DArcyComplianceConsulting
We Build Compliance Cultures

Named "Best SME Life Sciences Compliance Consultancy NE USA" by Global Health & Pharma's Healthcare & Pharmaceutical Awards

Characteristics of Best Practice SOPs

⟩ The Importance of Good SOPs

Effective SOPs are the backbone of the drug development industry and are an integral part of an organization's Quality System.

In development and commercialization of drug products, Regulatory bodies provide guidance on what is expected. Companies interpret these details into a set of policies and SOPs. **Compliance is achieved through adherence to these SOPs and evidence of this adherence is what Inspectors expect to see.**

SOPs if well written **can drive strategic benefits** for organizations. Good SOPs drive uniformity and consistency, which over prolonged periods of time, lead to enhanced performance.

Poor SOPs or a lack of SOPs amounts to a lack of guidance causing **confusion, duplication of effort or omission of key activities.** This can manifest into errors leading to costly rework and delayed timelines.

In DArcy's view, Compliance is achieved through **Simplicity** and **Clarity,** not **Complexity** or **Extensive Detail.**

Characteristics of Best Practice SOPs

In assessing a Company's SOPs, DArcy Compliance compares the SOP to what it would characterize as best practice.

1. Documents are classified in **clear categories** with a unique ID #.

2. The tasks listed in SOPs are written in an **action oriented, concise manner.**

3. A documented workflow drives the process and ensures the **right people** are creating content with appropriate people to **review and approve.** The workflow facilitates document identification, storage and the document review cycle.

4. **Appropriate individuals are trained** on the process outlined in the document. Training requirements are assessed, implemented and documented.

5. Documents are written in a **consistent way.** All SOPs have the same 'look and feel'.

6. The documents are organized in a framework (people, process, system) to protect integrity and facilitate accessibility.

7. There is an **administrator for the overall framework** that provides oversight.

Additional Attributes That We Look At

In addition to the characteristics listed, DArcy Compliance also assesses relevance to applicable guidelines, the availability of appropriate references as well as evidence of compliance.

Other regulatory requirements	For example, ICH E6 and ICH E8
Action oriented tasks	Removes ambiguity so all are clear on not only what is done, but who is responsible for taking the actions
Consistent look/feel	Inspectors look for consistency, ease of use, training
Evidence of regular reviews	Requirement that documents be reviewed and updated at regular intervals or when there is a change to guidelines or processes
References	Critical for doing trials/filing in US and ROW