Risky Business - Taking Another Look at Manual vs. Automated Compliance

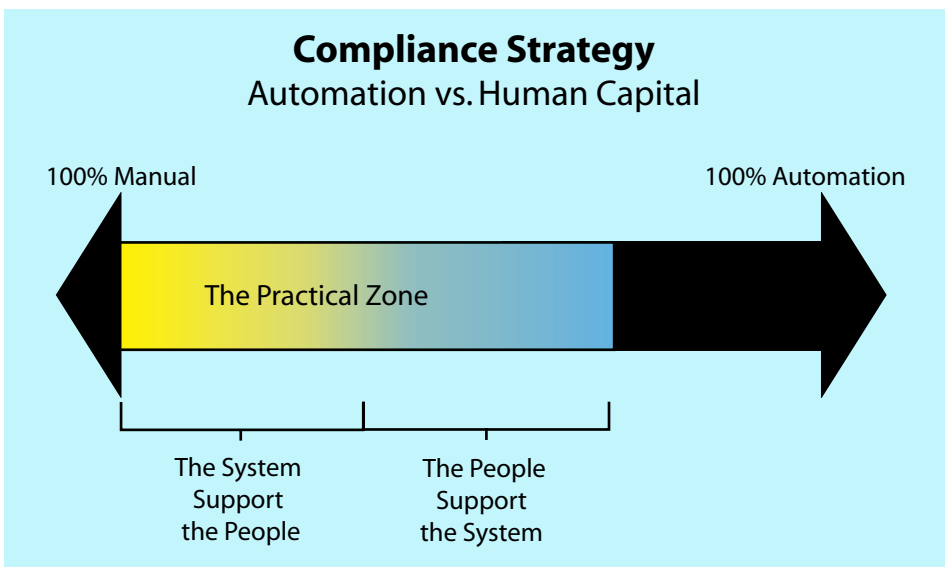
By Bill Burke, President, Merit Solutions

Time to take another look at automating FDA compliance?

"Gosh", you say, *"need we or any pharmaceutical manufacturer look any further than the mountains of forms we fill out hourly in order to get an order out the door?"*

YES, it's time to take another look at compliance because the FDA's swelling ranks give you new reason to do so. This means even more FDA inspectors fully schooled in the 21 Code of Federal Regulations (CFR) that pharmaceutical firms must live or die by. In our post 9/11 reality, you would be in your rights to suspect that these ranks will swell even more in years to come because, like it or not, public security demands that this be so. However, the BIGGER reason why you should revisit this now is that there are a growing number of systems out there that will allow FDA compliance for fast-growing firms, and finding right-sized solutions can be THE KEY to profitability.

FDA regulations do not require you to automate your business systems, and you will never find an FDA regulator who will tell you to do so. But if you make a frank comparison of man vs. machine, you can see why any FDA regulator worth their pay breathes a sigh of relief when they monitor pharmaceutical manufacturers that use widely recognized and standardized integrated business systems known to be adapted for FDA 21 CFR Part 11 compliance. Pharmaceutical manufacturers that use such integrated business systems can be expected to be a long way down the road of compliance. An otherwise comparable pharmaceutical manufacturer that uses entirely manual processes and handwritten records is quite a bit more suspect.



Graph A

Unlike you or me, an automated system will do a programmed task exactly the same way every time. Humans have moods; machines do not. Humans are subject to sleep deprivation, attention lapses, bad attitudes and bad days. Good 'ol automated systems just plug away the same way each and every time. While a very human production supervisor working in the context of a paper-based system might forget to consult the proper logs of quarantined materials, a properly programmed computer will never make that mistake and never prompt an operator to skip required steps for quality control and authorized signatures. No system that involves human action is bullet-proof, but automated systems can reduce risks of sloppy practices considerably. On the other hand, machines might fail miserably at finding creative solutions to new situations, and to the extent that compliance hinges on skills to handle exceptional situations, human hands and minds come to play a part.

It's the FDA's job to keep an eye on how much of a risk your business poses to the public. In turn, it's your job (along with all members of your company's executive team) to determine the limits of regulatory risk your company can handle. Regulatory risk is the risk of being found out of compliance. The financial risk of non-compliance includes costs of additional inspections, lost production time, unsellable product, recalls, plant shut downs, company fines, jail time for executives, and/or public relations fiascoes that put you out of business.

On the other side of the equation are the costs for compliance. (See Graph A) In a totally manual system those costs usually involve added head count, along with all the salary and benefits such staffing requires. Automated systems not only have upfront costs for software (and sometimes hardware) but also for training, and validation of the systems. Sometimes automated systems themselves bring on added costs for IT expertise, and ongoing costs to ensure that the systems are updated and in synch with evolving Standard Operating Procedures.

Because information systems can lower people costs but generate their own costs, there has to be a balance to create the right level of automation at an appropriate cost. The type of products that your company manufactures and the processes that it takes to do so have a right-sized mix of manual and automated systems that will rely on computers for repetitive operations and humans for handling exceptions. Moreover, the size of your company is one of the best indicators of the degree of automated compliance that will pay off for your firm.

The largest pharmaceutical manufacturers that have numerous plants spanning several continents and many product lines, are the only types of companies likely to benefit from full (or nearly 100%) automation for compliance. Such large companies need centralized control and standard procedures to leverage their size advantage and lower the overall compliance costs (and risk!) on a per plant basis.

The smallest start-up pharmaceutical manufacturers that still have one foot in the research lab from which they spawned, are right to have sticker shock when they consider the integrated business systems the behemoth-sized pharmaceutical firms employ. But where many of these companies get into trouble is in not re-visiting the equation as their company grows. First of all, integrated business systems vary widely in cost, with the ones geared for the largest companies in need of near total automation cost as much as 5 times what a comparable system geared for a mid-sized company would need. Secondly, the costs of compliance and costs of non-compliance are only a fraction of value created by integrated business systems. Within or without the pharmaceutical industry integrated business systems pay for themselves by helping cut the costs of production and doing business, e.g. by speeding product cycle time, cutting inventory costs, and more. Third, the disorganization potential of paper-based business systems is far more dangerous to a rapidly growing company. If you feel that you are already awash in paper, you may well be one of those companies that is so consumed in managing paper trails that you cease to see how crippled your operation is. And finally, a host of 3rd parties that can be critical to a mid-sized pharmaceutical firm's continued success - from FDA inspectors, to Venture Capital sources, to banking institutions, etc.-will look positively on pharmaceutical firms with business systems on par with their scientific expertise.

Bill Burke is President of Merit Solutions (www.meritsolutions.com), that specializes in software for full FDA CFR 21 Part 11 compliance for pharmaceutical manufacturers and other Life Sciences firms using Microsoft Business Systems. Questions can be forwarded to Bill Burke at bburke@meritsolutions.com, 630 - 510 - 3238.