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Short Communication

Are these Three Fear Factors Holding You Back from Regulatory Compliance?

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In the TV series called "Fear Factor" contestants had to overcome various challenges that most of us found disgusting and/or fearful in order to achieve a large cash prize. If they failed to overcome the challenges presented, their hopes were gone and the contest ended for them. The same can be true for industry in trying to achieve the "cash prize" of being compliant when audited. While the fear factor challenges faced by the contestants was obvious, the fear factors presented to industry are several and each is equal as to its impact. As my disclaimer, these fear factors are not published in any year end regulatory summary but rather are based on what I have encountered working with various clients ranging from big Pharma to the largest cosmetic companies as each strives to claim their compliance to applicable regulations. These fear factors of industry, as demonstrated by their actions, are summarized below.

I don't understand the applicable regulatory requirements

While it may be of a surprise to many, it has become upsetting through years of auditing both suppliers, drug and API manufacturers and others that the first fear factor encountered was a lack of understanding the regulatory or industry requirements that applied to the product made or service provided. In addition, and what was true of many audit findings with the supplier was the fact they were unaware of the regulations to which their customer audited them against, thus raising a challenge to additional requirements to which they had to address. As a supplier, one must realize the nature of the industry they provide their product or service to and what they need to have in place to be "compliant" to their expectations. Because suppliers are not audited by the FDA, the final responsibility lies with the customer. Because of this, not only must they assure the suppler is compliant to the regulations that apply to them, such as ISO or CLIA in the case of laboratories, but that their processes also comply with the quality regulations that cover the product manufactured by their client. That is an expectation that is often challenged.

The most common shortcoming was often found to be in the area of documentation, notification of changes and investigations of any complaints received. I do not mean to imply these observations were true for the many companies, but when found they have a significant impact on the results for both parties. In an attempt to avoid this factor, expectations need to be defined in quality agreements that define the applicable expectations of both parties so there are no surprises when an audit is performed. The FDA has just published its current Guidance to Industry entitled "Contract Manufacturing Arrangements for Drugs: Quality Agreements" (November 2016) which define the importance of such agreements to help assure compliance with cGMPs. If companies had a supplier qualification program, shortcomings should have been noted when performing an on-site audit to evaluate the acceptability of their quality systems for those considered to be critical. As with the other fear factors to follow, proper and adequate venting of potential critical suppliers will certainly help avoid these concerns.

The same is true for drug manufactures and the level of ignorance displayed by some of them relative to entering the sterile product market. In cases like this, their level of understanding remains with the nature of their non-sterile product and wrongly assume there "isn't much difference between the two". This couldn't be further from the truth. Not only do they need to know the US regulations but also those of foreign countries should the product be sold overseas. In many cases, the assumed time line to become compliant is another sign of the lack of understanding of the requirements possessed by management. The typical approach is do it quick, within an unrealistic budget and make sure we meet our desired date. This is certainly not the norm but to think this scenario doesn't exist is also a misconception. I have even been exposed to an attitude that can only be described as "the longer we don't talk about it, the better our chances it will go away".

Of the three fear factors I discuss in this article, this one is probably the easiest to address. It starts with management that is committed to achieving compliance, implementing a strong quality system that is staffed by knowledgeable people and a work force that is trained on the regulations. In my experience, the best run companies are those that have upper management with production experience and a commitment to do things right. Having the manufacturing experience provides a more realistic approach and resolution of deviations and one that tends to better identify probable cause and corrective actions. At the same time, there is no hesitation to quarantine such product when things go awry, despite the pressure to send product out the door. Companies that have this structure are better able to perform a risk assessment of their processes, set priorities based on the levels of risk defined and continually work on achievement and maintenance of their degree of compliance.

I don't have sufficient resources to support the quality system

The second fear factor that is the availability of resources to perform the responsibilities of the quality unit. As supply chains grow and outsourcing of activities increase, there is a growing need to assure that these providers are managed, and that there is assurance that items purchased or services provided meet the expectations of the company. As the activities normally performed at the company are outsourced, there tends to be a reduction in the workforce (often quality) until shortcomings are discovered during an audit. Then the pendulum swings 180° and the quality unit once again swells to a point where efficiency is lost. It seems like the mindset is the larger the quality unit, the better our chances to be compliant. There seems to be little attempt to evaluate whether or not the problem was truly too little resources or lack of managing the workloads of those already employed. (Please note, I certainly respect anyone in quality based on the vast array of responsibilities associated with all quality positions).

The issue of resources is most demanding today as companies strive to minimize overall costs and increase their margins on the products or services they provide, while still trying to establish an acceptable level of compliance. By running lean, companies today are continually increasing the outsourcing of many activities normally done in house. This can include cleaning, laboratory testing, packaging and labeling, calibrations and facility and equipment qualifications to name a few. There is nothing wrong about this practice, but companies must not forget that they are the ones responsible for the management of these activities and not the contracted service providers. Companies must be aware of problems that occur, be an active part of their resolution and both approve and understand the processes performed. I have experienced many companies who contracted out qualification services and made no attempt to understand what was done, how or why. Because of this, I would often wonder how any question raised during an audit could be addressed since no one was involved with the testing or even tried to learn.

Compliance-related costs are greater than I can afford

The third factor --and one that should not surprise anyone-- is costs. Today the "bottom line" tends to dictate the degree of compliance, the management of the quality system and the growing expectations put on either staff or consultants, both of whom are impacted by the first two factors described above. It is understood by all of us that the "business" of business is to make money to pay salaries, benefits, and to expand but when the expenditures are cut or minimized in areas critical to achieving and maintaining compliance, the problems only start to multiply and grow. The final results in many cases, are warning letters or even consent decrees whose financial impact far exceed what it would have cost to do things right from the start.

There will always be the need for the industry to strike a balance between the "cost" of compliance versus the economic status of the company. What cannot happen is putting the public at risk at the expense of forgoing compliance due to cost. To think that those companies who have the "deepest pockets" are the best and most compliant is also not completely true. Look at the size of the companies who have entered into consent decrees over the years and you will find the largest and most well-known of today's pharmaceutical giants. We all have heard of the saying that quality needs to be built into the process to achieve quality results. By doing so, the costs associated with compliance will drop over time as deviations are reduced, processes are streamlined, and business and opportunities increases due to fewer regulatory issues.

Conclusion

In summary, compliance does not come cheap, it demands maintenance of the processes employed and training that will always be required as regulations change with time. By overcoming the fears listed above, the cash prize is there to those who do it the best.

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