Writing SOPs

Best Practices for Life Sciences Companies

Table of Contents

Introduction

Regulatory Requirements for SOPs 5

Core FDA Requirements 5

What SOPs Do You Need? 7

Using FDA Warning Letters to Identify Needed SOPs 10

Best Practices for SOP Development 13

Defining the SOP Process 13

Fundamental SOP Components 18

SOP Development Checklist 19

Understanding the Policy-SOP-Task Hierarchy 20

A Role for Senior Management 21

Revising the SOP Purpose for Focus and Specificity 22

Process Mapping 24

What Is a Process Map? 24

Identifying Process Inputs, Components and Controls 24

Creating the Process Map 24

Putting the Process Map to Use 25

Using Forms to Aid Workflow 26

Adding a Recordkeeping Section to SOPs 26

SOP Metrics 27

Writing for the Right Audience 29

The Playscript Format 29

Readability: Understanding Adult Comprehension and Retention 31

Layout and Wordsmithing Checklist 33

Making SOP Training Stick 35

Designing a Training Session for Adult Retention 35

Six Common Training Pitfalls 36

The Elements of a Successful SOP Training Program 36

Cautions and Frequent Mistakes in SOP Policy 39

Maintaining and Controlling SOPs 41

Overseeing and Ensuring Self-Compliance 43

Appendices *(can be found on the CD in the back of this report)*

A. 21 CFR Part 210: Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General

B. 21 CFR Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals

C. 21 CFR Part 820: Quality System Regulation

D. Environmental Protection Agency Guidance for Preparing Standard Operating Procedures

E. List of 25 FDA Required SOPs

F. EU Good Manufacturing Practice Guide, Chapter 4: Documentation

G. EU Good Manufacturing Practice Guide, Chapter 7: Outsourced Activities

H. Investigator Responsibilities: Protecting the Rights, Safety and Welfare of Study Participants (FDA guidance)

I. Quality Systems Inspection Technique (QSIT) Manual

J. Presenting Risk Information in Prescription Drug and Medical Device Promotion (FDA draft guidance)

K. Write It Right: Recommendations for Developing User Instruction Manuals for Medical Devices Used in Home Health Care (FDA guidance)