How to Write, Organize and Maintain Effective SOPs

Presented By:

Kaitlin Cady and Tyler Foutch

Moderator: Joy Frestedt, PhD, RAC, CPI, FRAPS

Webinar on August 4th, 2016
2:00 PM to 3:15 PM US Eastern time

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Kaitlin Cady has a degree in Marketing Communications and Human Resources. She has been an executive team leader and is dedicated to quality support and office management. She has developed, maintained and trained staff to manage and develop SOPs and enjoys helping clients improve best practices. Kaitlin currently supports clinical, regulatory and quality projects in the drug, device and food industries as the Office Manager for Frestedt Incorporated.

Tyler Foutch has a biology degree and has worked as a bench technician, manager and executive director. Tyler has worked in business operations and experienced SOPs as trainee, team member, initiator, reviewer, author, trainer and subject matter expert. He has helped review and develop SOPs to improve existing practices or deploy new efficient, reproducible solutions. Tyler is knowledgeable in quality system development for ISO 9001 and 13485 and is a practitioner of the 5S Lean process and uses the “5 Why’s” analysis method to get to the core of processes.
Joy L. Frestedt, PhD, CPI, RAC, FRAPS founded Frestedt Incorporated (www.frestedt.com) in 2008 and Alimentix, the Minnesota Diet Research Center (www.alimentix.com) in 2012. Dr. Frestedt has a PhD in Pathobiology from the University of Minnesota Medical School and has managed clinical, regulatory, and quality affairs for more than 35 years at companies like Johnson and Johnson, Medtronic, Mayo Clinical Trial Services, AstraZeneca and Orphan Medical.

Frestedt Incorporated recently received the “Best for Biotechnology Clinical Research 2016 – Minnesota” in the 2016 Healthcare and Pharmaceutical Awards from the Global Health and Pharma Magazine. Dr. Frestedt was named one of the “100 Most Inspiring People in the Life Sciences Industry” (PharmaVOICE, 2011) and the top 25 “Industry Leaders” (Minneapolis/St. Paul Business Journal, 2011). She can be reached at jf@frestedt.com or 612-219-9982.
Course Description
Are the essential processes and procedures of your organization documented for easy reference? If a natural disaster occurs, will you be ready to transition key tasks and responsibilities? What if you lose a crucial employee? Can you transfer the knowledge needed for business to continue without costly glitches?
Documenting Standard Operating Procedures (SOPs) takes thought and effort, but the end result is a resource that can be used over and over again by you or anyone who needs it.

Course Highlights
During this comprehensive webinar, you will learn tips for creating a set of SOPs to save time and money, create easier transitions from old to new employees, maintain compliance and protect your organization in case of catastrophe.
Learner Objectives

By the end of this comprehensive session, attendees will be able to:

- Describe Standard Operating Procedures (SOPs)
- Explain why SOPs are needed
- Explain how SOPs help streamline operations
- Identify key areas where SOPs are needed within an Organization
- Write, organize, and maintain SOPs.
- Generate samples and templates for creating SOPs
- Create an SOP checklist to stay on track and consistently write SOPs
- Get employees engaged in the SOP development process
- Discuss real life examples and how to avoid common SOP problems
- Develop best practices to maintain SOPs (paper/electronic formats)
Agenda

• Understand SOPs and why they are needed
• Develop SOPs and Training
• Engage Organization in Quality Management System
• Manage SOP Life Cycle
What are SOPs and Why are they needed?

- Describe SOPs
- Explain why SOPs are needed
- Explain how SOPs help streamline operations
- Identify key areas where SOPs are needed
SOP Definition

- Written rules, steps and/or work instructions (WI) to outline steps or actions for completing processes.
- SOPs can ensure consistency and quality of actions or responsibilities are performed.
- SOPs can be important tools in communicating company policies, best practices, government law or regulations.
Why SOPs are Needed

- Improve efficiencies and enhance quality controls
- Deliver consistent messaging, process patterns and expectations
- Engage employees and involve team members who perform functions to ensure SOPs and documents are complete
- Assist in training to ensure all processes/topics are included
- Provide step-by-step directions for trainers and trainees
- Encourage follow-up
- Aid cross training to enable teams to perform “uncommon” tasks
- Support employee safety
- Promote a healthy work environment
- Offer legal protection – insist SOPs are followed
SOPs Streamline Operations

Identify Responsibilities
• know who or what team is responsible

Provide Training Tools for Staff
• work with employee attrition and coverage (e.g., someone is out sick, vacation, on leave of absences or leaves the company), having SOPs allows cross-training and built in redundancy

Save Time
• reduce questions (e.g., conducting travel arrangements – employees will be able to identify appropriate hotels and car services and will understand the number of quotes required)

Boost Team Confidence
• employees feel confident when completing each task
Do not reinvent the wheel every time!

Show everyone how well it rolls!

- Reduce time for new employee on-boarding, on-going training and learning curves to have written guidelines
- SOPs are important training and reference tools for employees, managers and business!
Accountability is the key to success!

Hold teams and team members accountable

• Removes mystery of why some teams excel and others do not meet expectations
• Helps managers and employees focus on processes or tasks
• Avoids making work processes personal
• Allows specific evaluation of tasks listed in the SOP or WI
Break down department silos and mystery

Demonstrates company efforts to communicate trainings, policies and regulations

• Makes SOPs available to engage the workforce
• Allows employees to be more fluid within the organization
• Helps the business stay compliant
SOPs stop emergency triage!

Encourage prospective business management and tactics rather than retrospective fire drills

SOPs can create a company culture to stop, write and demonstrate how to approach future issues. SOPs can ensure consistent outcomes and may reduce managerial oversight with simplified decision making
SOPs Standardize Outcomes

Enhances client/team satisfaction

- Standard way to ensure intended process outcomes are met
- Standard way of handling complaints, questions, or refunds, you can ensure consistent messaging is delivered

Remember: SOPs are always subject to change and should grow and develop with the company
Global SOP Planning

Determine which SOPs are needed

HR may be responsible for training the entire company

For example, HR-related SOPs may include:

- Training
- Staff planning
- Performance reviews or disciplinary actions
- Company requirements, policies or procedures
- Hiring, termination or staff management
- Insurance or benefit management

First develop the SOP on SOPs (this will detail how to create, organize and maintain SOP processes and documents)
The need for SOPs is everywhere!

Other departments should have their own SOPs

Example:
Information Technology (IT)
Setting up a workstation for new employees
• What equipment?
• What programs?
• What location?
• What logins or passwords?
SOPs Support Business Operations

Examples of specific SOPs for Industries:

- Investigate methods or testing SOPs (e.g., manufacturing)
- Operate equipment (e.g., construction or retail environments)
- Receive or register clinical material (e.g., healthcare field)
- Manage complaints (e.g., customer services)
- Collect reports (e.g., insurance firms)
- Facilitate safety (e.g., disaster recovery, health or hazardous processes)
Develop SOPs and Training

• Write SOPs
• Create SOP checklist to stay on track and consistently write SOPs
• Generate samples and templates for creating SOPs
• SOP library Organization and Maintenance
Make Time to Save Time

Treat SOP efforts as a long term investment!
Development of SOPs incurs an upfront cost (because time is needed to write the SOP) but significant long-term gains are expected (standard processes lead to time savings).

- Lead the change, be positive and keep reinforcing...
- Highest priority first
- Find quick wins
- Show the value of SOPs to the organization
- Be precise and complete
Create Standards for Custom Work

- SOPs differ from department to department and task to task
- Complexity of business area may require more or less SOPs and related documents
- Number of people involved
- Audience demographics
Standardizing your company **SOP Template** is a great place to start. Give your authors a canvas to work on to ensure a consistent look, feel and brand.

SOP Templates should contain:
- Company logo
- Header and footer
- Unique identifier
- Title
- Revision number
- Approval date
- Page numbers
ISO 9001 Compliance

ISO 9001
Quality Management System

- Document Management System
- Applies to all industries, organizations, company sizes
- Aligns processes to meet regulatory requirements
- Identifies risks or gaps in organizational processes
- Provides expansion into new markets

Some clients require ISO 9001 certification

Writing SOPs – Development

- Align Policies, SOPs, WIs, Forms, Records and Templates
- Focus on SOPs for each functional area (Quality, Mfg, R&D)
- Define purpose, scope, references and related documents
- Assign responsibilities to write procedures, task descriptions and/or appendices
Document Pyramid in more detail

- **Policies**
- **SOPs**
- **Work Instructions**
- **Forms, Records, Templates**

- Corporate Manual
- Who, What, When, Where
- Specific tasks and how to do them
- Documents to record compliance
Document Pyramid SOP Focus

- Policies
- SOPs
- Work Instructions
- Forms, Records, Templates
- Regulatory
- Quality
- Clinical
- Research
- Manufacturing
Keep things simple

Remember SOPs become complicated and hard to follow if too long

- Highly detailed SOPs are really WIs, NOT SOPs!
- Be aware of capturing “tribal” knowledge and language.
- If company uses internal vocabulary or acronyms on a regular basis, consider developing an SOP definition section or a corporate glossary.
Sample SOP Template # 1

1. PURPOSE
   To describe the process of …

2. SCOPE
   This procedure applies to …

3. REFERENCES
   General Reference
   Document Description (Title)
   Website

4. RESPONSIBILITIES
   The President has responsibility for … All staff are responsible for …

5. PROCEDURE
   5.1 FIRST STEP OR PARAGRAPH OF THE PROCEDURE

6. FORMS
   6.1 DOCUMENT XX-XXX TITLE

7. ATTACHMENTS
   7.1 ATTACHMENT A: TITLE

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Sample SOP Template # 2

- **Header**
- **Authorize Signature**
- **SOP Content**
- **Procedures**
- **Footer**
- **Revision History**
- **Attachments, References, Appendices**

### Company X Standard Operating Procedure

**Title:**

**Number:**

**Revision:**

**Supersedes SOP No.:**

**Page:**

**Effective Date:**

**Author:**

**Reviewer:**

**Approver:**

**Name/Title**

**Name/Title**

**Name/Title**

**Date**

**Date**

**Date**

**Revision History:**

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1) POLICY
2) PURPOSE
3) RESPONSIBILITY
4) PROCEDURES
5) REFERENCES

6) APPENDICES

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Authoring SOPs for the first time can be a daunting task. Here are some simple techniques to keep on task and stay focused on goals to make sure company SOPs are effective.

- If you are not the PRIMARY operator of a function in the SOP, talk to employees who do the work and consider observing the work process.
- Make a checklist
  - Bullet points are great
- Pictures are powerful
  - Flow charts
  - Annotated pictures
SOP Development: Purpose

Write SOPs with a focus on reason for or business need to frame the outline

• Past or recent experiences necessitating a specific SOP
• Owner or Corporate policies needing functional instructions for employees
• Business Planning
SOP Development: Scope

• Describe operations or tasks included in the SOP
• Identify operations that are omitted from the SOP
• Who is the audience for the specific SOP
SOP Development: Responsibilities

- Empower employees nearest to the process or procedure in authoring SOPs
- Use internal subject matter experts to review and comment
- Establish a Responsibility Matrix identifying what role or department is responsible for authoring, reviewing, approving and being informed during the SOP lifecycle
  - Responsibility Assignment Matrix - RAM
  - Responsible, Accountable, Consulted and Informed - RACI
  - Linear Responsibility Chart - LRC
Matrix Examples

### RAM

<table>
<thead>
<tr>
<th>Function</th>
<th>Project Sponsor</th>
<th>Business Analyst</th>
<th>Project Manager</th>
<th>Software Developer</th>
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<tr>
<td>Initiate Project</td>
<td>I</td>
<td>C</td>
<td>AR</td>
<td></td>
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<tr>
<td>Establish Project Plan</td>
<td>I</td>
<td>C</td>
<td>AR</td>
<td>C</td>
</tr>
<tr>
<td>Gather User Requirements</td>
<td>I</td>
<td>R</td>
<td>A</td>
<td>I</td>
</tr>
<tr>
<td>Develop Technical Requirements</td>
<td>I</td>
<td>R</td>
<td>A</td>
<td>I</td>
</tr>
<tr>
<td>Develop Software Tools</td>
<td>I</td>
<td>C</td>
<td>A</td>
<td>R</td>
</tr>
<tr>
<td>Test Software</td>
<td>I</td>
<td>R</td>
<td>A</td>
<td>C</td>
</tr>
<tr>
<td>Deploy Software</td>
<td>C</td>
<td>R</td>
<td>A</td>
<td>C</td>
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### LRC

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<td>A</td>
<td>R</td>
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<tr>
<td>Establish Project Plan</td>
<td>I</td>
<td>A</td>
<td>R</td>
<td>C</td>
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<td>Collate User Requirement</td>
<td>I</td>
<td>A</td>
<td>I</td>
<td>R</td>
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<tr>
<td>Define Technical Requirements</td>
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<td>A</td>
<td>I</td>
<td>R</td>
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<tr>
<td>Develop Software Tools</td>
<td>I</td>
<td>A</td>
<td>R</td>
<td>C</td>
</tr>
<tr>
<td>Test Software</td>
<td>I</td>
<td>A</td>
<td>C</td>
<td>R</td>
</tr>
<tr>
<td>Install Software</td>
<td>C</td>
<td>A</td>
<td>C</td>
<td>R</td>
</tr>
</tbody>
</table>

### RACI

SOP Development: Procedures & Tasks

- Who or how many people to complete the task
- Audience skill level
- Equipment or supplies needed
- Personal protective requirements
- Safety or health concerns
- Associated hazards
- Define each task in specific detail
  - Any specific order of completion?
  - Allotted timing?
  - Any specific tools or materials to use?
  - Any measurement or monitoring required during any given process steps?
- Description of end results
SOP Development: References

During SOP development
• Collect and cite references
• References may change, be revised, retired or become dated

Examples include
• Regulatory documents
• Legally required forms
• Websites
• Directories
• Maps
SOP Development: Related Docs

- Ties process and documentation system together
- Connects next steps
- Links correct forms or other documents each time

Examples include:
- Other SOPs
- Protocols
- Work Instructions
- Forms
Appendices are included with SOPs when additional internal or external information is required but is not a direct output of the work.

Examples include:

- Approval forms
- Related templates
- Check list
- Flow chart
SOP Organization and Maintenance

Keeping a new SOP system in good working order requires some basic organization and oversight. Luckily, we live in a time with computers and software, so use those tools!

SOP Organization and Maintenance considerations:

• Document Control
• Revision Control
• SOP Life Cycle Management
Document Control System Process

Assign next available document management number with document type

Create a new document

Yes

New Document?

No

Discuss priority/plan with Management

Revise the editable document

Originator/Editor notifies Approver and describes changes if a revision

Approver reviews the document

Approver provides comments to Originator/Editor

Yes

Approved?

No

Issue or publish into Quality Management System

Notify and Train Employees

Yes

No
Revision Control SOPs

As new SOPs are used they will need to be improved, updated and over-hauled

• Document formatting process
• Leave room for versioning
  • Version control and a description of changes or relines for each version will show the evolution of the process
  • Sometimes looking back at the history of the process is helpful when looking at a problem
SOP Life Cycle

1. Purpose for SOP
2. Draft
3. Review and Approve
4. Implement and Train
5. Update and Archive
Engage Organization in SOP Ownership

- Get employees engaged
- Discuss real life examples
- Avoid common SOP problems
Create a Culture of Ownership

• “Experts” actually do the work being done
• Accolades! SOPs allow employees to show off the great working already being done!
• Diffuse situations by focusing on process first, second and third. Not the person.
Real Life Example #1- How does this get done?

**Situation:**
Company A wrote down a certain “group” would be gathered to deal with product recall events. The SOP did not identify appropriate team stakeholders or the goal of the team.

**Approach:**
Business unit allies were contacted to determine stakeholders. First 2 meetings determined the groups mission and scope.

**Process:**
SOP was revised to provide more detail and subsequently broke off into a new Work Instruction.

**Outcome:**
On-going recalls were better managed and international distributors and sales issues were triaged quickly and issues escalated to top management quickly.
Real Life Examples #2- What is being done?

**Situation:**
Company B was experiencing yield issues in a refinement process causing erosion of margin and production totals. One technician had higher yields and was designated the only one to perform refinement of material.

**Approach:**
The business decided to send in a scientist to observe the tech with high yields against what was written in the SOP. The scientist observed the tech would use a technique not described in the SOP but was not prohibited by the SOP.

**Process:**
This method was then validated and amended to the SOP so all technicians would perform the optimal detailed refinement technique.

**Outcome:**
Yields increased across all techs, returned most of the lost margin and increased supply chain leads due to increased build size.
Real Life Examples #3- Zombie process

**Situation:**
Company C had gone through a major business overhaul, all areas were affected. During a routine process, management noted documentation did not contain the correct company logo. Further review found the entire process around a group was not aligned with new business appearance and practices.

**Approach:**
The business first inquired with the group supervisor, who was not aware of the changes in the business. The group supervisor was sick the day of manager training. Subsequently, the whole team did not receive training. The team went through documented training immediately and business communications were reviewed and updated to prevent future issues.

**Process:**
The team was integrated back into the business internal communication and work product returned to normal.

**Outcome:**
The team quickly took to the new appearance and practices. Some even took the initiative of immediately updating procedures.
Tips to Avoid Common SOP Problems

• Plan, plan, plan and execute
• Be light, deliberate and efficient with SOP deployments
• When drafting put more on the page than needed and finds ways to get reviewers engaged
• Write clearly first then write concisely
• Make sure your process owners (upstream and downstream too) review the SOP before they attempt to do the process
Training

Training signals to your team things are about to change

• Implement changes and train employees
• Training is an ongoing process as documents are revised, added and retired
• Make sure employees document their SOP training on all appropriate SOPs for their job/s

The TWO most important SOPs to start out are:
• SOP on SOPs
• SOP on Training
Manage SOP Life Cycle

- Develop best practices to maintain SOPs (paper/electronic formats)
Maintain SOPs

- Change the SOP if workers are constantly deviating or redlining a document
- Change the SOP if workers have memorized the process to “save the headache” of writing a new SOP
- Review SOPs every year
  - Too many SOPs?
  - Use auditing methods to test the system or processes needing better performance.
- Designate a “Document Control” group or team member to ensure a quality control check for SOPs
Maintaining SOPs in Hard Copy

- Anticipate administrative burden
- Record employee signature and initials
- Designate locations for most current documentation
- On-site or remote storage for archived files?
- Develop copy policy
- Develop retention/destruction policy
Sample QMS Checklist for Hard Copy System

The purpose of this form is to provide a checklist of steps to control changes to Company X documents. Record document number here: ___________

Draft to final version document

☐ Revise documents and secure approval with appropriate signatures and dates.

PDF and MS word storage

☐ Make a PDF of the signed approved document.
☐ Store PDF copy in file “Signed PDF Versions” on shared drive.
☐ Move obsoleted PDF copy in file “Archived PDFs” on shared drive.
☐ Store MS Word copy in file “Current Word Versions” on shared drive.
☐ Move obsoleted MS Word copy to “Obsolete” folder on shared drive.

Paper copy storage

☐ Mark obsolete paper copy “VOID” with initial/signature/ date on bottom right hand corner.
☐ Insert signed paper document into QMS binder.
☐ Insert obsoleted paper version into Archive binder.

Maintenance and Quality Assurance

☐ Record changes to QMS documents in the F-XXX SOP Schedule Spreadsheet. Copy existing line item and paste to bottom of “Archive” tab. Return to “Current” tab and update Revision History (Column D), add comments documenting changes (Column E) and record sign off date (Column F).
☐ Document SOP, WI or Form training in “Employee Training” binder.
☐ Ensure “Quality Management System: Standard Operating Procedures” binder contains all current SOPs, WIs and Forms.
☐ Ensure record of all changes to QMS documents are maintained in “Archive - Quality Management System: Standard Operating Procedures” binder.
Maintaining SOPs in Electronic Format

- Anticipate administrative burden
- Record employee e-signature and initials
- Designate locations for most current documentation
- On-site or remote storage of archived files?
- Compatible with existing IT infrastructure
- Recommend purchase (do not develop in house)
- Employees have access to computer terminal for current revision
- Policy on use of hard copies
- Policy for document retention and destruction
Electronic Format System Sample Specification List

- Auditing function
- Electronic Document Routing
- Secure Document Approvals and Sign Offs
- Secure Login
Disaster Recovery

Hard Copy Security, Backup & Recovery
• On-site locked drawers
• Copy’s clearly marked as “COPY” with date and initials
• Off-site storage

Electronic Copy Security, Backup & Recovery
• VPN protocols in place
• User passcodes protocols
• On or off site server security parameters
• Daily back-up protocol
Wrap UP

- Review Learner Objectives
- Question and Answer Session
Agenda

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Questions?

Thank You for attending this course!

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