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Five Mistakes Biopharmaceutical Companies Make When Selecting Software Applications

Innovative software technology is a key ingredient for growth and risk reduction in the bio-pharmaceutical industry. Selecting the right type of software for applications across the continuum of product development is a massive task. These systems house data with significant regulatory and clinical impact, are typically in use for a long time, and are costly to purchase, maintain, and replace. And the consequences of making poor choices are great: IT systems don't work as intended (often requiring manual workarounds); high cost of ownership; and decentralized information that decreases efficiency across development cycles to name a few. This document summarizes five common (and avoidable) mistakes bio-pharmaceutical companies make when selecting software.

MISTAKE #1

Solving One Business Problem at a Time with Separate Applications

Commercial life science companies must acquire new software applications on a regular basis just to function. Common practice is for a business unit to identify a specific need, detail requirements, and then task the IT organization with surveying the competitive landscape and finding the best fit to meet that need. By addressing needs one at a time, IT tends to focus on commercial, off-the-shelf, single-purpose applications. But, this approach results in a company with many unnecessary applications, each with their own license costs, maintenance requirements, and interfaces. A collection of applications also results in information trapped across different places, barely accessible without expensive integrations. **RESOLUTION:** Recognize that technology has evolved. IT systems now can be composed of applications built on the same Work Platform that can be easily integrated and accessed from a single interface.

MISTAKE #2

Consider Use by Other Bio-Pharmaceuticals Equates to Success

All too often—and especially in the bio-pharmaceutical industry—business users mistakenly assume solutions recommended by IT are preferred industry-wide to address a given business challenge. It's all too common to put too much credence in the success stories of others. You've seen it… the selection team is walked through how long a prospective software vendor has been in business, and is sold on the idea that every competitor is using the same technology. In this case, the decision appears clear; it's virtually impossible all those other companies made the wrong decision…right? Applying this logic runs counter to the practice of scientific method, where holistically understanding a scientific problem is vital. Also, obscured in this type of evaluation are key questions to ask, such as "Will this solution actually improve quality or data assurance?" It's important to consider that just going with solutions widely used by others leads to incomplete market analyses where decisions are made without all feasible options explored. **RESOLUTION:** Selection teams should focus on the anticipated intrinsic value a solution delivers. Describe the business problem to be solved, identify unmet needs with current solutions, and examine the solution in the context of how it will both broadly satisfy specific business needs, as well as improve quality. Finally, consider all financial components when weighing the merits of known solutions, as licensing fees are at times extraordinary and integration time and cost can fluctuate. A misstep can result in both millions of dollars wasted and years waiting.

MISTAKE #3

Assume Off-The-Shelf Solutions Can be Adapted to Your Needs

Developers of off-the-shelf solutions promote their understanding of the industry's best practices, and claim to have built this insight into their software. Where this approach fails is in the realization that every bio-pharmaceutical organization is different with unique challenges and specific needs. Companies benefit most when acquired software can be adapted to solve these specific problems. But, this runs counter to the business model of off-the-shelf software companies, which are most profitable when one application is produced and sold to everyone. These vendors may offer rudimentary ways to configure parts of the application, but this approach is insufficient. While customization is often offered for a fee, it is usually quite costly; customizing off-the-shelf software requires extra validation for use in the bio-pharmaceutical industry. Upgrades to off-the-shelf software in this case have more complexity and cost—the two very things companies try to avoid by going with an off-the-shelf offering!
RESOLUTION: Recognize that off-the-shelf software can work to fix common problems, but if you stray from its specific, published intent, you will likely end up with an inferior solution that continually drains your budget.

MISTAKE #4

Dismiss Customized Solutions as too Expensive to Validate, Risky from a Regulatory Perspective, and Requiring Extraordinary Time to Develop

The traditional approach to software development has historically required extensive requirements-gathering exercises coupled with teams of coders programming multiple software languages. It's marked by long, exhaustive cycles to uncover requirements from all potential users. Requirements become extensive, often even conflicting! The bio-pharmaceutical industry has not fully recognized the alternative. Unfortunately, the industry at-large has incorrectly concluded that these systems are cost prohibitive and laced with "unknown" regulatory risks related to CFR Part 11 compliance. **RESOLUTION:** Explore the Agile development approach, which has been successfully deployed for mission critical processes for years. The modern Work Platform employs visual "composition" environments (as opposed to traditional coding), reduces effort (and the accompanying time) for requirements gathering, and delivers a "validated" product at an unexpectedly rapid pace.

MISTAKE #5

Embrace the Status Quo Due to Fear of the Unknown

There is a strong (and at times blind) tendency among bio-pharmaceutical companies to rely on technology solutions that have worked in the past. This may not be surprising in an industry where the professional orientation of decision makers stresses caution and risk avoidance. Some of this reluctance may sound like it makes sense (why fix something that isn't broken), while some simply defies good judgment. The idea that being innovative will impact quality negatively is counterintuitive to the notion of innovation: the primary premise on which the bio-pharmaceutical industry is based. Innovation cannot exist without calculated risks. What is most troubling is that fear-based thinking causes many bio-pharmaceutical companies to select less efficient technologies and adopt innovations much more slowly than necessary.
RESOLUTION: Better understand newer technologies. For example, did you know the modern Work Platform has a documented history of significant improvements in user adoption, process efficiencies, data quality, transparency, collaboration, decision making and total cost of ownership? Moving forward, make sure to better understand the fit of a technological solution, its functionality across a given application, and how it will improve work (and by consequence, data quality) rather than automatically assuming what is known is what is best.

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