Mastering the Art of Writing Effective SOPs

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Take Away:

- Learn best practices to create effective, clear, concise, and unambiguous SOPs
- Explore why SOPs are a cornerstone in ensuring regulatory compliance, product quality, and consumer safety
- Understand the crucial role of SOPs
- Discover the impact of well-structured SOPs on minimizing errors, deviations and inefficiencies
- Explore how visuals, flowcharts and other aids improve comprehension and implementation
- How to navigate regulatory frameworks and industry standards
A standard operating procedure (SOP) is a written set of instructions (or defined procedure) for carrying out a particular task or work.

SOPs seek to minimize ambiguities and failure to adhere to regulatory requirements while increasing effectiveness, high-quality output, and consistency of performance.
POLL 1:  
I am new to SOPs and don't have adequate knowledge of creating, implementing, and maintaining SOPs complying with standards and guidance documents.  
☐ Yes  
☐ No
Standard Operating Procedure (SOP): Best practices

1. Clear and Concise: Easy to understand, State the purpose. Be specific

2. Well-Structured (and preferably digitalize using an EQMS): Numbered steps, East Navigation, Access digitally

3. Appropriate Detail and Sequence: Adequate, but avoid excessive detail. Chronological order, Practical, Incorporate Visual Aids

4. Roles & Responsibilities: Clearly defined for each process or task.

5. Compliance and Regulations: Address relevant regulatory, and industry standards. Aligns with legal and quality standards.

Why SOPs are crucial for an organization?

**INTERNAL REQUIREMENT:**
- Quality System
- GxP
- CAPA
- Risk Management Process
- Manufacturing Process
- Verification and Validation

**EXTERNAL FACTORS:**
- Regulatory Agencies
- Inspection and Audit
- Product Launch
- Business Expansion
- Traceability
- Customer complaints & feedback
An organization with well-defined SOPs: Business Impacts

- Standardization → Streamlined Processes → Enhanced Communication & Clarity → Improve Organizational Efficiency
- Consistent Quality → Continuous Improvement → Risk Mitigation & Regulatory Compliance → Customer Satisfaction
- Increase Profit Margins → Organizational growth
Visuals Aids and Images improve comprehension and implementation of an SOP
Well-structured SOPs minimize errors, deviations, and inefficiencies: General Content of an SOP

- **Purpose**
  - Standardized

- **Scope**
  - Coverage
  - Limitations

- **Responsibilities**
  - Who
  - What

- **Procedure**
  - Steps
  - Consistency

- **Referencing**
  - Internal
  - Regulatory
  - Standards
  - Guidance

- **Document History/changes**
  - Changes
  - Continuous improvement

- **Reviewer & approver**
  - Reviewed
  - Approved
  - Dated
Navigate regulatory frameworks and industry standards

- ISO 13485:2016
- 21 CFR PART 820
- Good Manufacturing Practices (WHO)
- MDSAP
- EU MDR/IVDR
POLL 2:
We have all SOPs in place but now require updating them based on today's learning.
Yes
☐ Yes
☐ No
Conclusion

For MedTech and LifeScience companies to maintain effective standard operating procedures (SOPs), there must be clear communication, consistent procedures, and regulatory compliance. Always keep in mind that an effective SOP should offer concise, practical advice that produces predictable results. You can establish SOPs that contribute to increased operational efficiency, quality, and compliance inside your organization by using the procedures and best practices you heard and learned today in the webinar.
POLL 3:
ComplianceQuest should contact me for an initial level of discussion on how digitization, EQMS and Automation can help our organization

☐ Yes
☐ No

POLL 4:
On a scale of 1 to 5, with 1 being poor and 5 being excellent, how would rate the webinar by ComplianceQuest

1  2  3  4  5
About ComplianceQuest
AI-powered cloud platform for Clinical, Quality and Safety management solutions

**CLINICAL MANAGEMENT**
- Clinical Trial Operations
- Study Start-Up
- CTMS
- eTMF
- EDC
- Safety & Pharmaco-vigilance
- Decentralized Clinical Trials

**MARKET SURVEILLANCE**
- Complaint Management
- Regulatory Assessment
- Regulatory Reporting
- MDR eGateway
- Field Service Connector

**QUALITY MANAGEMENT**
- Audit
- CAPA
- 5 Why RCA
- Change Control
- Deviation
- Equipment
- Investigation
- NC
- OOS/OOT
- Product Inspection

**SUPPLIER MANAGEMENT**
- Audit
- On/Off-Boarding
- Accreditations
- Deviations
- SCAR
- 5 Why RCA
- Supplier Central
- Inspections
- PPAP
- Document Exchange
- Supplier Ratings
- Score Cards
- Permit to Work
- Investigation

**RISK MANAGEMENT**
- Audit
- Risk Register
- Process Inspection
- JSA
- Permit to Work
- Investigation

**WORKFORCE DIGITALIZATION**
- Document Management
- SOP Enforcement
- Training
- Change
- Learning Portal

**HEALTH AND SAFETY**
- Injuries, Vehicle, Security, Property
- Claims Management
- Safety Observations
- Near Miss
- Investigation
- 5 Why RCA
- Regulatory Forms
- Inspections
- JSA
- Permit to Work
- Management of Change
- Toolbox Talk

**ENVIRONMENT & SUSTAINABILITY**
- Spills and Releases
- Sustainability
- Permits
- Regulatory Library
- Notice of Violation
- Audit

**INTEGRATIONS**
- CRM
- EBR
- ERP
- HRMS
- LIMS
- MES
- MOM
- PLM
- RIMS
- Others

**CONNECTIVITY**
- Analytics
- Dashboards, Reports
- Collaboration
- Community
- Communication
- Mobile
- Validation
- Artificial Intelligence

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THANK YOU

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