SOPs Clear and Simple

For Healthcare Manufacturers

Susan Schniepp, Brian Matye,
and Jeanne Moldenhauer

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PREFACE

There are four simple sentences that define the concept of compliance and its relationship to SOPs: Say what you do. Do what you say. Prove it. Improve it. Companies usually use their SOPs to show that they have control over their processes, thereby demonstrating compliance to regulatory expectations. "Say what you do," relates directly to the written SOP defining the steps taken to fulfill regulatory requirements for compliance. "Do what you say" equates to following the SOP. This concept seems simple enough yet the number one topic of 483 observations for biologics, drugs and devices from 2013 through 2016 included failure to follow SOPs, procedures not in writing and lack of adequate procedures. This trend is disappointing because there are numerous webinars, seminars and workshops designed to train personnel in writing and following SOPs. In addition, there are a myriad of articles, books and manuals discussing the who, what, when, where and how of SOPs. If that isn't enough, there are several experienced consultants who companies can hire to help write, review and critique their SOPs.

This book was written to offer some practical advice to the pharmaceutical, biotechnology and medical device industries so they may better understand why they need SOPs, how to write them and what should be included in them. It is a simple, straightforward approach to writing SOPs and highlighting their importance in maintaining compliant operations critical to manufacturing quality products.

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