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KEY TRAINING: THE RECIPE FOR EFFECTIVE, EFFICIENT AND ENGAGING COMPLIANCE TRAINING

When you mention at a party that you are ‘into compliance training’, it is guaranteed that the temperature will drop immediately below zero. At its best, people see compliance training as a necessary evil. Most times, people will roll their eyes and give the conversation a different direction. Still, compliance training is a critical element of a pharmaceutical quality system.

So, what should we do: pretend we love it or just hate it? At Janssen Research & Development – the pharmaceutical R&D branch of Johnson & Johnson – we firmly believe that there is a third way. In 2015, the article 'Shifting the Paradigm: Tailoring Training to Elevate Excellence' already explained how Janssen R&D was exploring the concept of risk-based training. People will never cheer when a new compliance course has been assigned, but that does not mean that we should be complacent. Five years later, our training programme has matured. Before we discuss our programme, we need to demystify some common misconceptions about compliance training.

MISCONCEPTIONS

Let's start with the Learning & Development (L&D) industry. Many suppliers and so-called experts believe that all compliance training is like the annual safety or anti-harassment training, but that is just the tip of the iceberg. They don't realise that in complex industries – like pharmaceutical R&D – people undergo up to 50 compliance courses on procedural documents per year. Hence, typical solutions like 'give people a serious training game and they will love your compliance course' don't work, except for a few die-hard puzzle fans. To make compliance training more effective, efficient and engaging, one must sufficiently factor in the element of scale.

Whereas people in L&D are knowledgeable about designing good training material, the focus of quality professionals and health authority inspectors is primarily the auditability of the training programme. For example, they verify if an employee was trained on a certain procedure before applying that procedure in practice. Therefore, they compare the dates of training assignment, effective date of the procedure and any evidence about the date the procedure was followed. Such metrics have become an industry standard during audits and inspections. As a result, there are two competing interests that need to be brought in accordance with each other.

HUMAN RISK

So, what is the essence of compliance training in a pharmaceutical quality system? To recap the article from 2015[1], the central element is risk. Compliance training aims to reduce human error and to maintain the state of compliance of the quality system. At Janssen R&D, people are trained in more detail when the circumstances create a higher risk of non-compliance (because of many handoffs, complex procedures, etc.), than when the circumstances present a lower risk of non-compliance and when variability in execution is not critical for the end-result of the process.

This occurs when knowing that formal training is the very first step in people's learning process. It creates awareness of the what, who, why and when. Further learning happens on the job with coaching by peers and functional managers. For any further details on the how, people can rely on job aids or other supportive resources. Training is not always the solution. Take for example an annual course about an expense policy. Training may not enforce compliance with the policy. Rather, it may be more effective to bring guidance and control to the moment of execution by building supportive guidance and controls into the expense system, for example.

Finally, we should not forget that much of compliance training in pharmaceutical R&D occurs with staff working on clinical trials. That's a whole other dimension of human risk compared to, for example, manufacturing or sales. We are not just dealing with the behaviours of employees, but with those of individuals outside of our immediate control, such as doctors, nurses and pharmacists, who have an impact on the behaviours of subjects in a clinical trial.

DESIGN THINKING TO THE RESCUE

Although our training strategy was already repositioned a few years ago, we sought feedback from our colleagues and found more opportunities for improvement.
Not only was the time spent on training an issue but also people's engagement during training and the access to helpful materials after training. Instead of looking at this problem with a traditional quality hat or with the eyes of a L&D person, the Bioresearch Quality and Compliance department at Janssen R&D applied a more creative approach, called 'design thinking'.

The essence of design thinking is that you practice empathy for the real needs of a trainee in order to discover new ways to address those needs. In contrast to normal problem solving and waterfall methodologies, design thinking is by nature highly iterative. Through small experiments and pilot projects, a pipeline of innovation projects was started. At some points, the boundaries of our technological capabilities, the science of learning and the regulations were put aside intentionally to stimulate people's creativity. Of course, these were retaken during the design of the final solutions. For us, it proved to be the only way to fulfill people's true needs and, at the same time, stay in compliance.

BRINGING THE HUMAN ELEMENT BACK

Large pharmaceutical companies with global audiences heavily rely on learning management systems to distribute training materials. Compared to old-school classroom training, this is very efficient and it is highly compliant on paper during an audit or inspection. Although this is well accepted, there is still room to improve the learning effectiveness in the long-term.

If you have in-house eLearning developers with a good knowledge of instructional design, training can be made more efficient. Unfortunately, eLearning can also be a bit impersonal. That's why we look for avenues that bring the human element back into training. For example, we ask the business representatives for a process ('business process owners') to introduce the key changes in a brief video during the introduction of the training. As learning is also a social process, we invite people to webinars where more time is given to case scenarios and where there is room for debate. The more people can engage with the learning content together with others, the better.

PERSONALISED COURSES AND CURRICULA

Building upon the risk-based approach, we apply personalisation wherever we can. Our people receive multiple training curricula based upon their role, region and managerial level. Other curricula for specific tasks or systems may be requested or be exempt when not applicable for an individual. On top of that, central and local roles in clinical teams also have protocol-specific training curricula with courses on the protocol, monitoring guidelines, etc.

Next to the granular assignment of curricula, personalisation also occurs at course level. When there are multiple roles in a procedure, they may receive different training content. If we update a procedure, retraining is only needed for the sections that were significantly revised. For administrative or small changes, retraining is optional and people just receive a communication on the update.

Our latest addition to personalised training was implemented in the mandatory course on Good Clinical Practices (GCP). Previously, new employees were given a full GCP course during their induction; however, some of these new employees were experienced professionals in clinical trials. It created an impression that their experience was not being valued. From now on, these experienced professionals can either take the full course (as it was before) or first go through a series of scenario-based questions. If they succeed on the test, they are recertified for their knowledge on GCP. We are examining the same approach for other annual courses.

DIGITAL TRAINING BY NATURE

Modern training should take advantage of all digital capabilities. In addition to delivering training over a learning management system and using video, we introduce more and more animation. Animations are ideally suited to illustrate scenarios or the steps of a procedure. It is our firm belief that training material should not just track that procedure. Instead, we build cases into the training material based upon some real-life scenarios and examples. This increases the relevance of training for the trainees.

Since our audience is often travelling or working remotely, we decided to make all new training content available on mobile devices. Instead of using traditional eLearning authoring tools, we are now putting all training content into one database. This opens a wealth of new possibilities. When a colleague accesses a course on this platform, the platform will recognise the device (desktop, tablet or smartphone) and deliver the optimal user experience. After formal training has occurred, all content remains accessible for the trainees through several search channels. Since all content is in one database, we can apply single-sourcing; meaning that if some course content is used in multiple locations, we must change it only once.

ASSESSING TRAINING EFFECTIVENESS

During an audit or inspection, we are often asked for training records of trainees. Auditors meticulously verify if people have completed their mandatory training and if this was done on time. This is the reason why companies rely on metrics like 'completion on time' to assess the health of their training programme. While we understand the need for this metric, we look to assure effectiveness, which is not measured by this metric. While many types of training include knowledge assessments to courses, these are an indication of people's knowledge at one point in time. The most relevant moment is not the moment of training, but the moment of execution.

What we really want to know is if people demonstrate the right behaviors and what the impact was of the training programme to realise those behaviours. Through long-term monitoring of training events and quality incidents, we hope to achieve the first part. For the second part, we are still searching how we can isolate training interventions from all other parameters in a complex business environment. In knowing that the measurement of people's time investment or confidence level is not ideal for the evaluation of our training programme, we remain hopeful that the data scientists in our company can bring us closer to a real answer.

REBRANDING PROCEDURES AND TRAINING

From behavioural science, we know that the word 'compliance' makes all alarm bells go off. It also positions compliance training as the problem of the Quality and Compliance Department, whereas ideally every department of a company should feel accountable for maintaining the state of compliance. To change the perception of compliance training, we introduced a brand name and a corresponding visual identity that intentionally does not refer to compliance or quality at all.

We chose 'KEY' as a brand since it nicely stands for 'Knowledge Empowers You'. This way, the brand name covers the full scope of our department: process flows, procedural documents, job aids, knowledge hubs, formal training and optional training resources. In a scientific environment, there is always the fear of over-training. The word 'KEY' stresses that we focus on key concepts that people must remember.

Together with the new brand, our Quality Department also repositioned itself. Instead of being the group that mandates new training, we are, in reality, an intermediary that delivers training and procedural documents that are owned by our business partners in Research & Development. In our most recent communications, we underline that any change to a procedural document is a partnership between quality and another department in R&D. Just like in the movies, our announcements now have a list of credits so trainees can see who the quality and business people that contributed to this change of the quality system are.

A NEVER-ENDING STORY

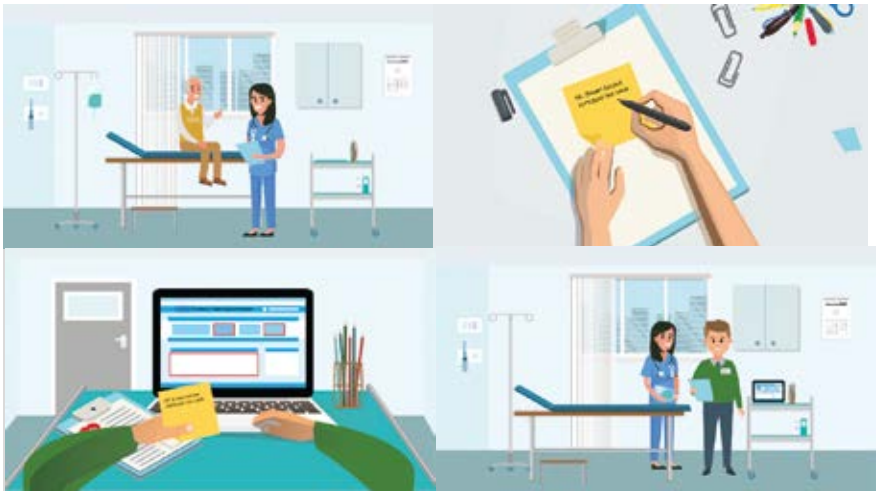
Standing still is going backwards. Our design thinking exercise opened a pipeline of innovation projects and since then, new ideas continue to be explored.

At this moment, the focus is shifting from formal training to what happens after training. The complexity and variability of clinical trials increases every year. It has become impossible for one person to remember all those details. Hence, it is equally important that our people can very quickly get answers to their questions. Whether this be through chatbots, learning experience platforms, digital job coaches, virtual classrooms or other fancy tech is not known yet. That's the beauty of the innovation pipeline. We can now easily determine whether we should jump on a train or let a hype pass by.

The evolution of our framework will not just depend on technology. We continue to invest in the personal development of our business process management experts. Since they are responsible for the training material, it is critical that they have a good understanding of instructional design and adult learning principles. If we can upskill their competencies, they can also design compliance courses that are not just knowledge containers, but also ways to improve the skills of our target audience.

Since our department controls both compliance training and underlying procedures, we also need to talk about the underlying procedural documents that are being trained upon. If you want to make training for your end-users a hard job, design a complicated procedure that feels counterintuitive for the people that need to execute it. In other words, training cannot make up for all the tradeoffs and bad decisions that occurred during the design of the process.

Last but not least, we also hope that by encouraging critical thinking, and by helping to advance the culture of compliance, the need for detailed compliance training will diminish.



These images are being used to explain policies and procedures in videos and animations.

These images are being used during the recertification courses on Good Clinical Practices.

REFERENCE

1. Mike Coakley, Shifting the paradigm: Tailoring Training to Elevate Excellence, Quasar, October 2015, p24-25

PROFILE

Erwin De beuckelaer works at Janssen Pharmaceuticals (J&J) as Director of Innovative Capabilities. He brings innovation to the space of quality and compliance. Erwin's mission is to make complicated things as simple as possible, while thoroughly understanding the complexities of today's business challenges. He is an advocate for human-centered design and design thinking and his background is in communication and user experience design.