



# THE COST OF QUALITY: CAN WE REALLY AFFORD TO IGNORE IT?

by Andy Barnett

## SOME PERSONAL EXPERIENCES

If prevention is 100 times cheaper than external failures, why isn't management pushing for prevention? In a former role as a Division Quality Manager, I asked my engineers to invest at least 10 percent of their time on prevention activities. Just four hours every week. Frankly, I was tired of fighting fires and I was willing to let a few fires burn to prevent more fires in the future. This simple directive laid the foundation to support improvement and prevention activities, **ultimately adding 8 percent to the bottom line** in just three years. Not a bad return on investment.

In a recent situation, a client was experiencing periodic environmental excursions 10 to 20 times higher than the action limit for nonviable particulates. This had been going on for a long time. I created a trend chart from the data, pinpointed when the problem began and asked for the change log for that day. It turns out the HEPA filter was changed on the day the problem started. During an interview, the person responsible for the filter change mentioned he bent, by accident, a linkage on the filling equipment while making the change. It turned out that the linkage was rubbing and causing a high non-viable particulate count. Total

analysis time – one hour. The **savings in firefighting time and potential batch rejections?** Probably more than **\$500,000**. The trouble is this company, like many others, doesn't bother to measure the cost of quality (COQ).

## COST OF QUALITY: SO HOW IS OUR INDUSTRY DOING?

Jeffrey Macher, Associate Professor at Georgetown University, has some sobering statistics from an industry survey covering a range of dosage forms:

- > Nearly 62 percent of respondents claimed that they do not calculate the cost of poor quality
- > Ninety-two percent said they have not compared the cost of improvement with the cost of poor quality (recalls, rejections, low yield, downtime, etc) which, in our experience can be considerable
- > Twenty-eight percent estimated that a simple failure investigation costs over \$10,000
- > Sixty-five percent estimated that a complex failure investigation will cost over \$100,000. Complaint investigations are even more expensive
- > The costs associated with regulatory sanctions (recalls, import bans, fines, disgorgements and lawsuits) were routinely over \$1M

Many of you liked our recent article "How to Talk to Senior Leaders in a Way They Can't Ignore" (Issue 30 of the Journal). Frank Dollard made it very clear that to influence senior leadership you must know your numbers and speak their language. Just imagine how much easier it would be to convince your leadership teams if you actually costed quality. The cost of doing things right, as well as wrong...and the return on investment.



# HOW TO ESTIMATE QUALITY COSTS: THE BASICS

## FIRST, SOME DEFINITIONS:

1. **Prevention Costs:** Include all prevention costs, such as training, product reviews, quality planning, improvement projects and the use of tools such as failure mode effects analysis (FMEAs), capability studies, process characterization studies, measurement studies, quality by design (QbD) and process analytical technology (PAT) initiatives, etc.
2. **Appraisal Costs:** Include incoming inspection, in-process and final inspection and testing, shelf-life stability studies, audits, calibration, validation studies and the materials and equipment used to complete these activities.
3. **Internal Failures:** Include scrap, rework and re-inspection of non-conforming materials, material review board (MRB) meetings and investigations for failures identified prior to release to the customer.
4. **External Failures:** Include failures detected by the customer including processing returns, customer complaints, recalls, lawsuits, adverse events and any rejected stock in response to a field incident.

To estimate each cost we have a simple choice. We can get very detailed or we can calculate a ballpark estimate as a function of total production costs or as a function of sales. For instance, capture your training costs both in terms of full-time equivalents (FTEs) dedicated to training and hours employees spend on training. To estimate prevention costs or time on proactive activities such as continuous improvement projects, conduct a poll asking engineers and managers how much time they spend on prevention-type activities. Then multiply the FTE by the average fully weighted salary. For most companies, this will be a relatively small number, probably less than 0.5 percent of COQ. It should be much higher! Even this simple example demonstrates one thing: If you invest in prevention, your total cost of quality will actually come down!

- > **For appraisal,** start with the headcount for inspectors (assuming they are a separate function) or use a percentage if production

workers spend a portion of their time in appraisal activities. Multiply the FTE by the fully loaded average labor cost. Use a similar estimate for maintenance personnel who calibrate and maintain automated and semi-automated inspection equipment. For pharmaceutical manufacturers, appraisal costs are higher than many other industries due to regulatory commitments, but these costs probably account for less than 25 percent of total COQ

- > **For internal failures,** obtain the scrap rate as a percentage of production and apply this number to annual sales. In other words, 5 percent scrap is equal to 5 percent of annual sales. If scrap data is not readily available, take a random sample of batch records. Thirty batches should be sufficient for this initial estimate. Down the road, you can refine this estimate, since some products are more expensive than others. This approach will get you in the ballpark without investing in a new reporting system or counting every rejected vial, bag and label. Again, don't get too granular and avoid the tendency to pursue too much detail in the initial stages – simply look at the big picture. Additionally, you should include labor for internal investigations; even simple investigations can cost thousands of dollars
- > **For external failures,** estimate the headcount for conducting complaint/recall investigations and multiply by the typical weighted annual salary. Include the cost of returns, market withdrawals, recalls and a percentage of management costs for regulatory affairs, QC testing and management oversight

Once you have completed these initial estimates, add them up for the total cost of quality. It is important to state the amount in financial terms, rather than a percentage of sales or production quotas. In our experience, this initial estimate will probably understate the true cost. But at this stage, it is more important to gain awareness and establish a baseline.

Senior leaders frankly switch off to compliance risks or risk of regulatory censure. In contrast, just imagine the impact these numbers would have. Leaders are far more likely to support improvement initiatives once they realize the magnitude of the opportunity.



## STRUGGLING TO GET LEADERSHIP SUPPORT? FOCUS ON TAKING THE QUALITY COSTING APPROACH:

- > Start small – don't get bogged down in detail
- > Focus first on eliminating failures. Prioritize projects based on size of opportunity, likelihood of success and ease of implementation
- > Although appraisal costs may represent a significant percentage of total COQ, defer efforts to reduce these until achieving a substantial reduction in failure rates

Over time, success will be measured by reduced internal and external failure rates, gradual reduction in appraisal costs and a greater percentage of the budget devoted to prevention.

Here at NSF we're passionate about helping our clients succeed in a very tough climate. Decisions have to be fast and right. Quality costing, when done well, will prove to be invaluable. Please contact us if you have any questions on how to conduct and measure your COQ. We can also help support your process improvement and process optimization efforts.

If you have any questions or would like more information contact Andy Barnett at [abarnett@nsf.org](mailto:abarnett@nsf.org)

### ABOUT THE AUTHOR



For over 20 years, Andy Barnett has worked with clients in the pharmaceutical, medical device, biologic and biotechnology industries to develop quality assurance and regulatory strategies for compliance with U.S. FDA regulations. His particular expertise includes providing statistical support for process development, process characterization and optimization; assisting with remediation activities, especially corrective actions and process improvement; and providing training in root cause, corrective actions and statistical methods for process improvement. Mr. Barnett has achieved outstanding results in operations, including research & development (R&D), new product development, process design and development, manufacturing and field quality. He is a Certified Six Sigma Master Black Belt and an ASQ Certified Quality Engineer.

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