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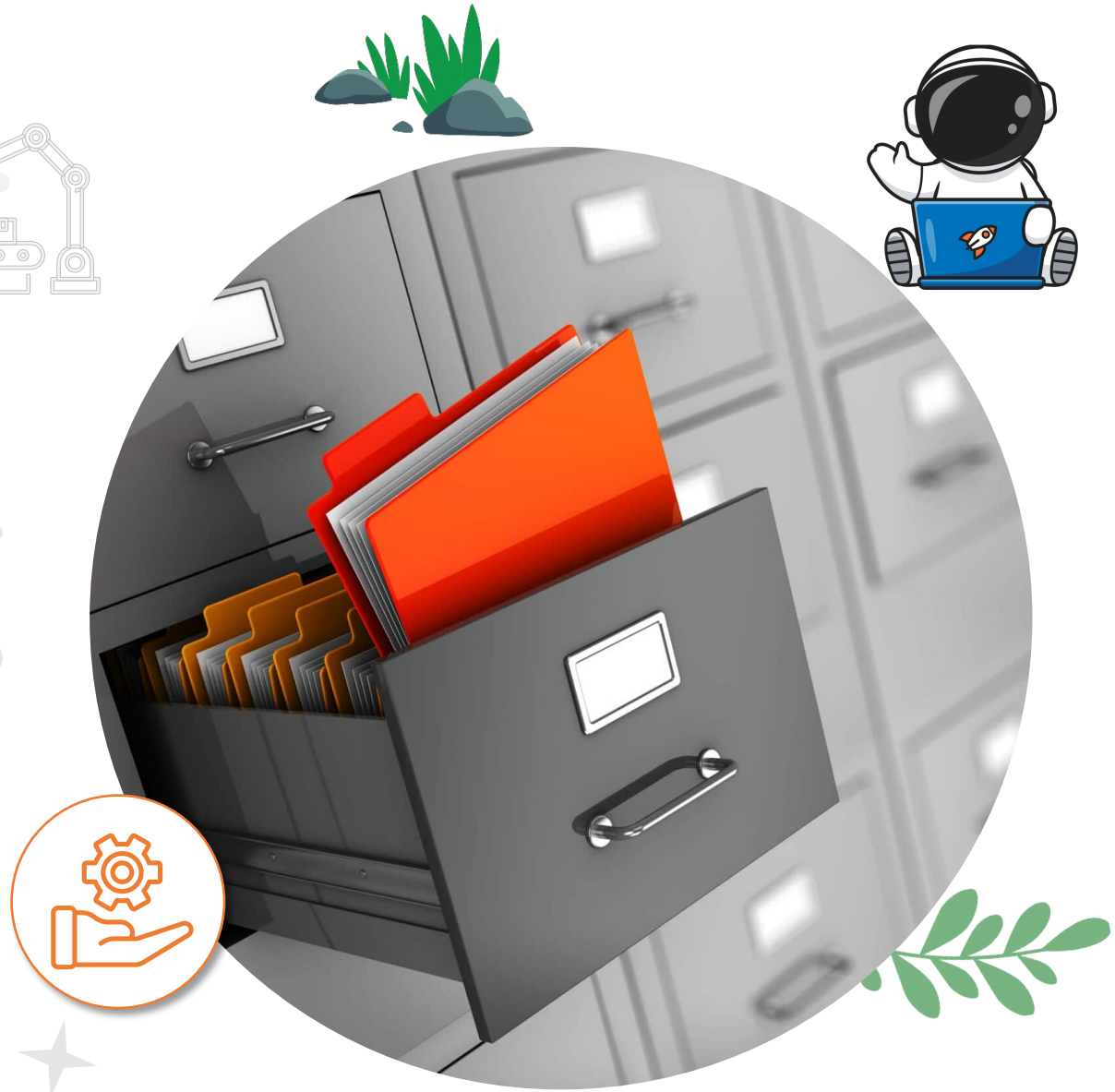
Mastering the Art of Writing Effective SOPs

Presented by | Sundeep Agarwal



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Speaker Introduction

SUNDEEP AGARWAL

Trainer, Speaker & Consultant

An expert in medical and IVD devices & life sciences, Mr. Sundeep Agarwal is a speaker, trainer and consultant in the field of Quality Assurance, Regulatory Affairs, QMS, GMP, Software Validation, SaMD, Artificial Intelligence, Combination Devices, GCP, Design & Development, Risk Management and Industrial Manufacturing. He is a lead auditor for medical devices and has expertise in ISO 13485, EU MDR, IVDR, CE Certification, CER, PMS, USFDA, 510(K), ISO 14971, MDSAP.

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Take Away:

Standard Operating Procedure:

A standard operating procedure (SOP) is a written **set of instructions** (or defined procedure) for carrying out a particular **task or work**.

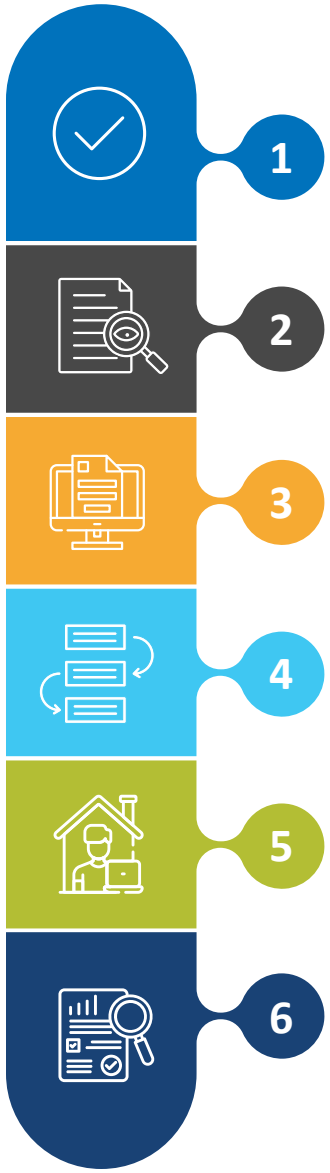
SOPs seek to **minimize ambiguities** and failure to **adhere to regulatory requirements** while increasing **effectiveness**, high-quality output, and **consistency of performance**.

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.
6. **References, Version Control, Approver and Reviewer, Document History.**

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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

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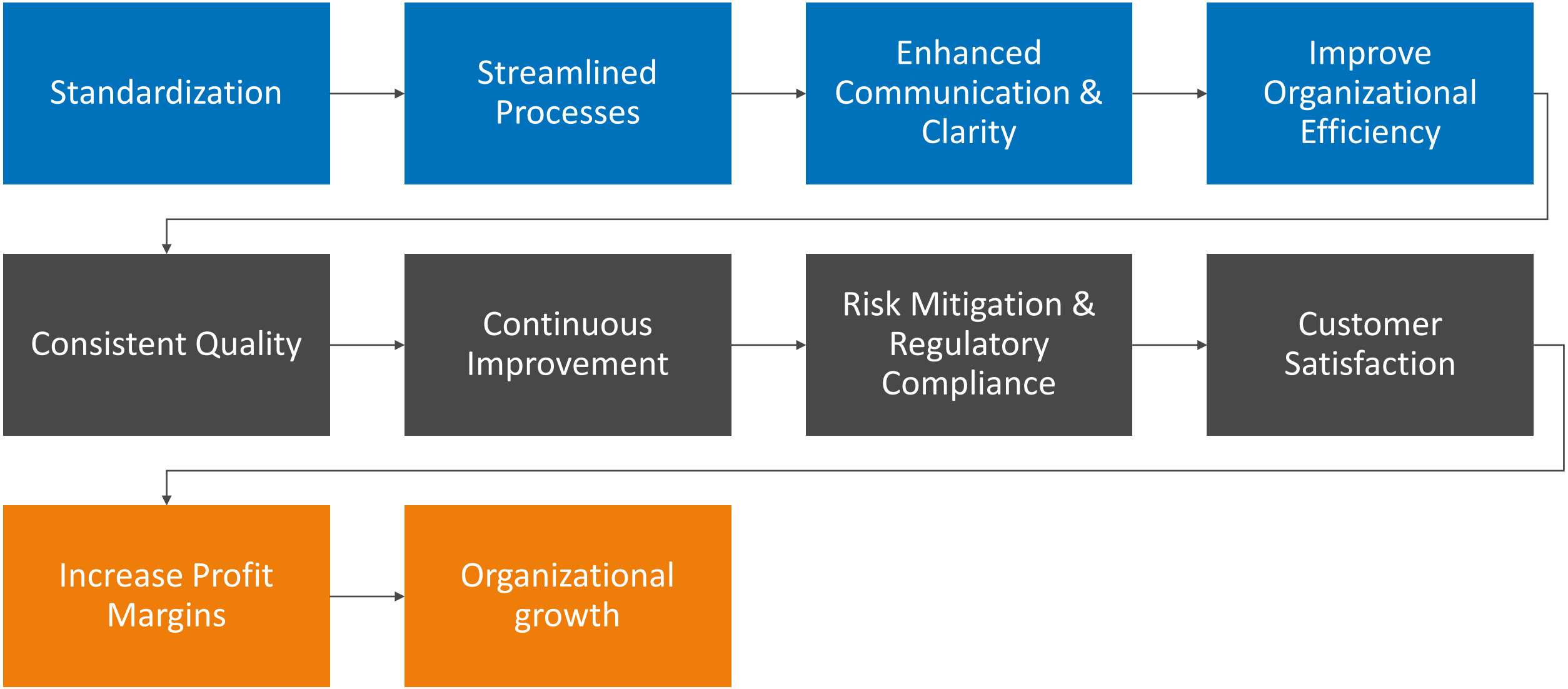
An organization with well-defined SOPs: Business Impacts



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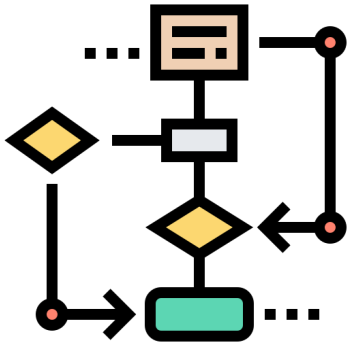
Visuals Aids and Images improve comprehension and implementation of an SOP

Flowcharts and Process Diagrams



Infographic. Photographs, Images

Color Codes and Highlighting

Safety and Hazard Symbols

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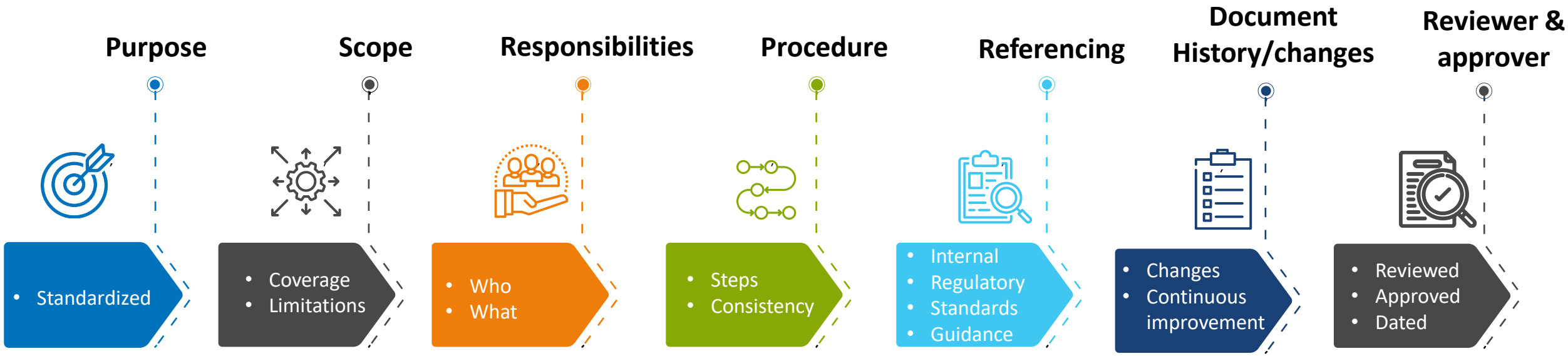
Well-structured SOPs minimize errors, deviations, and inefficiencies: General Content of an SOP



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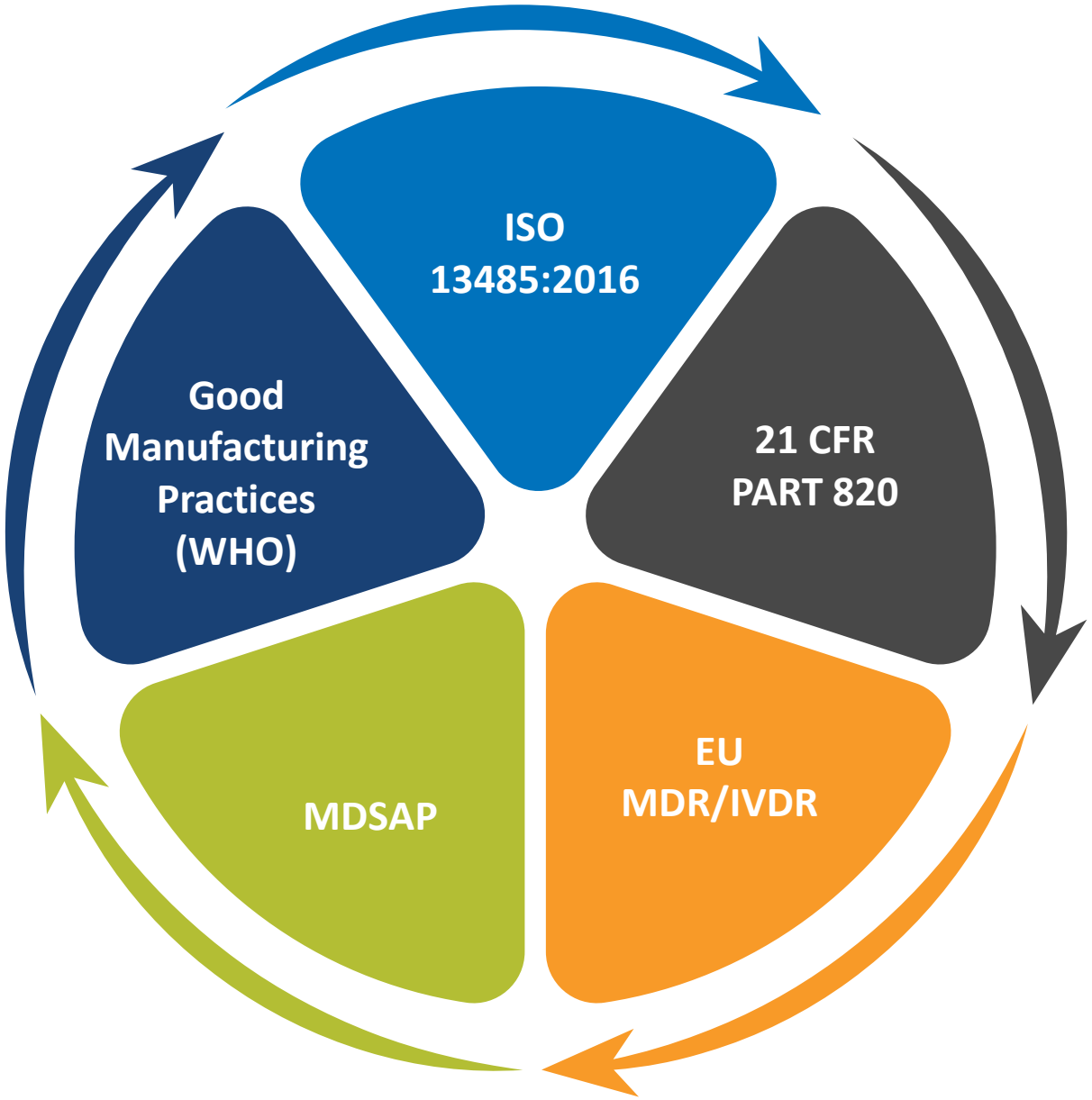
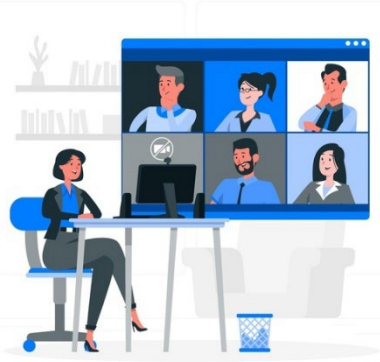
Navigate regulatory frameworks and industry standards





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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

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About ComplianceQuest

AI-powered cloud platform for Clinical, Quality and Safety management solutions

Clinical | EQMS | EHS

INTEGRATIONS

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

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

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

CONNECTIVITY

salesforce, CLOUDBYZ, rootstock software, SERVICEMAX, TAVANT, Microsoft, Google, box, MuleSoft, tableau

MANAGEMENT REVIEW

Analytics | Dashboards, Reports | Collaboration | Community | Communication | Mobile | Validation | Artificial Intelligence

PLATFORM POWERED BY salesforce

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THANK YOU

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