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Implementing an Effective CAPA System: What You Need to Know

by a Panel of Experts from FDA & Industry

Date: **Thursday, March 6, 2008**

Time: **1:00pm – 2:30pm** **Eastern Standard Time** (GMT –5 hours)

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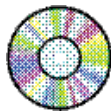
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Dan Olivier is President, Certified Compliance Solutions and an acknowledged expert in the field of medical system validation and safety risk management. He has supported over two hundred medical device and pharmaceutical companies in addressing regulatory issues and process improvement. Dan has been engaged by FDA to provide contract training for field investigators and to prepare inputs for FDA validation guidance documents. He is an ISO 9001 RAB certified lead auditor and has been a reviewer for ISO WG10 defining software process assessment standards. He can be contacted at dolivier@certifiedcompliance.com

Nancy Singer is President of Compliance-Alliance, LLC, a firm that specializes in professional development for those employed within the medical device industry. Previously, Nancy served as AdvaMed's Special Counsel for FDA compliance and enforcement matters. Her food and drug career began as an attorney at the Department of Justice where she did litigation for FDA. Subsequently she was a partner at the law firm of Kleinfeld, Kaplan and Becker**.** Nancy can be contacted at nancy_singer@juno.com

Jan Welch is a Quality System/IVD Expert in FDA's Center for Devices and Radiological Health. She serves as a Quality System expert for medical device legal actions and other medical device issues involving complex, controversial, and precedent-setting regulatory actions involving GMP requirements. Jan identifies and recommends new policy and administrative or regulatory approaches in highly intricate situations in specialty areas where no policy or precedent exist. She also reviews enforcement actions proposed by FDA's field offices, and decides when regulatory action (based on adherence to the Quality System regulation) is appropriate. Jan can be contacted at jan.welch@fda.hhs.gov

Implementing An Effective CAPA System:

What You Need to Know

Nancy Singer, Compliance-Alliance

Richard DeRisio, Advanced Medical Optics, Inc

Jan Welch, Office of Compliance, CDRH

Linda L. S. Lovett, Medtronic Spinal and Biologics

Daniel P. Olivier, Certified Compliance Solutions, Inc

Agenda

- Overview
  - Compliance-Alliance Survey
  - FDA Quality System Regulation Requirements
  - Key Definitions
  - ISO 13485:2003 Requirements
- View From the FDA
  - FDA 483 Observations
  - Warning Letters
- Practical Examples of CAPA Implementation
- Pitfalls

Overview

Richard DeRisio, Advanced Medical Optics, Inc
&
Nancy Singer, Compliance-Alliance

Compliance-Alliance Survey January 2008

- 374 respondents
- Small, medium and large firms
- 262 individual comments regarding survey questions
- The 24 survey questions included:
  - Sources of quality data inputs
  - Use of risk management tools
  - Use of statistical methods for CAPA management
  - Criteria for opening and closing CAPAs
  - Metrics for measuring CAPA effectiveness
  - Techniques for managing the CAPA program
  - Review of CAPA data during management reviews
  - CAPA Challenges

Quality System Regulation
21 CFR 820.100

- Establish a CAPA Procedure
- Analyze (with statistical methodology) sources of quality data to identify sources of quality problems

Sources of Quality Data

- Customer complaints — 91%
- Internal audits — 89%
- Incoming components/Materials — 86%
- Inspection/test data "final" — 80%
- Inspection/test data "in process" — 79%
- Record/document issues — 77%
- Rework and nonconforming material — 77%
- Supplier nonconformances — 76%
- Management review — 75%
- 3rd party audits — 75%
- Process control data — 74%
- FDA observations — 73%
- Supplier audits — 73%
- Validation issues — 73%
- Facility control/environmental issues — 73%
- Training records — 72%

Sources of Quality Data (continued)

- Device history records   70%
- Field actions (corrections and removals)   68%
- Equipment data   67%
- Change control records   65%
- Scrap/rework/yield data   64%
- Temperature monitoring/control   63%
- Design control data   61%
- Returned goods   61%
- MedWatch/MDR/Vigilance reports   61%
- Handling/storage of product data   61%
- Field service reports   44%
- Clinical data   34%
- Employee complaints   29%
- Product warranty   24%
- Clinical literature and journal articles   21%
- Legal claims   21%

Establish a CAPA Procedure (continued)

- Investigate causes of nonconformities
  - Most firms (73%) use risk management to determine whether to open a failure investigation
    - FMEA   84%
    - Hazard Analysis   43%
    - Fault Tree Analysis   38%

Establish a CAPA Procedure (continued)

- Criteria used to open failure investigation
  - Severity   85%
  - Frequency   78%
  - Impact   68%

- Effective CAPA Management Reduces Risk
  - Safety
  - Business interruption
  - Product liability
  - Regulatory compliance
  - Loss of customer goodwill

Establish a CAPA Procedure (continued)

- Identify actions needed to correct and prevent recurrence
- Verify or validate effectiveness
- Implement and record changes in records and procedures
- Disseminate information to affected personnel
- Submit information about problems and corrective/ preventive action for management review
- Document activities

Information Examined During Management Reviews

- Volume and Aging Report   77%
- CAPA Quality System Effectiveness Report   47%
- Analytical statistics from quality data sources   47%
- CAPA Effectiveness Report   46%
- Comparison across all quality data sources   35%
- Scrap/Yield Report   35%
- Comparison to other product lines   21%
- Use "As Is" Report   19%
- Risk Impact Report   19%
- Change Control Impact Record   12%

QSIT

- 1997-1999 FDA reengineered Quality System Inspections
  http://www.fda.gov/cdrh/comp/qsitpage.html
- QSIT training provided definitions

Definitions From FDA QSIT Slides

- <u>Correction</u> refers to repair, rework, or adjustment and relates to the disposition of the existing nonconformity

- <u>Corrective action</u> refers to action taken to eliminate the causes of an **existing** non-conformity, defect or other undesirable situation in order to prevent it recurrence

- <u>Preventive action</u> refers to action taken to eliminate the cause of the **potential** non-conformity, defect or other undesirable situation in order to prevent occurrence

ISO 9000:2005

- <u>Nonconformity</u>: non-fulfillment of a requirement (3.1.2)

- <u>Correction</u>: action to eliminate a detected nonconformity (3.6.2)

- <u>Corrective action</u>: action to eliminate the cause of a detected nonconformity (3.6.2) or other undesirable situation

- <u>Preventive action</u>: action to eliminate the cause of a potential nonconformity (3.6.2) or other undesirable potential situation

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Examples from QSIT Training

- Correction: Devices returned because out-of-box failures are repaired and put back into inventory

- Corrective action: Defective components damaged by ESD during assembly caused out-of-box failures. ESD controls instituted; operators are trained in ESD controls.

Examples from QSIT Training

- Preventive action: SPC chart indicated process is drifting toward the upper limit for diameter of injection molded part. Investigation determines cause of drift is wear to mold. Replace mold, and verify/validate that process yields parts meeting specs.

ISO 13485:2003

Corrective and Preventive Action Requirements of the Standard

8.5.1 – Improvement: General

- Organization shall:
  - Identify and implement changes to ensure suitability and effectiveness of the quality management system
    - Quality Policy
    - Quality Objectives
    - Audit Results
    - Analysis of Data
    - Corrective and Preventive Action
    - Management Review
  - Establish documented procedures for the issuances of advisory notices
  - Review customer complaints and provide information if necessary to other organizations involved
  - If complaint not followed by CAPA, document the reason
  - Establish procedures for reporting adverse events

8.5.2 – Corrective Action

- Organization shall take action to eliminate the cause of nonconformities to prevent recurrence;

- The corrective action shall be appropriate to the level of the effects of the nonconformance

- Documented procedure shall include:
  - Reviewing nonconformities including complaints
  - Determining the cause of nonconformities
  - Evaluating the need for action to prevent recurrence
  - Determining and implementing action needed
  - Updating documentation, as appropriate
  - Recording the results of any investigation and action
  - Reviewing the corrective action taken and effectiveness

8.5.3 – Preventive Action

- Organization shall determine action necessary to eliminate the cause of potential nonconformities to prevent occurrence
- The preventive action shall be appropriate to the effects of the potential problem
- A documented procedure shall define how to:
  - Determine potential nonconformities and their causes
  - Evaluate the need for prevent nonconformities
  - Determine and implement the action needed
  - Record the results of an investigation and action taken
  - Review preventive action and its effectiveness

CAPA System Practices: From the FDA Perspective

Jan Welch

Quality System Expert

Office of Compliance, CDRH

Food and Drug Administration

CAPA System Advice

► "CAPA system" is not just the formal, tracking mechanism for elevated, opened investigations

► More than the paper files or databases established for these functions

► A true and robust CAPA system encompasses all of the mechanisms and data sources that a sound quality system uses to monitor the quality of people, processes, product, and problems

► This includes complaint handling, nonconforming product mechanisms, medical device reporting, corrections, removals, and recalls

"BIG C"

75(c)
70
30(i)
80
198
22
20
100
CAPAs/CARs
"little c"
90
806
803
200
50
40(b)
170
72
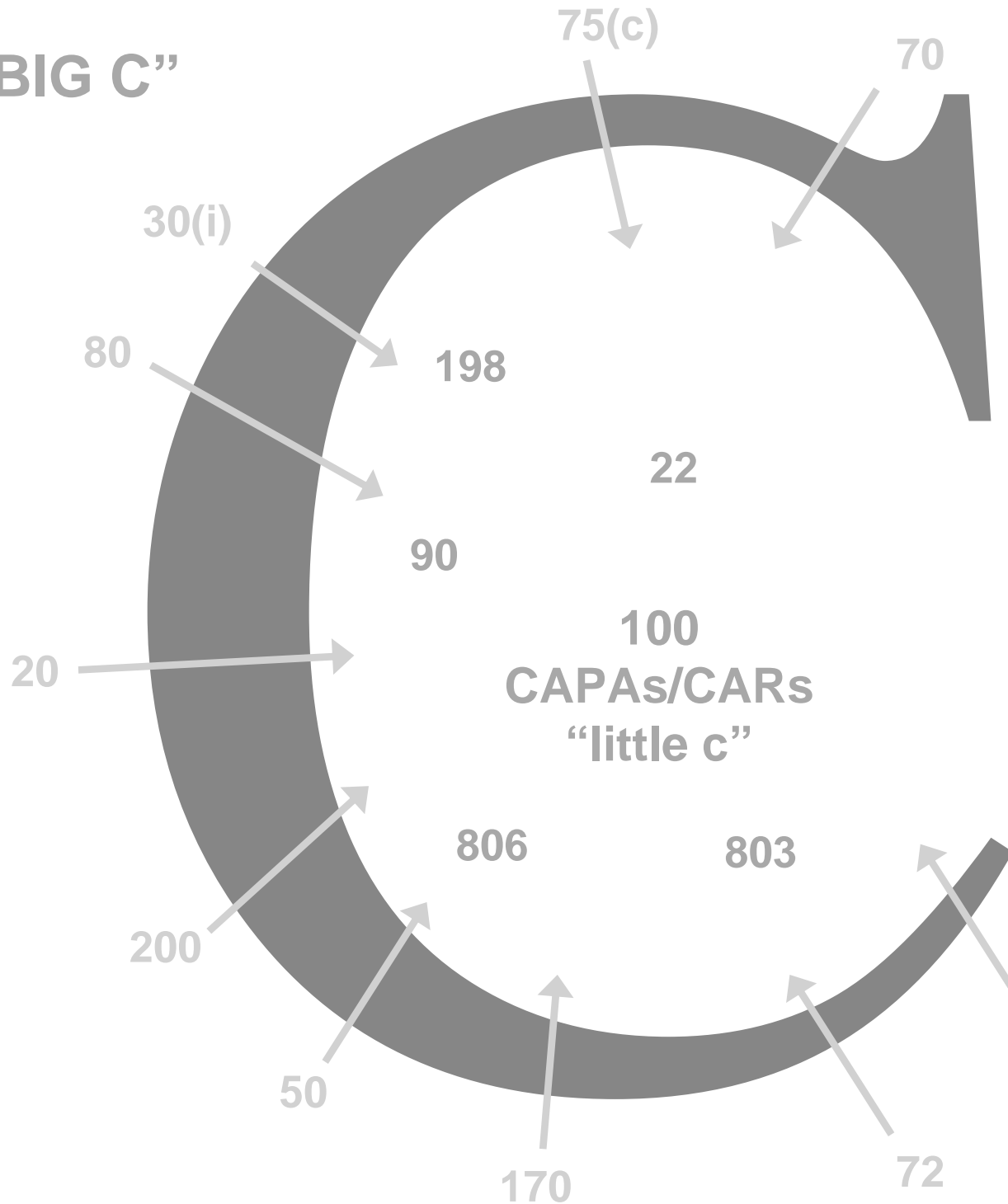
820.100 CAPA
820.22 Internal audits
820.90 Non-Conformances
820.198 Complaints
820.75(c) Process Changes
820.70 Production
820.30(i) Design Changes
820.80 Acceptance
820.20 Management
820.200 Service
820.50 Purchasing
820.170 Installation
820.72 Calibration
820.40(b) Document Changes
806 Corr/Removals
803 MDRs

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CAPA System Advice

► A robust CAPA system will constantly be supplied with data from many sources within the QMS, and from several external to the QMS

► Feed the CAPA system! Don't be afraid!

► Management often afraid to have numerous CAPAs; perception that this is a bad thing and reflects poor control of the QMS

► Au contraire!

► Must have appropriate mechanisms in place to determine when a situation merits a formal CAPA

CAPA System Advice

►FDA's focus is not on numbers of CAPAs

►FDA wants to see how the QMS handles the data flow

►Is the CAPA system doing what it needs to?

►Not every situation can be a code red, priority one, major fire…really!

►So what to do about that?

►Use risk management tools to prioritize CAPA work

CAPA System Advice

►When CAPAs are open for longer periods of time, include status information and milestones in the record

►It is not good when a CAPA is open for a long period of time, with no indication of activity

►Document decision-making rationale in the CAPA record

CAPA System Advice

►If corrective action is made to only some devices and not all devices, this decision-making process needs to be thoroughly explained

►FDA certainly focuses on this

►See this in software "fixes," "upgrades," "corrections"

►Corrective action made on new models, returned devices, but not made to all devices in use; document why!

2007 CAPA Data

► Analysis of data from FDA's Turbo EIR database.

► Time frame 1/1/2007 to 12/31/2007

► 3332 observations were cited on the FDA-483s for 21 CFR 820 deficiencies

2007 CAPA Data

- 200 observations were cited for 21 CFR 803 deficiencies (MDR Reporting)

- 38 observations were cited for 21 CFR 806 deficiencies (Corrections/Removals)

- 1 observation was cited for 21 CFR 821 deficiency (Tracking)
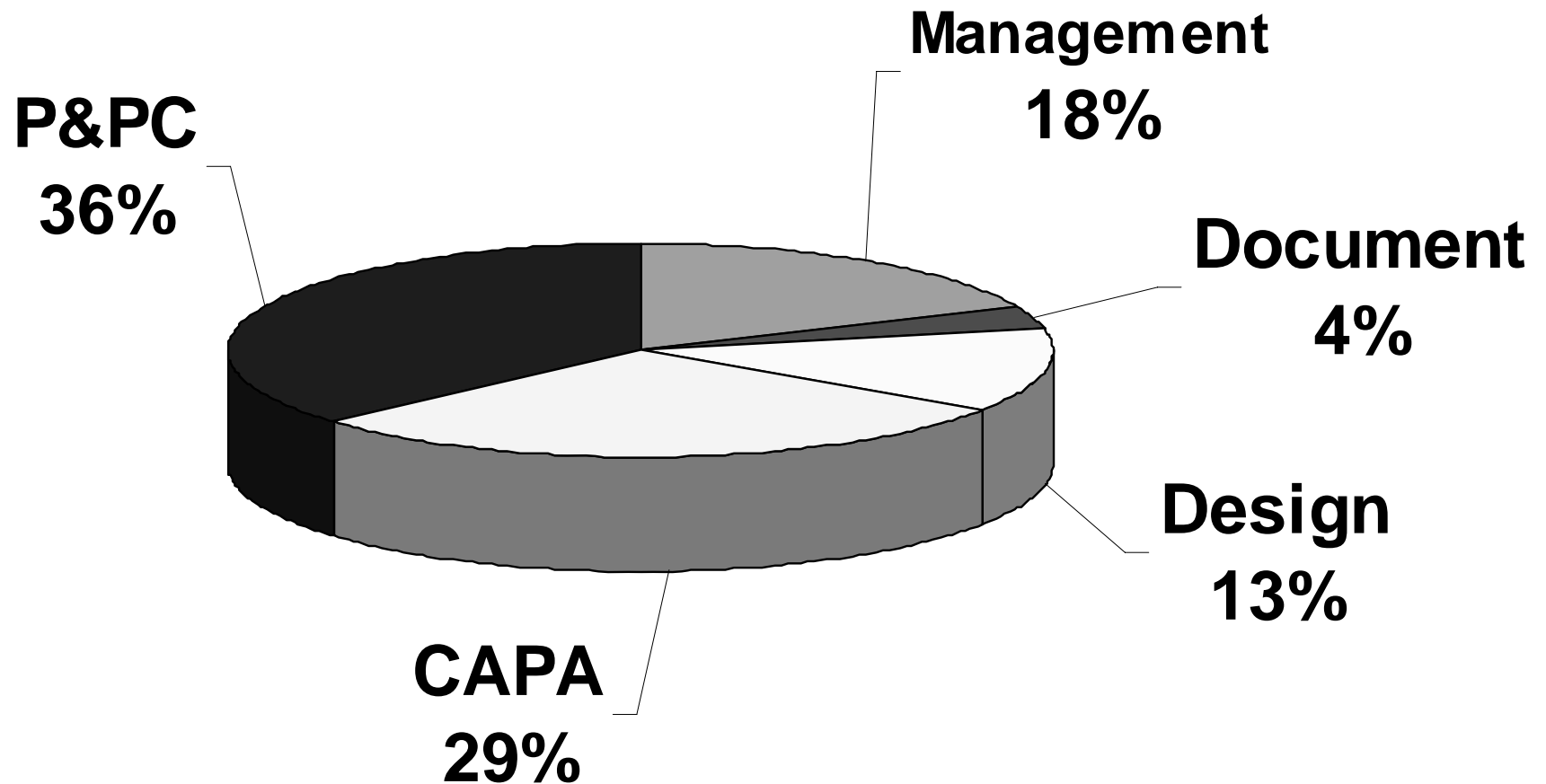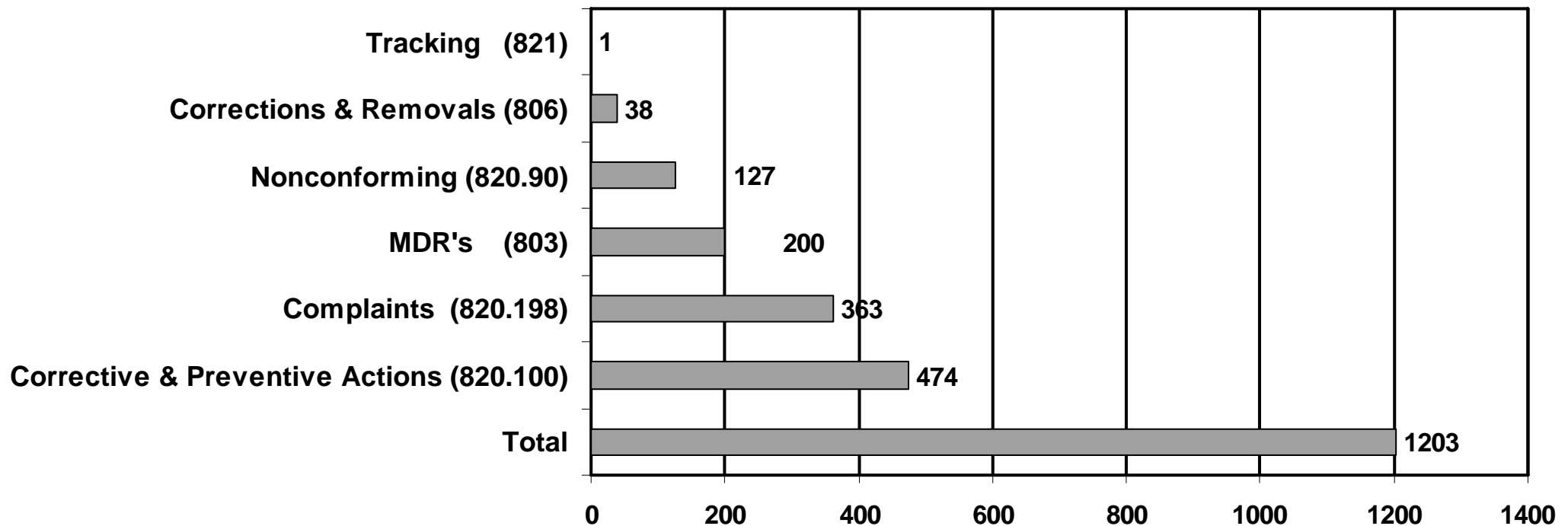
FDA-483 Observations (n=3332) 1/1/2007 to 12/31/2007
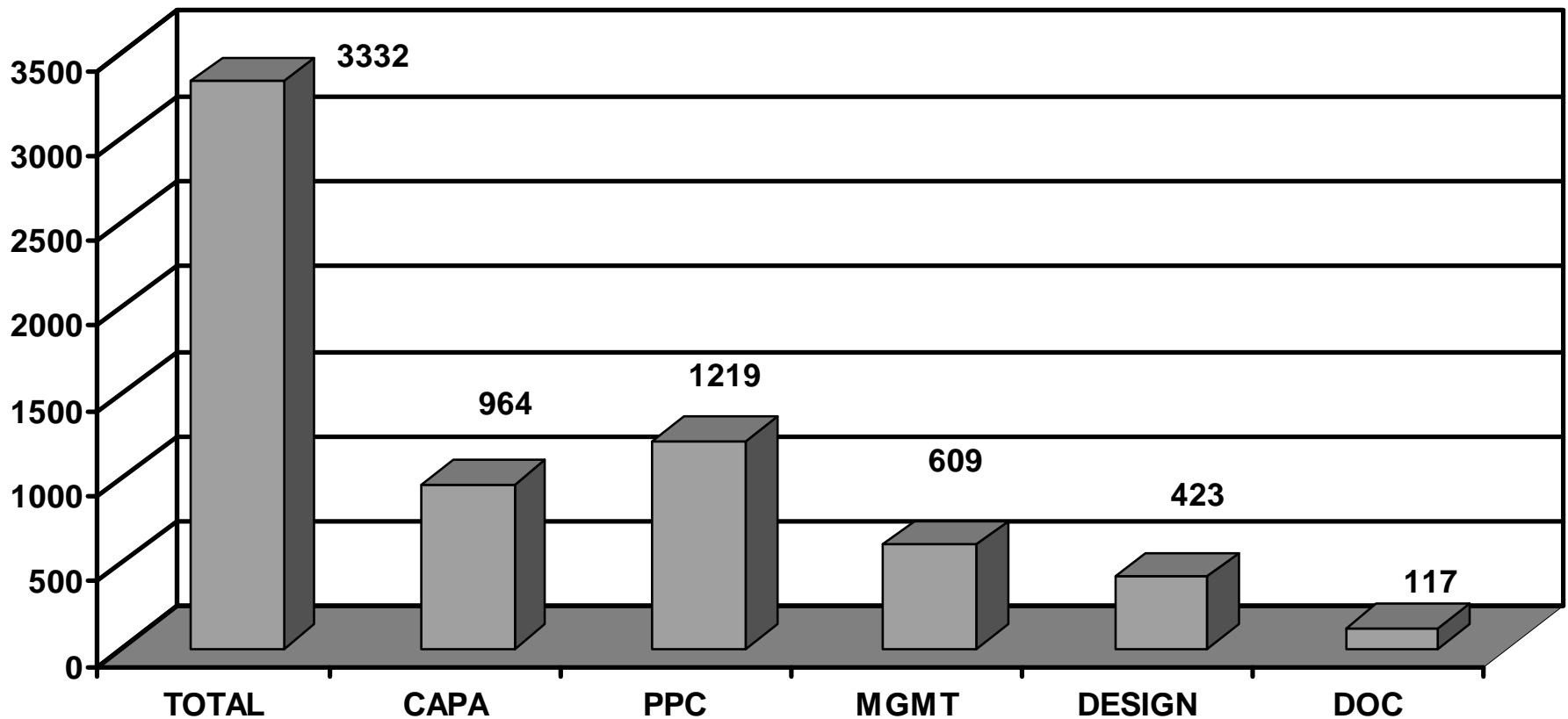
Observations by Subsystem
1/1/07 to 12/31/07

Management 18%

P&PC 36%

Document 4%

Design 13%

CAPA 29%

Number of CAPA Subsystem Observations by CFR Cite -2007

21 CFR 820.100 Data

820.100(a)	104
820.100(a)(1)	79
820.100(a)(2)	36
820.100(a)(3)	45
820.100(a)(4)	27
820.100(a)(5)	25
820.100(a)(6)	4
820.100(a)(7)	10
820.100(b)	144
Total	474

Warning Letters with CAPA System Cites 2007

- January – December 2007

- FDA issued 74 Warning Letters to medical device firms for QS/GMP deficiencies

- 62/74 or 84% contained cites for CAPA system deficiencies

- 21 CFR 820.90, 820.100, or 820.198 cites
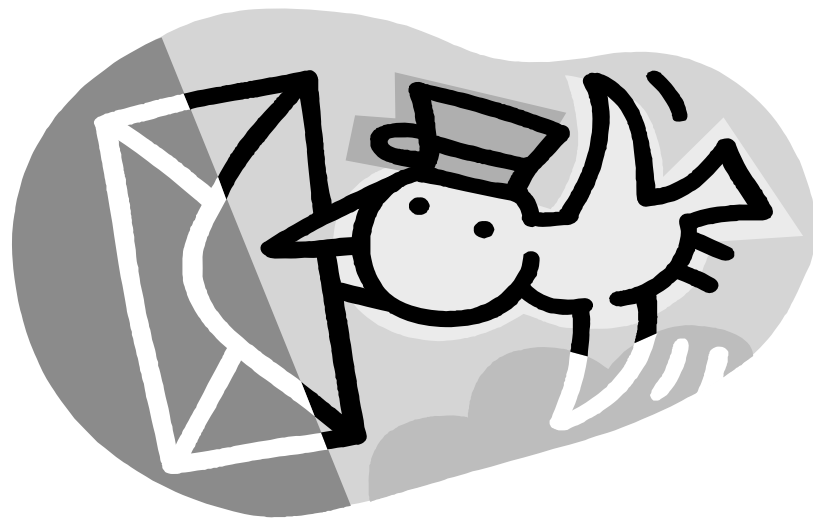
Warning Letters
CAPA Data

Year	# WLs	# w/ CAPA cite	%
2007	74	62	84
2006	79	69	87.3
2005	97	85	88
2004	113	89	79
2003	69	61	88

2007 Warning Letter Example

"Specifically, your complaint files are incomplete, investigations are incomplete and in some cases not performed at all, and some complaints have no documentation of activity for 5 or 6 months after receipt. [21 CFR § 820.198]"

2007 Warning Letter Example

"Management reviews at your …. facility did not include non-conformances and quality data analysis from all sources, in that re-works, re-sterilizations, preventive maintenance corrective actions and returned goods (sources of quality problems) were not addressed in management reviews."

Warning Letter Database

➢ Go to FDA's web site and use this link:

http://www.fda.gov/foi/warning.htm

➢ These WLs redacted for FOI purposes; trade secret, proprietary info blacked out

Implementing an Effective CAPA System: What you need to Know

Presented by:

Linda L. S. Lovett

Quality Systems Director

Medtronic

Spinal and Biologics

Key Challenges:
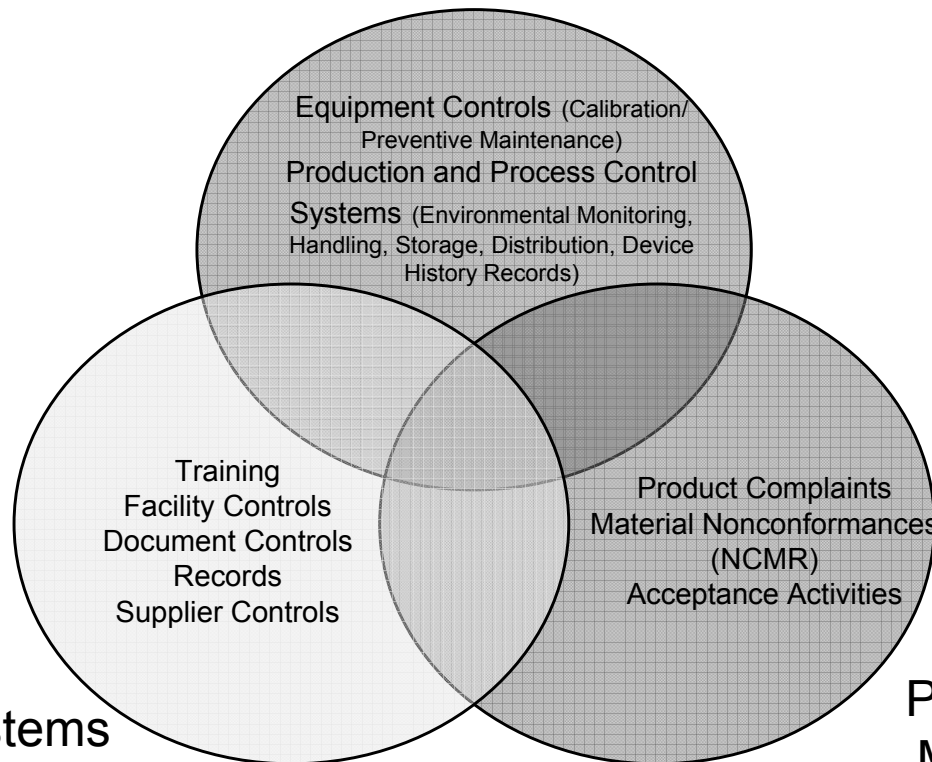## CAPA in Medical Device Industry

Companies are struggling with some of the same fundamental challenges….

- **More companies are under increased scrutiny by regulatory agencies and authorities**
  - Enforcement Actions taken (Form 483 Observations, Warning Letters, Consent Decrees, Injunctions, Product Seizures, etc.)

- **Focus is on product/ material issues rather than efforts to resolve systemic issues**
  - Companies tend to look at product/ material issues and correcting them and neglect to look beyond into the processes and procedures (quality systems).
  - Fast forward to the solution without identifying the "Root Cause"

- **Developing, Implementing, and Maintaining a "Closed Loop" CAPA system that "Integrates Compliance" into business practices and quality systems**
  - Not all inputs are identified
  - Required process steps are not always completed
  - Trending and data is not always analyzed and/ or visible to the appropriate level in the organization.
  - Employees don't always know or understand their responsibility or authority

- **Using your CAPA system to "Improve Profitability by Decreasing the Cost of Quality"**
  - High cost of quality impacts the bottom line (rework, scrap, delays in product approval, resource inefficiency, etc.)
  - Data and risk driven – helps to determine where to focus actions and resources

- **Many companies are still using manual paper based systems**
  - Difficult to manage

# What is an effective Nonconformance Control/ CAPA system?

Examples:

Processes

Equipment Controls (Calibration/ Preventive Maintenance)
Production and Process Control
Systems (Environmental Monitoring, Handling, Storage, Distribution, Device History Records)

Training
Facility Controls
Document Controls
Records
Supplier Controls

Product Complaints
Material Nonconformances (NCMR)
Acceptance Activities

Quality Systems

Products/ Materials

A system that ……

- includes all nonconformance inputs from internal and external sources for product, processes, and quality systems

- identifies existing or potential causes of nonconforming products or other quality problems.

- evaluates/ investigates for root cause consistent with the associated risk

- identifies actions needed to correct or prevent recurrence

- verifies/ validates the CAPA for effectiveness and assures that the actions do not adversely affect finished product

- has a closed feedback loop – data that is collected, reviewed, analyzed and further action is identified as an output that becomes an input back into the process

- is measured, monitored, and reported to management

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Developing an Effective
Nonconformance Control and CAPA system

Mission Statement

Scope

Goals

Benefits

Communication Plan
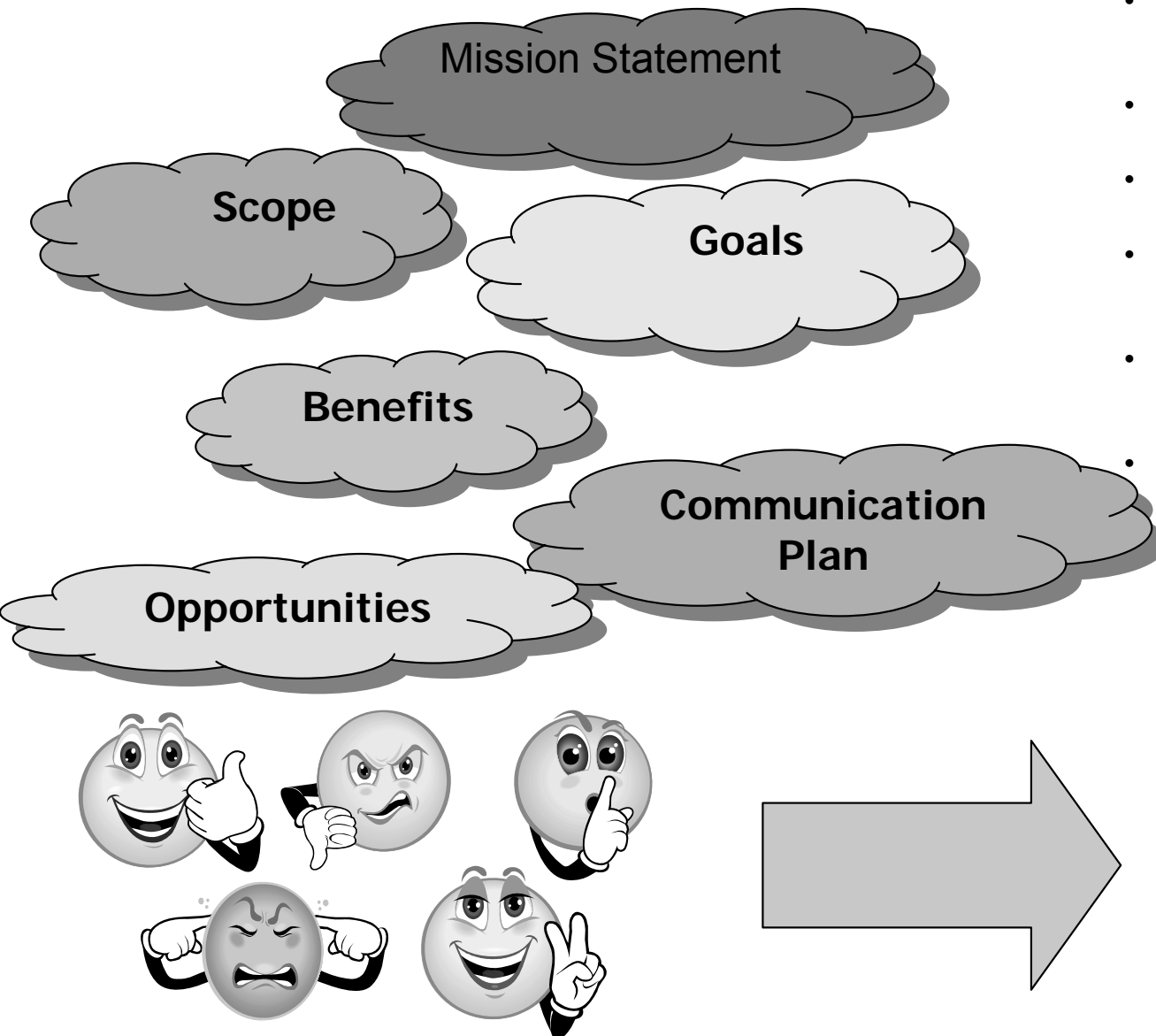
Opportunities

- **Identify Team Resources, Champions, Executive Sponsors**

- **Determine the timeline and schedule**

- **Kick-Off Meeting**

- **Provided CAPA System Training (QSR, QSIT, ISO 13485:2003, MDD, etc.)**

- **Team Discussion – Benefits, Opportunities, Experiences**

- **Established the Project …**
  - **Mission Statement**
  - **Scope**
  - **Goals**
  - **Communication Plan**
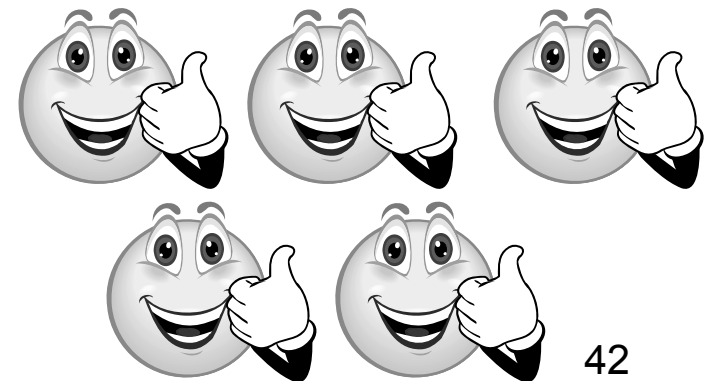
Developing an Effective
Nonconformance Control and CAPA system

Benefits

- **Increase Capacity and Revenue**

- **Increase Company Credibility, Reputation, and Good Will**

- **Enhance Supplier Communication and Relationships**

- **Increase resources for Product Development**

- **Increase Customer Base**

- **Decrease Cost of Quality (Non conformances, Field Actions, Complaints, Operational Scrap, Process Variability)**

- **Decrease Resource Consumption**

- **Decrease Supplier Risk**

- **Prevent Regulatory Sanctions (Fines, Consent Decree, Injunction, Product Seizure)**
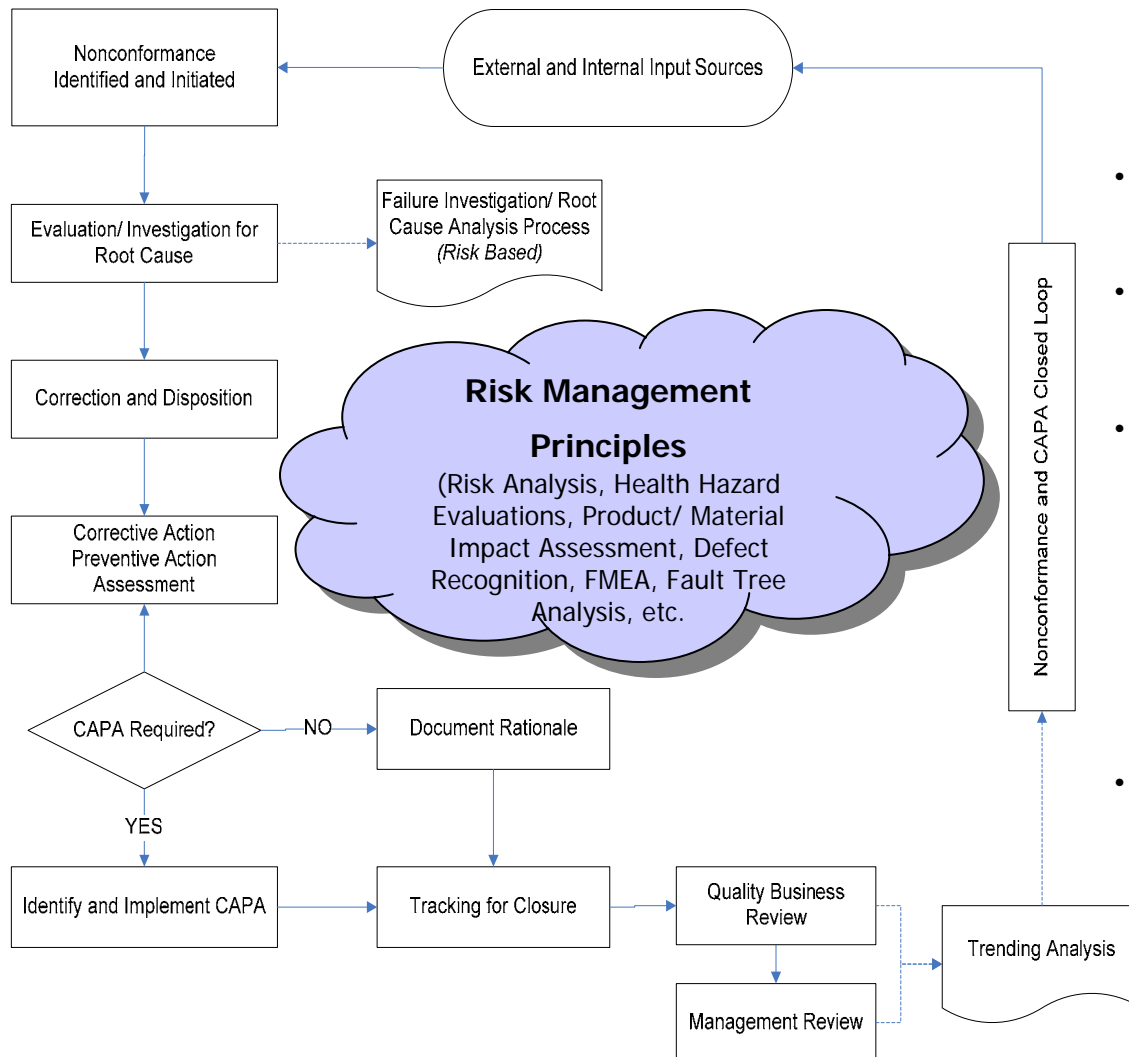
Goals

- **Meet global requirements (QSR/ISO/MDD/CMDR/etc.)**

- **Design and implement a comprehensive enhanced Closed loop CAPA system that includes inputs from product, processes, materials, and Quality System nonconformances.**

- **System will be scalable, simple, risk based, and easily integrated throughout the organization.**

- **Achieve Global employee understanding and ownership (Accountability) without adding additional resources.**

- **Achieve consistent and sustainable practices by utilizing tiered training programs, subject matter experts/ trainers, and process owners.**

- **Implement measurement, data analysis tools, and processes for different levels of the organization.**

Developed Gap Analysis - Example

- Identify all potential opportunities for non conformances for each key support system
- Determine current documentation practices
- Identify/ Classify potential nonconformance types – product/ material, process, or QS
- Develop the plan to eliminate gaps

Quality System Elements	Potential Nonconformance Opportunities	Current Procedures	Record or Form used to document the nonconformance (Current)	Nonconformance Type (Product, Process, QS)
Control of Inspection, Measuring and Test Equipment	New Equipment not Calibrated	Calibration Management		
	Calibration record not reviewed			
	Calibration record/ form incomplete			
	Equipment not labeled as to calibration status			
	Limited Calibration not appropriately identified			
	Parameters not approved			
	Procedure Not Followed			
Training	Inadequate training	Training Procedure		
	Job performed before training			
	Not training to matrix requirements			
	Procedure Not Followed			
	Trained by an unqualified trainer			
	Training to incorrect revision			

Nonconformance Control/ CAPA Process

Flowchart (left to right, top to bottom):

- Nonconformance Identified and Initiated
- External and Internal Input Sources
- Evaluation/ Investigation for Root Cause
- Failure Investigation/ Root Cause Analysis Process (Risk Based)
- Correction and Disposition
- Corrective Action Preventive Action Assessment
- CAPA Required?
  - NO → Document Rationale
  - YES → Identify and Implement CAPA
- Identify and Implement CAPA → Tracking for Closure → Quality Business Review → Management Review → Trending Analysis
- Nonconformance and CAPA Closed Loop

Risk Management Principles (cloud)
(Risk Analysis, Health Hazard Evaluations, Product/ Material Impact Assessment, Defect Recognition, FMEA, Fault Tree Analysis, etc.)

- **Identification, Evaluation/ Investigation**
  - Determine the nonconformance type and Risk level
    - Products/ Parts
    - Process
    - Quality System
  - Isolate the issue (lot number, timeframe, etc)
  - Identify root cause

- **Correction**
  - Immediate fix of the issue
  - Product or material disposition

- **CAPA Assessment**
  - Determine the need for a corrective and/ or preventive action
  - Document Rationale

- **CAPA Identification and Implementation**
  - CA: Actions necessary to eliminate the cause(s) of the nonconformity and to prevent recurrence.
  - PA: Action necessary to eliminate the cause(s) of the potential nonconformity to prevent occurrence.
  - EV: The objective evidence that the root cause was appropriately corrected and/ or the investigation has adequately addressed the root cause.
    - Identify a measurable, statistically significant objective
    - Don't rely only on post distribution data

- **Trend and Data Analysis**
  - Day to day data collection and analysis (SPC, NST, etc.)
  - Monthly Nonconformance Control, CAPA Oversight, and Business Metric Reviews – Trending Analysis
  - Management Reviews for suitability and effectiveness

Implementing an Effective CAPA System: What you need to Know

CAPA Assessment – Thinking/ Talking Points

Questions to ask to determine the need for a CAPA……

Corrective Action: What needs to be done to prevent or stop the cause(s) of the same nonconformity from happening again (*prevent or stop recurrence*)?
  –Does the procedure need to be updated for gaps or clarification?
  –Is the procedure missing?
  –Do risk documents require an update?
  –Was training not adequate or missing?
  –Are multiple corrective actions required?
  –Are there other same products, different lot or serial numbers affected?

- If a corrective action is not performed, why?

Preventive Action: What needs to be done to prevent or stop the cause(s) of a similar nonconformity from happening within other parts of the quality system, other products, or other processes *(prevent/ eliminate occurrence)*?
  –Do other procedures need to be updated for gaps or clarification?
  –Are other procedures missing?
  –Do other product or process risk documents require an update?
  –Are multiple preventive actions required?
  –Are there other parts of the quality system, other products, or other processes affected?

- If a preventive action is not performed, why?

Effectiveness Verification: Evidence based to address the root cause of the issue.
  –What will be measured and what is the acceptance criteria?
  –How many records or products need to be reviewed, measured, trended, or tested to the acceptance criteria? Statistically significant sampling plan.
  –Who will perform the effectiveness check?
  –When will the effectiveness be performed? How long after the CAPA implementation?
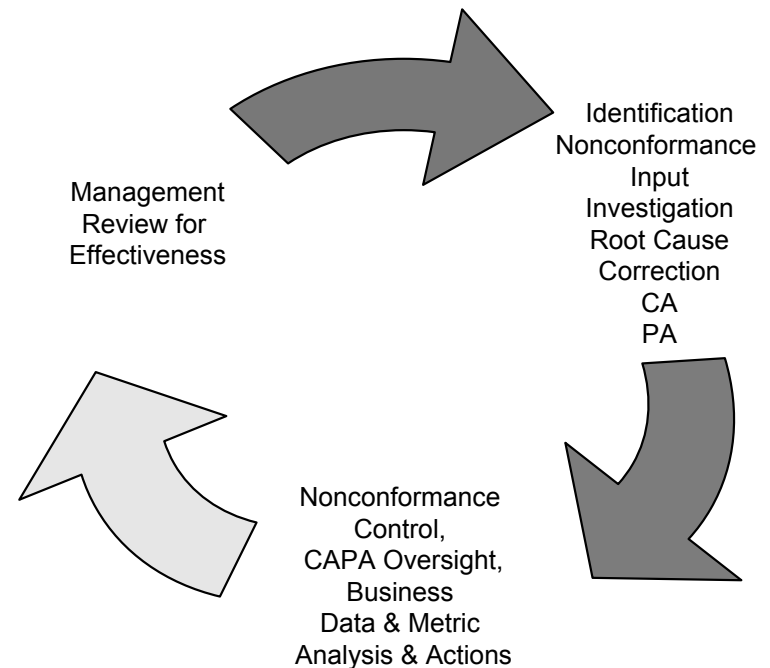 –Are multiple effectiveness checks required?

- Don't rely only on post distribution data!

RESULTS

Effectively and Continuously Improves
Products, Processes, and Quality Systems!

Closed Loop Monitoring, Trend Analysis, Effectiveness Reporting

- **Determine frequency of data analysis and metric review and to what extent.**

- **Determine risk based measurement, data analysis tools and processes for reviewing data**
  - Assure meaningful data is captured
  - Configure data such that problems can be identified
  - Determine when and what actions should be taken

- **Assure accurate and timely communication to management**

- **Metric and Data Analysis and Review (Examples)**
  - Facility/ Equipment Control (*Calibration/ Preventive Maintenance*)
  - Training
  - Inspection Results (*Incoming, Production/ Manufacturing*)
  - Nonconformance Control/ CAPA Oversight
  - Complaint Handling/ Corrections/ Removals
  - Business metrics (*Technical Support, Cost, Strategic Initiatives*)
  - Audit Results and responsiveness
  - Cost of Quality

Identification
Nonconformance
Input
Investigation
Root Cause
Correction
CA
PA

Management
Review for
Effectiveness

Nonconformance
Control,
CAPA Oversight,
Business
Data & Metric
Analysis & Actions

Key Support System	Metric ID	Functional Area Owner	Frequency	Description of the Metric	Action Criteria
Facility/ Equipment	**CAL 1**	**Quality**	**Monthly**	***Number of items Scheduled for calibration per month vs. Actual**	**NST, 3 consecutive increases for late calibration**
	CAL 2	**Quality**	**Monthly**	***Number of Calibration Impact Assessments with Out of Tolerance (OOT) results and disposition**	**NST, 3 consecutive increases for OOT calibrations/Impact Assessments**
Training	**TRN 2**	**Quality**	**Monthly**	**Late Training Exceptions (Approved/ Unapproved)**	**NST, decrease in overall or department compliance**

Nonconformance Control and Closed Loop CAPA Program
In Summary

- Make the Nonconformance Control/ CAPA system *scalable, simple, risk based, and easily integrated* throughout the organization. Assure that sufficient mechanisms are in place so that all steps are completed for each event.

- Have a *Closed loop Nonconformance Control/ CAPA system* throughout the entire organization that *includes external and internal inputs* from *product life cycle, processes, and quality systems*.

- *Integrate risk management* throughout product life cycle, processes, and quality systems.

- Implement *measurement, data analysis tools, and processes* for different levels of the organization. *Configure data such that problems* related to product, process, or quality system *can be identified.* Results of the analysis and/ or any further decision to take action are identified as an output of the CAPA system.

- Assure that there are *linkages* within between products, processes, quality systems, and across multiple divisions and/ or facility locations.

- *Drive for employee understanding and ownership* (*Accountability*) by implementing consistent and sustainable practices and tiered training program.

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QSR Complaint and CAPA Compliance

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Achieving the Right Balance

- How much is enough

  - Number of process steps

  - Number of signatures

  - Detail of CAPA forms

  - Depth of investigations

  - Follow-up required for closure

Defining the Criteria for CAPAs

- The CAPA system should be significant sources of quality problems, not:

    - All complaints

    - All safety complaints

    - Variable based on proximity to next audit

    - A means to get more attention to problems that are overdue

Failure Investigations

- These "root causes" suggest that the failure investigation did not go far enough

  - Training

  - User error

  - Operator error

  - Testing

- Is a failure investigation always required?

Effectiveness Checks

- 820.100(a)(4) Verifying or validating the … action to ensure that such action is effective and does not adversely affect the finished device

- ISO 13485:2003 8.5.2.e reviewing the … action taken and its effectiveness

- Emphasis should be on finding the right fix, not on monitoring

- Effectiveness for design should be V&V

- Monitoring should be in place for all processes, not just CAPAs

Concealing CAPA Problems

- Extending the due date for late CAPAs

- Closing out several CAPAs to create a new one(s) to reset due dates

- Evaluating CAPA completeness based on report volume

- Defining training and SOP updates when a substantive root cause can't be found

- Relaxing closure criteria when deadlines get close

CAPA Process Solutions

- Resolving problems is key to achieving significant quality improvements

- Escalating the right elements heightens process effectiveness (risk based)

- Streamlining processes provides efficiency

- Measurement provides visibility

Questions and Answers

Please return the evaluation form!

Your completed evaluation will be entered into a drawing for a $100 Amazon.com gift certificate.

Training Evaluation Form

Implementing an Effective CAPA System: What You Need to Know
March 6, 2008 — Presented by a Panel of Experts from FDA & Industry

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