

WRITING HIGH-QUALITY SOPs

One-day workshop to hone your SOP writing skills



Pharmaceutical, biotechnology and life-sciences companies rely on standard operating procedures (SOPs) to ensure the quality and safety of their products and services. From cleaning a machine to running a production process to testing a product, SOPs guide all critical processes.

Paradoxically, in many cases, SOPs themselves lack quality. Containing important technical instructions, SOPs are often wordy, confusing and imprecise, thereby increasing quality and compliance risk for the organisation.

The problem is not lack of technical knowledge. The professionals who write SOPs are technically qualified, but what they lack is sound SOP writing skills.

This hands-on, one-day workshop offers a step-by-step roadmap to take your SOP writing skills to the next level—and write high-quality SOPs.

■ LEARNING OBJECTIVES

1. **Compliance and quality:** How SOPs fit into the overall GMP framework, and what are the key FDA and EU requirements related to SOPs? What are the qualities of a high-quality SOP?
2. **Structure:** What's the basic structure of an SOP? What's the significance of its key elements?
3. **Process:** What's the right process for writing high-quality SOPs?
4. **Best technical writing practices:** How to apply the best writing practices for high-quality SOPs?

■ LEARNER'S PROFILE

- Pharmaceutical, biotechnology and life-sciences industry professionals who actually write SOPs.

WRITING HIGH-QUALITY SOPs

One-day workshop to hone your SOP writing skills

■ COURSE OUTLINE

Module 1: SOPs and GMP compliance

- How SOPs fit into the overall GMP framework?
- What are the key FDA and EU requirements related to SOPs?
- What are the qualities of a high-quality SOP?

Module 2: Structure and process of writing SOPs

- SOPs: Three-part structure and key parts
- How the process of writing SOPs affects its quality?

Module 3: Best writing practices (Part 1)

- How your empathy for the users affects the quality of SOP?
- How much detail?
- Content organisation: simple/hierarchical steps, graphical format and flow chart
- Clear, concise and precise writing
 - Writing short sentences
 - Using imperative sentences
 - Being specific
 - Using parallel phrasing
 - Writing positive phrases
 - Using acronyms and abbreviations with care

Module 4: Best writing practices (Part 2)

- Writing informative title and action-oriented headings
- Ensuring consistency
- Reader-friendly formatting
- Using checklist to ensure quality

■ PROGRAMME

- 8:30 - 9:00 am: Registration
- 9:00 - 10:30 am: Module 1 (SOP and GMP)
- 10:30 am - 10:45 am: *Coffee break*
- 10:45 am - 12:30 pm: Module 2 (Structure and process)
 - 12:30 - 1:30 pm: *Lunch*
 - 1:30 - 3:00 pm: Module 3 (Best writing practices)
 - 3:00 - 3:15 pm: *Coffee break*
 - 3:15 - 5:00 pm: Module 4 (Best writing practices)
 - 5:00 - 5:30 pm: Feedback and closing

WRITING HIGH-QUALITY SOPs

One-day workshop to hone your SOP writing skills

■ TRAINING MATERIALS

1. A training manual providing description of the key principles, examples, case studies, tips and exercises.
2. Hand-outs (PDF) of PowerPoint slides.
3. Certificate of Participation.
4. Book: "Writing High-Quality Standard Operating Procedures: A Practical Guide to Clear, Concise, and Correct SOPs."

■ TRAINER'S PROFILE

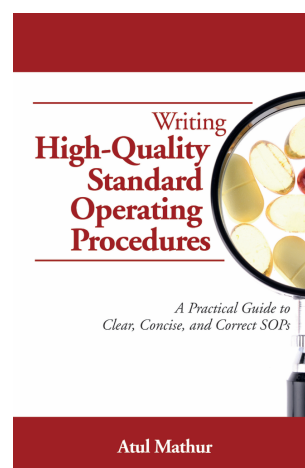
Atul Mathur is the author of the book "Writing High-Quality Standard Operating Procedures: A Practical Guide to Clear, Concise, and Correct SOPs."

Atul Mathur is an engineer with more than fifteen years of experience in technical writing. He has conceptualized, written, and edited hundreds of technical documents, including case studies, guidebooks, reports, training manuals, position papers, specifications, test protocols, and procedures.

As an engineer, he has worked on the design, construction, and commissioning of several pharmaceutical projects.

He has been a guest speaker at several conferences and workshops organised by the International Society for Pharmaceutical Engineering (ISPE). In 2015, he was invited by ISPE to conduct a workshop on "Writing Clear, Concise and Effective SOPs."

He holds a master's degree in engineering from the Indian Institute of Technology (IIT). He runs his own consulting firm, Content Alive, and lives in Singapore. For more information, visit www.atulmathur.com



CONTENT ALIVE

10 Anson Road, #31-10 International Plaza

Singapore 079903

Email: atul@atulmathur.com | Phone: +65 9489 6150 | www.atulmathur.com