

Learning management in the pharmaceutical industry

Higher product quality through professional training

Frankfurt, May 20, 2020 – In the strictly regulated pharmaceutical industry, product quality determines long-term success. It is estimated that quality assurance and the cost of remedying defects lies between 20 and 30% of the total cost. Up to a quarter of production staff in the pharmaceutical industry work in quality assurance and their numbers are on the rise. This has dramatic consequences for companies that are under increasing cost pressures. However, product quality can be significantly improved through professional e-learning that clearly conveys the knowledge employees need to perform routine activities properly and without error. Language boundaries and fluctuating staffs are major challenges in meeting this task, especially for companies operating on a global basis.

The latest figures from the European Federation of Pharmaceutical Industries and Associations (EFPIA) show that more than five million people work in the pharmaceutical industry worldwide. The number of production-oriented jobs has increased by 22% in the past ten years. At locations producing sterile forms of pharmaceutical, 20 to 25% of these work in quality assurance; at plants making non-sterile forms, the figure is 10 to 15%.

In most cases, these employees are only being trained on the basis of standard operating procedure (SOP) documents.

Ideally, these documents serve two requirements:

1. meet the regulatory requirements for audits
2. clearly provide employees with the knowledge they need to perform their routine activities properly and error-free.

This poses a particular problem as the pressure from legal requirements continues to grow. Most SOP documents therefore meet the first requirement very well, using the verbiage used by the auditors, as revealed when 94 experts from the industry were interviewed for the MAIN5 study "Pharma Insights 2019." 70% of them believe that the SOPs of the pharmaceutical industry are so incomprehensible because of the way they have evolved without an eye to good, meaningful communication practices. 65% believe that they are primarily focused on audits. Only 8% of the respondents consider these processes and training to be future-oriented.

This confirms that the second requirement for SOP documents is mostly being neglected. Production staff will usually find it hard to find the relevant content at a glance. This comes at the expense of learning success. Formally, it appears that employees are well-trained, but their actual understanding of the content often falls by the wayside. This just results in pitfalls that they may very well fall into.

Quality defects lead to high costs

Since 2010, the number of drug recalls has almost doubled, according to figures from the Federal Institute for Drugs and Medical Devices (BfArM). At the same time, the amount spent on personnel to eliminate these defects has climbed to between 20 and 30% of the total costs.

Employees, especially those working in production, need access to a learning system that enables them to carry out all of their routine tasks reliably, correctly, and without errors.

Modern e-learning modules offer an excellent set of tools for this purpose. Once created, they will save additional staff costs, ensure consistent quality of the training content, allow individuals to learn at their own speed, and enable a deeper understanding of the content. Even with high employee turnover, they can be used at any time. At an advanced level, training outside of real production can be done using "virtual reality."

E-learning with a focus on a deeper understanding of the content is not a trivial challenge, however.

Learning with pleasure instead of red tape

The experience with current major projects shows that e-learning can be very successful, but also requires a lot of work.

In the age of YouTube, employees around the world have become accustomed to receiving instructions and training for all situations in a skillful and effective manner. They increasingly expect this same high standard on the job. For many of them, this may be the only way to reach them didactically. Providing clear, audiovisual demonstrations of learning content also overcomes many language barriers.

On the contrary, audit-focused learning content is text-based and just seems to be a lot of red tape. For effective e-learning, it is not enough to ask existing specialists to pass on their knowledge. Rather, this information must be visually and audibly presented in an easily understandable and appealing form (learning from sense of duty is always less effective than enjoyable learning).

E-learning that follows best practices has proven to be a very successful form. It should be interactive, easy, and with individual modules of 20 to 40 minutes duration. The special software required to create these formats should be selected according to customer requirements. Templates are thus developed that provide a basic framework for the content and motivate learners in an appealing way. These templates also make it easier to quickly create additional training sessions without the need for special IT skills.

The time gained can then be meaningfully used for the didactic processing of the content. In the future, the topic of training through e-learning will require more management attention and sufficient financial support from the company.

Choosing the right target group

With the introduction of effective e-learning, one must also correctly identify the target group. This must meet the regulatory requirements, but must not go too far. On the one hand, training for employees who cannot do anything with the content in their day-to-day work is not only useless, but will cause general training fatigue and unnecessary costs when they are kept from doing their regular jobs. On the other hand, if too few employees are trained, this can lead to compliance problems. It is often not possible to determine the target groups only on the basis of employee job descriptions, because, in most cases, they are only a static representation of the organizational structure. It is different when companies describe their processes in the form of processes, process roles, and responsibilities. Because processes reflect the day-to-day work of companies, they can make it easier to identify who ought to have what training.

Effective e-learning for the right target groups not only can significantly improve product quality in the medium term, it can also be a positive experience for employees – all in the company's own interest.

About MAIN5 (www.main5.de)

MAIN5 was established in 2013 as a Management Consulting firm and focuses on strategy, process and solution consulting with international life science companies in the regulated R&D and Regulatory Affairs and Quality Management sectors. The consultants at Main5 combine their methodical and systematic approach with years of experience in the industry. The holistic approach, which places the primary focus of the route to the digital future on people, is also used to implement complex ideas from leading industry customers.

Further information: MAIN5 GmbH & Co. KGaA, Administrative Headquarters: Schumannstr. 27, 60325 Frankfurt am Main, Germany Tel.: +49 (0) 69 505 027 228, email: presse@main5.de, Web: www.main5.de

PR Agency: euromarcom public relations GmbH, Tel.: 0611 / 973150, email: team@euromarcom.de