

Going From

# **Red to Green**

(Probation to Preferred)

Princeton Section ASQ

February 13, 2013

Speaker

**Jim Werner**

# Frantic Call

- Got Call for Help - SOS
- “Urgent - Business Critical”
- Need help NOW !!!!!

# **BIG** Incentive to Act

- Placed on Probation by Key Customer
- Meet FDA-QSR\*\* within 6-months or out – **LAST CHANCE!!!!**
- Potential Loss of >\$1.0mm Sales

\*\*21 CFR Part 820, Quality System Regulation

# Made Site Visit

- Well Established Business
  - Long time employees
  - Complete Lack of FDA Regulations
  - Processes well understood & controlled
  - **No Procedures - No Records**
- Not uncommon with small medical device mfg'ers

# Company Background

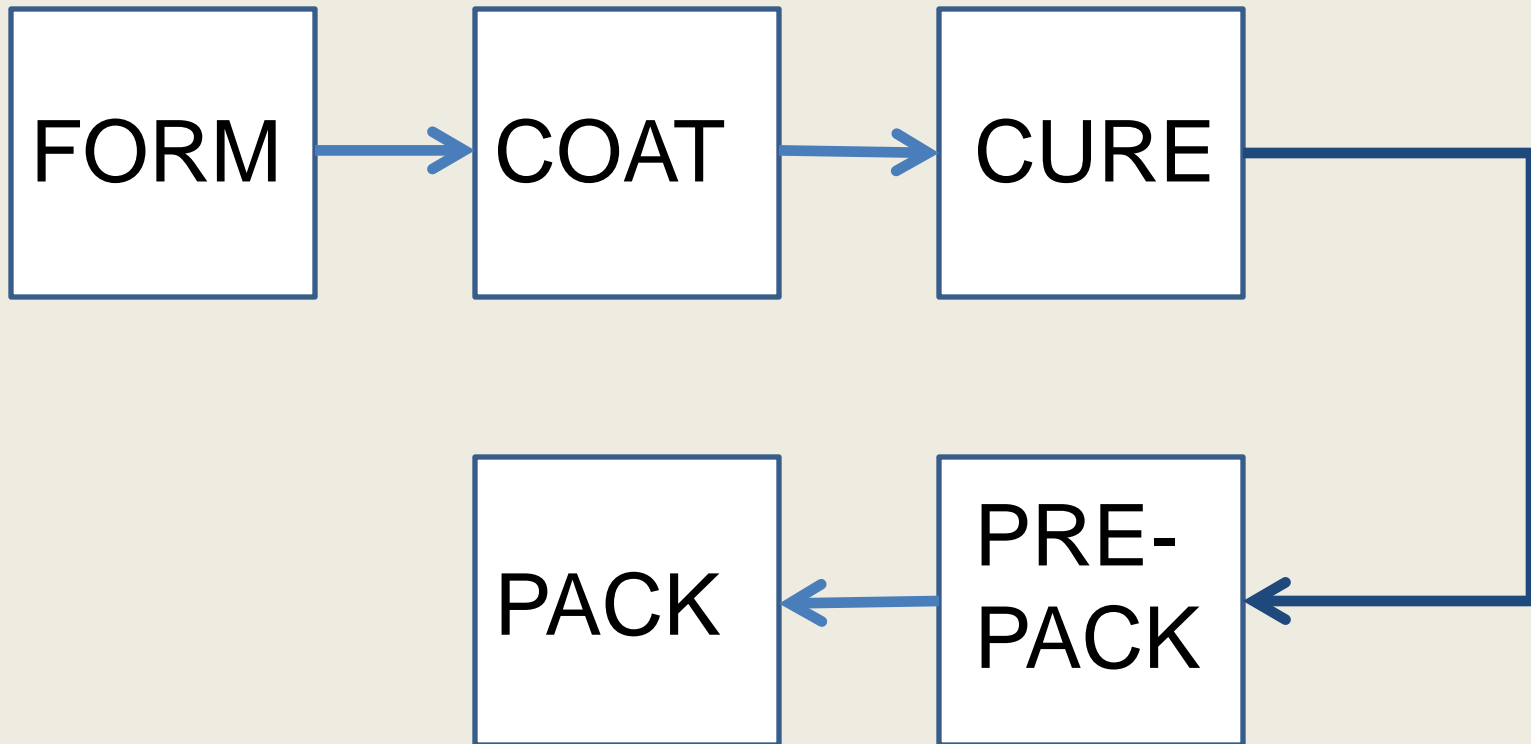
- **Class I** Medical Device Mfg'er
- Very Low End User Complaints
- In business 15+ years
- 12 Employees
- \$ 2- 2.5mm Sales
- Highest sales for Private Label, Off-the-Shelve, National Retail Pharmacy Chain

# Compliance History

- Failed every past customer audit
- Corrective actions promised & promised
- No Corrective actions actually taken

□ Note: Retail Pharm. Chains under FDA scrutiny for no control over Private Label Products – Warning Letters

# BASIC PROCESS FLOW



# 3 Prong Parallel Approach



1. Training (WHY?)



2. Facilities Improvements



3. Documented Quality Sys.



# Training (WHY)

- Realization: dental products are medical devices under US Law (Title 21 CFR)
- Not new law
- FDA Establishment registration
- Penalties \$\$\$\$\$\$
- Training & understanding ongoing

# Facilities

Viewed as perfect time to make improvements

- Removed clutter (messy, messy ...)
- Established designate areas
- Yellow lines on floor to mark off areas
- Partitions installed where appropriate
- Signs in place
- Acceptance status labeling
- Housekeeping improvements

# Documented QUALITY SYSTEM

(Focus of Tonight)

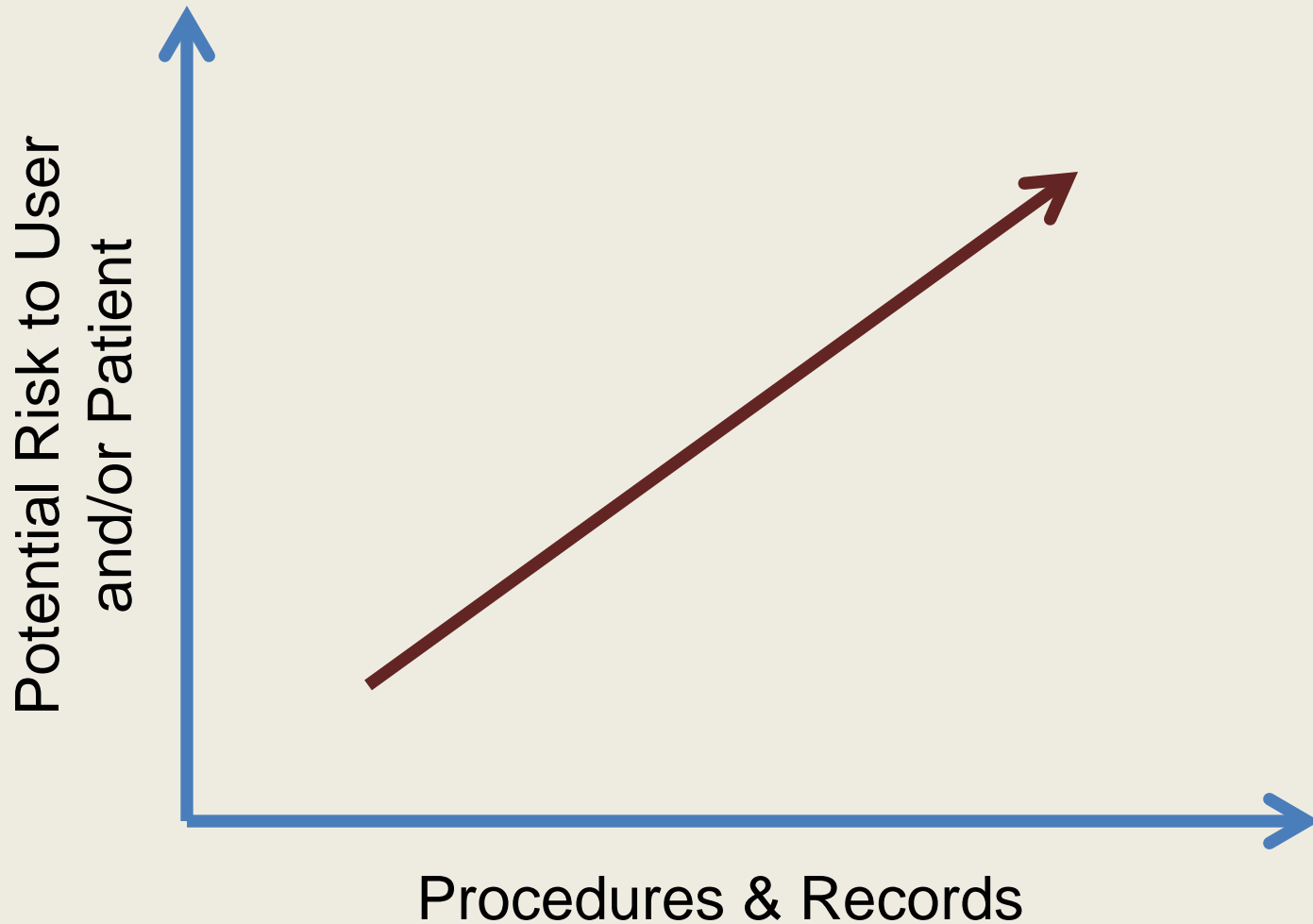
# §820.5 *Quality system* Says:

Each manufacturer shall establish\* and maintain a quality system that is ***appropriate for the specific medical device(s)*** designed or manufactured, and that meets the requirements of this part.

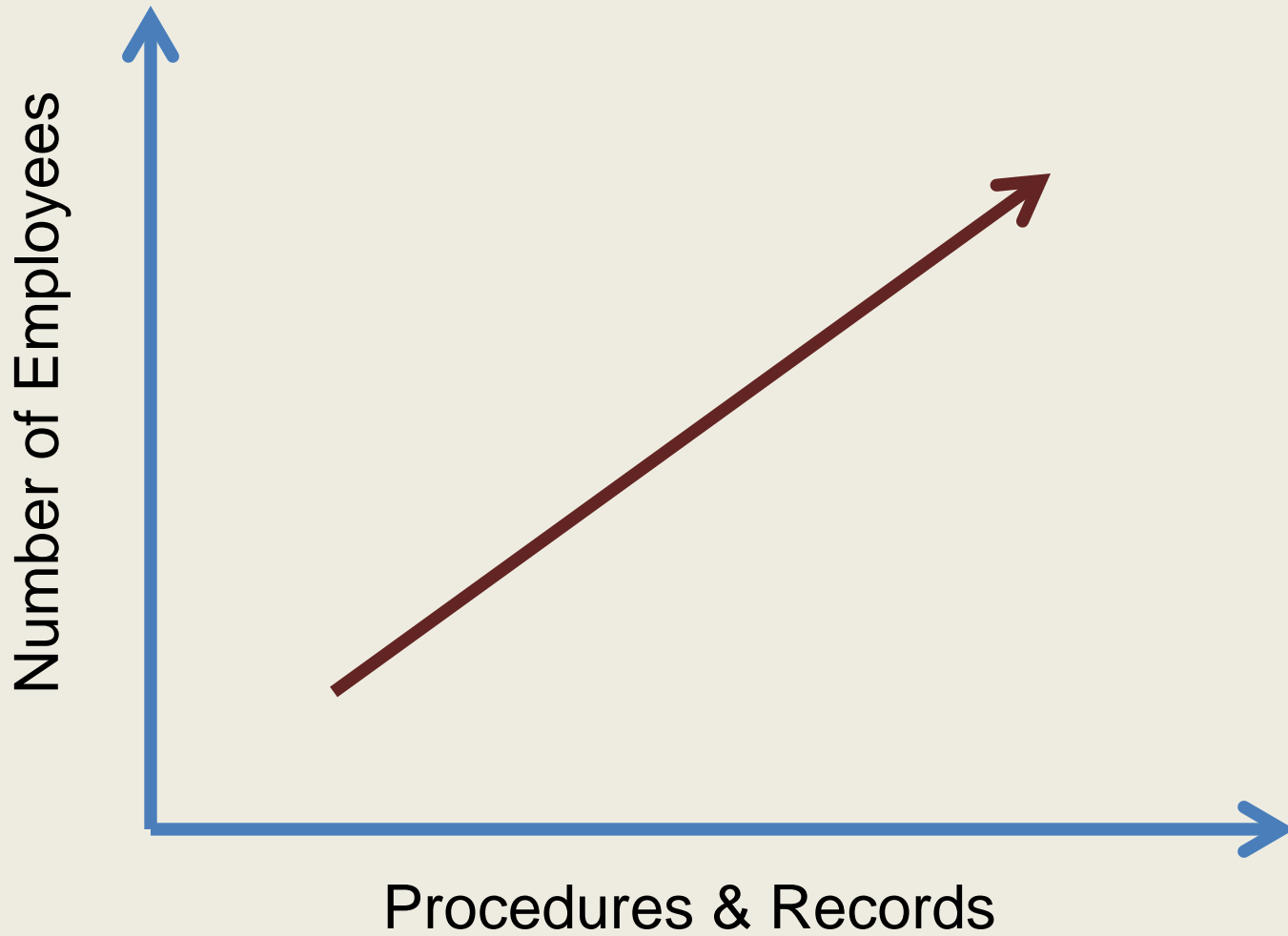
\*To define, document (in writing or electronically), and implement

- What is this saying?*
- Why not re-label Siemens' SOPs and Use?*

# Device Class (I, II, or III)



# Company size



# Problem Statement

A well established, small manufacturer of a Class I medical device is in danger of losing business to a major customer because its quality system does not comply with FDA regulation 21 CFR Part 820. Its quality system is not well established lacking the required documents, procedures and records.

# 1<sup>st</sup> Step ?

A. Create Plan

B. Start Writing SOP's

C. Cry



**Failure to Plan is . . .  
. . . Planning to Fail**

# Plan Should Be Based On?

A. Cost?

B. Risk?

C. Time?

# Risk Priorities Created:

- **High** – Product and/or QMS is potentially at risk
- **Medium** – Little or no risk to product, QMS needs to be improve to prevent risk
- **Low** – No risk to product, little or no risk to QMS

(See: ISO 14971 – Risk Management for Medical Devices)

# Place in Order of Importance?

- A. Regulatory control (Failure reports, etc to FDA)
- B. Process control (Making the device)
- C. Management control (Audits, mgm't review. Etc)
- D. Quality control (Inspection & test activities)

# Answer to Put in Order of Importance?

- D. Quality control
- B. Process control
- C. Management control
- A. Regulatory control

# Creating a “Working Plan”

- Using the index to FDA regulation created tactical plan on EXCEL spread sheet.
- The spread sheet was then used as the tool to monitor what was done and what needs to be done.
- Plan modified as necessary

# Index to 21 CFR Part 820 – Quality System Regulation

## Federal Register

Monday October 7, 1996

Department of Health & Human Services  
Food and Drug Administration

### 21 CFR Part 820 -

### Quality System Regulation

Final rule: October 1, 1996

Effective: June 1, 1997

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#### - Contents -

#### Subpart A - General Provisions

- 820.1 Scope
- 820.3 Definitions
- 820.5 Quality system

#### Subpart B - Quality System Requirements

- 820.20 Management Responsibility
  - (a) Quality policy
  - (b) Organization
  - (c) Management review
  - (d) Quality Planning
  - (e) Quality system procedures
- 820.22 Quality audit
- 820.25 Personnel
  - (a) General
  - (b) Training

#### Subpart C - Design Controls

- 820.30 Design controls
  - (a) General
  - (b) Design and development planning
  - (c) Design input
  - (d) Design output
  - (e) Design review
  - (f) Design verification
  - (g) Design validation
  - (h) Design transfer
  - (i) Design changes
  - (j) Design history file

#### Subpart D - Document Controls

- 820.40 Document controls
  - (a) Document approval and distribution
  - (b) Document changes

#### Subpart E - Purchasing Controls

- 820.50 Purchasing controls
  - (a) Evaluation of suppliers, contractors, and consultants
  - (b) Purchasing data

#### Subpart F - Identification and Traceability

- 820.60 Identification
- 820.65 Traceability

#### Subpart G - Production & Process Controls

- 820.70 Production and process controls
  - (a) General
  - (b) Production and process changes

- (c) Environmental control
- (d) Personnel
- (e) Contamination control
- (f) Buildings
- (g) Equipment
- (h) Manufacturing material
- (l) Automated processes
- 820.72 Inspect., meas. & test equip.
  - (a) Control of Inspect., meas. & test equip.
  - (b) Calibration
  - (c) Calibration standards
- 820.75 Process validation

#### Subpart H - Acceptance activities

- 820.80 Receiving, in-process, and finished device acceptance
  - (a) General
  - (b) Receiving acceptance activities
  - (c) In-process acceptance activities
  - (d) Final acceptance activities
  - (e) Acceptance records
- 820.86 Acceptance status

#### Subpart I - Nonconforming Product

- 820.90 Nonconforming product
  - (a) Control of nonconforming product
  - (b) Nonconforming review and disposition

#### Subpart J - Corrective & Preventive Action

- 820.100 Corrective and preventive action

#### Subpart K - Labeling and Packaging Control

- 820.120 Device labeling
  - (a) Label integrity
  - (b) Label inspection
  - (c) Labeling storage
  - (d) Labeling operations
  - (e) Control number
- 820.130 Device packaging

#### Subpart L - Handling, Storage, Distribution, and Installation

- 820.140 Handling
- 820.150 Storage
- 820.160 Distribution
- 820.170 Installation

#### Subpart M - Records

- 820.180 General requirements (records)
  - (a) Confidentiality
  - (b) Record retention period
  - (c) Exceptions
- 820.181 Device master record
- 820.184 Device history record
- 820.186 Quality system records
- 820.198 Complaint files

#### Subpart N - Servicing

- 820.200 Servicing

#### Subpart O - Statistical Techniques

- 820.250 Statistical technique

# Cut-out Section of actual EXCEL Spread Sheet of Plan to Document the Quality System to Meet FDA 21-CFR Part 820

QSR Section	Title	Document	Procedure	Records	Priority H-M-L	Targeted Completion Date
820.40	Document controls		P		H	<b>1-Jun-12</b>
820.40(a)	Document approval & distribution	D			H	<b>1-Jun-12</b>
820.40(b)	Document changes			R	M	1-Jul-12
820.50	Purchasing controls		P		M	1-Jul-12
820.50(a)	Evaluation of suppliers, contactors, & consultants		P	R	L	1-Aug-12
820.50(b)	Purchasing data	D			M	1-Jul-12
820.60	Identification		P		H	<b>15-May-12</b>
820.65	Traceability		P	R	n/a	n/a
820.70(a)	Production & process controls		P		H	<b>15-May-12</b>
820.70(a)(1)	P&PC instructions and methods	D			H	<b>15-May-12</b>
820.70(a)(2)	P&PC device characteristics	D			H	<b>15-May-12</b>
820.70(a)(5)	Workmanship criteria	D			H	<b>15-May-12</b>
829.70(b)	Production and process changes		P		M	1-Jul-12
820.70(c)	Environmental control		P		H	<b>15-May-12</b>
820.70(d)	Personnel	D			H	<b>15-May-12</b>
820.70(e)	Contamination control		P		H	<b>15-May-12</b>
820.70(g)(1)	Equipment - maintenance schedule	D		R	M	1-Jul-12



# Example:

QSR Section	Title	Document	Procedure	Record	Priority H-M-L	Targeted Completion Date
820.22	Quality audit		P	R	L	1-Aug
820.25(b)	Personnel training		P	R	H	1-Jun
820.30	Design controls				n/a	n/a
820.40	Document controls		P		H	1-Jun
820.40(a)	Doc. Approve/dist.	D			H	1-Jun
820.40(b)	Document changes			R	M	1-Jul
820.50	Purchasing controls		P		M	1-Jul

**Discuss:  
Benefits in doing this?**

# Worked with Client to *Establish*\* Specifications

- Product
- Purchasing
- In-process
- Product release

\*To define, document (in writing or electronically), and implement

# Process Followed

1. Write Procedure
2. Approve & Release
3. Train & Implement
4. Records
5. Follow-up

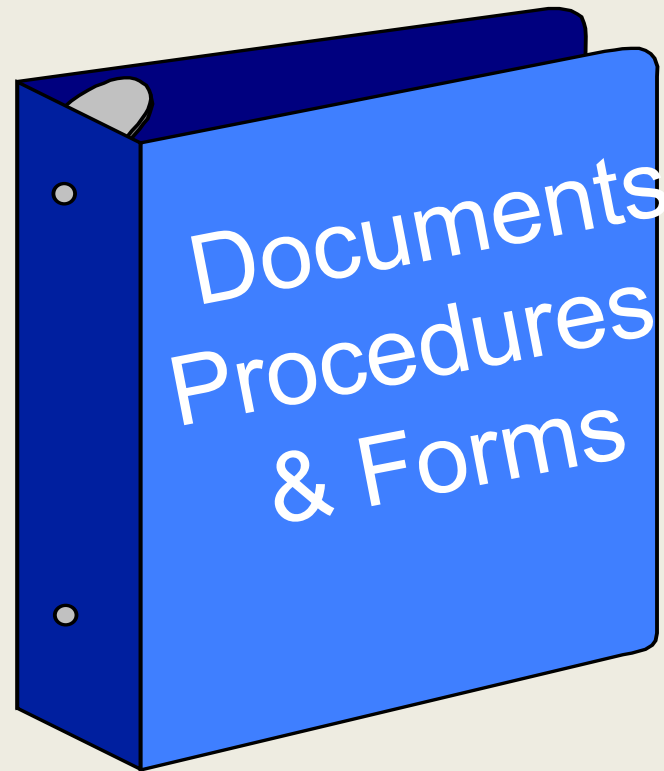
# 1<sup>st</sup> SOP's to do?

## Which one does not fit?

- Receiving acceptance
- Training
- Management review
- Document control
- Product release

# Results – Followed the Plan

3 Documents, 23 SOP's & 13 Forms



# Quality Records

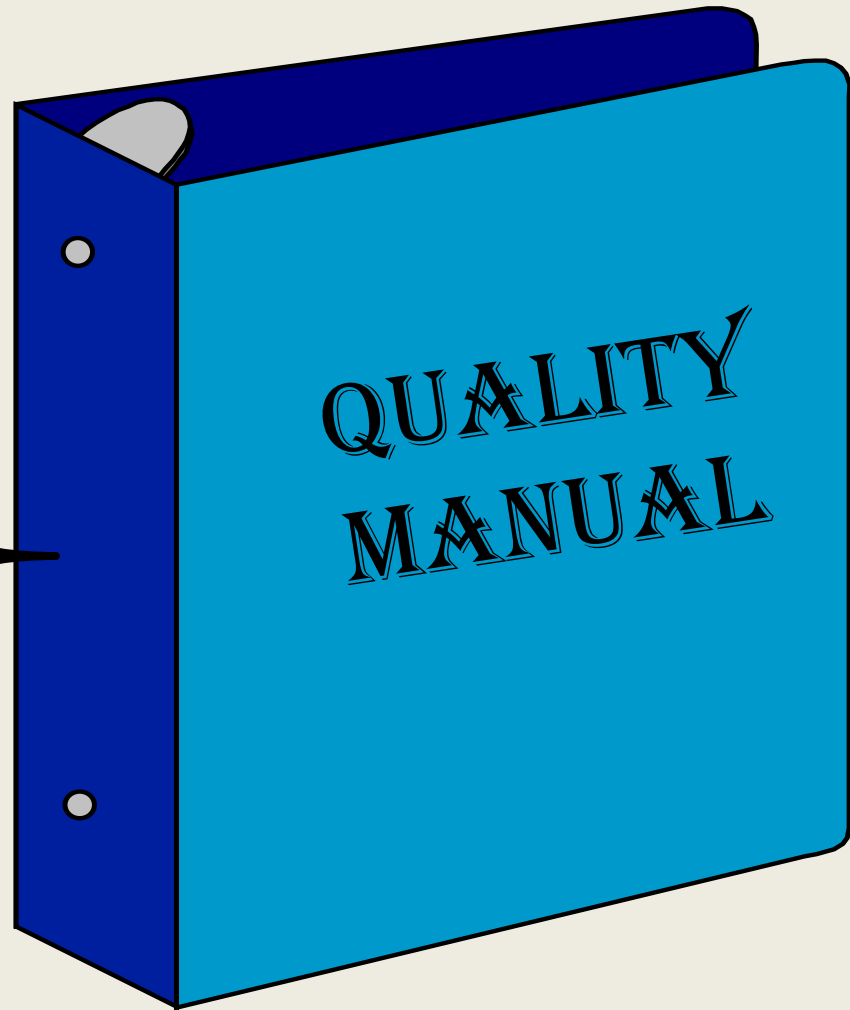


If it's not recorded it didn't happen!

# Beyond FDA Requirements

- Quality Manual
- Manufacturing Control Plan
- Quality Gates (Positive Release System)
- Responsibility Matrix
- Approved Supplier List

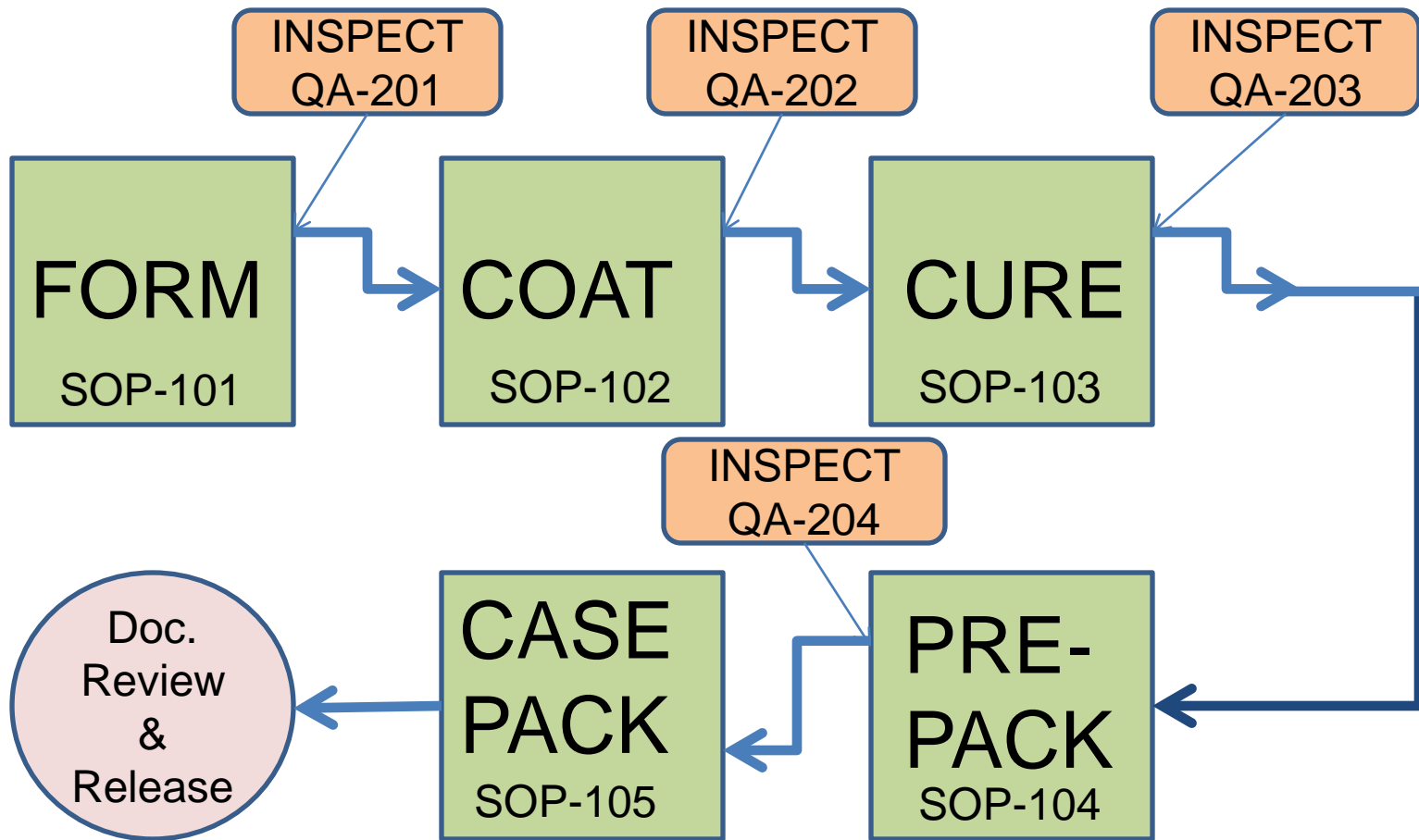
- Quality policy
- Quality Objectives
- Commitment to Quality
- Organization
- Responsibility & Authority
- Mgm't Representative
- Quality Plan
- Exclusions to Quality System





# Mfg'ing Control Plan

(Only output passing inspection is passed on)

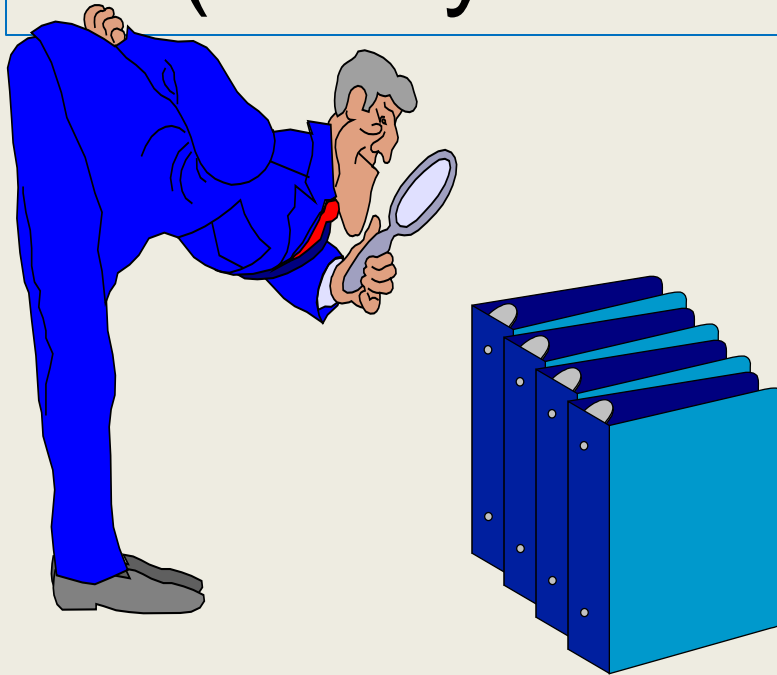


## Responsibility Matix Example

section	Title	Pres	VP	Ops	QA	Admin
820.5	Quality Manual				X	
820.20(a)	Quality Policy	X				
820.20(b)	Organization	X				
820.22	Quality Audits				X	
820.25	Personnel training		X			
820.40	Document control					X
820.50	Purchasing		X			
820.70	Production control			X		
820.72(a)	Calibration				X	
820.80(a)	Acceptance activities			X		
820.70(g)	Equipment Maint.			X		
820.20(a)	Records					X

# Final Exam

## (2-Day 3<sup>rd</sup> Party Audit)



\*3 minor nonconformances  
92% Supplier Rating = Preferred

## \*3 Minors were:

1. Document Control Procedure: no reqm't for annual SOP review\*\*
2. Purchasing Procedure: No reqm't suppliers *must* notify of changes\*\*
3. Labels not approved *upon receipt*\*\*

\*\* *None are a FDA-QSR Requirement*

# SUCCESS !



# In Conclusion

- **PROBLEM** – Problem statement
- **PLAN** – Establish & Follow (Modified it)
- **RESULTS** – Recorded / Measurable . . .  
Was problem solved or at least its affect minimized?

# Leadership





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