Compounding Quality Center of Excellence Training Program

Elevating SOP, Job Aids, and OJT in a GMP setting

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Agenda

- Intro/Background
  - Regulatory Requirements
- Human Error Reduction Principles
- Baseline on Lean Principles
- SOP Design
  - Process
  - Roles
  - Examples
- SOPs vs Job Aids
- Doc. Revision and OJT
- Q&A

Intro./Background

- My Background and why I am here
- FDA Regulatory Expectations
  - Title 21 CFR 211.100)

Sec. 211.100 Written procedures; deviations.

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

Purpose of Workplace Documents

- Record of process
- Transfer of training
  - Reduce/eliminate the “human variable”
- Job Aids
  - Checklists
  - Charts
- Instructions
  - SOPs or flowcharts

Human Error Reduction Principles

- Consistent format/orientation
  - Consistency drives predictability
- Use of Patterns
  - Data not imbedded in text rather in charts
  - Shading where no data required
  - Lines to group work into sections
- Boxes/blocks instead of lines
  - Box instead of an underline
  - Signature blocks with embedded format
  - Clear calculation blocks
- Use of color/icons
  - Safety
  - Indicate good, marginal, bad
- Use of common units

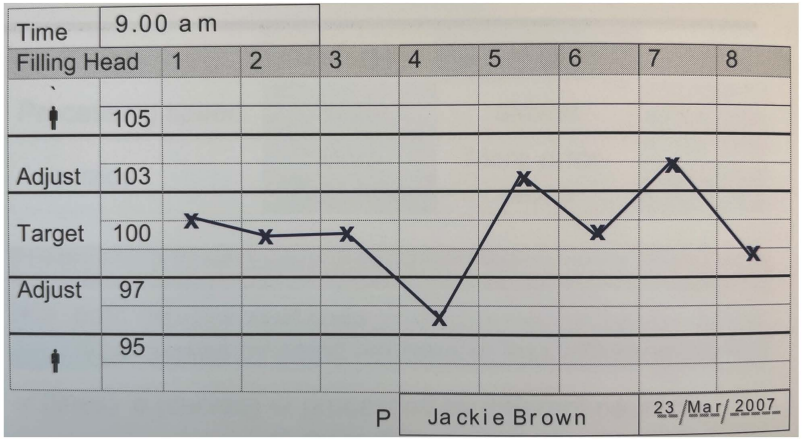
Examples

No. tablets taken from side 1: 100 No. tablets from side 2: 200
Total Number: 400 Avg tablet weight side 1: 6mg :
Avg tablet weight side 2: ____ Avg tablet thickness side 1: 5.4mm
Avg tablet thickness side 2: 5.3mm

	Side 1	Side 2	Total
No. Tablets Taken	100	200	400
Avg Tablet Weight	6 mg		
Avg Tablet Thickness	5.4 mm	5.3 mm	

Weight of bulk tablets (kg)	X	X 1000 grams	÷	Average Table Weight (g) (from Primary Packaging Cert)	=	Quantity of bulk tablets picked	÷ 30 =	Theoretical Lot Quantity (bottles)
	X	1000	÷		=		÷ 30 =	

#	Step
1.1	**Weight of bulk tablets** picked in warehouse for packaging: kg (see page 4 of this doc) P V __/___/____
1.2	This is a sample step that doesn't require signoff. Information only but required for the process. Make sure you don't miss this step and ensure you do it in the correct order.
1.3	this step is an instruction that doesn't require a signature
1.4	Neither does this one. It is a rather long instruction so may take several rows Steps given to do tasks More steps
1.5	**Average Tablet Weight** g (obtain this information from Release for Primary Pkg Certificate) P __/___/____
1.6	Using the information above calculate the Theoretical Load Quantity as follows:: **Quantity of bulk tablets** picked for packaging = Weight of Bulk tablets / Average Tablet Weight = g/ g = Tablets P V __/___/____
1.7	**Theoretical Lot Quantity** = Quantity of bulk tablets picked/30 = /30= bottles P V __/___/____
1.8	Another step that requires 2 people to sign it this step is simple but requires a signature and P V __/___/____



End User Expectations/Feedback

- Need to be concise
- Enough detail to have only one interpretation
- Logical flow to minimize waste of motion and work
- More graphics and pictures to drive clarity
- Alerts to indicate critical risk points for safety and compliance
- Break SOPs into specific tasks

Lean Principles

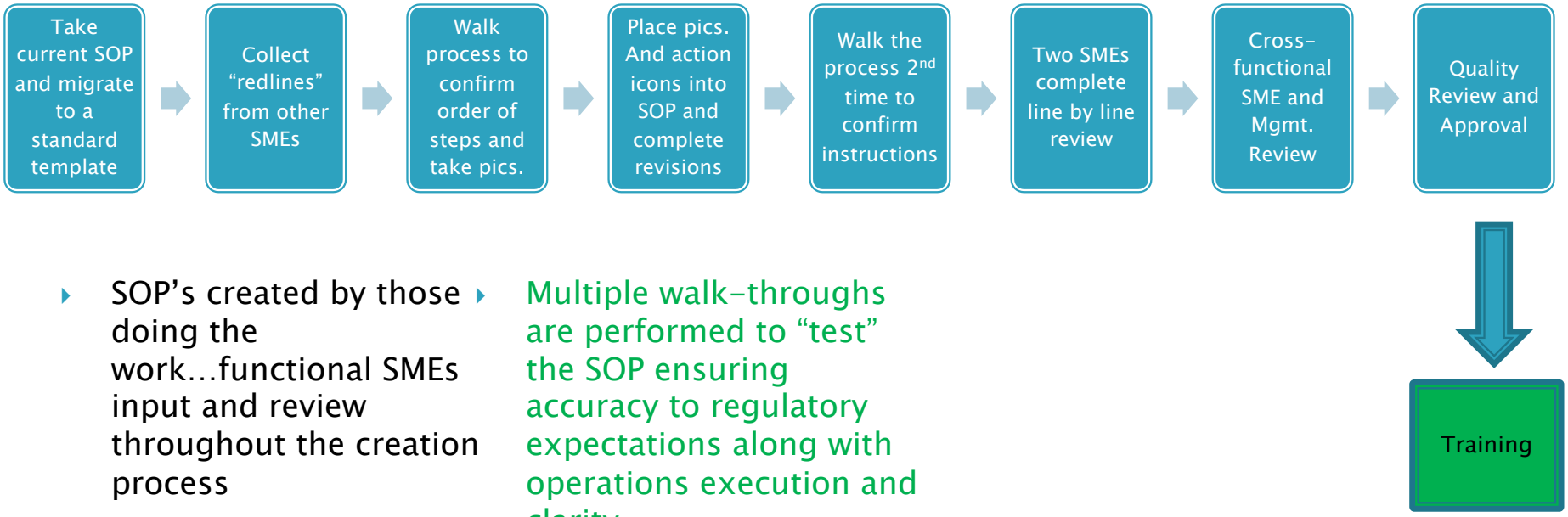
- Key Capabilities
  - Process Design
    - Design the work to eliminate waste
    - Balance work content
    - Standardized Work
  - Problem solving
    - Drive to Point of Cause
    - Drive to Root Cause
  - Share best practices to help standardize
  - Leaders being Coaches and Mentors

Lean Principles (cont.)

- Process Design
  - Define what good looks like
    - Makes Problems Visible…a good thing
  - Define a process, even if it is not optimal…it is a starting point
  - Ultimately leads to Standardized Work
    - Based on Takt Time
    - Task designations and order
    - Tool for training
    - Tool for improvement
  - Derived from:
    - Observation
    - Data collection and analysis
    - Operator engagement/input
    - Define best practice and then standardize

SOP Design…one approach

- The Process



- SOP's created by those doing the work…functional SMEs input and review throughout the creation process

- Multiple walk-throughs are performed to "test" the SOP ensuring accuracy to regulatory expectations along with operations execution and clarity.

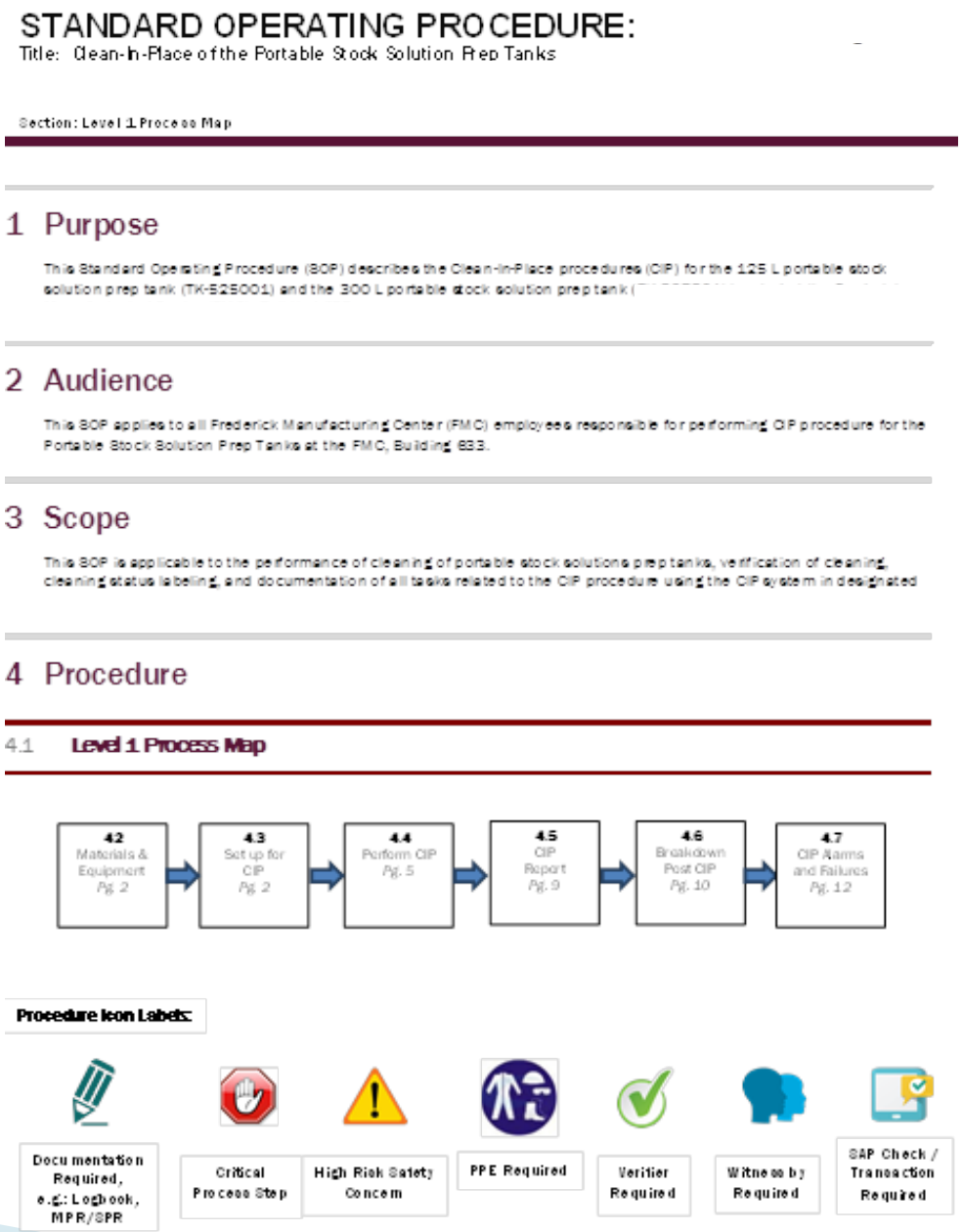
SOP Design…one approach (cont.)

- Roles and Responsibilities
  - SMEs (operators/technicians) drive the flow and content since they execute the work!
  - Doc editors are trained and competent to edit SOPs to follow standard template expectations.
    - Many vs few trade-off
  - Functional support areas, i.e. Validation, Quality, etc., provide input as the new format SOP is developed.
  - Management and Quality Approval
  - Supervisors (and QA) are accountable to ensuring employees are trained in the current version and executing to SOP
  - Updates as necessary to drive improvement and eliminate potential gaps

SOP Design…one approach (cont.)

Process map for Navigation

Standard Icons for Clarity and Alerts



STANDARD OPERATING PROCEDURE:
Title: Clean-In-Place of the Portable Stock Solution Prep Tanks

Section: Level 1 Process Map

1 Purpose

This Standard Operating Procedure (SOP) describes the Clean-In-Place procedures (CIP) for the 125 L portable stock solution prep tank (TK-525001) and the 300 L portable stock solution prep tank (

2 Audience

This SOP applies to all Frederick Manufacturing Center (FMC) employees responsible for performing CIP procedure for the Portable Stock Solution Prep Tanks at the FMC, Building 833.

3 Scope

This SOP is applicable to the performance of cleaning of portable stock solutions prep tanks, verification of cleaning, cleaning status labeling, and documentation of all tasks related to the CIP procedure using the CIP system in designated

4 Procedure

4.1 Level 1 Process Map

4.2 Materials & Equipment Pg. 2 → 4.3 Set up for CIP Pg. 2 → 4.4 Perform CIP Pg. 5 → 4.5 CIP Report Pg. 9 → 4.6 Breakdown Post CIP Pg. 10 → 4.7 CIP Alarms and Failures Pg. 12

Procedure Icon Labels:

Documentation Required, e.g.: Logbook, MPR/BPR

Critical Process Step

High Risk Safety Concern

PPE Required

Verifier Required

Witness by Required

SAP Check / Transaction Required

SOP Design…one approach (cont.)

- Standard Template Example
- Example Application

Example

Icons in 1st Column to alert Technician

STANDARD OPERATING PROCEDURE:

Section: Set up for CIP

Icons	Instructions and Explanations	Illustrations
⚠	4.3.3 Verify that the tank has a calibrated pressure gauge that is within expiration and that the calibration seal is intact. If the pressure gauge is expired or the calibration seal is broken / removed, DO NOT PROCEED. Contact a supervisor.	
⚠	4.3.4 If applicable, verify the battery condition of the digital pressure gauge prior to use. If the battery indicator is not at three bars, DO NOT PROCEED. Notify I&C department. In the event the battery indicator drops below three bars during use, the displayed pressure value is still valid.	
⚠	4.3.5 Verify that the tank is empty via the sight glass. If the tank is not empty, the end use was not performed correctly. Contact supervisor prior to proceeding. 4.3.6 Verify that the tank is vented to ambient pressure via the digital pressure gauge. If the tank is under pressure, relieve the pressure by opening the bleeder end cap on the vent filter port. Note: When the tank is stationary for operation, apply safety brakes on the wheels.	
	4.3.7 Open the bleeder cap on the vent filter port to verify there is no pressure, then remove the bleeder end cap from the vent port and the end cap from the spray ball port and place them in labeled dirty bin for delivery to 5P33 for cleaning .	
⛔	4.3.8 Place a check valve on the vent port of the tank with the spring of the check valve visible to the operator. 4.3.9 Place an elbow on the check valve and secure both to the vent port of the tank with a clamp.	

Pictures and illustrations in 3rd column

Brief clear instructions for each step in active voice in 2nd column

SOPs vs Job Aids

- SOPs
  - Outline procedure
  - Safety
  - Compliance
  - Req. Doc. Mgmt.
  - Drive Consistency
- Job Aid
  - More granularity
  - Specific “high risk” tasks
  - Consistency
  - Critical Part of OJTs

Document Revision

- Critical gaps drive updates ASAP
- Other input during use by SMEs is captured in "Comment Log"
- Non-critical changes are assessed and aggregated to quarterly updates
- Approved authors update docs.
- Revision history update in SOP
- Docs. Updated on shopfloor
  - Rev. Date
  - Effective Date

On The Job Training

- Objective
- Safety
- Process Context
- Observe
- Perform
- Assessment
- Documentation
- Refresh as needed
  - Minimally, annually

Questions/Discussion?