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EDITORIAL ARTICLE

The need for Quality

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ABSTRACT

Hearing about pharmacovigilance (PV) and patient safety, both non-professionals and professionals tend to focus only on the safety aspect of the story; most of us were guilty of that at a point in our careers, but what about Quality? Where does it fit, and how does it help?

The "holy" triangle includes safety, efficacy and also quality. Undoubtedly, the quality element should be built into PV to ensure high standards, efficient workload management, the safety of our patients and public health. This article aims to guide readers through the starting points of integrating Quality into PV related processes, focusing on Standard operating procedures (SOPs).

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Introduction

Constructing a good quality management system (QMS) is not easy; a thorough action plan is a must, but even the most exhaustive one with well-defined milestones will not spare you from hurdles and stumbling blocks. As with any building project, a strong foundation will determine how high you can build; having well-trained professionals will strengthen any system's foundation, and harmony between the involved departments will only help build it more efficiently. Therefore, when working on different procedures, it is essential for the two departments - both PV and Quality - to communicate and work together - not only on PV-related processes but also on quality processes that could directly or indirectly impact the PV department. But communication is not always easy, and the current pandemic changed the way departments communicate across the globe. Not once do we hear the phrase "the left hand doesn't know what the right hand is doing" when we look at these departments. It is no surprise that larger companies started introducing a PV Quality Assurance (QA) segment to the Quality department, where PV professionals are forming the group to ensure proper communication and proficiency to fill that gap.

Proper communication channels should be adapted to any circumstance that may arise; modern technology allows for great communication methods, but it has a downside, like all good things, and it's easy to lose focus. Regardless of the level of expertise, a reminder that the PV and quality systems are strongly intertwined and the goals are common, will always prove useful. That being said, this is an essential pillar in creating good procedural documents.

Technicalities

It is also of utmost importance to be aware of the different documentation types recognised by legislation:

- Policies
- Manuals
- Standard operating procedures (SOPs)
- Working instructions (WINs), and

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- Forms/Records/Reports.

Companies are developing different terminologies for their internal processes, which may cause issues during audits or inspections. This can suggest that the company lacks a proper understanding of the legislation. SOPs will be examined more closely in the following section.

SOPs are quality controlled documents that aim to implement and enforce company policies. Essentially, SOPs are a set of written instructions describing and providing clear instruction to the end-user on the process in question, how to perform a task and sufficient detail to allow the task to be executed consistently and uniformly by all end-users. The implementation of SOPs is audited and inspected by the competent authorities (CAs) included, per respective sections and guidelines of the jurisdiction in question - hence, SOPs are a pivotal component of the system.

The caveat of writing and implementing proper SOPs is that many professionals and/or companies believe that a generic template and superficial information would be adequate to utilise - however, having this mentality will result in major, if not critical findings during an inspection or an audit. The golden rule that must be kept in mind is that SOPs are always product and company-specific. No pharmaceutical company is the same - each marketing authorisation holder is different, and each product is different.

To comply with PV legislations, SOPs have to be

- Well detailed
- Written using the correct terminology
- Adequate length
- Reflective of specific company structures and practices

To ensure the above requirements are in line with the regulatory requirements, the company must utilize highly experienced, knowledgeable and flexible PV personnel. It must not be forgotten that if the company is present in the Europe Union (EU), the EU Qualified Person for Pharmacovigilance (QPPV) should review and have good oversight of all the procedures impacting the PV Department so that the QPPV can ensure PV legislation adherence.

Another point that must be considered while drafting an SOP is the structure. Certain structural elements would serve the company well, including the following:

- Header (it could differ on the title page to include further information such as author, reviewer, etc.)
- Author, Reviewer, Approver - and the signatures
- Effective date
- Proper code assigned
- Version control
- Abbreviations
- Purpose
- Scope (it can be merged with the above having a Purpose& Scope section together)
- References (both internal and external)
- Responsibilities
- Process (it can include several subsections)
- Annexes
- History

Every activity carried out by the company must be covered by an SOP.

Further to the above:

- It is critical that responsibilities are allocated to the appropriate role(s).
- Timelines, even though they are internal, have to be specified.
- Inserting flowcharts where they are appropriate to facilitate easier understanding.
- The details written in the procedure should be unambiguous and not overly complicated. Information should be conveyed clearly and explicitly.
- Regularly reviewing the documents to ensure that they are fit for purpose. Companies should not be afraid to update their SOPs, so that the documents still serve their purpose - it is a part of its life cycle.

All SOPs must be kept up-to-date, describing current practice rather than obsolete procedures which are no longer used, no longer valid or compliant. Nevertheless, previous versions of an SOP should still be recallable; therefore, it has to be archived appropriately.

All SOPs should go under review by one or more individuals with appropriate training and experience with the process. This step serves not only as validation but also ensures that any further questions or challenges raised thereafter are considered and addressed appropriately. Once all comments are resolved, the finalized document is signed off, becomes effective, and distributed for training purposes. It is vital that the correct personnel receive the appropriate SOP for training to guarantee quality and consistency and that good practices are achieved appropriately at all times.

As already stated, SOPs must remain up-to-date to be useful. Hence, when there are changes in the legislative framework, SOPs should be updated and re-approved as well. Additionally, SOPs should also be systematically reviewed periodically, e.g. every two years at least, to ensure that the process is still fit for purpose and determine whether the SOP is relevant.

Conclusion

All in all, SOPs are essential building blocks of the QMS system from a PV point of view as well. It will always pay

off if the company deploys the right resources to develop procedural documents for operational purposes. While this article only scratches the surface, it can serve as a start-up guide for developing SOP documents.

Conflict of interest

The author declares that there is no conflict of interest.

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