AAF | Flanders

Top Three Areas of Focus for Improving SOPs: Risk Reduction vs. Complication of Change

Ensuring Standard Operating Procedures Stand Up to Scrutiny

It is generally believed that because of the pressures of increased production and tougher FDA regulation, the difficulty and cost of quality and compliance upgrades can make the path to improvement slow to investigate and even slower to execute.

This can make for an unhealthy status quo created by previous implementations and historically "adequate" processes, some of which may have become outmoded. Quality, compliance, and process validation are never stagnant; they must be viewed with a critical eye to continuous review.

But risk analysis can be an important tool to keep SOPs effective, as procedures and equipment are regularly evaluated and updated to optimum levels. And not all improvement procedures need to negatively affect cost, or time to value.

"Low Hanging Fruit"

Pharmaceutical companies, their employees, vendors, and suppliers must continually look to improve—for themselves and their customers. There are ways to approach even the most "tried and true" SOPs with efficiency and common sense. The process can begin with the theory of "Maximum Impact with Minimal Effort," commonly known as picking the low hanging fruit, making the kind of changes that don't demand bureaucratic intervention, architectural upheavals, or profit killing costs.

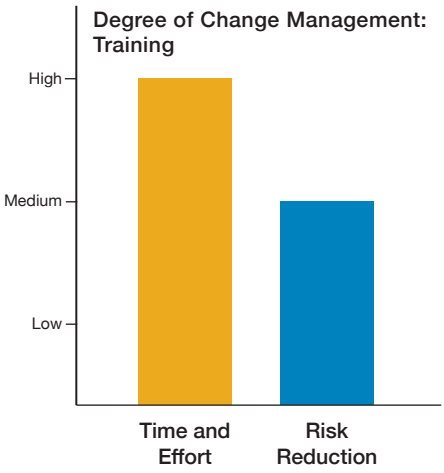
The purpose of this brief is to discuss some of the challenges and opportunities associated with SOPs in the Pharmaceutical Industry, and specifically, to review the top three areas of risk with a small degree of change management.

Reinforce Training

Reducing Errors in People and Processes

A major part of any validation process involves Risk Analysis—for equipment, machinery, utilities, cleaning inspections, and design maintenance. But all these procedures and protocols have something in common that adds complexity to the process: People. And for all these integral parts of the process, the key is to achieve buy-in for a culture of quality assurance and consistent improvement.

Human behavior is one of the most difficult parts of the process to monitor. It has been known in the industry for some time that a large part of deviations can be attributed to this factor, from simply not being clear during instruction regarding the complicated assignments that require more skill and attention. In fact, over 50% of deviations can be attributed to the combined cost of human error, not adhering to procedures, and lack of training.



However, training can improve these inefficiencies without the need to reinvent processes and procedures. "People need reminding more than they need instruction." —*Samuel Johnson*

Two basic elements that decide the success of any validated process are therefore people and plans. As with any group of people carrying out a plan, it becomes simply a matter of time and resources. Taking a hard look at a plan, such as performance tests, filtration audits, and cleanrooom supplies and accessories, is vital to its success.

Solutions can also include changing operation sequences and organizational devices that can be utilized to make the work less complicated. Manuals can be improved, inattention addressed, and the value of the risk emphasized. Because people respect what you inspect, auditing adherence to procedures should be a vital part of the SOP process.

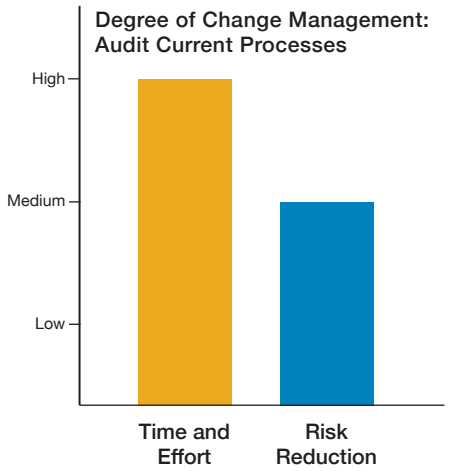
The point is, when it comes to cleanroom process improvement, training can be critical. It involves a minimal initial cost but can take a longer period of time to come to fruition. Training takes time and attention, but with patience, any cleanroom process can be improved.

Audit Current Processes

The Most Important Place Where Your Business Is Done

A cleanroom is the most important place where your business is done—the most critical part of any pharmaceutical industrial environment. From its architecture to filtration, to garments and personnel, the cleanroom must be a priority. Procedures must be as pristine as the room itself, with equipment and supplies that work on optimum levels.

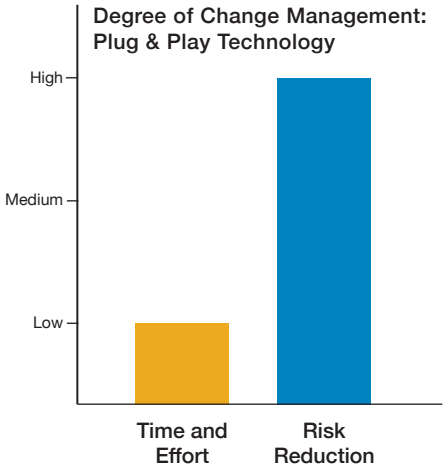
It should be remembered that every facility is unique. Customized validation and compliance controls must be examined completely. Audits and ongoing gap analysis can close critical holes in procedures and analyze existing processes to find what's working and what's not—working on the business not simply in the business to ensure continued improvements. This process cannot work without a clear plan, however. And remember, outside vendors and contractors working in concert with in-house experts can dramatically improve the cleanroom's quality.



Materials and equipment are a key factor in this process. Careful consideration is needed for cleanroom operation. It must be strategically developed, implemented, and managed in order to maintain the highest standards. This includes scrutiny of Current Good Manufacturing Practice's (cGMPs) brought forth by the FDA.

The validation team must start at the ground level to analyze and revise specifications, guidelines, and schedules, as well as to identify appropriate in-house expertise. Updated parameters must be established and protocols must be drafted. Conducting tests and audits with collectable data is key. The data is then evaluated and results documented.

This can be work-intensive and time consuming, but comes with minimal costs involved. Improving SOPs will always be positive and effective in the long run.



Invest in Risk Reducing, Plug & Play Technology

Change Demands Continuous Improvement

Upgrading equipment can be a daunting task. There are many challenges, from change control to FDA compliance, to the very real concerns of the "Next New Thing" to your cleanroom—how it may impinge on your processes, procedures, and workers. But there are strategies that can reduce these worries, as well as move your company forward in a way that embraces the best that new technology offers.

An effective solution for many of these challenges, both long term and short term, is an investment in new risk reducing technologies that can be categorized as like-for-like, or that clearly demonstrate functional equivalence. Doing so enables an organization to rapidly and safely reduce risk, while also avoiding unnecessary, costly, and time consuming revalidation activities.

Although the idea of replacing existing parts with equivalent parts is not new in manufacturing, nor is it new to the pharmaceutical industry, reasonable care must still be exercised to ensure that appropriate risk assessment measures have been taken. Functional equivalency facilitates a firm's ability to accomplish this objective. Therefore, time and investment priority should be given to technological advancements that fall within this category.

The advantage of utilizing this strategy is obvious, as well as cost effective. It is an opportunity to upgrade existing technology within a "Plug & Play" construct – without the difficulties involved in revalidated change control or bureaucratic red tape. While new technology does require investment, the right technology also provides the lowest level of implementation effort and the greatest level of risk reducing impact on your facility and current SOPs.

The Only Constant is Change

It is said that the only thing that never changes is change. That is certainly true in the pharmaceutical industry. But there can be more to risk from ignoring or procrastinating, versus embracing the fact that there are consequences in not keeping up. Here's just a few examples:

- ***Nature's Pharmacy and Compounding Center*** Recalls all Sterile Products Due to Lack of Sterility
- ***Baxter*** Initiates Worldwide Recall of Dextrose and Sodium Chloride Due to Particulate Matter in the Solution
- Particulate Matter found in ***Hospira Inc.'s*** Lidocaine HCI Injection
- ***B Braun Medical*** Issues Recall of Cafeprime and Dextrose Injections after Particulate Matter was found in a Unit
- Lack of Sterility Assurance Causes ***Abrams Royal Pharmacy*** to Recall All Sterile Products
- ***Agila Specialties/Mylan Inc.*** Recalls Etomidate Injection Due to Black Particulate Contamination
- ***Ben Venue Laboratories*** Issues Nationwide Recall Due to Gall Particulate in Acetylcysteine Solution

And that's certainly not the entire list. These companies would probably argue the day before these recalls that they were practicing due diligence and trying to follow SOP protocols to the letter. Their opinion the day after might have significantly changed.

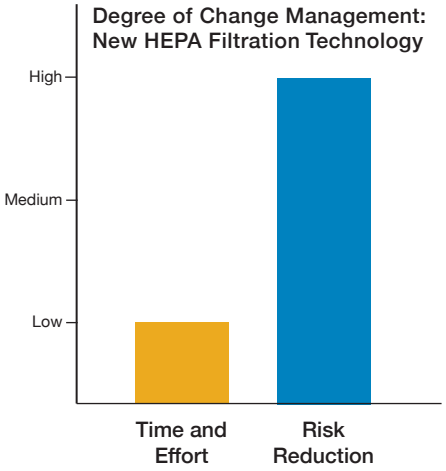
There are things we believe are true. They don't always stay that way: the belief that the world was flat, the earth didn't move, or that asbestos was a product that solved a multitude of problems. For instance, there has been a great deal of change in the testing of filters, from DOPs of the '60's to the '80's. Then aerosol photometers progressed to using solid state electronics. In the '90's, concerns about DOP as a carcinogen created a replacement—the Emery 3004 PAO.

Change is how we improve, how we reach the kind of quality that can lead an industry. Looking forward and trying to find a better way will continue to move companies into the future.

The trends in the Pharmaceutical Industry have become more and more clear as recent indicators show—new biotech products, more potent products, and pressure on more cost effective products and production equipment that necessitate continuous and aggressive upgrades.

Yesterday's Technology: An Unlikely Solution For Today's Challenges

Outdated technology is obviously not a plan for success in an industry that works and thrives every day on new ideas and bigger plans. What has worked before means just that: Before. Forward thinking isn't a cliché. It is a road map to tomorrow's survival.



75-Year-Old Technology Is A History Lesson, Not A Solution

If we told you the last breakthrough in cleanroom air filtration, microglass media, came 75 years ago, you might be surprised. As a matter of fact, name another cleanroom technology that has been used basically "as is" for three quarters of a century. If nothing comes to mind, that should be a matter of concern, because clean air in cleanrooms matters too much.

Considering an alternative to outdated microglass technology should be a priority. There are better pharma-grade media options that are far superior to microglass. These options will operate not only at an improved validated state—but also with a "Plug & Play" advantage.

There is a revolution in the way clean air is maintained in the Pharma industry, offering maximum impact with minimum effort, and a lifeline from an outdated technology whose very name implies fragility—glass. It's time to take another look at one of the critical components of every cleanroom.

Acknowledgements:

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