

# Today's Best Practices in Global Product Surveillance Systems

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# Management of Complaint and Service Experience

A Compliance Headache?

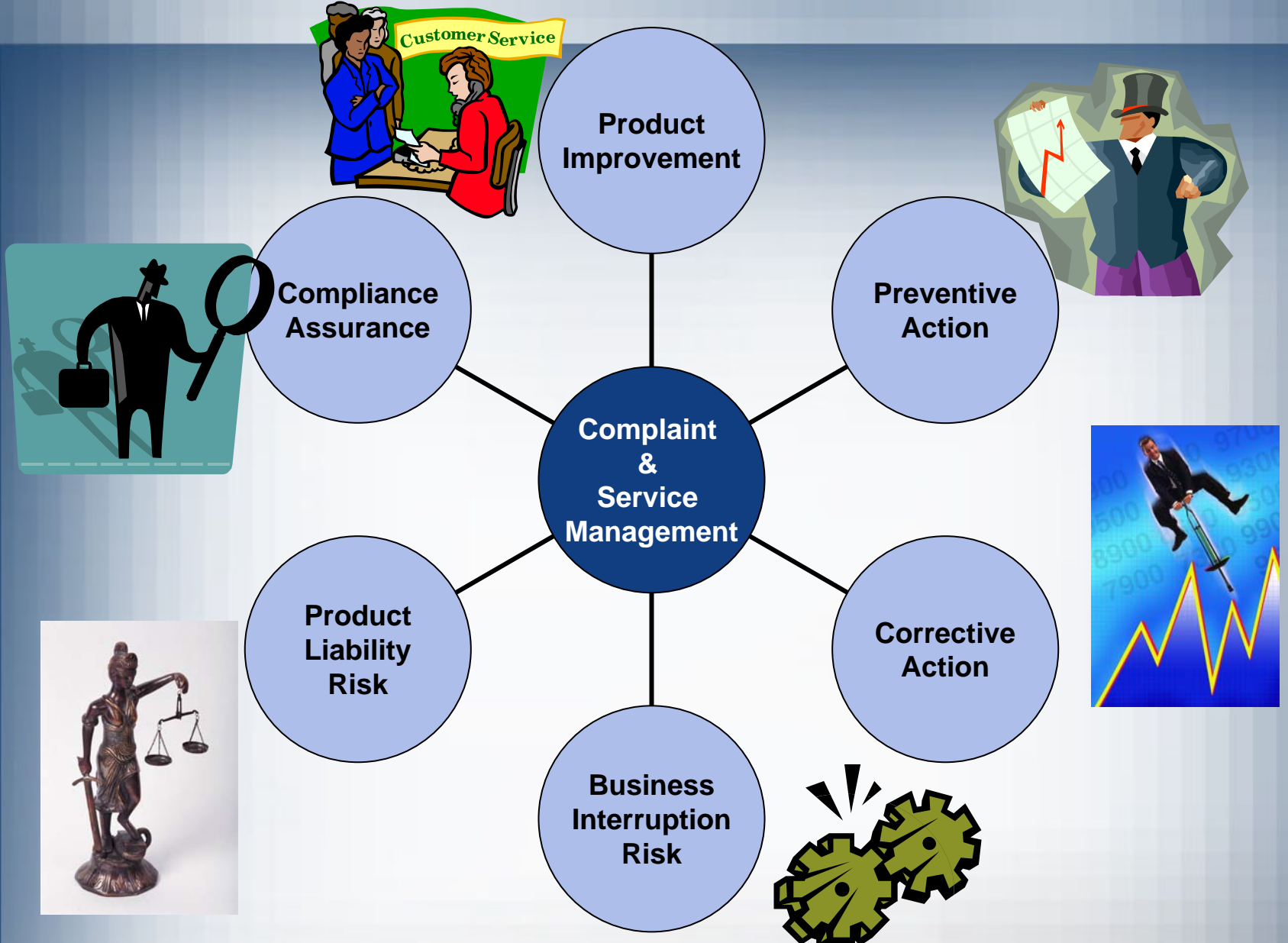


or

The Foundation for Continuous Improvement  
and Risk Reduction?



# Getting Into a Risk Mitigation State of Mind



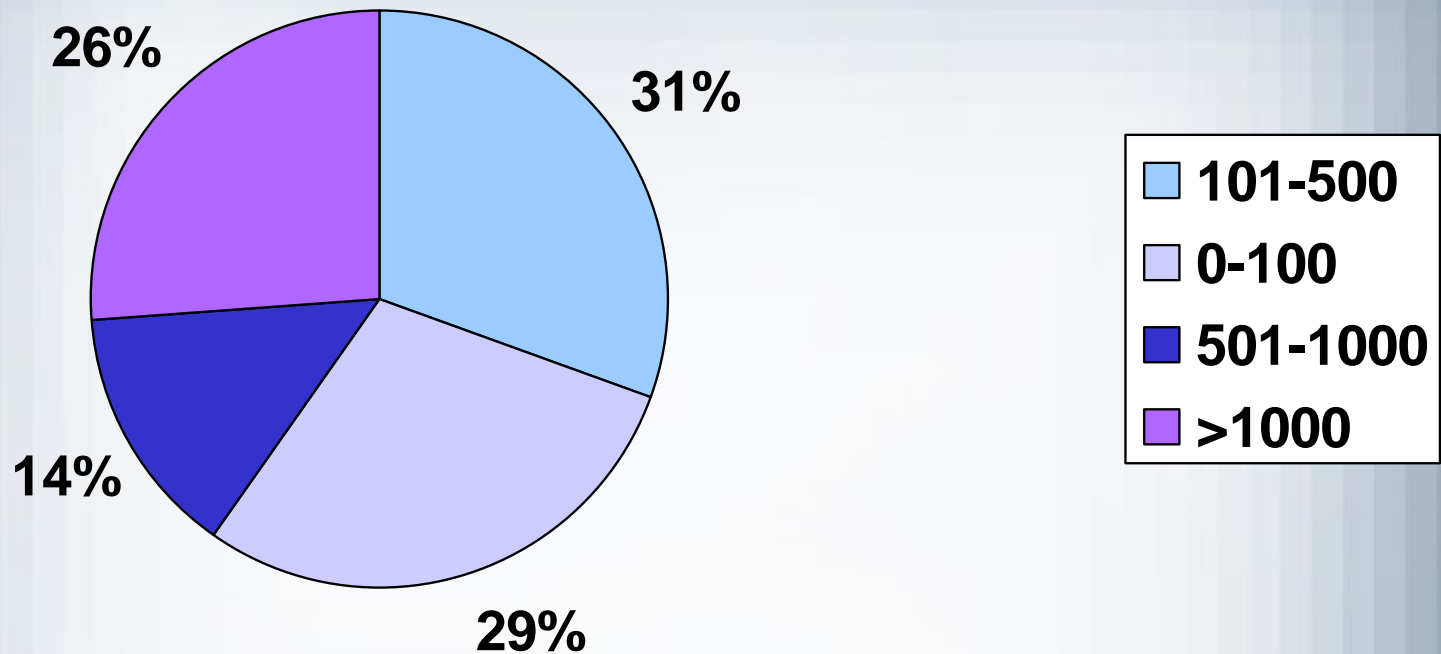
# Discussion Topics

- Complaint Handling Survey
- Designing Risk Management Into Your Complaint and Service Monitoring System
- Field Experience Process Flow
- Product Life Cycle Risk Management

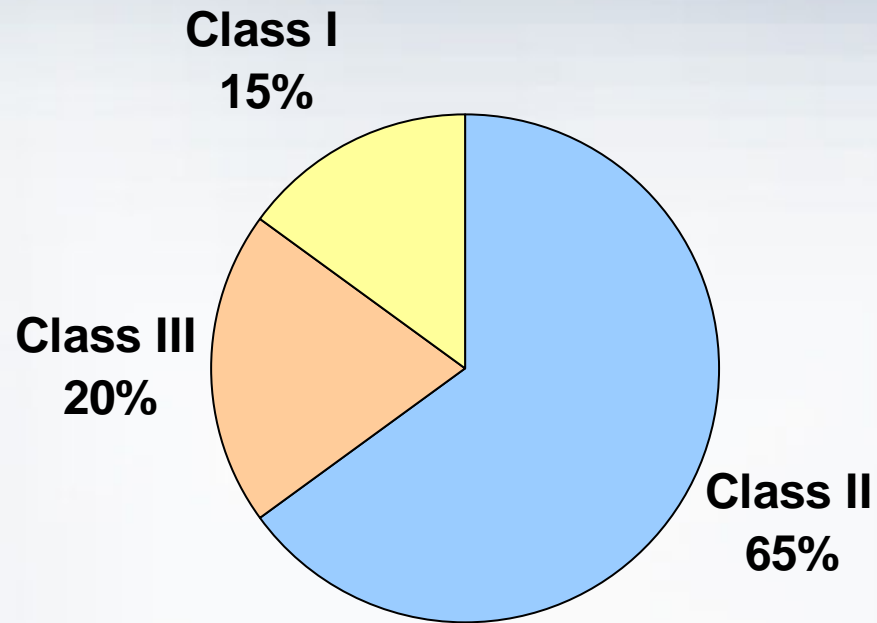
# Discussion Topics

- Reducing Safety Risk
- Reducing Liability Risk
- Reducing Business Risk
- Reducing Compliance Risk
  - Understanding the Regulation
  - Warning Letter Citations
- Complaint and Service Metrics

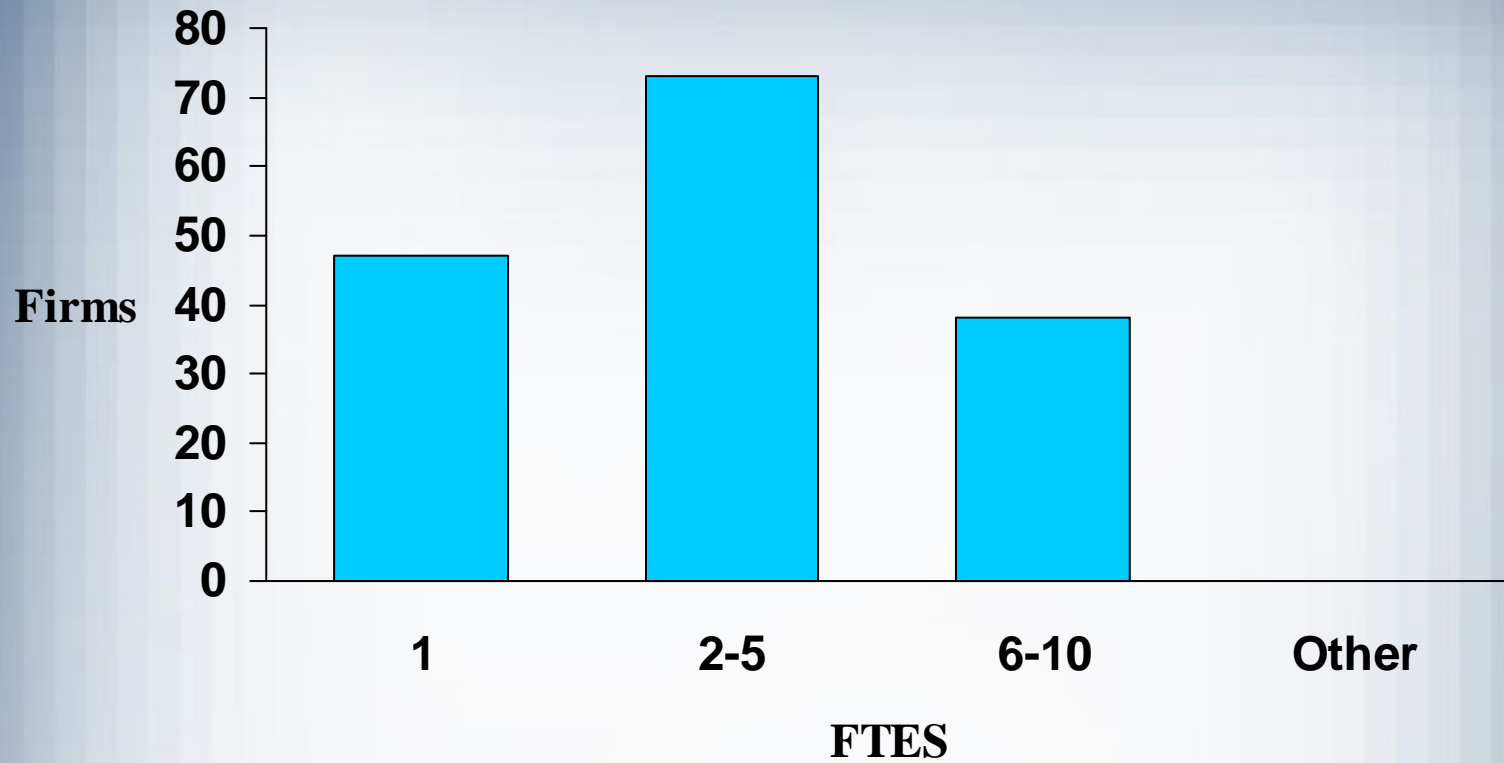
# Number of Employees



# What was the breakdown of device classifications for the first 200 firms that answered survey?

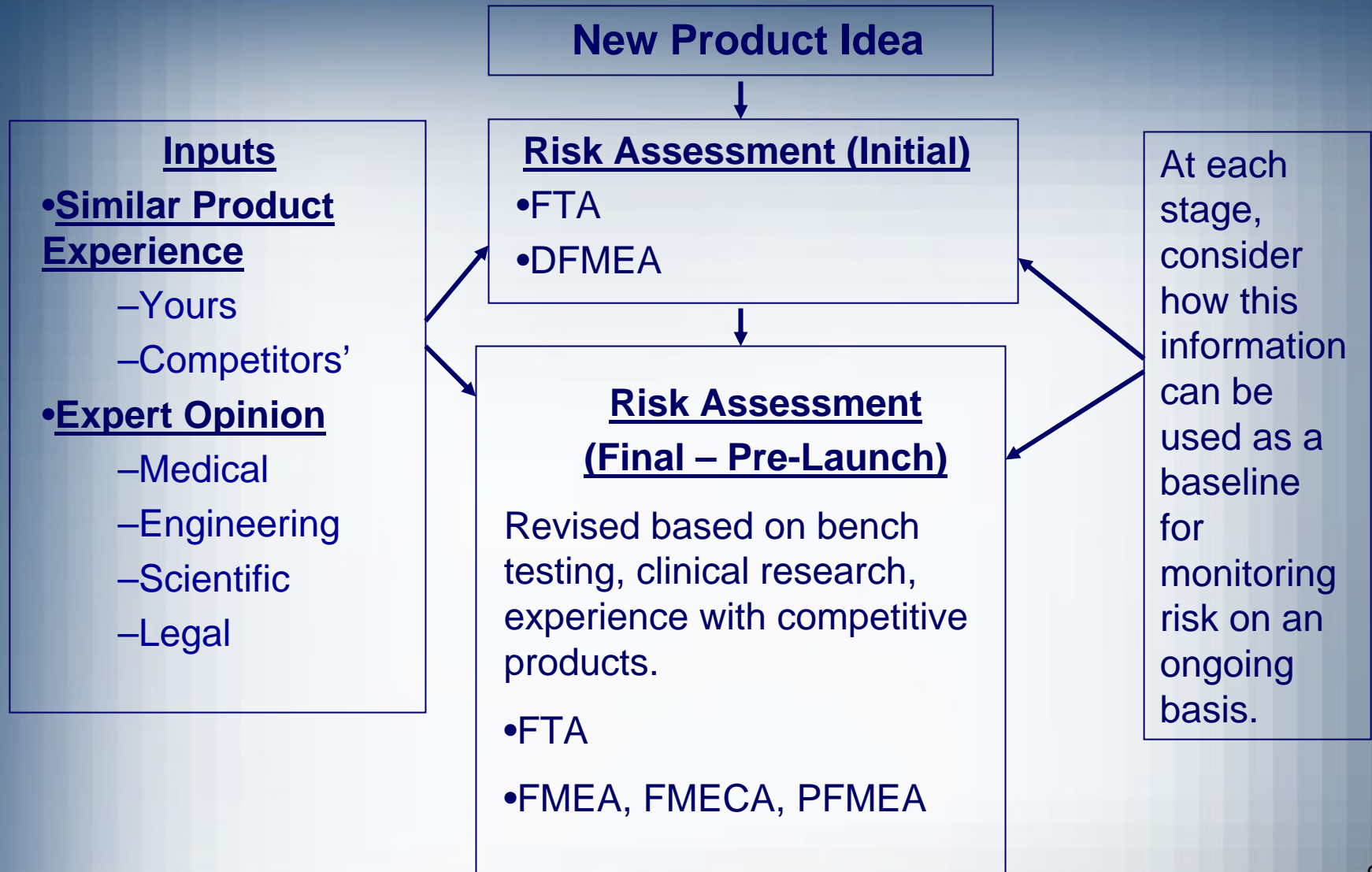


# Resources





# “Designing-In” Risk Management



# “Designing-In” Risk Management

## **Quality Plan – Risk-Related Elements:**

- Supplier Nonconformances
- Production Nonconformances
- Post-Market Surveillance
- Complaint and Adverse Event Investigation
- Trending Complaints & Adverse Events
- Trending and Analysis of Service Experience
- Failure Investigation/Analysis
- Corrective and Preventive Action
- Reviewing Current Experience with Current Risk Assessment Tools
- Periodic Management Review of Risk Levels

# “Designing-In” Risk Management

## Using Risk Assessment Tools for Management of Complaint and Service Experience:

1. DFMEA as an Objective Standard
  - Use the DFMEA severity level when setting “alert triggers” for taking action:
    - Detecting an adverse trend
    - Conducting a failure investigation
    - Establishing root cause of failure
    - Reporting to senior management
    - Filing a mandatory adverse event report

# “Designing-In” Risk Management

2. Recognizing that the original estimate of severity level was inaccurate:
  - Complaint and adverse event reports
  - Adverse events associated with service calls
  - Clinical trial experience
  - Published literature
  - User feedback
  - Competitive experience

# “Designing-In” Risk Management

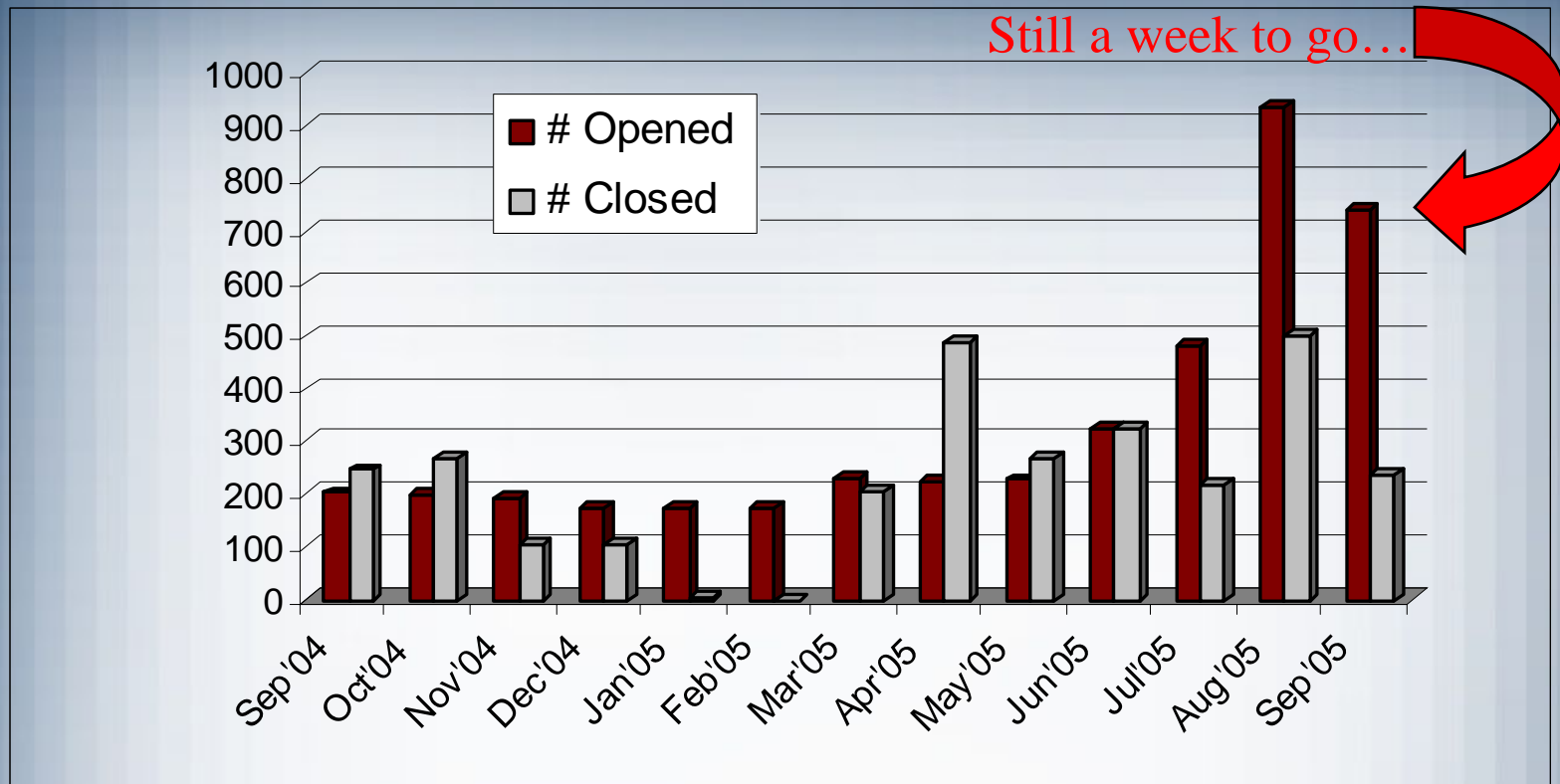
3. Recognizing that the original estimate for probability of occurrence or downstream detectability was inaccurate in the process FMEA:
  - Complaint reports
  - Production nonconformances
  - Out-of-box failures
  - Service, repair and warranty experience
  - Laboratory testing
  - User feedback

# “Designing-In” Risk Management

## 4. Effective Use of Management Reviews to Assess Risk

- Complaint Trends
  - Product categories
  - Reported failure modes
  - Confirmed root causes
  - Adverse event trends
  - Event types
    - » Death
    - » Injury
    - » Serious Malfunction
  - Care Setting

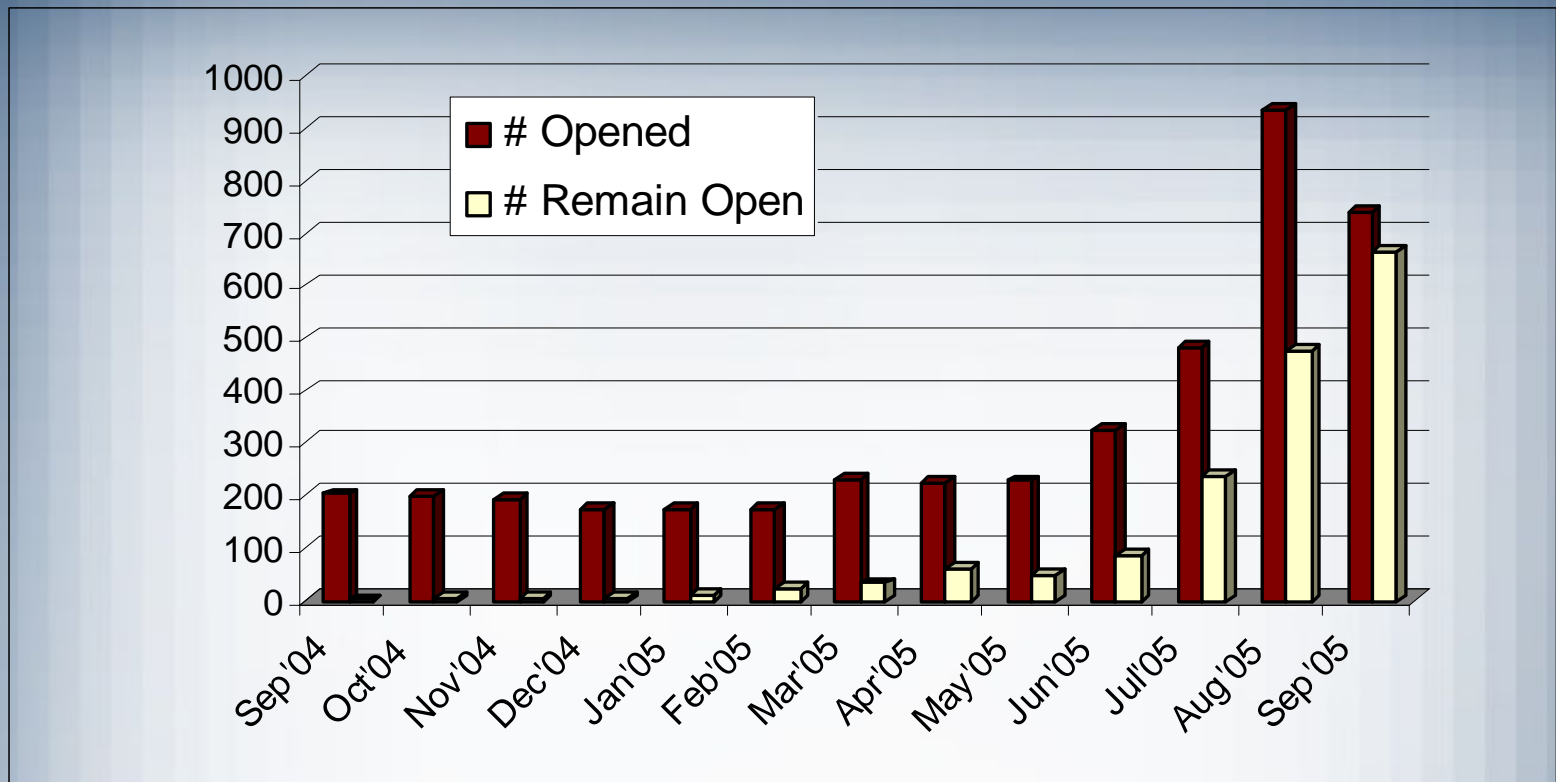
# Complaints Open/Closed



Dec '04 – Feb '05: Complaint process redesign period – few complaints closed.

May '05 – Aug '05: Campaign to increase complaint and service experience reporting from all sales, service and customer support personnel.

# Open Complaints by Month



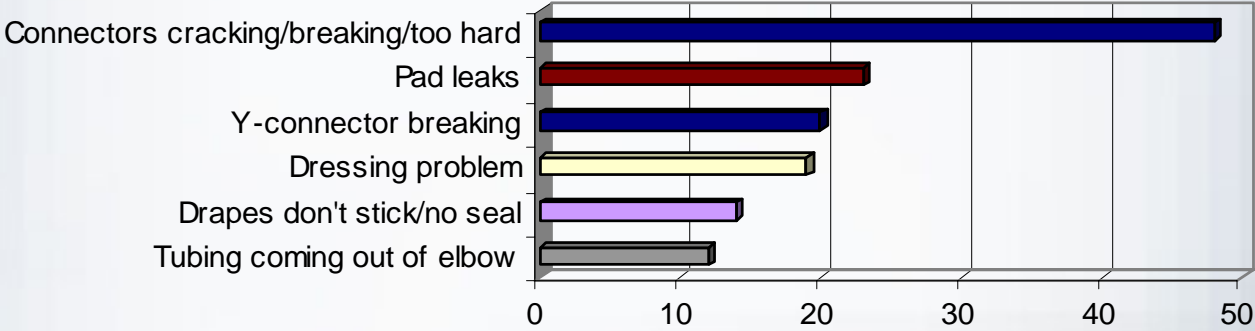
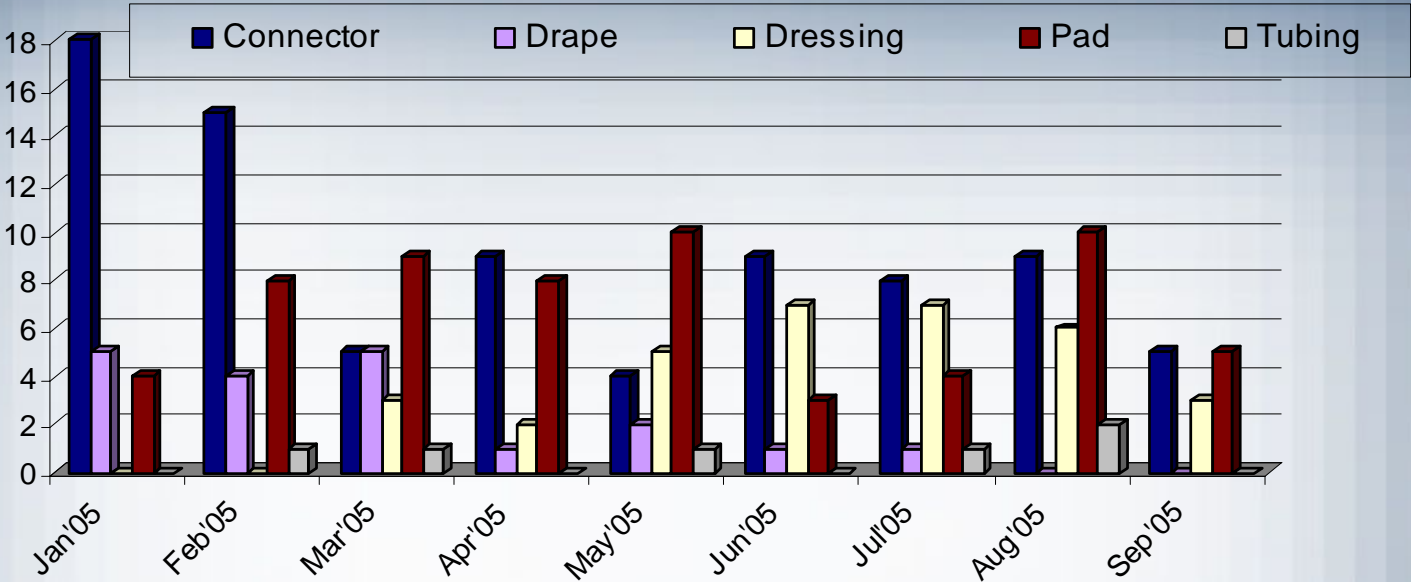
Increase in complaint input preceded increases in staff support requiring extra effort to close complaints in a timely manner.

Advantage: more detail regarding known failure modes; additional returned samples for analysis.



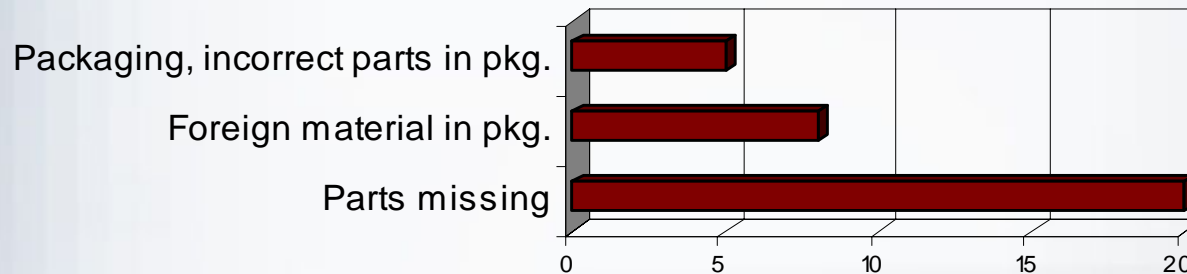
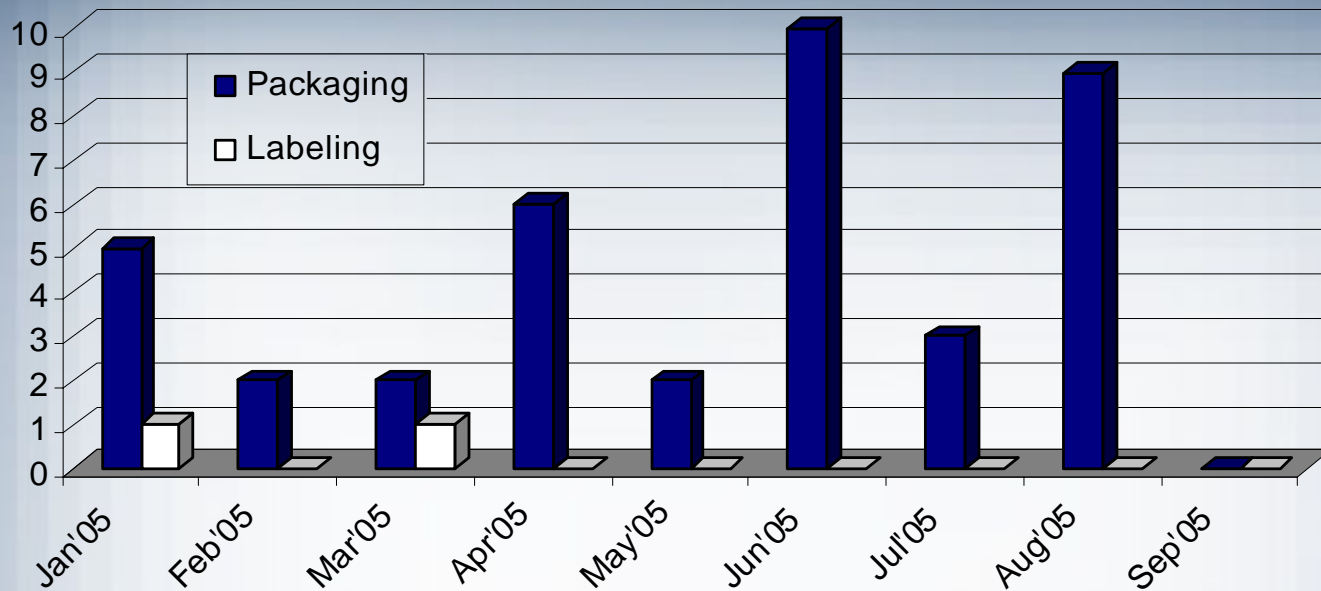
# Disposables – Dressings

(Sample Presentation of Metrics)



# Disposables – Packaging

## (Sample Presentation of Metrics)



# “Designing-In” Risk Management

## 4. Effective Use of Management Reviews to Assess Risk (continued)

- Corrective and Preventive Actions
  - Effectiveness of Prior CAPAs (Trends)
  - Timeliness of CAPAs in Progress
  - Need for New CAPAs
- Shop Floor Quality
  - Scrap
  - Rework
  - Process Variability

# “Designing-In” Risk Management

## 4. Effective Use of Management Reviews to Assess Risk (continued)

- Service and Repair Experience
  - Analyze Data from all Sources
    - » Field service centers
    - » Home office repair facility
    - » Contract service organizations
    - » Hospital experience (where available)
  - Pareto Diagrams
    - » Product line
    - » Part or subassembly
    - » Labor
  - Discuss all Safety-Related Service Issues
    - » Incident investigation results
    - » Planned and ongoing corrective actions

# “Designing-In” Risk Management

## 5. Management Review Risk Assessment

- Products and Processes Conform to Existing Risk Assessment
- Product Experience (Trends and Individual Events) Does Not Signal Need to Reassess Risk
- CAPAs are Appropriate for Maintenance of Existing Risk Levels
- External Inputs Support Levels for Severity and Probability of Occurrence in Current Risk Assessment
  - Published reports, articles
  - Conference presentations
  - Reports concerning similar competitive devices

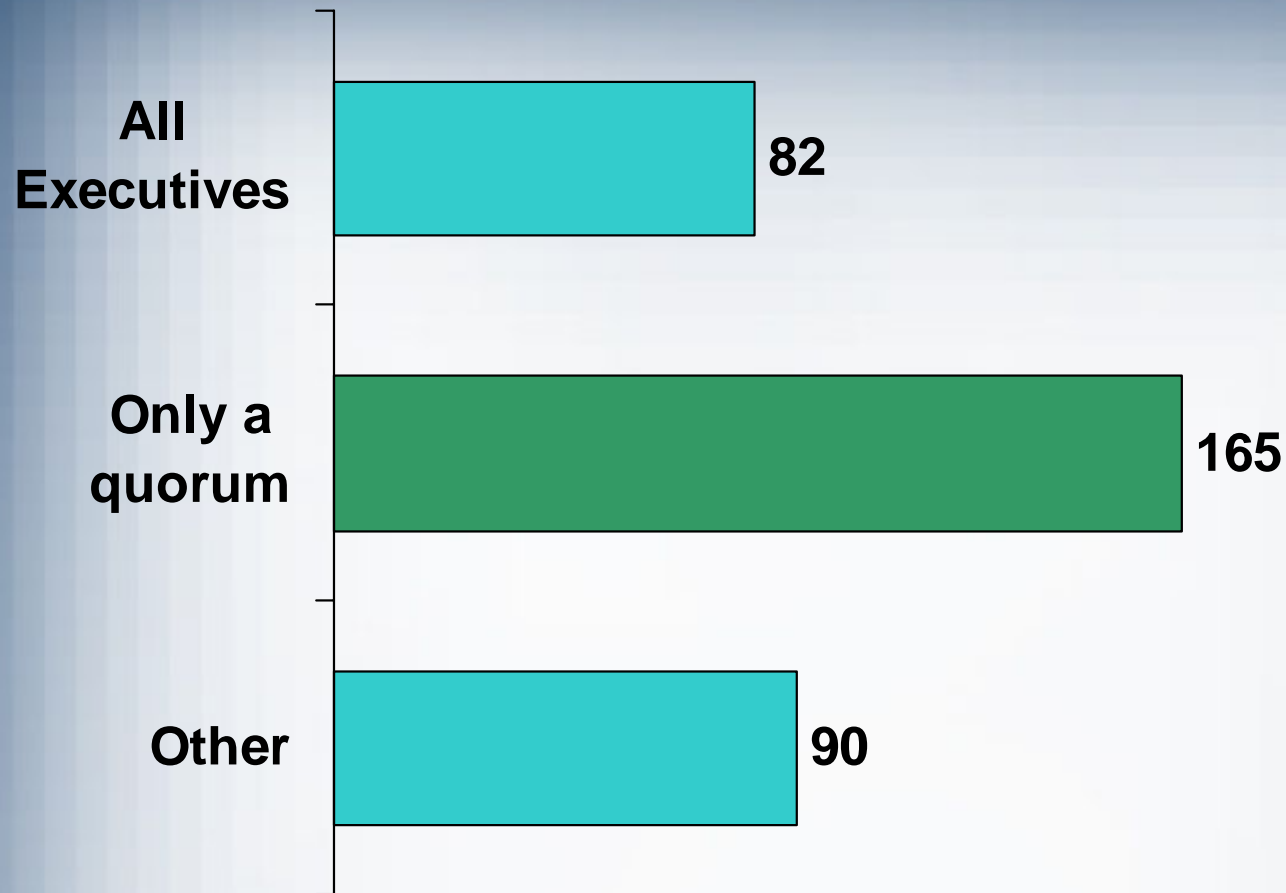
# **Management Review Survey**

**Sponsored by Compliance-Alliance**

# Compliance-Alliance Sent Out a Survey

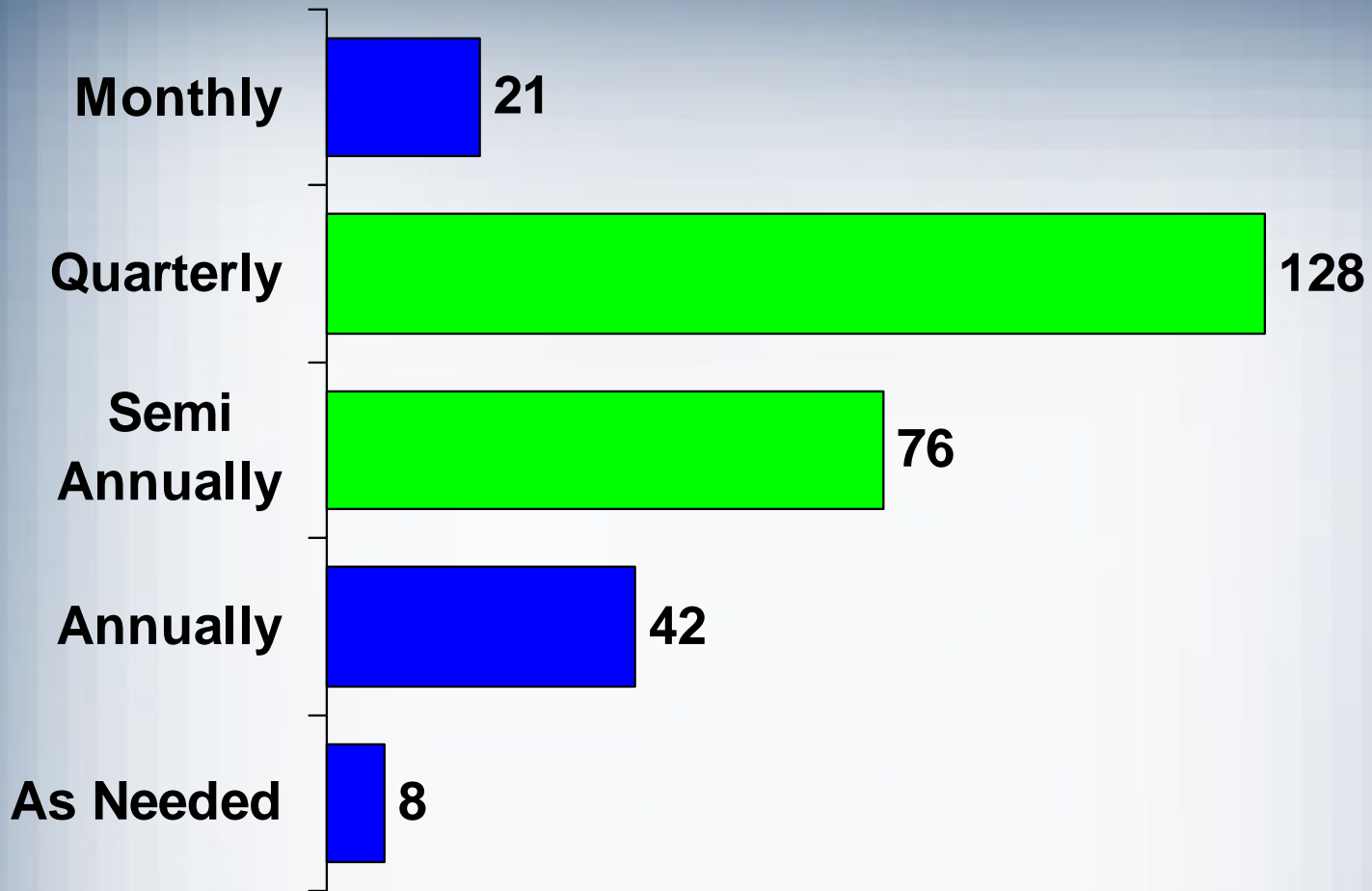
- 301 firms filled it out
- Response rate was higher than other surveys
- 90 individuals expressed interest in doing further benchmarking work

# To have a review, what functions besides the management rep. need to be present?

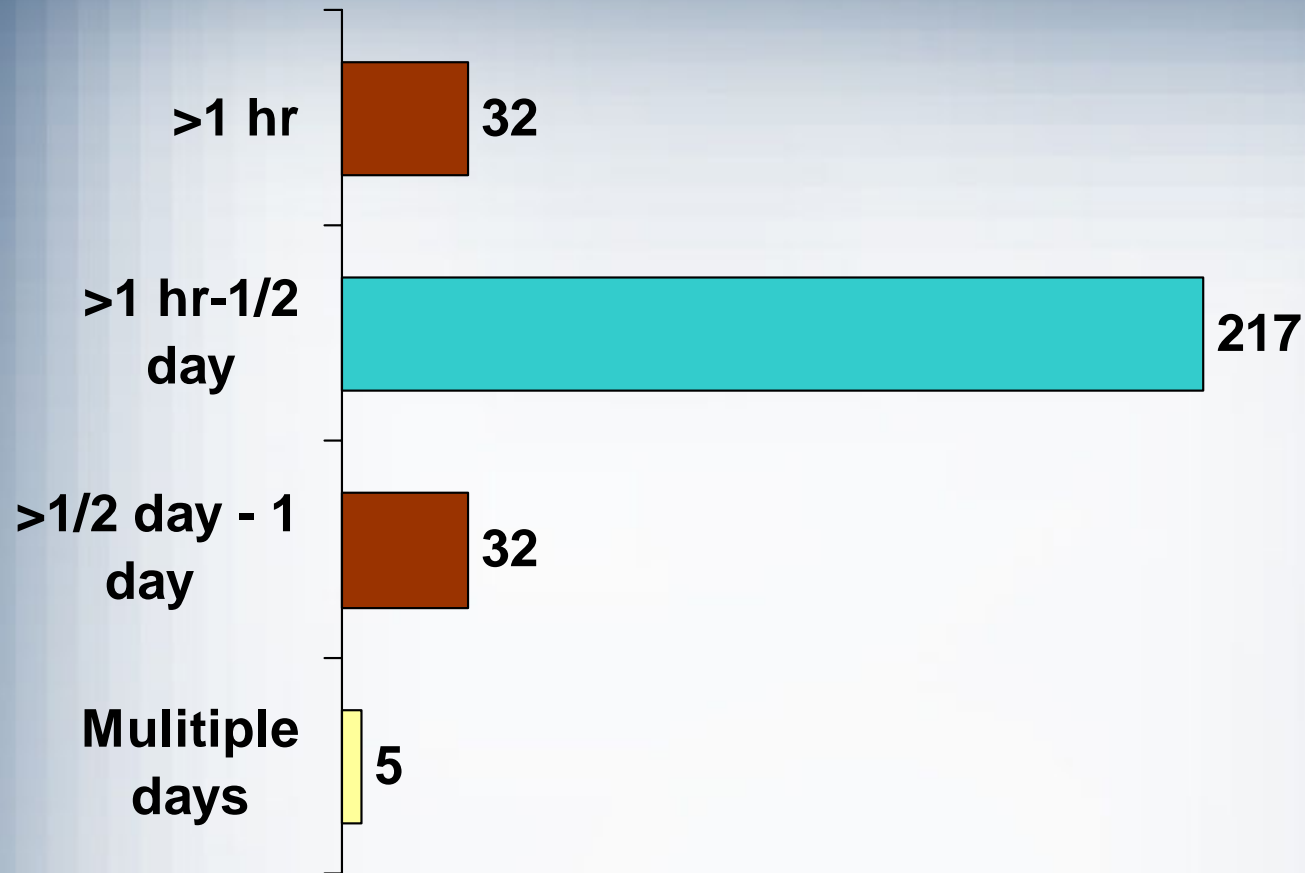




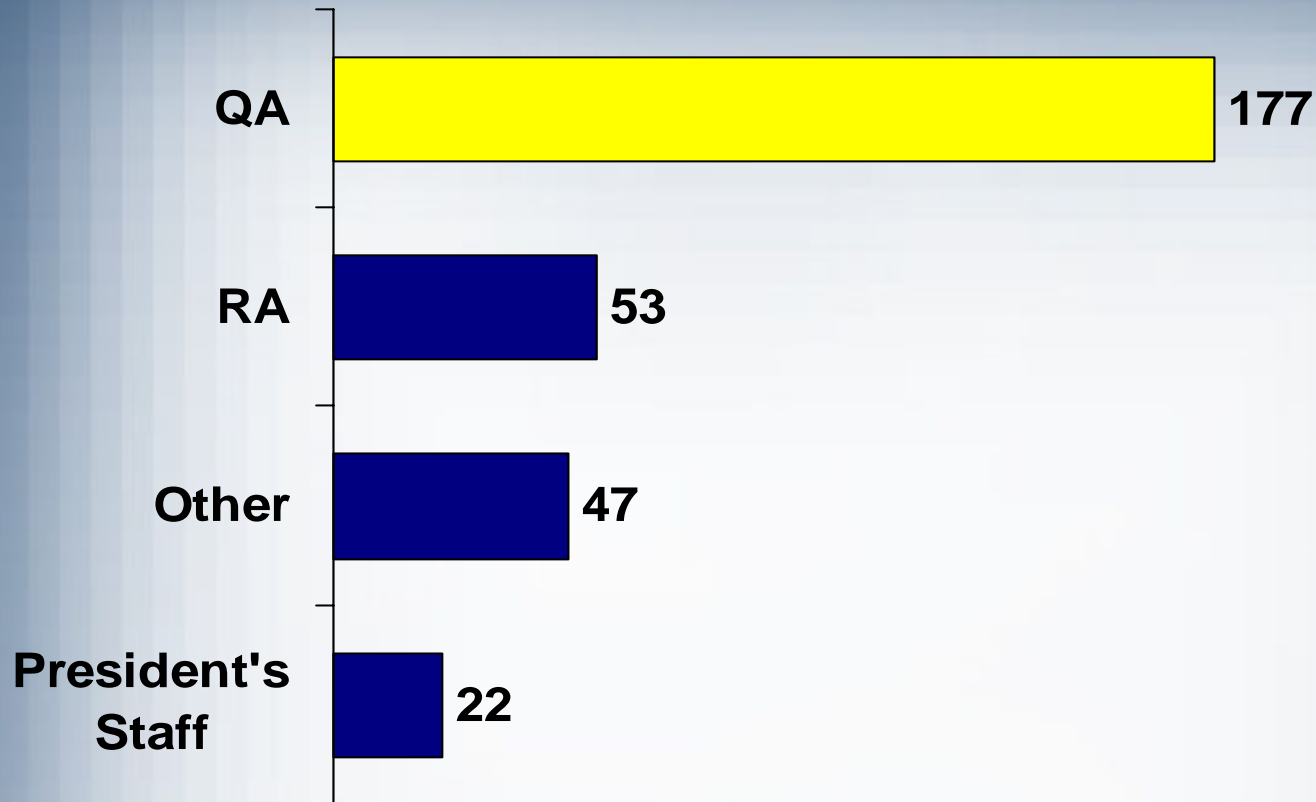
# How often does your firm conduct reviews?



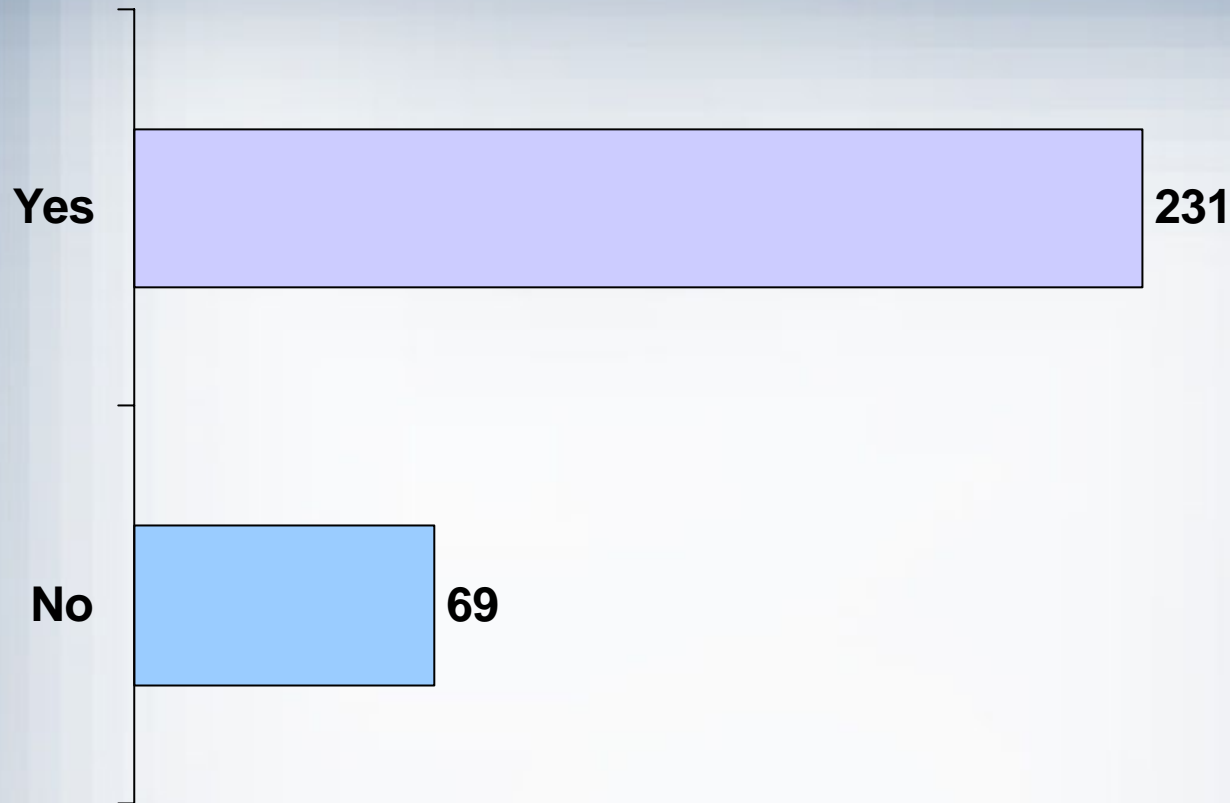
# How long does each review last?



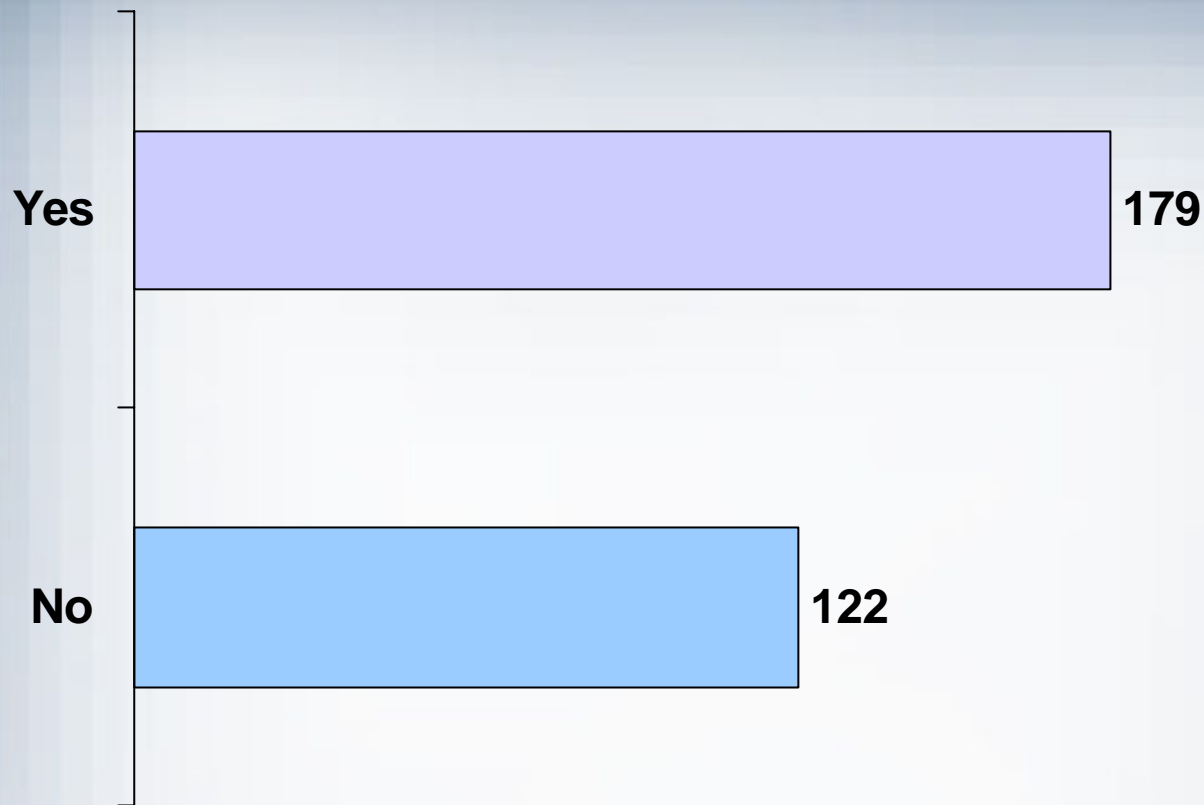
# Who is responsible for ensuring that follow-up issues are addressed?



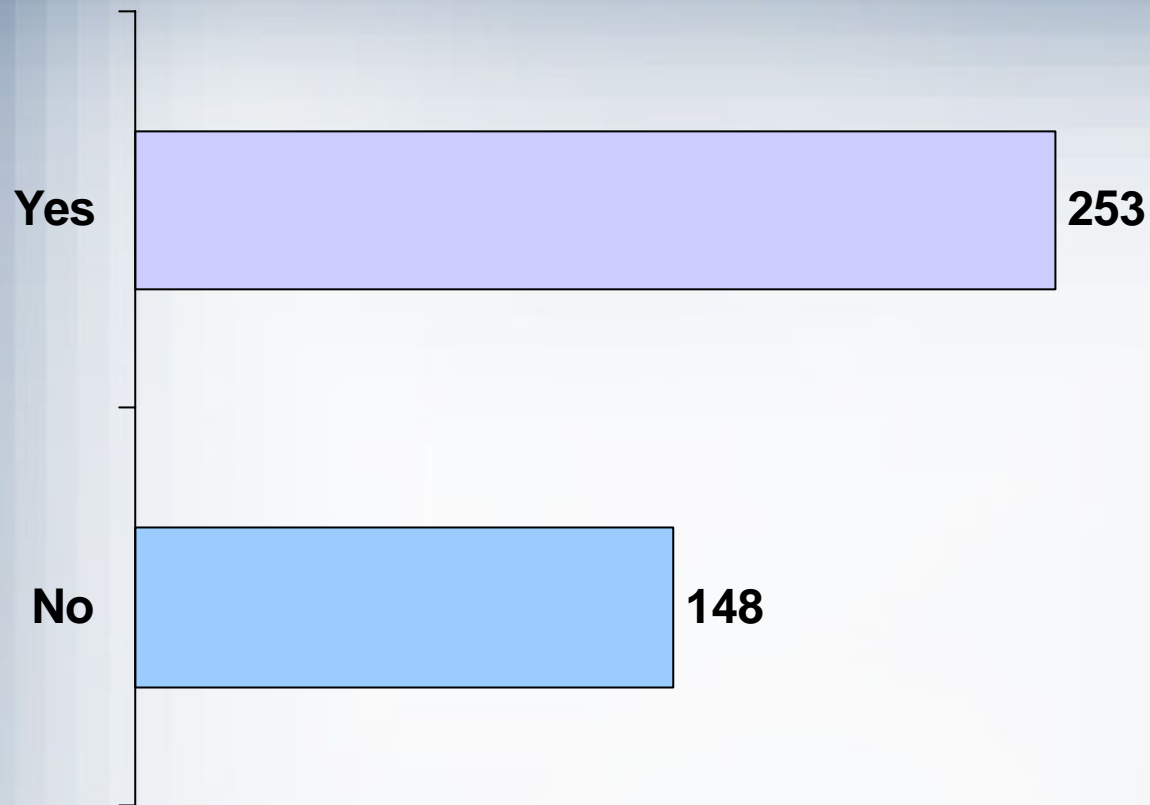
# Does management ask if there are appropriate resources?



# Does management ask if the staff has the appropriate skill sets?



# Does management ask if there are any new regulatory requirements?



# Are actions taken as a result of management reviews?

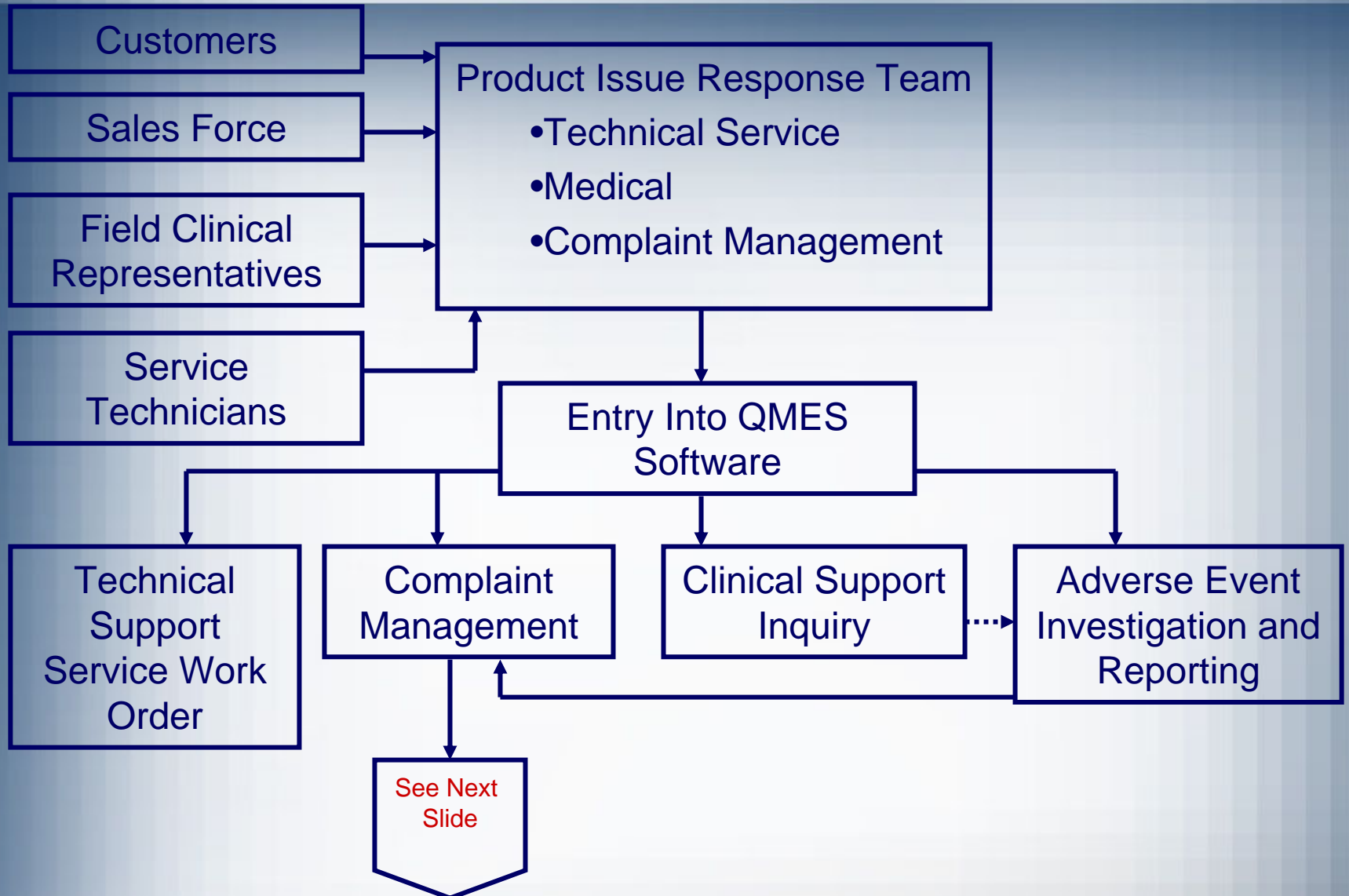
- Yes - 180 firms
- No - 120 firms

# Positive Actions Firms Have Taken As a Result of Review

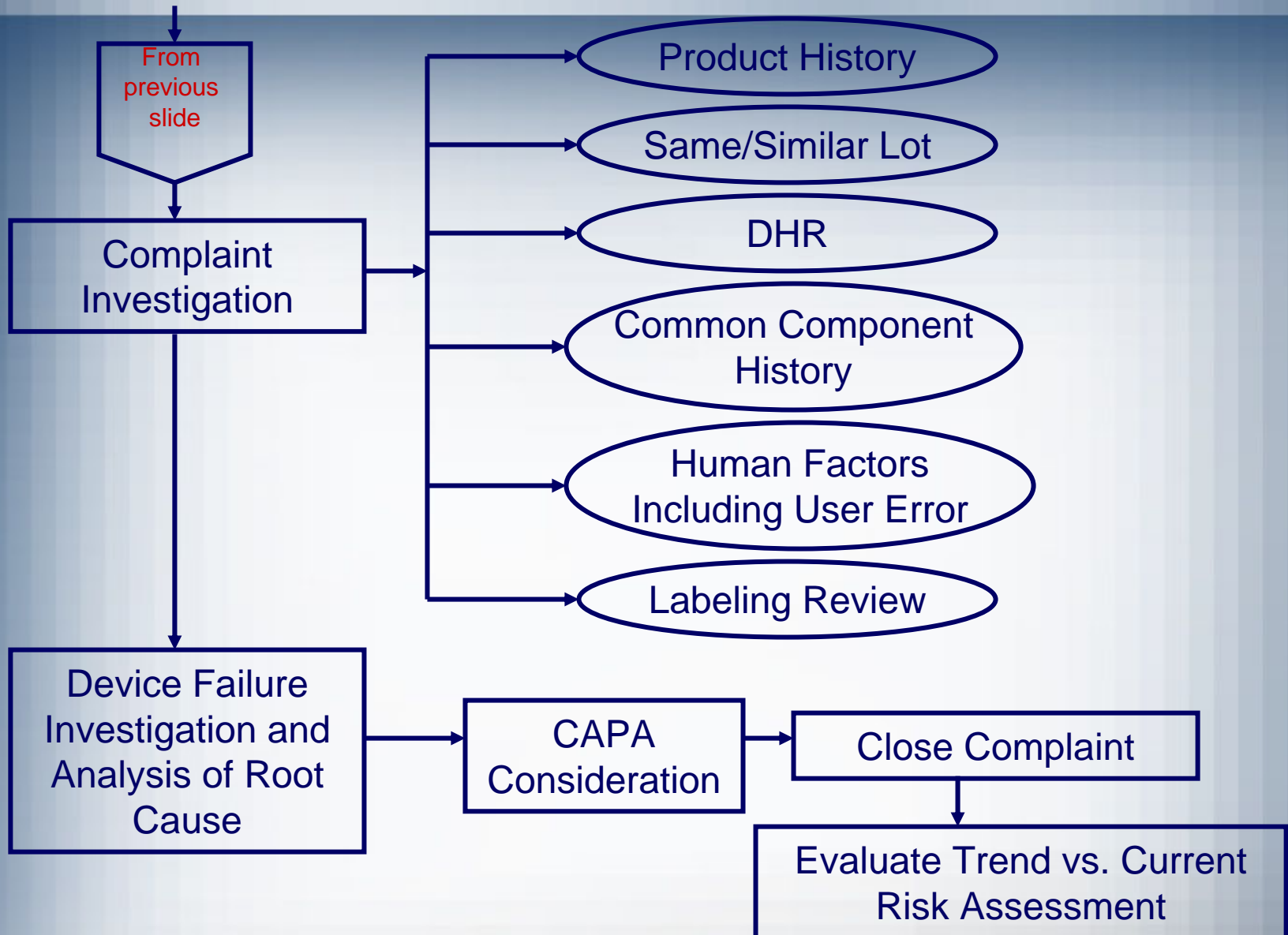
- Implemented new quality policy that reflects business objectives
- Established multifunctional CAPA teams
  - Action was assigned to responsible area
  - Time frames were provided for follow-up
- Reprioritized compliance issues
- Re-audited problems which ensured accountability



# Field Experience Flow Chart



# Field Experience Flow Chart



# Product Issue Response Team (P.I.R.T.)

- Designed to Assure That a Trained Professional Gathers Essential Safety, Performance and Customer Feedback Information
- Co-location of Specialists
  - Medical Personnel – Nurses with Product and Therapy Knowledge
  - Engineers – Provide Expert Problem-Solving Support
  - Complaint Analysts – Document and Investigate Complaints

# Product Issue Response Team (P.I.R.T.)

- Co-location Facilitates Communication
  - Access to products for hands-on training for reported failure modes.
  - “Bullpen” discussions of emerging failure modes.
- Reduced Dependence on Customer Service Personnel
  - Less opportunity for errors or omissions
  - Removes conflict with time-based goals
  - Simplifies training challenges related to skills and turnover

# Product Issue Response Team (P.I.R.T.)

- Use of Scripts to Assure That Needed Information is Captured During the Call in a Consistent Manner Among P.I.R.T. Personnel and from Caller to Caller
  - Adverse event reports
  - Requests for clinical consultation
  - Product performance complaints
  - Service technical support

# Product Issue Response Team (P.I.R.T.)

- Allows Company to Harvest those Rare “Pearls of Wisdom” that Could Be Lost Later
  - Complainant is a difficult-to-reach, night-shift nurse
  - Delay results in complainant’s inability to remember details of the complaint or adverse event
  - Risk management at facility prohibits communication
  - Complaint device has been misplaced, corrupted or discarded

# Reducing Patient/User Safety Risk

## Summary

- Assess All Sources of Safety Inputs
  - Complaints and Service Experience
  - Adverse events
  - Clinical inquiries
  - Published literature
  - Conference proceedings
- Compare Severity and Rate of Incidence to Current Risk Assessment
- Consider Revising Risk Levels Using Established Procedures
- Ongoing Review of Risk-Based Actions During Management Reviews

# Reducing Business Risk

- Types of Business Risks
  - High Cost of Poor Quality (COPQ)
    - Returns
    - Scrap
    - Reprocessing
  - Loss of Sales Revenue and Customer Goodwill
  - Field Correction or Removal (Recall)
  - Unforeseen failures at primary, secondary or tertiary suppliers



# Reducing Business Risk

- Use Complaints as Early Alert to Source of Business Interruption
  - Process Out of Control
  - Supplier Component or Subassembly Failing to Meet Specifications
  - Contract Manufactured Device or Service Not Meeting Specifications
  - Failure Mode Poses Risk to Health
  - Unanticipated service issues: parts, cost, required skills

# Reducing Business Risk

- Predictive Tools
  - Use DFMEA, FMECA, PFMEA to Supplier Level to Predict Critical Outputs
  - Establish Appropriate Risk Mitigation Steps
    - » Verification & Validation
    - » Process Controls
    - » Testing as appropriate

# Reducing Business Risk

- Predictive Tools (continued)
  - Establish Sensitive Triggers to Alert at Low Cumulative Number of Complaints
  - Predict Critical Failure Interruptions Such As:
    - » Field Corrections and Removals
    - » Line Stoppages
    - » Customer Conversion to Competitive Product

# Reducing Product Liability Risk

- Establish, Maintain and Follow Effective Procedures to Demonstrate Due Diligence in Investigating Complaints
  - Complaint Handling
  - Adverse Event Investigation and Reporting
  - Failure Investigation
  - Root Cause Analysis
  - Corrective and Preventive Action
- React Quickly and Consistently to Adverse Event Reports
  - Use Standardized AE Investigation Questionnaires
  - Fully and Clearly Document Association Between the Event and the Device
  - Be Cautious Regarding Attributing AE to User Error (Was it Actually Design? Labeling? Training? Malfunction? Manufacture?)

# Reducing Product Liability Risk

- Comply with Mandatory Reporting Requirements Promptly, Consistently and Accurately
  - Review Reporting Criteria with Clinical Experts
  - Ensure That a Complaint File is Opened
- Demonstrate Willingness to Take Necessary Corrective Actions to Improve Products and Their Labeling
  - Actions Meet the Test: “Is the Company Doing Everything Reasonable to Warn and to Protect?”
  - Corrective Actions are Taken Quickly and Audited for Effectiveness
- Address Servicing Issues Responsibly
  - Assure that service operations are reliable and accessible
  - Respond to trends effectively
    - » Analyze increase in repair frequency
    - » Identify troublesome components

# Reducing Compliance Risk

## Understand the Regulation!

- Read 21 CFR 820.198 – line by line with a cross-functional team
- Read the preamble!
- Verify that every requirement is supported by an established procedure

*The word “complaint” appears **82** times in the Quality System Preamble and Regulation*

## 820.3(b) – Complaint Definition

***“Complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.”***

*[Compare ISO 13485:2003: §3.4: Customer Complaint: “...written, electronic or oral communication that alleges deficiencies related to identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market...”]*

# Regulatory Requirements

## 21 CFR 820.198(a)

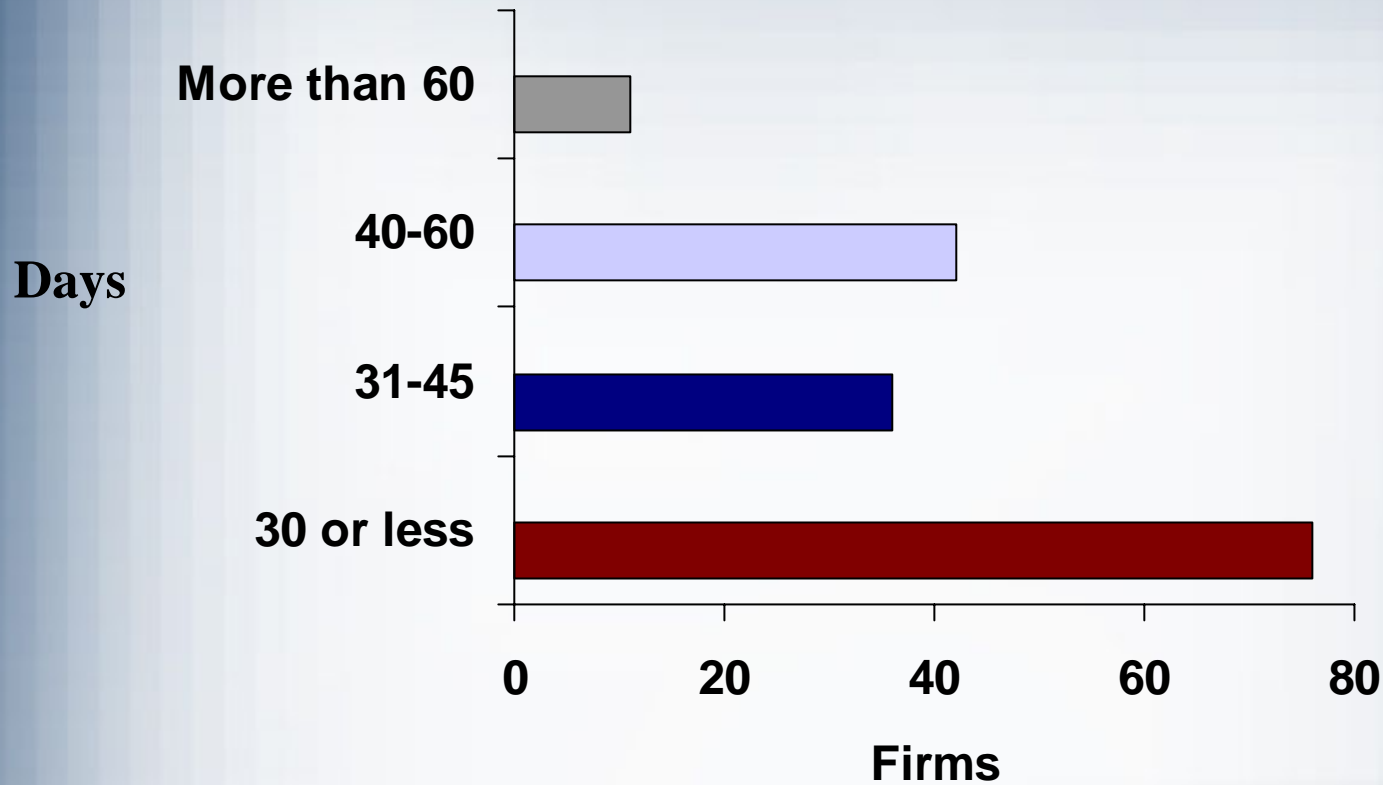
- Maintain complaint files
- Establish and maintain procedures
- Establish a formally designated unit

Complaint handling procedures shall ensure that:

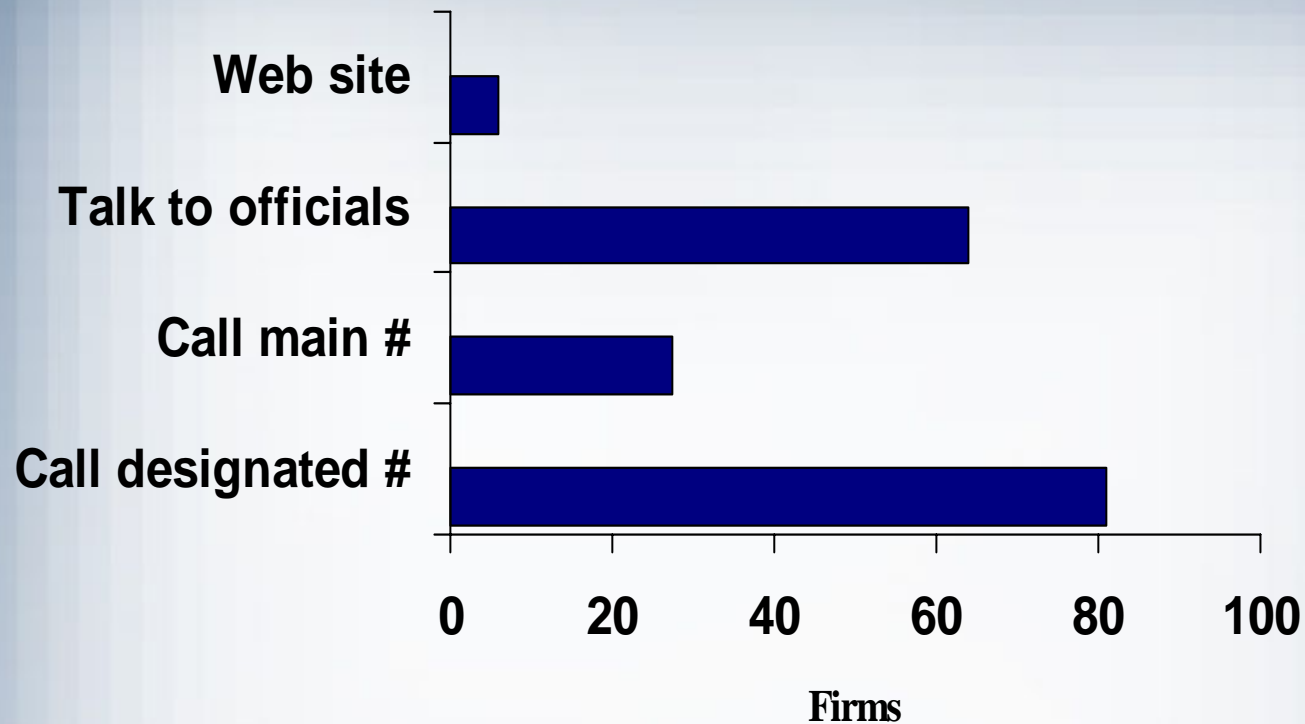
- Process complaints in a uniform and timely manner;
- Document oral complaints upon receipt;
- Evaluate complaints for MDR reportability.



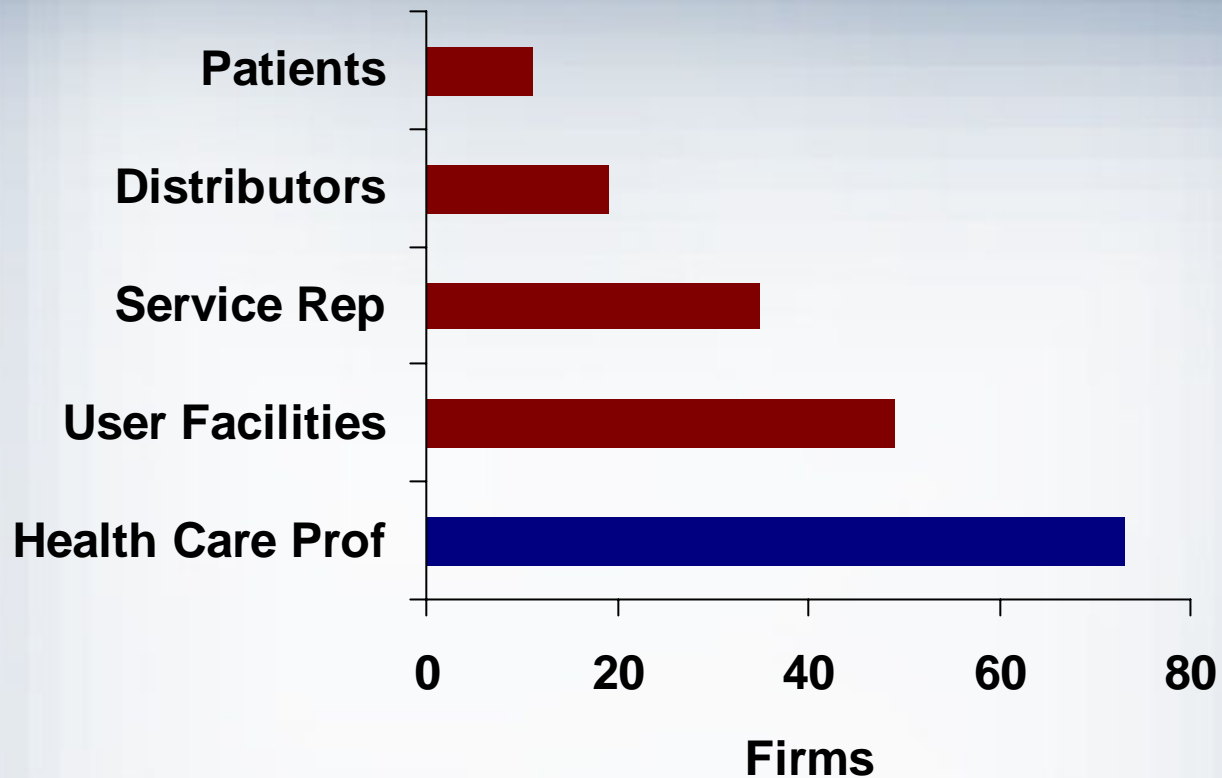
# What is our goal to close complaints?



# How do we receive complaints?

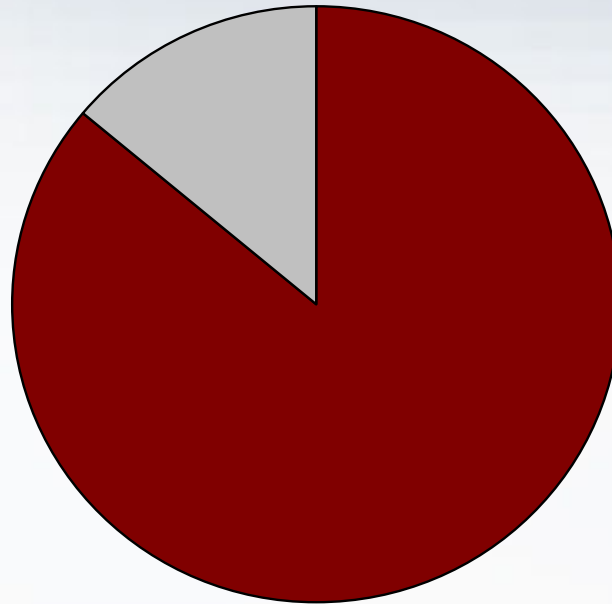


# Who's giving us this important feedback on our products?



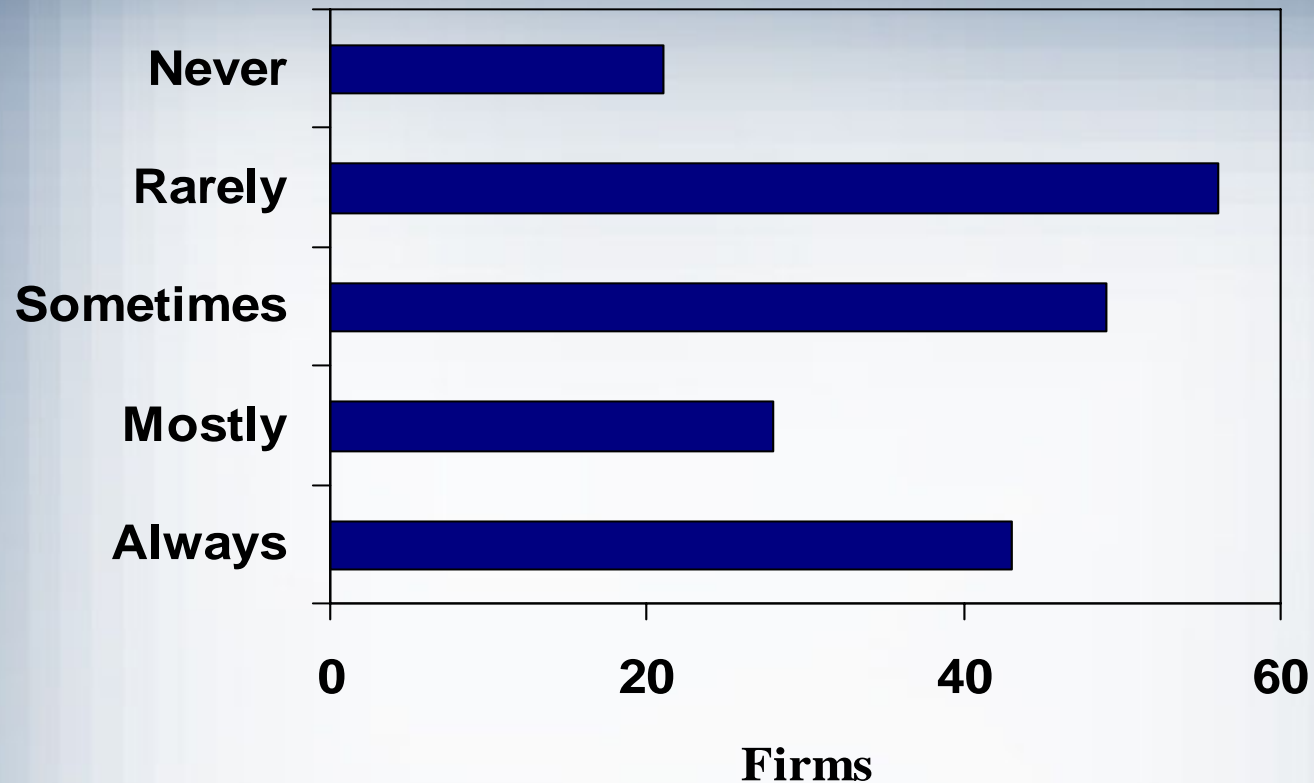
# How often do we acknowledge complaints?

**No = 14%**



**Yes = 86%**

# How often do we tell complainants what we're doing?



# Boston Scientific

## January 2006

- Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit to ensure complaints are processed in a uniform and timely manner.
  - Your SOP indicates that a complaint should be documented within **[redacted]** hours or less of "becoming aware" of the complaint.
  - Specifically, we observed time differences that ranged from 4 weeks to 11 1/2 months after you first became aware of the complaint.

# Haemacure Corporation

## January 2005

- Your firm failed to establish and implement complaint handling procedures as required by 21 CFR 820.198(a). Your Complaint Report form fails to include the need for review and/or investigation, who would conduct the investigation, their conclusions and any response back to the complainant.

# 21 CFR 820.198 – Regulatory Requirements (continued)

(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.

[Compare ISO 13485:2003, §8.5 – Improvement: “If any customer complaint is not followed by corrective and/or preventive action, the reason shall be authorized (see 5.5.1) and recorded (see 4.2.4)”.]



# 21 CFR 820.198 – Regulatory Requirements (continued)

(c) Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.

# Complaint Handling Upon Receipt

- **Review** to determine if report meets the definition of a complaint
- **Document** product identity: product code, lot/serial number
- **Assign** an “alleged failure mode” code for tracking
- **Evaluate** to determine if complaint is potentially reportable
- **Evaluate** to determine if an **investigation** is required
- **Establish** priority for **investigation** (adverse event, failure to meet specs, severe business risk = HIGH)
- **Determine** if there is a CAPA related to the complaint (open?, closed?)

# Complaint Investigation

***Extent of the investigation is a function of risk potential***

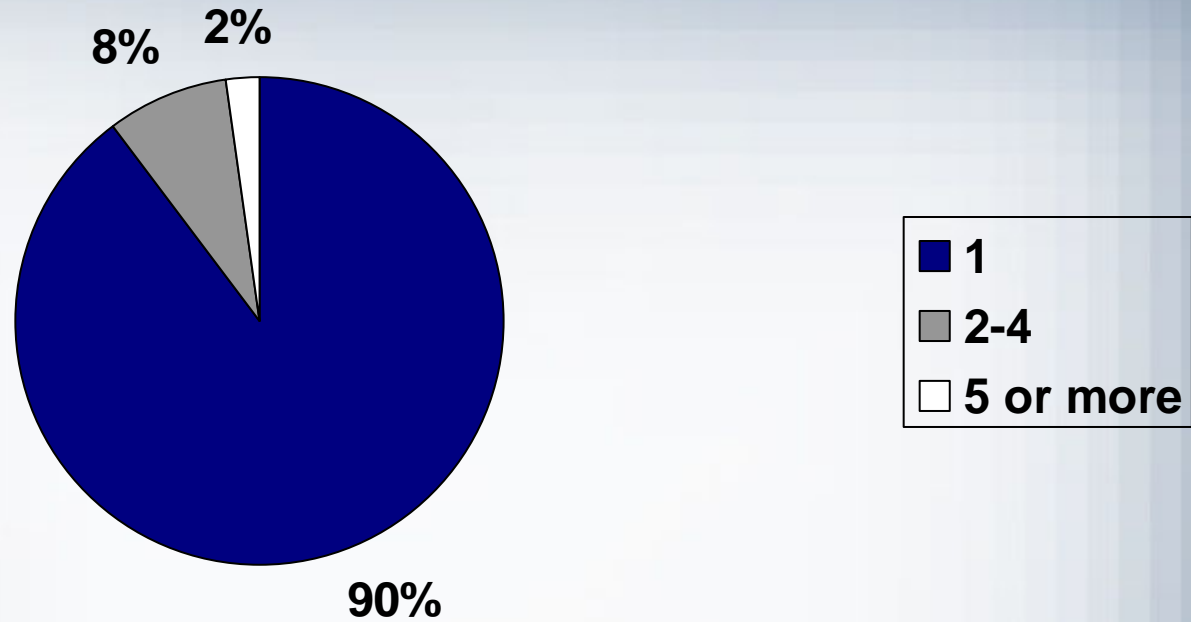
- Device History Record review
- Risk Analysis to determine severity/risk of failure
- Age, intended life or expiration date of product
- Service and repair history
- Review of recent upgrades or field corrections
- Review of recent design and process changes
- Review of labeling including warnings, precautions
- Review of previous corrective actions
- Review and timing of previous corrective actions

# 21 CFR 820.198 – Regulatory Requirements (continued)

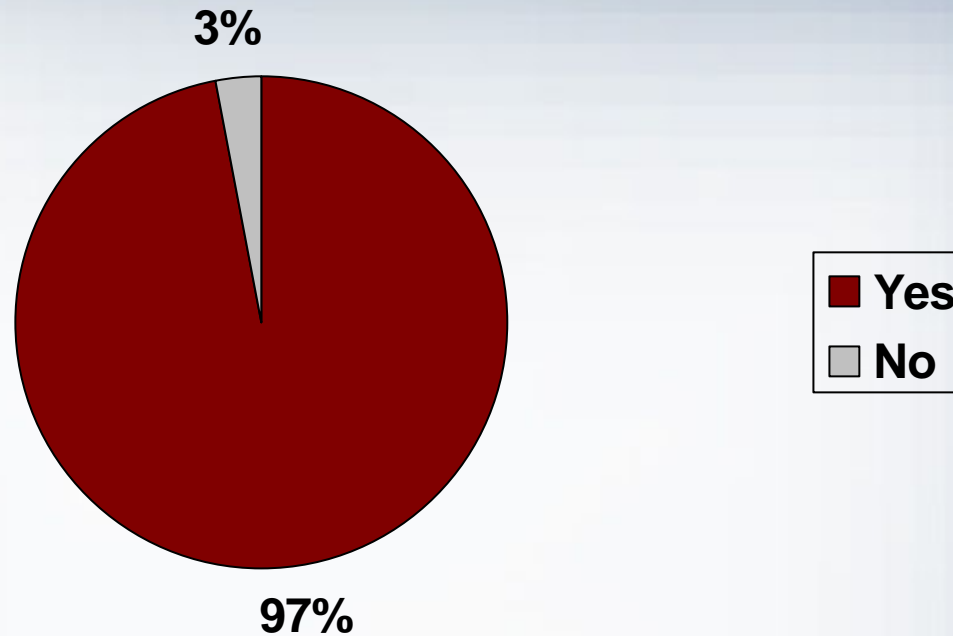
(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly **reviewed, evaluated, and investigated** by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. In addition to the information required by §820.198(e), records of investigation under this paragraph shall include a determination of:

- 1) Whether the device failed to meet specifications;
- 2) Whether the device was being used for treatment or diagnosis; and
- 3) The relationship, if any, of the device to the reported incident or adverse event.

# If patient safety could be affected, how many complaints for the same failure mode could trigger a failure investigation?



# Are service reports that represent an MDR processed under 820.198?



# Seecor, Inc.

## December 2005

- Your firm received two oral user reports that alleged the possible failure of two AC fibrillators occurring during surgery. You explained to the FDA investigators that the devices "burned up" due to user error. However, your firm failed to:
  - (a) conduct and document a formal complaint investigation;
  - (b) document the nature and details of the incidents;
  - (c) document your follow-up with the users;
  - (d) document your justification for why you did not consider the oral user reports as complaints; and
  - (e) document your determination of whether any adverse medical event had occurred during surgery.

# LifeScan

## December 2005

- Failure to review, evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications.
  - Patient's nurse contacted your company to report the OneTouch Ultra was reading high and patient was taken to the Emergency Room. This complaint was closed without performing an investigation.
  - Patient's daughter contacted your company to report the OneTouch Ultra was set in the wrong units of measurement. Complaint was closed without performing an investigation.



# Tyco Healthcare Group

## September 2005

- Failure to establish, maintain, and implement procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a).
- For example, the following service reports received by the firm and classified as complaints were not evaluated to determine if the complaints represented events which were required to be reported to FDA as MDRs:

# Survey Question: Why Are Some Complaints Not Investigated?

- 40% “Failure investigation is already open”
- 53% “Adequate investigation performed”
- 52% “CAPA already initiated for same failure mode”
- 23% “Device was not properly used”
- 34% “Complaint doesn’t involve a possibility that the device did not meet specs.”

# Complaint Investigation

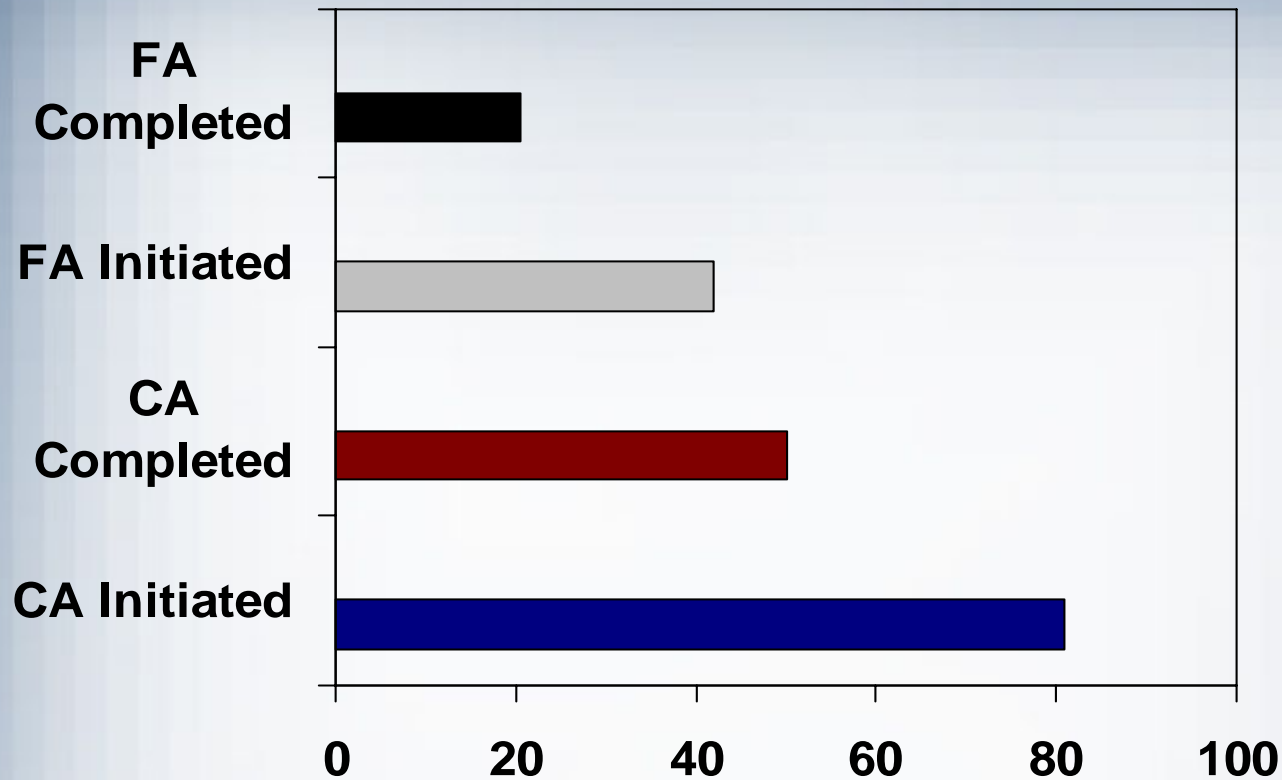
## ***When Complaint Investigation is NOT Required:***

- Documented evidence of a previous investigation(s) for similar complaints with established CAPA
- Product was not manufactured or distributed by firm
- Issue is related to billing, shipping, routine servicing or delivery, or product enhancement suggestions
  - These inputs are forwarded to appropriate department (CAPA)
- Reported information does not meet the definition of a complaint

# Rationale for Closing a Complaint Without a Corrective Action

- High correlation with complaints that have an established corrective action
  - Is CAPA still open?
  - Was complaint unit manufactured *before* or *after* CAPA implementation?
- If product was manufactured *after* implementation of CAPA, QE must evaluate
- Confirm alleged failure mode is consistent with subject CAPA

# When do we consider complaints to be closed?



# Ways That Firms Get Devices Back!

- Be responsive: have a courier or salesperson pick up the product
- Provide free shipping and product replacement or credit
- Educate the customer on company's corrective and preventive actions
- Continue to follow up with the customer until firm gets the product back
- Customized shipping containers to provide prompt, damage-proof return of components from service centers

# ConMed

## June 2005

- Failure to analyze complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. 21 CFR 820.100(a)(1). Your firm fails to conduct an appropriate analysis of complaints and reports of nonconforming product in that:
  - A. You fail to examine complaints by failure mode, and multiple failures reported for devices from a single lot are not individually analyzed.

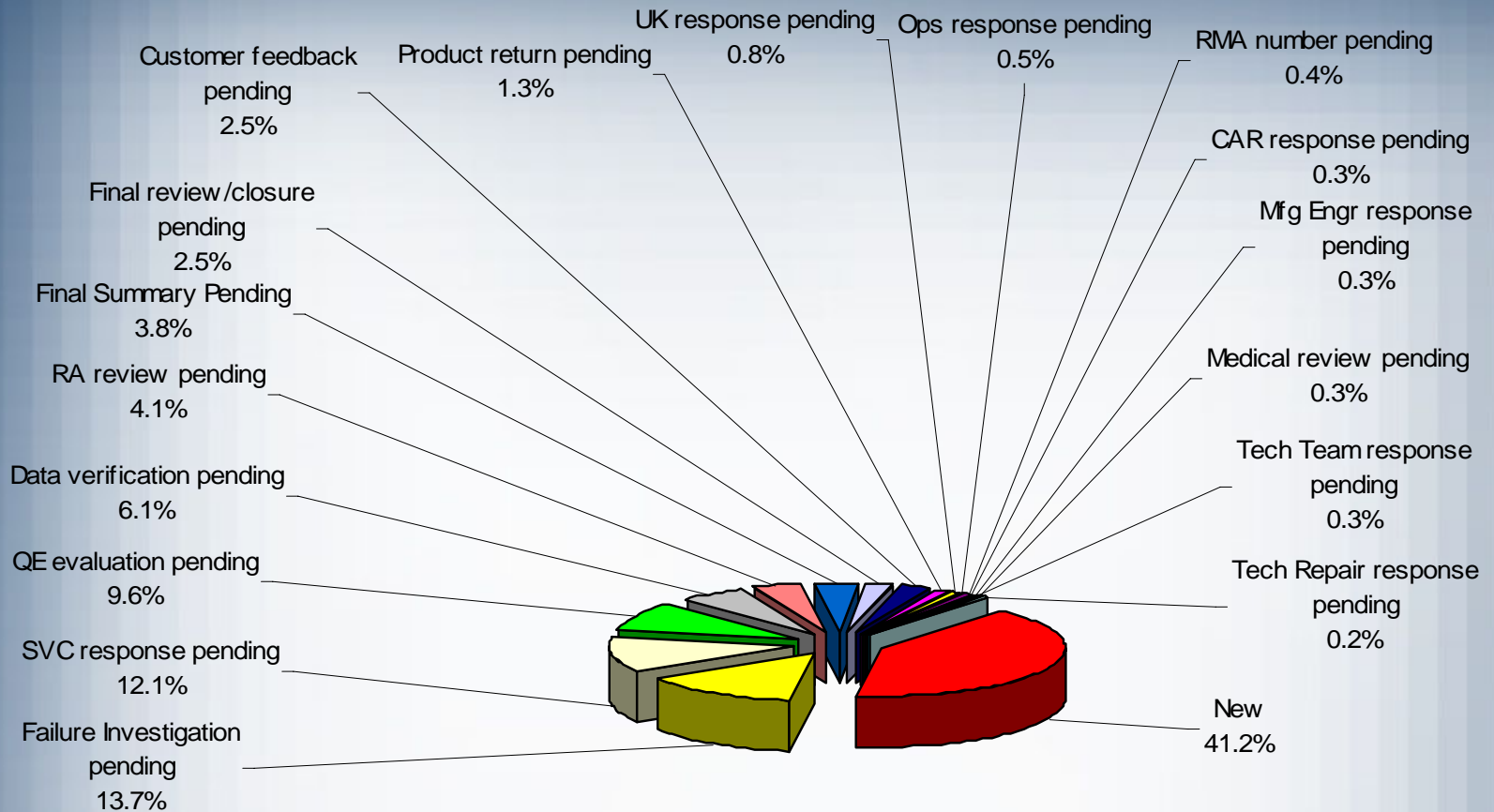
# Complaint File Review

## ***Final Quality Assurance Review of the File***

- Confirm required information is included
- MDR/Vigilance report and investigation, if applicable
- Failure codes assigned for use in trending
- Risk analysis reviewed to determine if failure mode is occurring with greater frequency or severity than anticipated
- Review DHR findings
- Confirm completion of failure investigation and summary
- Response generated for internal and/or external customers, if requested
- Rationale for complaints remaining open beyond closure goal will be revisited weekly until closed



# Status of Open Complaints



Complaint department's tool for identifying root cause of open complaints.

# Proactive Product and Safety Surveillance

- Don't Be Satisfied with Passive Customer Experience or Service Reporting
- Develop Tactics for Eliciting the Information Needed for Continuous Improvement (Model MedSun Program)
- Ensure that the Corporate Culture Recognizes and Values the Need to Report Safety, Compliance and Quality Issues:
  - Customer complaints
  - Adverse Events
  - Service trends and unanticipated events
- Provide Feedback to Internal and External Customers Regarding Action Taken on Their Issue

# Risk-Management Focus

- Leadership
- Training
- Standardized Complaint Reporting and Handling Processes
- Cross-Functional Complaint/CAPA Quality Improvement Teams
- Periodic reviews of system performance
- Clear published metrics to instill awareness
- An effective means for return of complaint-related devices

# Questions, Answers, Discussion