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

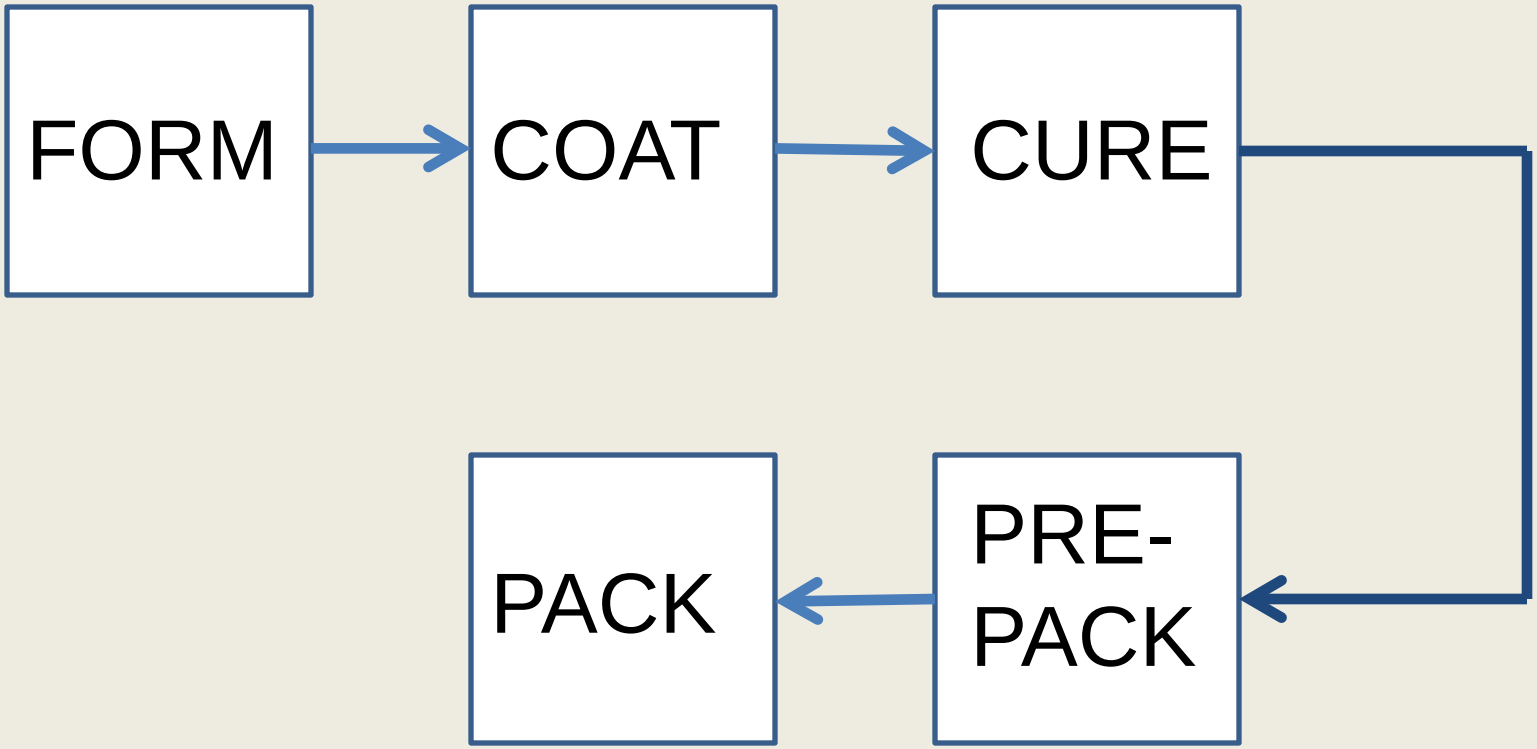
- **Class I** Medical Device Mfg'er
- Very Low End User Complaints
- In business 15+ years
- 12 Employees
- $ 2- 2.5mm Sales
- Highest sales for Private Label, Off-the-Shelve, National Retail Pharmacy Chain

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

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)

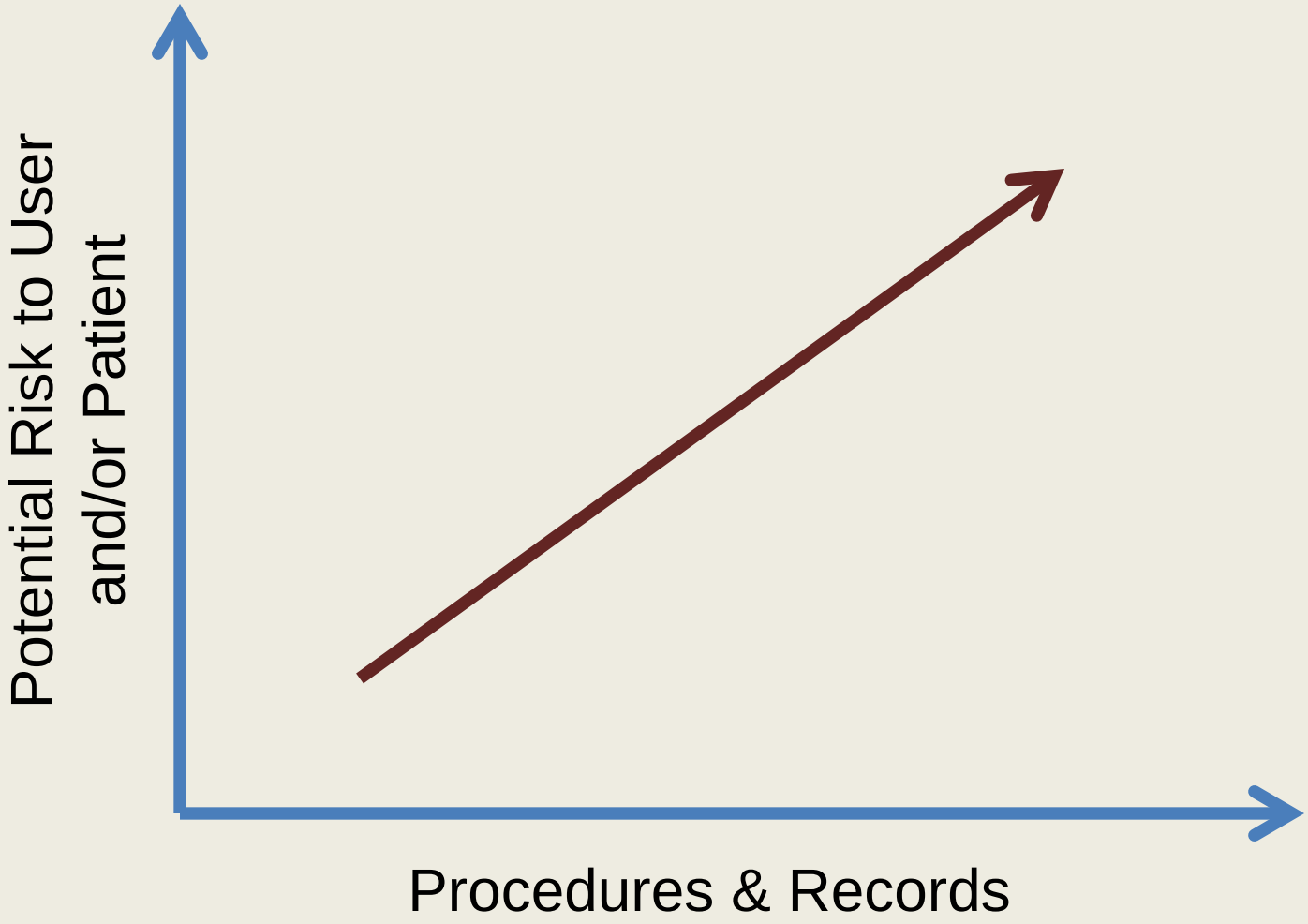
§820.5 Quality system Says:

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.

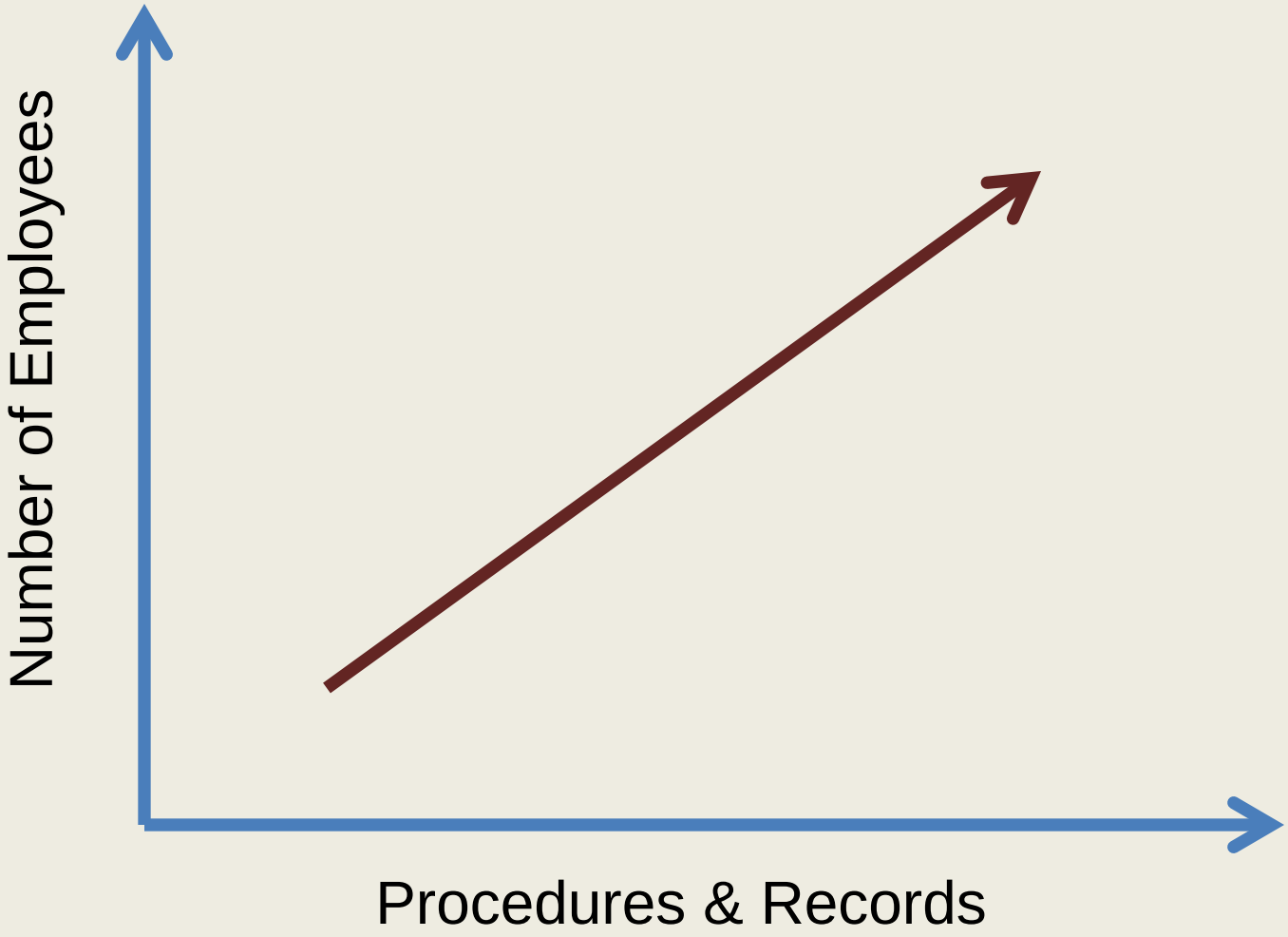
*To define, document (in writing or electronically), and implement

- ❑ *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.

1st 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**

- Contents -

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**	**1-Jun-12**
820.40(a)	Document approval & distribution	D			**H**	**1-Jun-12**
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**	**15-May-12**
820.65	Traceability		P	R	n/a	n/a
820.70(a)	Production & process controls		P		**H**	**15-May-12**
820.70(a)(1)	P&PC instructions and methods	D			**H**	**15-May-12**
820.70(a)(2)	P&PC device characteristics	D			**H**	**15-May-12**
820.70(a)(5)	Workmanship criteria	D			**H**	**15-May-12**
829.70(b)	Production and process changes		P		M	1-Jul-12
820.70(c)	Environmental control		P		**H**	**15-May-12**
820.70(d)	Personnel	D			**H**	**15-May-12**
820.70(e)	Contamination control		P		**H**	**15-May-12**
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

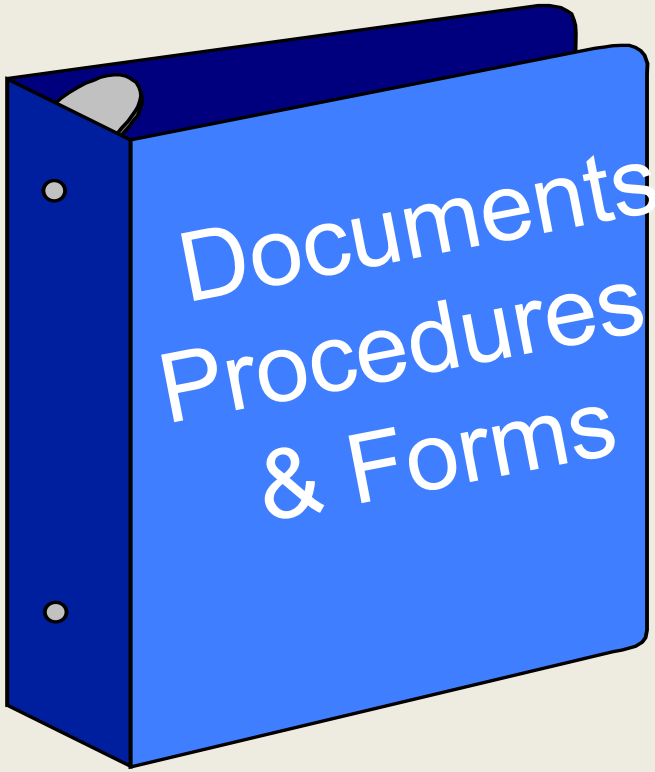
1st SOP's to do?

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

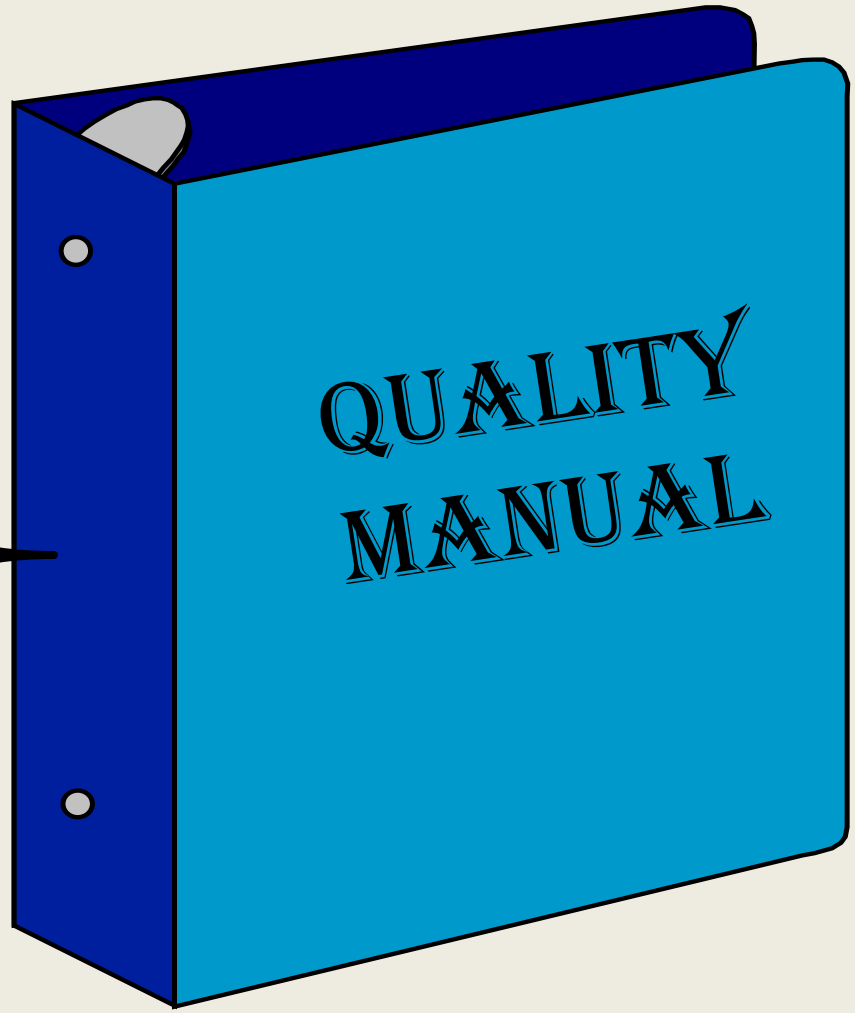
Organization

Responsibility & Authority

Mgm’t Representative

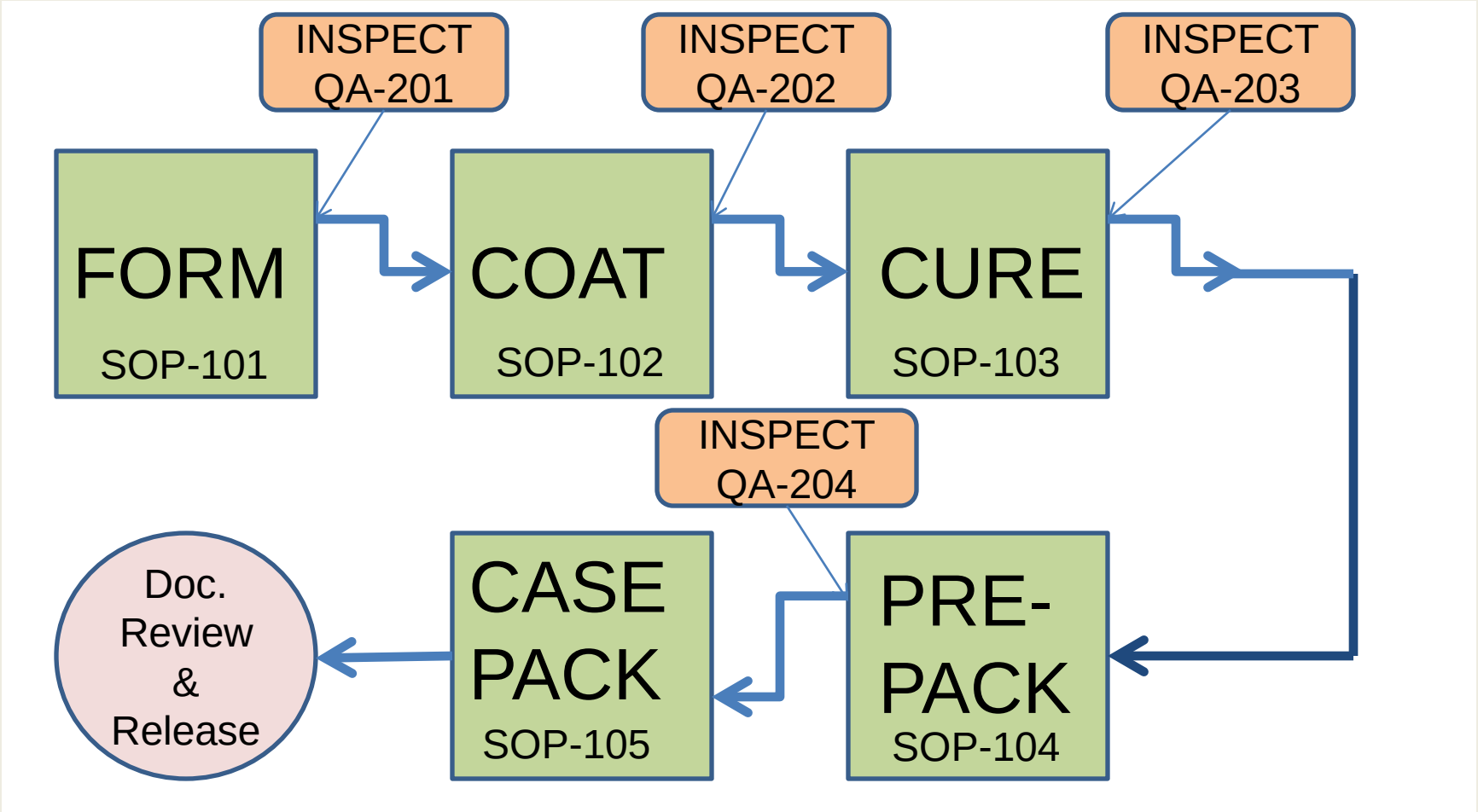
Quality Plan

Exclusions to Quality System



Mfg'ing Control Plan

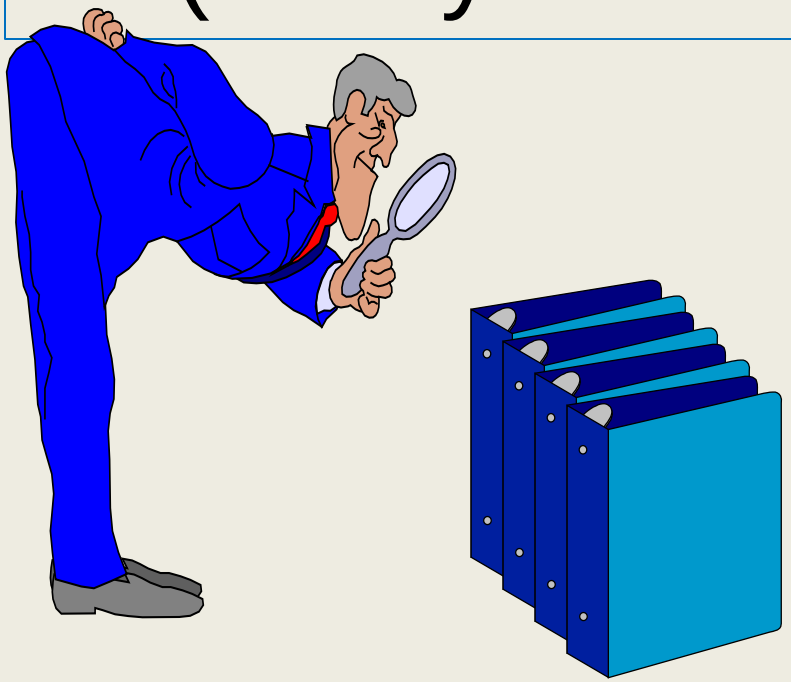
(Only output passing inspection is passed on)



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 3rd 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

MDQC

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