

Integrating Standard Operating Procedures Into GCP Training

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WHEN A TRAINER DEVELOPS AN INSTRUCTIONAL PROGRAM *on Good Clinical Practices (GCPs)*, he or she will typically include current U.S. Department of Health and Human Services (DHHS) regulations and guidelines as well as pertinent International Conference on Harmonization (ICH) Harmonized Tripartite Guidelines. GCP training would also reflect applicable state requirements as well as regulations for other countries if the clinical trials will be conducted outside the U.S. These regulatory and guidance documents form the foundation for any GCP training program, whether it is for investigators, coordinators, institutional review board (IRB) members, monitors, auditors, project managers, regulatory affairs specialists, data managers, or anyone else involved in the clinical trial process.

In addition to these references, another essential resource should be incorporated into a GCP training program — the organization's standard operating procedures (SOPs) for clinical research.

DEFINITION AND IMPORTANCE OF SOPs

The ICH defines SOPs as “detailed, written instructions to achieve uniformity of the performance of a specific function.”¹ Consistency and control are fundamental components of a clinical research protocol; they also are necessary for any organization, institution, company, department or office to achieve maximum effectiveness of its clinical research operations. SOPs help to

¹ ICH Harmonized Tripartite Guideline for Good Clinical Practice. (1.55). May 1, 1996.

ensure this consistency and control.

A clinical research organization — whether a sponsor, contract research organization (CRO), site management

organization (SMO), institutional review board (IRB) or clinical site — that has well-written, comprehensive, and practical clinical research specific-SOPs, is an organization that has a distinct advantage over those that do not. The advantage is that writing SOPs prompts an organization to take the critical step of interpreting and applying GCP regulations and guidelines to its unique clinical research operations.

SOPs ensure consistency, compliance, and accountability of personnel at all levels of clinical research. Organizations without clinical research specific-SOPs run a high risk of GCP noncompliance and poor productivity.

SOPs AND GCP TRAINING

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GCP regulations and guidelines, development of a GCP training program should include review of the organization's current clinical research SOPs. Because SOPs include the who, what, when, how, and why of clinical research operations, it is important for the trainer to become familiar with the SOPs and integrate them into the training program. When a trainer applies and explains GCP regulations and guidelines with examples of the organization's clinical research specific-SOPs, it ensures a more practical and meaningful interpretation of GCP documents and enhances learning. It also demonstrates that the organization is

committed to implementing its clinical research SOPs, and not have them languish on a shelf and go unused.

One important point of clarification — GCP training is not the same as SOP training and vice versa. They are two distinct training programs with unique goals and objectives. However, when trainers integrate well-written, comprehensive, and practical clinical research specific-SOPs into GCP training, they will emphasize the importance and relevance of SOPs and help to enhance GCP compliance for the organization.

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