NSF’s pharma biotech team is committed to developing tailored programs that make a difference. We teach fundamental skills/knowledge and link these to leadership objectives such as driving down repeat deviations, simplifying SOPs or increasing the knowledge and risk awareness of first line supervisors. We deliver enjoyable, highly interactive programs that impart knowledge in a meaningful way. If there is a common thread in many of our client requests it relates to reducing variability and simplifying operations. In that vein, there are two concepts we frequently employ; cognitive load and habit formation.

**COGNITIVE LOAD**

Cognitive load is the amount of information we can process at a given point in time. Some people have greater capacity than others and their capacity will vary with the time of the day – some people will process better in the early morning versus others late morning, etc. And while we cannot necessarily control the individual capacity of our personnel, we can control the distractions around them. Each distraction, whether a cell phone, email, or multitasking, impacts cognitive load. The more distractions, the greater the impact and the less cognitive capacity we have for performing the task at hand. If that task is attending to an equipment set-up, calculating the reconciliation of components in the batch record, or simply taking down instructions from our supervisor, what is the risk that the task is executed incorrectly? As cognitive load goes up, the risk of incomplete or incorrect task execution also goes up. See Figure 1.

**HABIT FORMATION**

Habits are formed through repetition, plus they are often anchored by our emotions. The MATH principle provides us with the sequence of Motivation – Ability – trigger – Habit. We need the three precursors – motivation, ability and the trigger – for a habit to be formed. See Figure 2 (on next page).

The motivation can be as simple as working with a subject matter expert (SME) and understanding WHY a task needs to be carried out. If our training is carried out by our SMEs, we form an emotional connection and a desire to respect the knowledge imparted by the more experienced individual. We are each motivated differently; however, the beauty of the manufacturing environment is that we are often motivated by our peers and the people whom we look up to.

**OUR CHALLENGE**

The challenge we have in most operations is that we do not respect cognitive loading and we do not offer people the opportunity to develop habits. Therefore, as you plan your work, consider the optimal loading of people. If the loading is too high or too low, we will see suboptimal performance. Find that sweet spot!
Secondly, along with optimal loading, it is important to think about habit formation, particularly for the most critical tasks. The vast majority of pharmaceutical operations are still in the read-and-understand mode of SOP training. One head of learning and development at a large biopharma manufacturer estimated that their company devoted 3.5 million hours annually to read/understand training and estimated that only 10 percent of the information is retained. This is a recipe for disaster; not to mention the loss of efficiency! And, frequently, procedures are issued just in time for use and the time available to train is virtually gone.

The best practice I have seen in certain biologic operations is to build the training into the calendar and ensure that competency is verified in a proactive way. This does not simply mean that a written assessment is carried out to confirm comprehension. An assessment is helpful and provides some measure of knowledge acquisition. However, we must go further. For the most critical tasks – such as filter integrity tests, sampling steps, pH adjustments – we must verify competency. And, this is not a one-off exercise. The habit is formed with repetition. Therefore, for someone to carry out a filter integrity test they must demonstrate competency through repeated and successful execution of the task. The number of repeats will be a function of the task complexity and adeptness of the person taking on board new information (cognitive load). As in aviation it’s the flight time or time on task that counts!

In conclusion, as we think about training and education in pharmaceutical plant operations, think about:

A. Optimal loading of your personnel; this impacts their cognitive load and potential error rate

B. The formation of habits through PLANNED repetition in a safe/supervised environment

C. The verification of competency through repeat verification

If you believe you can change – if you make it a habit – the change becomes real. This is the real power of habit; the insight that your habits are what you choose them to be. Once that choice occurs – and becomes automatic – it’s not only real, it starts to seem inevitable.


If you have any questions or require assistance, don’t hesitate to contact us at USpharma@nsf.org or pharmamail@nsf.org.

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