“Writing and Managing SOPs for GCP”
Susanne Prokscha, 2015, 206 pages, CRC Press, $129.95
Review by Norman M. Goldfarb

“Writing and Managing SOPs for GCP” miraculously transforms the boring floss of standard operating procedures into the interesting gold of...SOPs. A reader of this book will find it is hard to imagine managing SOPs without having read the book.

The following excerpts illustrate the insightful and practical nature of the contents:

A very important function of SOPs for both large and small organizations is to act as a kind of contract between departments to formally record who is responsible for which tasks. When SOPs are written, one goal should be to ensure that the most appropriate department or group is responsible for completing each activity listed in the procedure. Accepting responsibility for a task implies a commitment of the resources needed, including staff and materials, to carry out that task consistently. Senior management from each department involved in the procedure will approve the SOP, which implies agreement to commit the resources, and all groups will train on the SOP, ensuring that everyone is aware of the agreements regarding responsibility. In cases where this agreement is not formalized in an SOP, the commitment to allocating appropriate resources can be lost and may even be challenged. Note that the “service agreements” used by some companies for commitments of responsibility across groups do not come with training requirements and are often not known to the staff performing the work.

Unfortunately, and all too often, the policies are written after the SOPs or procedures, as a kind of abstract or summary of what is found in the SOPs. When polices are written this way, they have no value and are a waste of time to maintain. Even when written before SOPs, the main value of a policy is to writers of SOPs — if staff are required to read the policies at all, they would read them just once and then refer to SOPs to perform real work. Given their limited value, this book does not include policies in the document hierarchy, but readers may encounter them throughout the industry governing GCP activities. They may also be found outside Clinical Development to document a company’s expectations and requirements in other areas of the corporation, such as Information Technology, where they do provide value in setting expectations for employee behavior.

Just because a document is generated during the course of a study does not mean it is destined to be part of the TMF — and therein lies the art of document management. When considering whether or not to retain a document or form, we first have to determine if it is useful in showing GCP compliance, adherence to regulation, or quality of the data. If it is, then it is a candidate for filing in the TMF. But we should also ask if that document or form actually results in the information regarding compliance being recorded elsewhere in a key study document or other system. If there is other evidence, we do not necessarily have to retain the document being assessed.
SOPs need thorough review to ensure that the process can be followed, as written, is not missing any key steps, and assigns responsibilities appropriately from the day it becomes effective. Rather than send all the reviewers the first draft, it is best to send it out in waves or rings of review, improving the process and wording as it goes out until the final reviews for approval. Even though the number of people is not necessarily greater in each round, the document goes further out into the Clinical Development organization.

Controlled document identifiers provide a handy shortcut to finding and referring to a document. They also stay the same, even if the document title is modified to reflect changes in the SOP's scope over time. A system for arriving at document identifiers is a seemingly prosaic topic, but it is fundamental to a well-established and user-friendly SOP system. The worst system is a multidigit sequential number, such as SOP-0162003. People will rarely be able to memorize the random association of the number and topic and are unlikely to refer to it that way, much less find it again. They will be forced to ignore the number, refer to the topic of the document, and hope for a robust search engine in the controlled document system. Better to provide users with a way to identify those SOPs that are most likely to apply to them and to keep the sequential numbers to a minimum. We can do this by including the business process owner (BPO) in the identifier, so that SOPs whose BPO is Drug Safety would have DS, Clinical Data Management would have CDM, and so forth. Because people are most likely to need SOPs from their own group and the groups they work closely with, they can narrow down the selection easily this way. If we add a sequential number but keep it to two or three digits, people will have an easier time remembering the numeric portion.

The book consists of 19 chapters:
- Introduction to SOPs
- Document hierarchies
- When to have an SOP
- What the SOP should say
- Where to put the output
- Who writes SOPs
- Document a stable process
- Mapping a new process
- The SOP template
- SOP review and approval
- Posting: Setting up for success
- Deviations from controlled procedures
- Active SOP maintenance
- Finding SOPs
- Training on SOPs
- Department-managed documents
- Where to start
- SOPs during mergers and acquisitions
- Controlled glossaries

The book is available in bookstores.
Reviewer
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