



HOW NSF HELPED A CLIENT TO CHANGE GMP BEHAVIORS GENERATING MILLIONS IN SAVINGS

by Martin Lush

In the manufacture of sterile products, adopting good aseptic practice really matters. This is how operators in the Grade A areas (Class 100) interact with the product and process. Poor aseptic practices = increased risk of contamination = risk reduced assurance of sterility. One vital part of good aseptic practice is the routine sanitization of operators' gloved hands, every time they move between

Grade A and Grade B. This must become a vital habit. When the client came to us, it was experiencing...

- > Inconsistency in glove sanitization practice. Most sprayed their hands, but differently. Some operators simply forgot
- > Adverse trends due to bacteria being found on the gloved hands during routine monitoring
- > Very costly investigations and, even worse, batch rejects

Our client did its best to fix the situation, but the additional training, signature checking and SOP amendments only made the situation worse. We then took the client through our five step process which has, over the first six months, saved many \$ millions in direct and indirect costs.

STEP ONE: IDENTIFY THE SPECIFIC BEHAVIOR YOU WANT TO CHANGE

The behavior was defined as "Ensure operators spray their hands in a consistent manner each and every time they move from Grade A to Grade B and back".

STEP TWO: IDENTIFY WHAT DRIVES THE OLD BEHAVIOR

We spent many hours with the operators to understand their world and what was driving their old, inconsistent behaviors. This is what we found:



- > Some were totally unaware of the vital importance of effective sanitization. They had been trained in the how (follow the SOP) but not educated as to the why or, importantly, the consequences of getting it wrong (contaminated product!). They were not risk aware
- > The SOP was overly complex, confusing and impossible to follow
- > Operators were rushing due to production pressures
- > The sanitizer spray bottles were never in the same place
- > Some operators simply forgot, even though they had been trained
- > Poor design of sanitizer bottle made it difficult to use

STEP THREE: PROVIDE THE MOTIVATION FOR THE NEW BEHAVIOR

The team needed education to help them care more, so we took them into the micro lab. We showed them pictures of what microbes can do to people. We talked about the limitations of the sterility test and introduced them to the world of the microbe. We explained how just one microbe can kill a susceptible patient. They took lots of samples from their hands



before and after washing with and without gloves. We then covered their hands with a fluorescent powder before they sanitized them. With the help of a UV light we showed them the contamination they had missed. They looked at microbes on the agar plate and down the microscope. After a few hours they emerged very motivated. For the first time they understood the risks (the “why bother”). For the first time they were emotionally engaged with what they had to do.

STEP FOUR: PROVIDE THE RIGHT TOOLS, SYSTEMS AND PROCEDURES

In just one day the operators...

- > Agreed on a standard process for glove sanitization
- > Practiced and refined it until no fluorescent powder remained after washing
- > Ripped up the six page SOP and replaced it with a one page checklist, with just five action points – their action points
- > Printed checklists on highly visible (yellow) laminated paper and placed them on the walls next to the sanitizer. You couldn't miss them!

- > Replaced the old hand spray with one easier to use

These improvements were driven by the users, not by management. For example, the checklist was considered (by some who had not been involved) to have insufficient detail to satisfy an auditor. We pointed out that its role was to provide essential guidance to an operator, not the auditor. Thankfully we won the day!

SO, IF YOU ARE INTERESTED IN CHANGING GMP BEHAVIORS, HERE ARE YOUR “FIVE TO DRIVE:”

Step one: Identify the specific behavior you want to change

Step two: Identify what drives the old behavior

Step three: Provide the motivation for the new behavior

Step four: Provide the right tools, systems and procedures

Step five: Create the new habit

ABOUT THE AUTHOR



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