

Improving Compliance in an Economic Slowdown

By John Avellanet, Managing Director and Principal of [Cerulean Associates LLC](#)

A favorite drumbeat for regulators around the globe is the need for corporate compliance programs and executives to demonstrate continual improvement of their programs and quality systems.

But given the worldwide economic slowdown and the attendant cost-cutting measures in nearly every company, from biotech startups to big pharma, how is improvement to be demonstrated, much less achieved?

There are a number of steps that executives can take to successfully deal with an economic downturn and still achieve a positive, continually improving compliance environment. Here are some tactics from Cerulean's Lean Compliance approach.

Learn from the Past

Economic slowdowns do not affect all regions or industries at the same time; use this to your advantage.

In the 1970's, the US auto-industry went through a severe slump. All the measures we see around us in the pharmaceutical and biotech industries—layoffs, consolidations, outsourcing, exploration of non-core products—occurred in the 1970's in Detroit and elsewhere. However, those same companies are still struggling today.

In contrast, firms like Toyota and Honda did not choose the “panicked slashing” response. While they did look to trim costs, they focused on a more strategic level with an eye toward the longer-term. Quality and continuous improvement were seen as critical to the longer term. Today, these are the two firms dominating the international automobile scene...and will be for the foreseeable future.

What are you doing today to address the slowdown's impact? Cutting costs across the board irrespective of long-term impact? Or have you identified and prioritized areas to strengthen—or at least leave out of the slashing—that are critical to success once you emerge from the slowdown?

Achieving and demonstrating continual improvement in compliance and quality is one such area given the regulatory expectations of continuous improvement.

Prioritize the Budgeted Activities

Once you've recognized that not everything needs the same drastic approach, the next step is to look at your budget and planned activities with a critical eye.

We suggest you prioritize the following: advancing the next product, preferably the one closest to completion; and focusing on approximately 3-5 areas for improvement.

The next product is critical because this may give you the revenue you need to pull away from competitors who are still feeling the economic pinch.

If you're like most executives, you could spend five minutes and list out at least a dozen areas you'd like to see improved—from more controls to more flexibility to faster evaluations and speedier changes.

Prioritize these to the top 3-5 using three criteria:

1. Impact to current product safety, efficacy, quality and production (e.g., efficiency, timeliness, etc.);
2. Impact (as above) to the immediate new product you are trying to get to market; and
3. Resources (cost, time, manpower) required.

As a simple example, suppose there are two potential areas of improvement you are faced with: [1] improving the training process to document measures of effectiveness, and [2] improving the change control process to speed change request evaluations and approvals without lowering the level of control.

Both of these improvements are operationally based. Both improvements will impact the current product's production processes and the new product's processes, and both will require resources to make the improvement and conduct various points of training with follow-ups and monitoring.

However, looking at the three criteria above, improving the training process does not have as great a positive impact as streamlining the change control process does.

Therefore, during an economic slowdown, focus your resources on selecting the improvement with the greatest positive impact that will allow you to "escape" the slowdown the fastest.

Trim Expenses

To be able to justify a strengthening of certain areas while those around you cut across the board, you need to re-double your efforts to trim expenses. In fact, if you can manage to "give back" more monies in budget reviews than many of your colleagues while still strengthening your two priorities for improvement, the cost-cutting focus will shift significantly away from you.

The quickest way to do this is to look at all the expenses you've budgeted in December and November. Are those bills really going to hit and be paid then, or will they (based on your previous experiences) be rolled over to be paid in January? If so, eliminate every single dollar/euro of spending in those months EXCEPT in your two priority categories.

Why leave those priority monies if you know that the bills will likely not hit and be paid until January anyway?

Three reasons:

1. In a pinch, those are dollars/euros you can "give up" if pressed.
2. It helps draw attention to their importance to you and to the company.
3. They can serve as your "buffer" if any other expenses run over toward the end of the year.

It has been my experience when taking this tact, I was always first on the list of folks that Finance called at the end of the year when they had news that the company had a little more money leftover than originally thought, and was there anything I would like to spend it on?

Final Thoughts

There are other tactics you can take as well such as negotiating longer-term contracts, taking upfront payment discounts, and so forth. But these pale in comparison to drawing upon the past to prioritize the present for future success.

Achieving compliance improvements in an economic downturn is about making smart choices that give you—and your company—the biggest bang for the money.

Are you ready?

About the Author

John Avellanet is a former *Fortune 50* subsidiary C-level medical device and biotechnology executive where he created, developed and ran his firm's Records Management and IT departments. In 2006, he founded his independent consulting firm, Cerulean Associates LLC (www.ceruleanllc.com) and has since become one of the leading experts on Quality by Design.