



MethodSense News  
January 29, 2011

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### White Paper: How Risky is Risk for FDA-Regulated Life Sciences Companies?

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The simple word "Risk" is certainly one of the most frequently used terms in the contemporary Compliance Lexicon. It has become a cliché to say that the FDA advocates a "risk based approach." Risk Management, Risk Assessment and Risk Mitigation are staples on the menus of virtually every life science conference and exhibition. Life Science publications behave similarly and as a case in point the tag line of the AssurX Blog site is "Compliance, quality and **risk**: Straight talk for regulated industries" (emphasis mine).

But what the heck is "risk"? Should the very nature of "risk" in and of itself really matter to life science companies on a level beyond scenarios of potential harm, SOP creation and record generation?

First, the (sophomoric) exercise of reviewing alternative definitions of risk to get us started:

- risk = an *unwanted event* which may or may not occur.
- risk = the *cause* of an unwanted event which may or may not occur.
- risk = the *probability* of an unwanted event which may or may not occur.
- risk = the statistical *expectation value* of an unwanted event which may or may not occur.
- risk = the fact that a decision is made under conditions of *known probabilities* ("decision under risk" as opposed to "decision under uncertainty")

All of these definitions, as well as others, have a couple of things in common: risk involves *unwanted consequences* and *uncertainty*. Obvious, right? (Remember this was a sophomoric exercise). Nevertheless, it is interesting to note that unwanted consequences and uncertainty are something we humans tend to fear and hate. Uncertainty is also generally unpopular with humans.

Now consider this within the context of a medical device, pharmaceutical or biotechnology company. Among the passions driving life science companies is scientific knowledge (humans love knowing) and the practical execution of knowledge on behalf of at least two other passions: improving the length and quality of our lives (something humans generally endorse on a wholesale basis) and economic success (a value that is a tad more controversial, but still generally endorsed by most of us). Not surprisingly, these two values are intimately connected: if a life science company can successfully improve our lives, we tend to be willing to pay for it.

Recall now that element of risk called 'uncertainty'. Uncertainty seems to be diametrically opposed to knowledge, a core value of a science based endeavor. Uncertainty seems at cross purposes to the other passions of life science companies. There is nothing like the uncertainty about the performance of devices or drugs to keep them out of the market or drive buyers away. (But isn't that the way things should work?)

How a life science company responds to uncertainty will tell you a lot. We have seen fear, fearlessness, dissembling behavior, aggressive truth seeking..., you name it and everything in between.

Uncertainty has the powerful ability to threaten everything built by the driving passions of a life science company from market share to profitability. No wonder the reactions to uncertainty vary so greatly from organization to organization. But there is something special about uncertainty and the advocacy of a risk based approach that should be strongly embraced by life science companies.

Confronting and overcoming uncertainty means that at a level much deeper than SOPS and Quality Records we gain knowledge, the very kind of knowledge that fuels the passions of contributing to our welfare and success. Assessing and understanding risk, managing risk and mitigating risk accomplishes this by delivering a better understanding of a company's products, their manufacture, new products, better operations, etc. which invariably creates greater opportunities to improve our lives and enhance our wealth.

Yes, peeling back the veil of uncertainty can reveal the possibility or even the probability of unwanted consequences. It is very difficult to keep the 'bad' out of everything. But the strength of successful life science companies comes from what they know, when they know it, and what they do with that knowledge. The more skillfully life science companies look for, root out, and drag risks into the appropriate (not just any) well lit forum, the more uncertainty is condemned to understanding. Consequently, the opportunity to forestall the possibility or reduce the probability of unwanted consequences improves dramatically.

In other words, risk is a lot more risky if you take the risk of not facing it.

### **About MethodSense**

MethodSense is a Life Science service company adding value to pharmaceutical, medical device and contract service companies with the convergence of Quality, Regulatory and Technology Expertise. Where technology impacts your company, either as a critical business solution or part of your product portfolio, MethodSense can contribute to your success. MethodSense delivers FDA submission support, compliance strategies, quality system development, process and validation strategies and execution, vendor and internal audits, software development methodology optimization, software design control evaluations, risk remediation and GxP, 21 CFR Part 11, ISO, HIPAA, CMM expertise. We invite a discussion and your communication today.

### **About Michael Causey**

Michael Causey is a veteran reporter on the FDA and the editor of Edata Integrity Report at [www.edataintegrityreport.com](http://www.edataintegrityreport.com). He blogs at <http://blog.assurx.com/author/michael-causey/>.