# HOW SIMPLIFICATION AND BEHAVIOR CHANGE CAN OPTIMIZE A PHARMACEUTICAL OPERATION

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**A focused simplification strategy will offer game-changing results in pharma operations. Regulation is inherently complex, and the bar seems to get higher with each passing year or with the issuing of new guidance. Staying current is not easy and managing the inherent, ever-growing complexity can be a serious challenge.**

NSF International's Pharmaceutical Executive Director Jim Morris's webinar, Implementing a Simplification Strategy, describes several ways to increase the efficiency of a production plant by helping operators execute tasks with greater consistency and confidence, and less effort.

A key principle is to ensure a reduction of cognitive load for personnel who work in the operational side of the business, helping them to complete their daily tasks with less effort and to a greater degree of success.

Another key principle is that the health of a company's pharmaceutical quality system (PQS) has a significant impact on operational success. A plant's PQS needs to be designed to support the volume of events a site must manage. Backlogs in investigations, change controls and CAPAs are symptomatic of poorly designed systems and potentially under-resourced operations. Focusing on backlog prevention needs to be an ongoing area of focus for management.

Morris suggests three simplification strategies that will make a significant difference and improve pharmaceutical plant operations: identifying and implementing GMP habits, institutionalizing effective triage techniques and pursuing SOP simplification.

## IDENTIFYING AND IMPLEMENTING GMP HABITS

GMP habits can be instilled in staff in many ways, but it's important to do so early in their employment. This must happen during unit operation training, where personnel are shown the unique documentation

practices, gowning and hygiene habits and those routine tasks everyone must perform when working in the GMP areas.

GMP habits are established by stepping back and assessing any issues or problems that are occurring frequently. For example, if a plant is experiencing repeated incidents with logbook entries, the development of a GMP habit around logbook entries should become an area of focus. This requires standardizing the logbook design to ensure consistency, and training personnel around logbook entries describing what good and bad entries look like. By focusing on one major source of error and developing a GMP habit in that area, the number of incorrect or missing entries will be dramatically reduced.

Therefore, Morris recommends that sites identify the reoccurring and easily preventable issues common to all unit operations and develop good GMP habits in those areas. Everyone must know what "good" looks like and practice it flawlessly every day with little effort. That is what a good GMP habit is all about.

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## INSTITUTIONALIZING TRIAGE TECHNIQUES

It's also important to employ a triage system to ensure the right amount of effort is placed on those issues presenting the greatest risk (reference ICH Q9 – Quality Risk Management).

Manufacturers can establish a triage system by evaluating which events are of minor, major or critical patient safety and/or compliance risk. Minor events may only need monitoring for any future occurrences, while major events will require a quality investigation, and critical investigation plus notification to management.

This will vary from operation to operation, but in all cases training about which events fall into which category should be given to all employees and this should be routinely monitored.

Effective triage allows a manufacturer to have much more robust corrective and preventive actions (CAPAs), less incident re-occurrence and ultimately less systemic risk. This will indirectly improve the health of the company's pharmaceutical quality system and result in better decision-making at all levels of the organization.

## DOCUMENTATION SIMPLIFICATION

Most standard operating procedures (SOPs) in pharmaceutical operations are overly complicated, not written for the users and extremely difficult to follow. Many of the SOPs can be cut down, reduced in size and revamped with a more intuitive, user-friendly format.

This can be done by assessing each SOP alongside the subject matter experts (SMEs), asking them to highlight which tasks they feel are critical, incorrect or unnecessary. A revision document should then be drafted, reviewed and tested alongside the current SOP to see which version is more beneficial.

However, in practice, SOP revision projects are doomed from the start. SOP revisions fall to the bottom of the daily to-do list in most plants. SOP revisions that are associated with regulatory commitments, CAPA commitments or general audit commitments will take priority and the mantra becomes "just get it done!". In addition, new SOPs are constantly entering the system to support new equipment, new systems, products and processes. Thus, SOP re-engineering begins to appear like a Herculean task. Just like remodeling a house – it is often more difficult to remodel than building the house from scratch.

However, a site will make steady progress by following these tips:

1. Ensure management and site-level buy-in for an SOP simplification initiative is visible
2. Ensure site-level/department-level ownership is clear
3. Ensure there is a common process in place for SOP simplification
4. Select the SOPs well – those that are frequently used and not inordinately complicated. Generally, consensus around which SOPs require simplification is easy to obtain.
5. Involve the SMEs or those personnel most familiar with the SOPs
6. Ensure the documentation system is primed and ready to move the revised SOPs through to implementation relatively quickly
7. Celebrate early successes!
8. Keep this process going for at least 12 months and measure the outcome

Procedures that are inadequate or not being followed are all too often cited by regulators as a systemic weakness in pharmaceutical companies. Plus, the link between SOP simplification, error reduction and data integrity risk warrants taking action in this area.

NSF offers a series of workshops on SOP simplification that help companies tackle this issue and get ahead of the task before it is cited as a problem. The eight-step simplification methodology provides a framework that is easily understood and replicated across a plant network.

As a leader in the field of quality system improvement and quality system remediation, we know each of the above practices will reduce risk and improve compliance. As so often stated by Maxine Fritz, NSF International's Pharmaceutical Executive Vice President, companies should see compliance as a by-product of good practice rather than an end in itself.

## ABOUT JIM MORRIS

Jim Morris has over 25 years of pharmaceutical management experience in both plant operations and corporate offices, working with Pfizer, Cilag AG and Mass Biologics in the U.S. and Europe. He has held positions as Deputy Director QA/QC and Regulatory Affairs while at Mass Biologics, Director of QA/QC for the Biologics business unit of Cilag AG and a number of quality assurance and manufacturing roles with Pfizer over a 16-year timeframe, culminating as the head of Quality Assurance for Pfizer in Latina, Italy.

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