GMP, Quality, Responsibility, Integrity, and Accountability

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GMP – Regulations for the manufacture of pharmaceuticals, medical devices, blood products, biologics, dietary supplements, and food. GMP can be viewed as the foundation for a Quality System.

Quality – distinguishing attributes of products and services which customers desire and are willing to pay for.

Responsibility – moral and legal liability, reliability, trustworthiness.

Integrity – firm adherence to a code of moral and ethical values.

Accountability – to assume the sole and primary factor for the performance of a product or service rendered.

The four words above are interminably linked. It is literally impossible to speak about one without referring to the others. Just check the dictionary definitions for quality, responsibility, integrity, and accountability and you will often find each referenced in the other's definition.

With the economy causing upheaval over the past two years, we have seen too many examples where organizations have drifted away from these four words.

The Cost of a Recall

At the start of 2010, we have seen a huge recall of an iconic brand product – Tylenol. The recall was due to an odor traced to a chemical used on wooden pallets being used in the distribution of the final product.

The manufacturer of Tylenol, McNeil Consumer Healthcare, a Johnson & Johnson company, was accountable and took responsibility by initiating a recall. And at a HUGE cost to the company.

Outside our industry, Toyota, another iconic brand, recalled millions of cars for a sticky accelerator pedal and stopped selling certain models until a

permanent fix is found and implemented. And at a HUGE cost to the company.

Dr. W. Edwards Deming, one of the 20th century's leading quality gurus, often said that the true costs associated with quality problems were unknown and unknowable[i]. Consider the cost to the reputation of both Johnson & Johnson and Toyota. Consider the cost of lost sales of their other products now and in the future. Consider the cost to the pride of the workforce of both companies.

And in the case of McNeil Consumer Healthcare, the cost of responding to the FDA-483 Observation Report and Warning Letter they received in January 2010. It can take years, even decades, to develop a reputation for quality. And a weekend to lose that reputation.

Now consider that in both examples these problems could and should have been avoided. GMP compliance, quality, responsibility, integrity, and accountability are not just necessary at the end of the product trail. They need to be paramount in everything we do - at every step of the process.

Cost Reduction or Optimization?

There is immense pressure due to the economic downturn to reduce costs. However, we need to evaluate the impact of any cost savings on the quality of the product or service.

A good way to approach cost reduction is by working to optimize your systems and processes. Deming defined optimization as "a process of orchestrating the efforts of all components towards the achievement of the stated aim whereby everyone gains."

Deming also warned us about sub-optimization, or what he called Tampering[ii]. Tampering with a stable system ALWAYS makes things worse. The global economic crisis is causing every organization to rethink and reevaluate how they do business.

Too often people implement changes without proper testing or evaluation on how the change may impact stages of the process downstream. The change may have a positive effect at the immediate stage, yet have an overall negative effect to the final product or service.

Although it's an old cliché, it's one that is very timely now – "Work smarter, not harder."

Working smarter means we should strive to optimize our systems and processes. Avoid the knee-jerk reactions, the

quick fixes, the band-aid approaches.

Over the years, we have observed the following four ways to approach problems.

1. Absolve yourself of the problem – "It's not my problem." This is either denial, ignorance, or "passing the buck."
2. Solve the problem – identify and implement the quick fix and apply it.
3. Resolve the problem – identify and implement a permanent solution.
4. Dissolve the problem – resolve the problem (#3 above) and optimize the process or system to prevent its reoccurrence.

Of course, the most effective is #4 – Dissolving the problem. However, it is also the approach applied least frequently.

Dissolving problems requires resources and the discipline to stick with it. The conundrum is that so much time is spent on #2 – Solving the problem by applying the quick fix – that there is no time left to devote to Dissolving the problem.

You should also see in the above example a Corrective and Preventive Action (CAPA) system in that Solving the problem is CA and Dissolving the problem is PA. Too often people in organizations get caught up in CA-CA-CA with no time left for the PA.

They may say they have a CAPA system, and even a policy or Standard Operating Procedure describing their CAPA system, but in practice they have a CA-CA-CA system.

Just review FDA Warning Letters from the past year or two for examples.

GMP Tips

In your GMP training sessions, take time to discuss Quality, Responsibility, Integrity, and Accountability. Go into depth with people into what these words really mean in our industry and at your company.

A general observation I have made in over three decades in the FDA regulated industries is that when companies find themselves in violation of one of the GMP requirements, it almost always comes down to "Somebody didn't do what they were supposed to do."

They either didn't consider Quality to be all that important, or they shirked their Responsibility to do their job properly, or they didn't understand that Integrity is

critical in our industry, or they weren't being held Accountable.

In our trainings with new employees, we stress that it is a privilege to work in an industry where the aim is improving the quality of life, and in many cases, sustaining life itself. And along with that privilege comes an awesome responsibility.

It is the responsibility to 1) know your job well, 2) always do your job properly (which in most cases in our industry means following your procedures), and 3) stop and ask for help when you're not sure how to proceed.

We also stress that whenever you affix your signature or initials on a company document, you are taking on legal liability. You are responsible and accountable for your actions.

This is a good time to reinforce these concepts with existing employees as well. This is especially critical now when we are under immense pressure to improve performance.

Compromising quality by cutting corners and taking shortcuts will ALWAYS lead to increased costs.

If you are not already doing it, integrate the concepts of optimization into your GMP training sessions.

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[i] The New Economics for Industry, Government, Education, Deming, W. Edwards, 1994

[ii] Out of the Crisis, Deming, W. Edwards, 1986

