Another Tool for Your Survival Kit

It is indisputable that life science companies, like all other businesses, are struggling to survive in these very rocky economic times. Uncertainty regarding the future of healthcare costs and global financial stability, unpredictability regarding certain FDA positions (e.g., will 510(k) rules be relaxed or not?, how will FDA regulate supplements?, increased/decreased regulatory burden on brand-name drugs?), difficulty in raising capital and resulting fear of hiring additional personnel (to name a few) will not make this challenging reality go away any time soon.

To date, in order to stay in business, the industry responded with predictable, though not necessarily pleasant, adjustments. We witnessed the unfortunate and numerous lay-offs, extended work hours for those who remain, salary and bonus cuts, mergers, restructuring and low morale. However, given the current state of affairs, this still may not be enough for some life science companies to stay afloat.

This brings us to an unconventional approach that we have passionately advocated for years and were quite successful at implementing across multiple life science companies. The motto of our approach is simple: when the times get tough, the tough get creative, especially when it comes to complying with regulations. What it means is that 1) all regulatory compliance issues should be viewed as symptoms of operational problems and 2) principles of regulatory compliance should be first and foremost integrated with business operations.

The principles of our methodology are listed below. They work consistently and to the companies' financial advantage. When applied correctly, these principles increase companies' chances of survival because they offer strategic operational and regulatory compliance guidance in ways that allow companies to reduce time-to-market without having to permanently increase resources and/or operating costs. In a nutshell, they are as follows:

- Before doing anything else, assess the efficiency of current operations and identify underlying business problems and risk factors that may eventually stifle growth and negatively affect profits. In essence, a company should identify, analyze and reduce waste before employing new strategies or proceeding with new directions.

  Some of the ways to achieve this goal include, but are not necessarily be limited to, 1) reducing downtime to maximize productivity, 2) defining clearer responsibilities to improve efficiency, 3) improving knowledge transfer from one group to another and 4) communicating the initiative across multiple departments and/or sites.

- Make transitions in organizational culture, if necessary, through 1) implementing the best tools, systems and training, 2) incorporating more automation, 3) involving QA early in the process to determine whether operational changes impact quality and 4) evaluating and engaging appropriate vendors.

- Leverage existing "overhead" components of the infrastructure, such as Quality Assurance (QA), in the best way possible by requesting that operational and business risks be considered in adopting any compliance practices.

  Keep in mind that interpreting FDA's or any other agency's regulations should always be based on hands-on knowledge and practical understanding of their intent and the operations they pertain to, rather than the theoretical "expertise" that results from academic knowledge only. Therefore, do not let your QA jeopardize your company's future because its interpretation of regulations is too stringent or otherwise impractical. Instead, insist that QA finds creative ways to simplify processes through eliminating redundancies and minimizing documentation without compromising quality or increasing risks of regulatory non-compliance.

- Perform periodic operational and regulatory reviews of newly implemented processes and continue to fine tune them to promote greater efficiency and compliance.

- Plan ahead and, if warranted, pro-actively seek advice and guidance regarding how to establish and maintain efficient yet compliant operations. This is especially true for those companies that lack specific operational and/or regulatory/QA expertise and competency and/or sufficient resources for projects with aggressive timelines and/or unfamiliar technology.

- Do not wait until a crisis (e.g., regulatory audit findings, tarnished industry reputation, increased regulatory scrutiny, loss of clients) to act or seek help.

- Even if a company is in crisis mode, keep the balance from the regulatory compliance perspective. Unfortunately, to lessen the impact of the issues described above, companies tend to over-promise (and sometimes under-deliver) which puts their operations back on the "inefficiency" track.

- Above all, do something that does not cost a penny: exercise common sense!

As the final thought, keep things in perspective. Remember that every storm results in a rainbow. So let your struggle for survival today end in nothing less than a pot full of gold.

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