THE COST OF POOR QUALITY

Poor quality costs have many hidden sources. For instance, in a recent situation, a client was experiencing a very large number of non-conformance investigations on the order of 2,000 to 3,000 per month. An investigation into this issue identified numerous underlying issues with the deviation processing systems, including inconsistent coding for non-conformances, superficial investigations that lacked root cause analysis, lack of effectiveness checks, lack of any formal training

for investigators and simply an overwhelmed quality group. The costs associated with repeat deviations, rejected product, human investigation time, excessive planning to accommodate the workloads and employee turnover were massive.

But how are these costs identified/calculated and what impact can they have? When discussing a methodology like the cost of quality it is sometimes easier to consider the rising costs of allowing a single defect to be processed through a manufacturing system. It is understood in the manufacturing industry by most quality experts that the cost of a defect will increase ten times at every major processing point if it is not caught. Simply stated, if a product defect is not prevented, perhaps during an incoming inspection or a routine monitoring process, it will cost ten times more to address the problem during production via rework, reprocessing and/or investigation time. If the defect was not caught internally and the impacted product was distributed, the cost to remedy the defect via return, recall and investigation would be another ten times, resulting in a 100-fold cost increase versus having prevented the problem initially.

This illustrates that if a company can spend $10,000 to prevent a defect, it could avert spending $100,000 to correct the problem internally and $1,000,000 to address the problem once the product has been

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distributed. This scenario illustrates the larger ROI potential that exists when companies focus their efforts and resources on prevention of defects in their processes.

NSF RECOMMENDATIONS

Given these benefits, how does NSF recommend companies begin to identify and tackle the cost of poor quality (COPQ) opportunity that exists within their organizations? First we recommend that companies identify what their baseline COPQ is, which will require an evaluation of existing processes and their associated costs. This exercise will also help the effort to get further traction from senior management once they realize the substantial hidden costs attributed to poor quality. NSF's approach is to group quality costs into four main categories: prevention, internal failures, external failures and appraisal costs. These four groups and our methodology are detailed in the **Cost of Quality: Can We Really Afford to Ignore It?** white paper written by NSF's Andy Barnett – visit **www.nsf.org/info/pblibrary**.

Once the baseline has been established, a strategic plan must be developed to explore the opportunities for improvement that became readily visible via the COPQ baseline. Opportunities to eliminate defects are prioritized and poor quality is eliminated from the processes, which is the intended outcome. The ROI on projects our experts at NSF have undertaken have been staggering, typically ranging from 10 to 60 times!

NSF is passionate about the COPQ and is here to partner with and assist clients in their ultimate success, both in the role of compliance experts (which we are perhaps better known as) and in facilitating a targeted reduction in poor quality within their organizations. Targeting and eliminating hidden quality costs at all points along the manufacturing process should be a priority for any successful pharmaceutical/biotechnology company. We look forward to any inquiries and questions your organization may have on how to conduct and measure your own cost of poor quality initiative.

Contact us at **USpharma@nsf.org**.

ABOUT THE AUTHOR

Jesse Ahrendt is an experienced industry consultant with over 15 years of active engagement in pharmaceuticals, biologics, medical devices and biotechnology as a certified Quality Auditor and Quality Engineer. His areas of expertise include QA compliance, third-party vendor evaluation, cGMP manufacturing, quality systems and quality auditing including validation, deviation/CAPA/EC, auditing/mock inspection, supplier qualification and QMS/risk assessment/SOPs. Mr. Ahrendt is an accomplished quality assurance and manufacturing improvement innovation leader who optimizes organizational resources. He has spearheaded organizational strategic quality assurance, manufacturing, vendor quality and supply chain operation optimization.

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