

## People Risk Management

### .....Should Training be part of our Risk Management Programme?

*An article on the role of training in a Quality Risk Management System*

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#### James's Problem

When James heard that the batch of terminally sterilised product was rejected due to the failure of the sterilisation cycle, he was concerned whether it meant trouble for himself. His concern was heightened when he heard the reason for the failure.

The chart paper had run out during the cycle and as there was no evidence that the cycle was acceptable, the batch was rejected. As the operator who set up the steriliser, it was part of James's tasks to check the recorder and to ensure that there was enough chart paper.

James *had* made the check, but had obviously misjudged the amount of paper required for the cycle. He was relatively new to the task, having been trained in a rather hurried manner in recent weeks. While he clearly understood from the SOP that the recorder must be checked, on reflection it was not made clear to him during the training how much chart paper was 'enough'. Furthermore, he was under the mistaken impression that the recorder was a backup system and that the primary record of the sterilisation cycle was computerised.

Imagine James' surprise when the corrective action to the failure investigation was to train James again. Once again failing to show him the correct amount of chart paper for a cycle! But this company's solution to a Human Error is common – retraining by the same system that failed to adequately train in the first place!

#### Mistake or Error of Judgement?

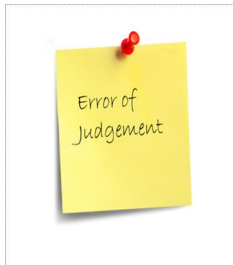
This company's solution is not uncommon. Our tendency to accept Human Error as a root cause is common. Our tendency to solve this problem with 'retraining' is equally common.

If Human Error is truly as common in our operations as our deviation systems would suggest, then there is surely an argument that the *people* in our operation are a significant risk. Yet perhaps some of the problem lies in our understanding of how to control this risk.

Human Reliability studies would draw a distinction between a 'mistake' (e.g. an omitted step) and an 'error of judgement' (I thought it was ok). The avoidance of *mistakes* in an operation can be achieved with good Hazard Analysis or Human Reliability Analysis (HEA) – both systems analyse the possible human failures that could arise in an operation and seek to implement active prevention systems. At the risk of digressing into process risk management, a process analysis should include the human interfaces with the process and identify the potential for omissions or errors. If these errors are potentially critical to a successful outcome, then active barriers such as a check or signage could be used to safeguard against their occurrence.



Errors of judgement, however, can be addressed and prevented through good structured training. Ensuring that people have the correct information and knowledge to correctly execute tasks is part of a good structured training programme.



### Learning by Experience

In many workplaces, training is a tool to familiarise a trainee with the requirements of the job. Experience comes with time and perhaps by making some mistakes along the way. In our industry, we do not have the luxury of this learning mechanism. Our training must ensure that even an inexperienced employee can make the correct judgements or recognise when advice is required in order to make a good judgement call.

In the case of our friend James, it was clear that his initial training did not include a demonstration of the minimum amount of graph paper required nor did it adequately explain the significance of the quantity of graph paper to a successful outcome. If it had, he surely would have consulted a more experienced colleague.

### Current Training Systems

The regulations clearly require that each person must be trained in the duties that they perform. This means that they must be trained on any SOP that they are required to follow and that there must be a training record demonstrating that this training occurred.

While we are all clear that training systems are required as part of our overall Quality System, the adequacy of these systems varies greatly.

Asking a trainee to read an SOP and then to follow up with 'any questions' is a high risk strategy. Many may recoil in horror that this still occurs! But the current trend for

electronic documentation systems often provide for a 'self certification' process in 'reading and understanding' SOP's. An on-line assessment of the material is common, but it has been demonstrated that these assessments can often be 'passed' without even reading the procedure!

Even when human interaction is introduced into the training programme, there can be problems. We now accept that trainers in the operation should be trained and many companies insist that trainers receive 'Train the Trainer' training. However, most of these courses (GMP Services Train the Trainer course is an exception!!) deal with 'how' to train and do not deal with 'what' needs to be taught. The result can be uncontrolled discrepancies in training content and an undue reliability on the trainers own experience with the task.

'Sitting by Nellie' is a traditional method of learning a skill. However, 'Nellie's' understanding of the significance of a task (or with the impact of failure to execute a task correctly) may not be as enlightened as the organisation might like to think. 'Nellie's' view of the operation may be quite limited and her overall understanding of downstream consequences may not be comprehensive.

### Controlling Training Content

In the 'Train the Trainer' course run by GMP Services, we are equally concerned with WHAT information is being passed on during on-the-job training. We ask participants to take along ANY SOP that they use to deliver training. We then use a competency based analysis to determine the **skills** required to successfully execute the task(s) required.

But we also analyse the **knowledge** that might be required to ensure that the criticality of certain steps are clearly understood; that the correct decisions are made; that problems are recognised; and consequences understood.

Furthermore, we determine if there are any specific behaviours or **attitudes** that are critical to the successful outcome of this task e.g. documenting *with care*; *concentration* during inspections; *accuracy* when measuring etc.

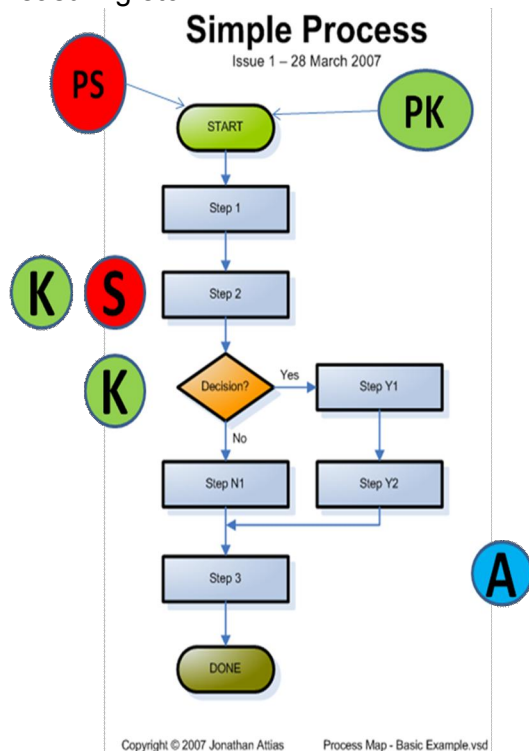


Fig 1: A Process Map indicating the Skills, Knowledge & Attitudes, including Pre-Skills(PS) or Pre-Knowledge (PK) required for a task

This SKA (Skills/ Knowledge/ Attitude) analysis clearly filters out the key training points from the SOP. With frightening regularity, when we ask our trainee trainers to go back and re-read the original SOP and determine whether these critical SKA's were apparent from reading the SOP alone, it is clear that in most cases they were not.

To return to the example of the chart paper once again, the SOP simply stated that the recorder should be checked to ensure that there was 'enough chart paper'. A SKA analysis will discover that in order for this step to be executed successfully, then the trainee must be shown what 'enough chart paper' looks like; must know how to refill the recorder if there is a shortfall; must understand the

consequences of the failure of this step; must ask for it to be checked by another person until sure that the correct decisions are being made; etc. The trainee is not truly competent to perform this task unsupervised until all these elements are understood. While this may sound like a lot of work, it is moments of time compared to the loss of a batch!

This concept is not a new one to safety training. Few safety trainers would simply show *how* to place a ladder correctly against a wall, without ensuring that the trainee understands *why* this is important & how to achieve the task safely in more challenging circumstances (uneven ground, uneven surface, etc).

In order to avoid an accident, deviation, batch failure or complaint, we need to be assured that the trainee receives *all* the information required to be truly competent at the task. The control of training content is an essential element to reducing the risk of incorrect human behaviour in our operations.

This approach has the added advantage of giving the trainee additional confidence as well. We wouldn't dream of writing an equipment validation protocol that said 'set this piece of equipment up like the previous model'! Why do we take this approach with training content?

### Validation vs. Training

When we consider the amount of effort we put into controlling the behaviour of our equipment and then compare it to the effort we make to control the way our people are trained, we see a frightening inequity of effort,

Yet an honest risk assessment would surely class the risk associated with human behaviour as far greater than that of equipment.

Most equipment validation strategies begin with the User Requirements Specification (URS), a document that clearly specifies what this equipment must do, how it is to be controlled, the level of accuracy expected, the alarm systems required,

the routine maintenance and calibration requirements, etc. The goal is a clear understanding of the role and functionality of this equipment in the process. The remainder of the validation lifecycle is spent testing and determining that these requirements were adequately met.

There is no comparable system for people. While accepting that people are not automated, there is surely an argument for a similar strategy to training content design i.e. a clear understanding of the task; how the correct and consistent execution of this task can be controlled; how failure can be recognised and avoided; how this understanding can be maintained or re-enforced; and how success or competence can be measured. All these are elements of a truly enlightened risk based approach to training.

#### How could this be achieved?

##### 1. Understanding the task

Any meaningful attempt at controlling an operation involves understanding that operation. This is the fundamental basis of Lean Manufacturing, Six Sigma, etc. The process mapping involved in these studies is also a good starting point for the control of training material. Process Mapping allows for the sequence of the task to be clearly visualised.

It further recognises that more than one SOP could be involved in the successful execution of a task. To be successfully trained in a task, may involve being trained or reminded of several SOP's.

##### 2. Determining the SKA required

The steps involved in the task are reviewed with the SOP(s). The key knowledge, skills or attitudes that are required for the successful understanding of the task are identified. (See Fig 1). Competency standards for critical tasks are identified.

So for James, the competency standard may include: can correctly adjudge the correct amount of chart

paper required for a cycle; can replace chart paper, if required (another SOP); and understands significance of chart paper to acceptable cycle.

##### 3. Controlling the training material

The key training points that the trainer must communicate in addition to the SOP or the information that must be emphasised / demonstrated are documented and controlled. This can be done either through training modules (more administration) or as an addendum to the SOP (better option)

##### 4. Implementing meaningful evaluations

Competency standards should be measured. Skills can be measured through observation. Knowledge and Attitudes should be measured through written evaluations. There is a skill in designing evaluation tests, especially in terms of transfer of learning or evaluating attitudes. Ensuring that this skill is included in your Train the Trainer Programme increases the assurance that the critical elements of a task are understood.

##### 5. Applying levels of competency

Not all users need the same level of training in an SOP. For some 'read and understand' may be adequate. For other users a more comprehensive training plan may be required. Categorise the users and determine the level of competency required.

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