Making Complaint Management an Effective Business Driver

Presented by:

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Preliminary Findings
Complaint Handling Survey

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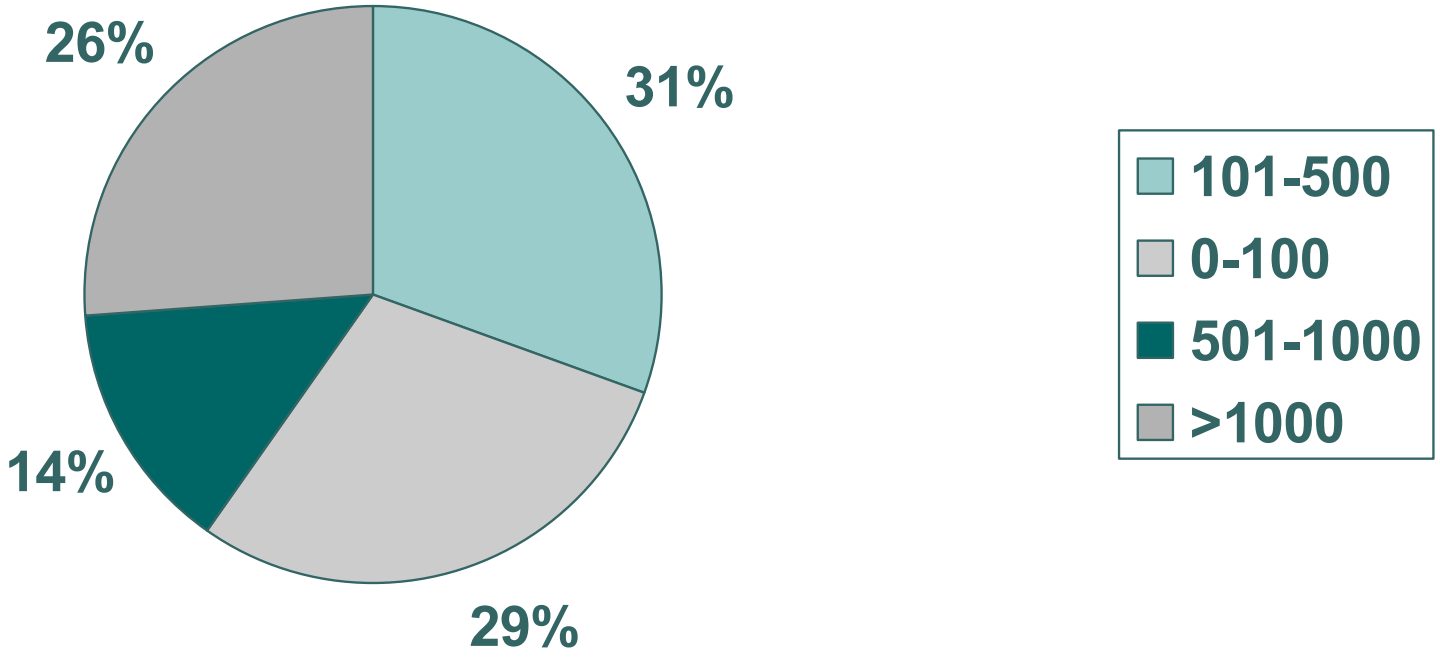
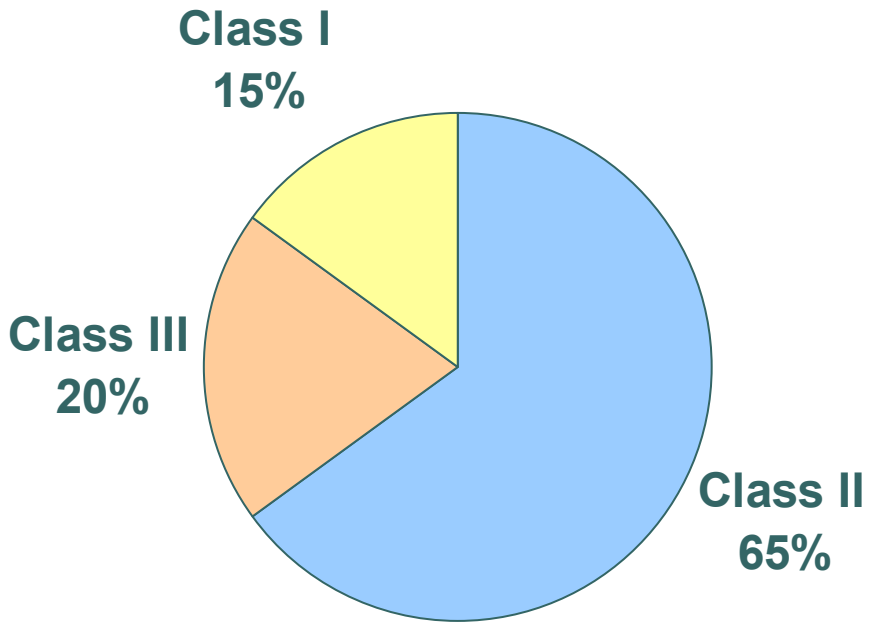
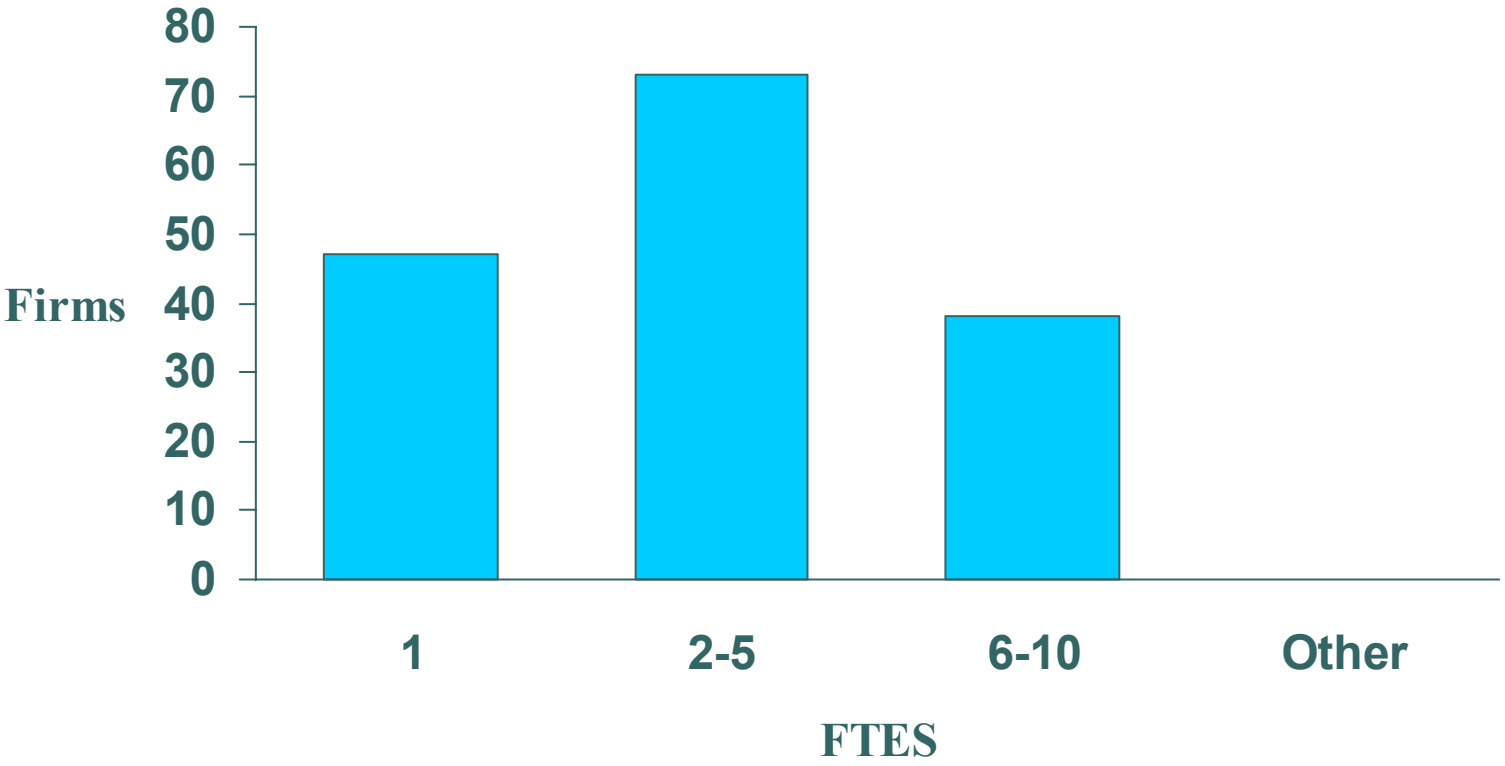
Number of Employees



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



Resources



Discussion Topics

- Benefits of an effective complaint management system
- Understanding FDA's regulations to establish a foundation of your SOPs
- The essential elements to include your SOPs for complaint investigations
- Using appropriate metrics to measure product performance and to manage complaint processing

Benefits of an Effective Complaint Management System

- Ensure that marketed devices have the highest possible levels of safety and effectiveness for both the patient and user;
- Facilitate identification and implementation of improvements in device design, reliability, manufacturing processes, and test methods;
- Create an environment where all company employees are aware of the performance of the company's medical devices and are prepared to respond quickly to trends and unanticipated events;

Benefits of an Effective Complaint Management System (continued)

- Establish a comprehensive system that effectively *and* efficiently meets regulatory requirements in all countries where the company's devices are sold;
- Minimize exposure to product liability lawsuits that could arise from system or product deficiencies; and,
- Reduce the Cost of Poor Quality arising from device rejects, customer returns (and replacements), failure investigations, and loss of goodwill.

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…"]

21 CFR 820.198 – Regulatory Requirements

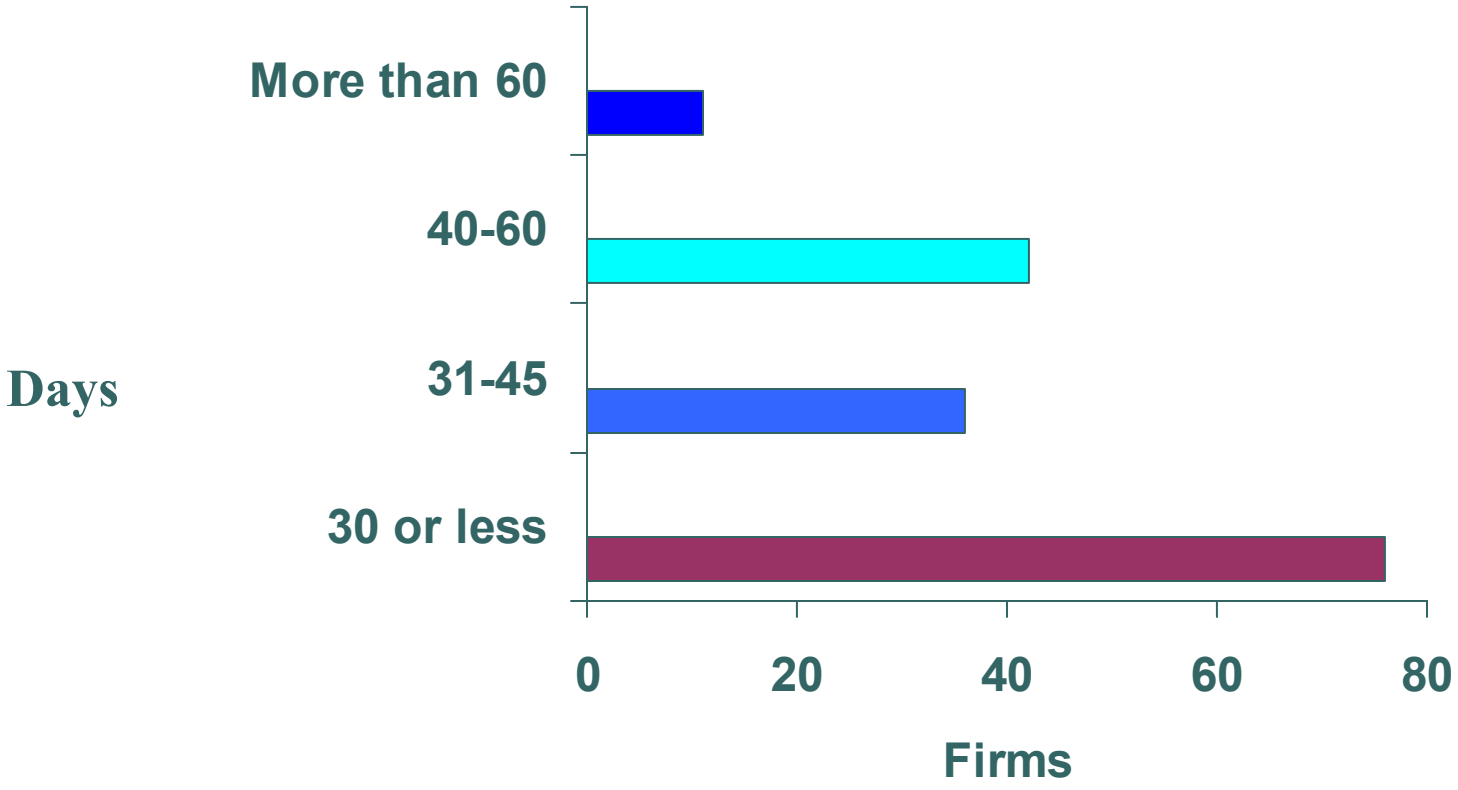
(a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit.

21 CFR 820.198 – Regulatory Requirements (continued)

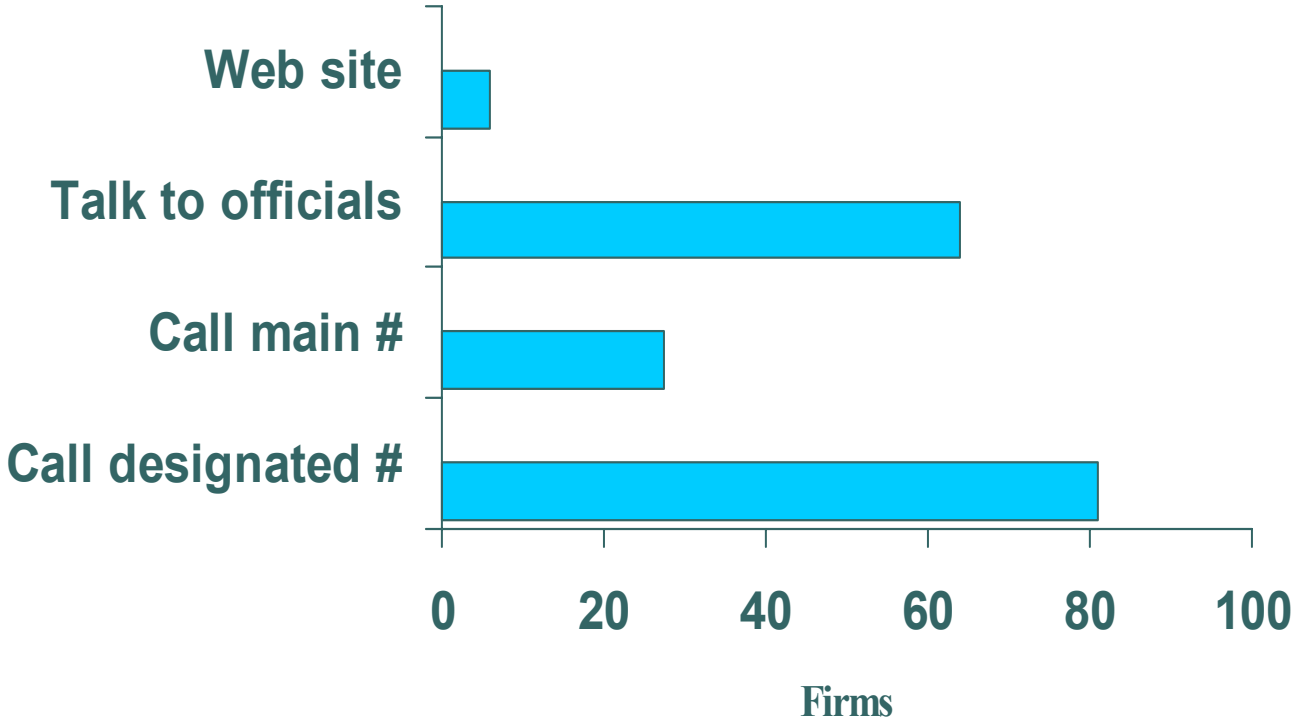
Such procedures shall ensure that:

- All complaints are processed in a uniform and timely manner;
- Oral complaints are documented upon receipt; and
- Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 or 804 of this chapter, Medical Device Reporting.

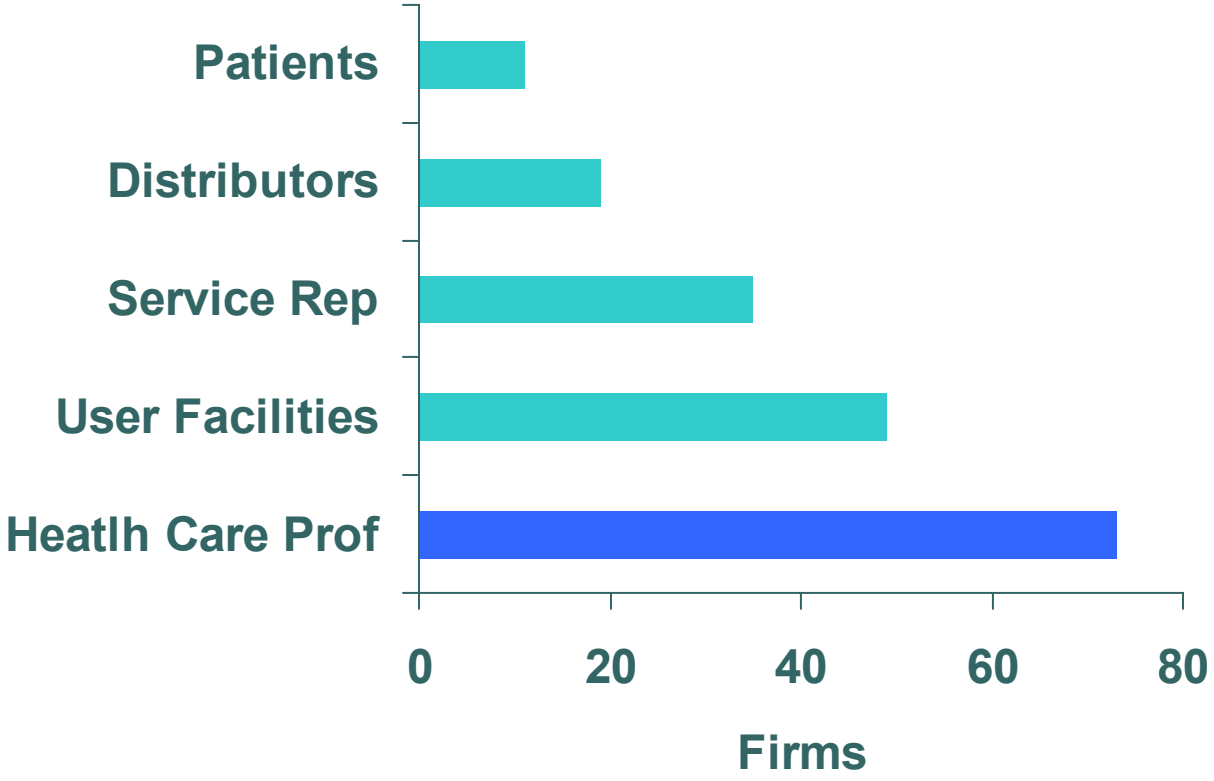
What is our goal to close complaints?



How do we receive complaints?



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

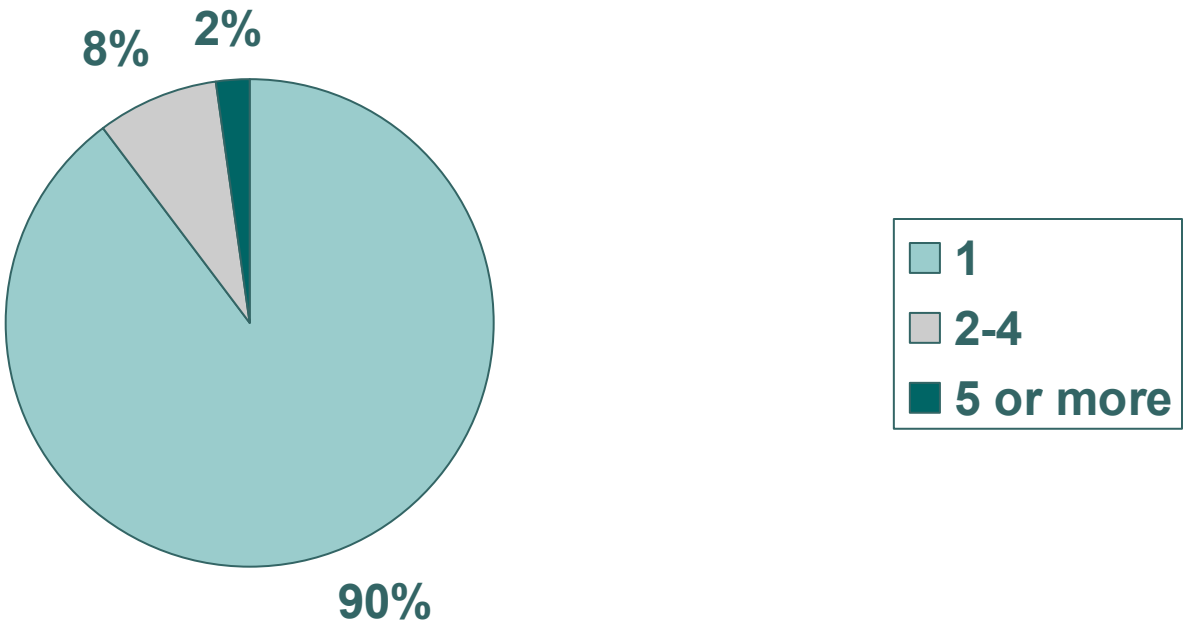


21 CFR 820.198 – Regulatory Requirements (continued)

(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)".]

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



21 CFR 820.198 – Regulatory Requirements

Processing Steps upon Receipt of Complaint

- ***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*** the 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?)

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.

21 CFR 820.198 – Regulatory Requirements (continued)

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)

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

21 CFR 820.198 – Regulatory Requirements (continued)

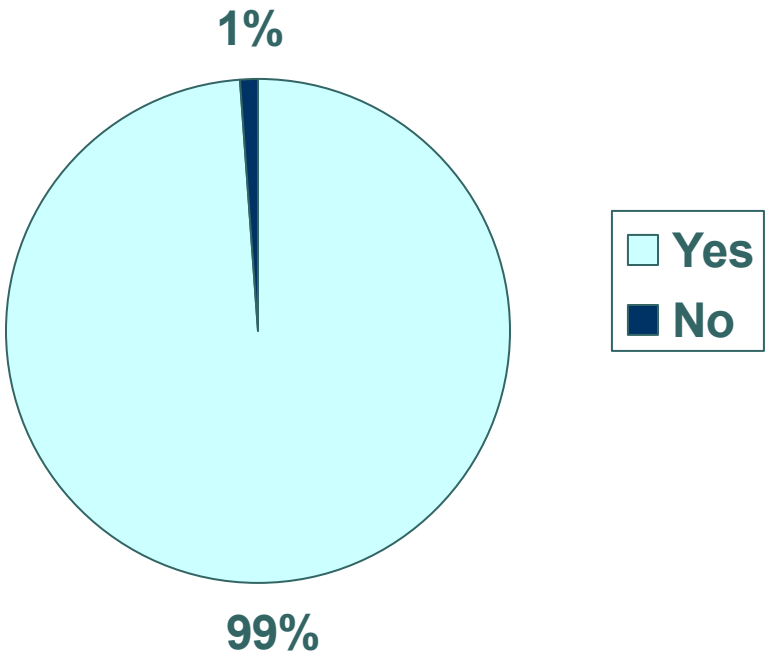
(d) Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly **reviewed**, **evaluated**, and **investigated** by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified. 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;

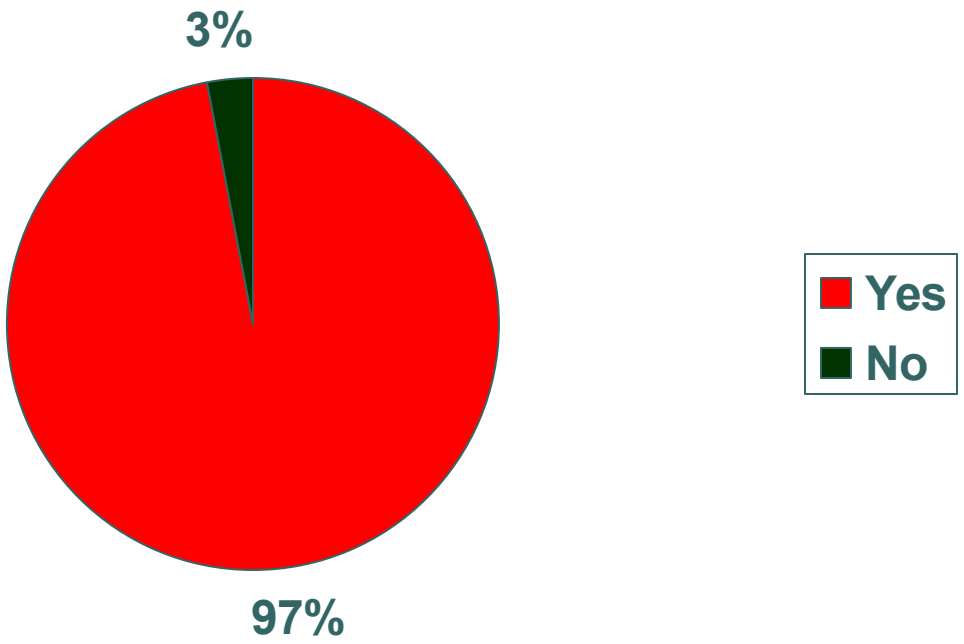
2) Whether the device was being used for treatment or diagnosis; and

3) The relationship, if any, of the device to the reported incident or adverse event.

Are we screening service calls to see if they're complaints?



Are service reports that represent an MDR processed under 820.198?



21 CFR 820.198 – Regulatory Requirements (continued)

(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:

1) The name of the device;

2) The date the complaint was received;

3) Any device identification(s) and control number(s) used;

4) The name, address, and phone number of the complainant;

21 CFR 820.198 – Regulatory Requirements (continued)

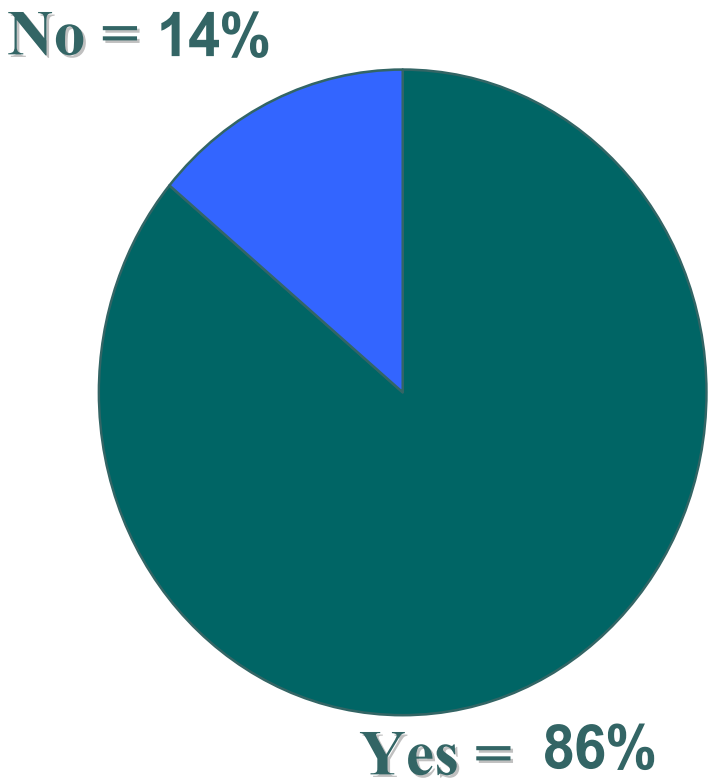
5) The nature and details of the complaint;

6) The dates and results of the investigation;

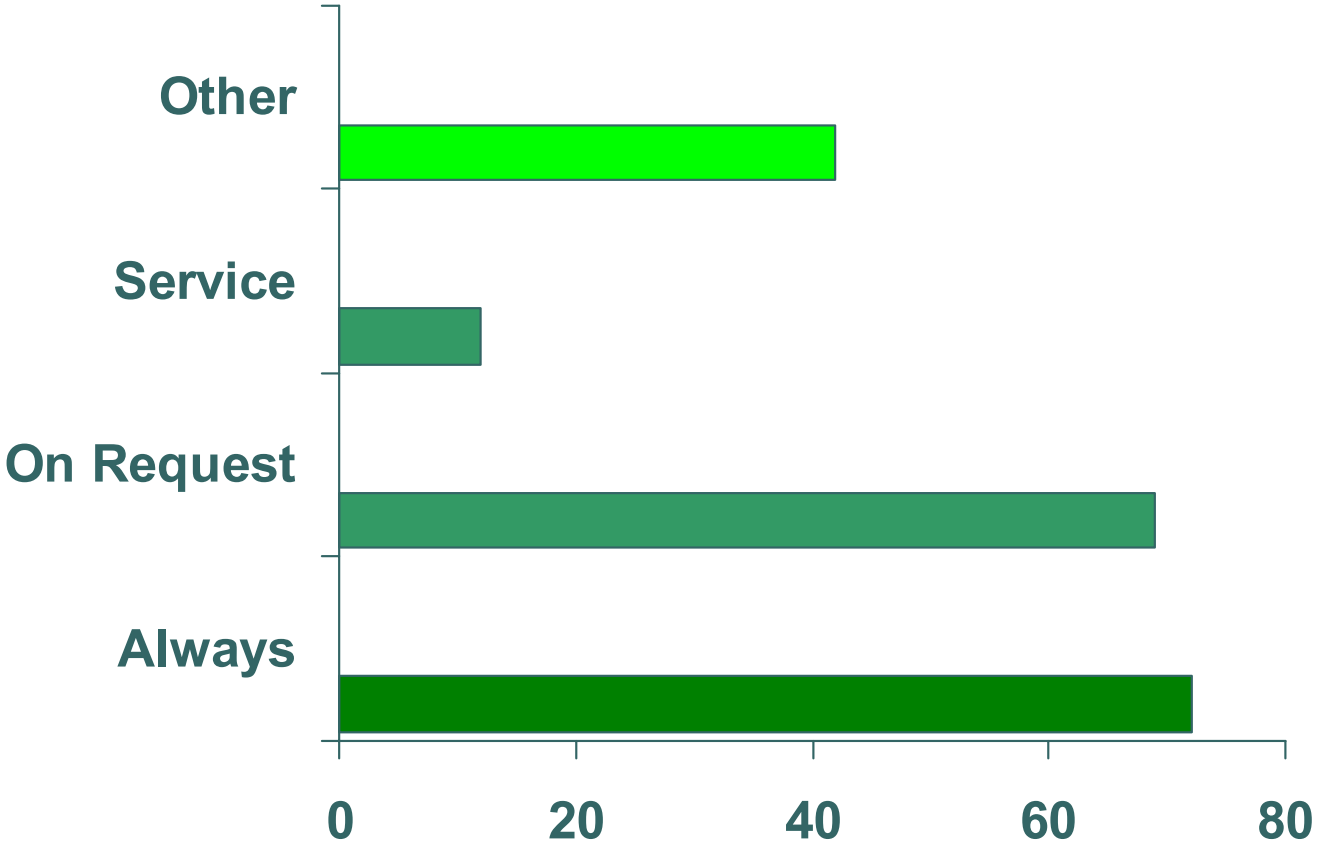
7) Any corrective action taken; and

8) Any reply to the complainant.

How often do we acknowledge complaints?



When do we RSVP?



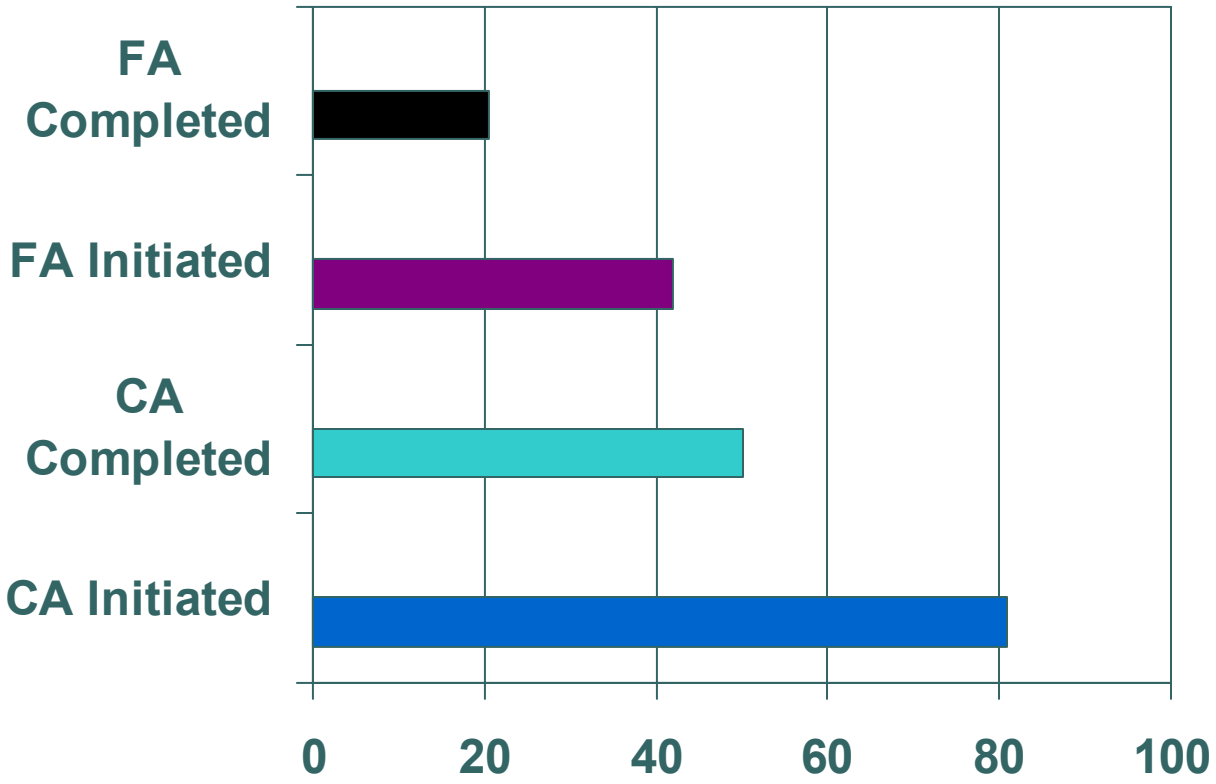
How often do we tell complainants what we're doing?

21 CFR 820.198 – Regulatory Requirements (continued)

Rationale for Closing a Complaint Without CAPA

- High correlation with complaints that have prompted opening of a 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?



Why don’t we investigate some complaints?

- 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 didn’t meet specs.”

21 CFR 820.198 – Regulatory Requirements (continued)

Final Quality Assurance Review of the file

- Confirm that all required data are present
- Data re: MDR/Vigilance report and investigation, where 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 customer (int./ext.) if requested
- Rationale for complaints remaining open beyond closure goal will be revisited weekly until closed

21 CFR 820.198 – Regulatory Requirements (continued)

(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.

21 CFR 820.198 – Regulatory Requirements (continued)

(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:

1) A location in the United States where the manufacturer's records are regularly kept; or

2) The location of the initial distributor.

Pertinent Preamble Pointers

#14 - Service reports representing reportable adverse events are complaints

- FDA clarified definition of complaints to exclude input unrelated to quality, safety and effectiveness

- Service requests and internal expressions of dissatisfaction are addressed under CAPA, §820.100

("Information generated in-house relating to quality problems should be documented and processed as part of this corrective and preventive action program.")

#161 - CAPA is broader than complaints: includes product issues before and after distribution as well as process and quality system nonconformities

#190 - Distinction between complaint evaluations and investigations: these are not the same

- FDA definition of a good-faith follow-up for complaint information

Tips and Tricks
Keys to Efficiency and Effectiveness

1. Strong leadership throughout the organization
2. A recognized, clearly designated Complaint Unit.
3. Clear written policies, procedures and forms
4. Standardized, validated complaint input forms
5. An effective, timely and reproducible process for investigating reported adverse events

Tips and Tricks
Keys to Efficiency and Effectiveness (continued)

6. A clear complaint-handling lexicon: product names and regulatory terminology
7. Effective, documented training of all employees
8. Cross-functional complaint focus groups.
9. A process for batching similar complaints where appropriate, for evaluation, investigation and closure.

Tips and Tricks
Keys to Efficiency and Effectiveness (continued)

10. Periodic reports on product and system performance to instill awareness.
    - Product performance
    - Complaint handling performance
11. Continuous monitoring of open complaints and trends
12. Clear designation of support groups' roles and responsibilities for complaint and failure investigations
13. Monthly reviews of products and system performance
14. A logical, understandable method of counting complaints

Tips and Tricks
Keys to Efficiency and Effectiveness (continued)

15. A system for prompt analysis of returned devices
16. Customer follow-up as a team effort
17. Standards for complaint processing productivity
18. Objective evidence of value to the business

Ways That Firms Get Devices Back!

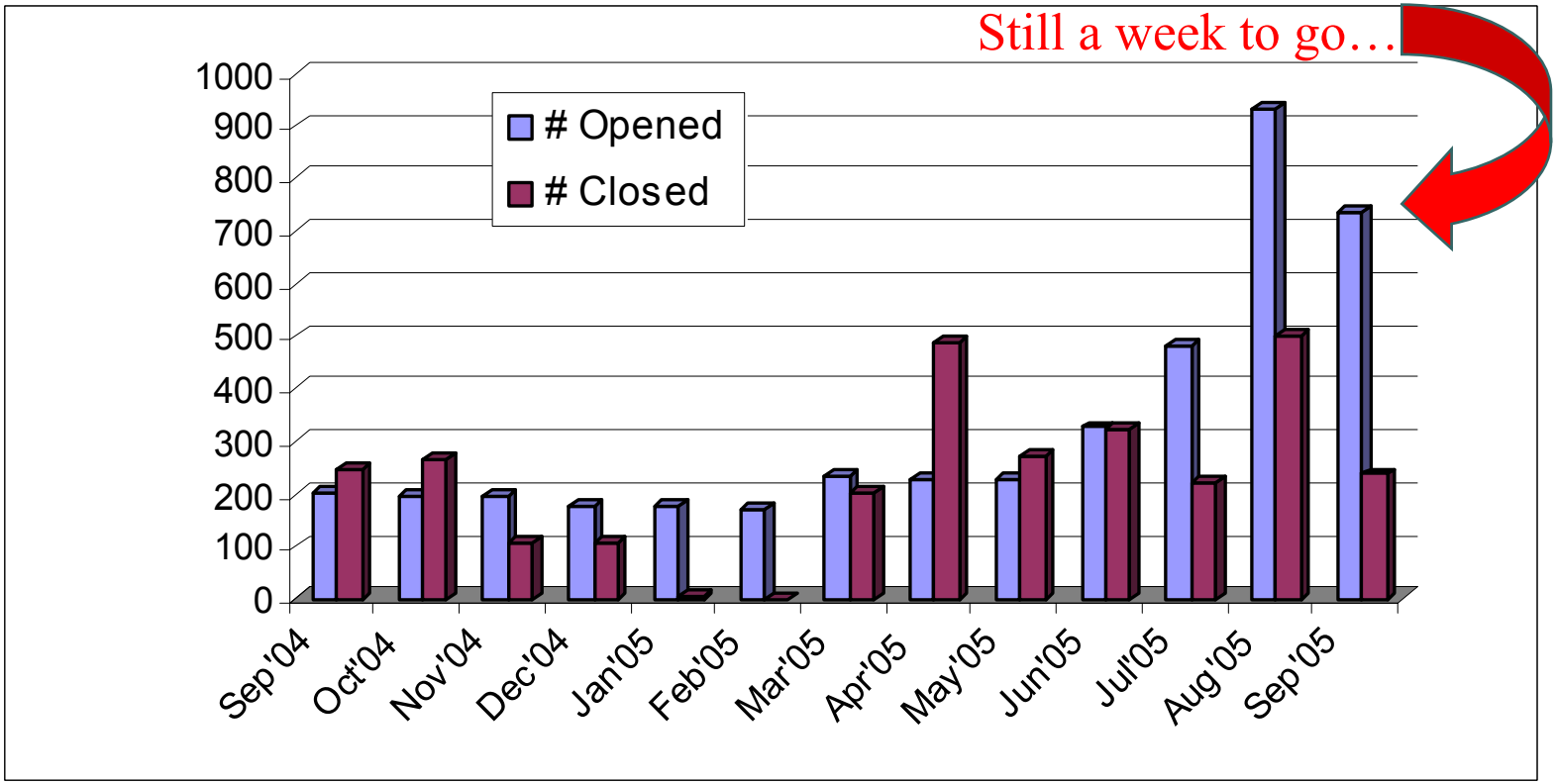
- Be responsive: have a courier or salesperson pick up the product
- Provide free shipping and product replacement or credit
- Educate the customer on company's corrective and preventive actions
- Continue to follow-up with the customer until firm gets the product back

Suggestions for Improving Complaint Reporting by In-House Personnel

- Obtain commitment from top management
- Have a simple reporting form
- Train
  - How to use the form
  - Benefits of finding out information from the user
  - Demonstrate that action is taken on the information provided
- Provide positive and negative reinforcement

Metrics: Complaint Process Management and Product Performance

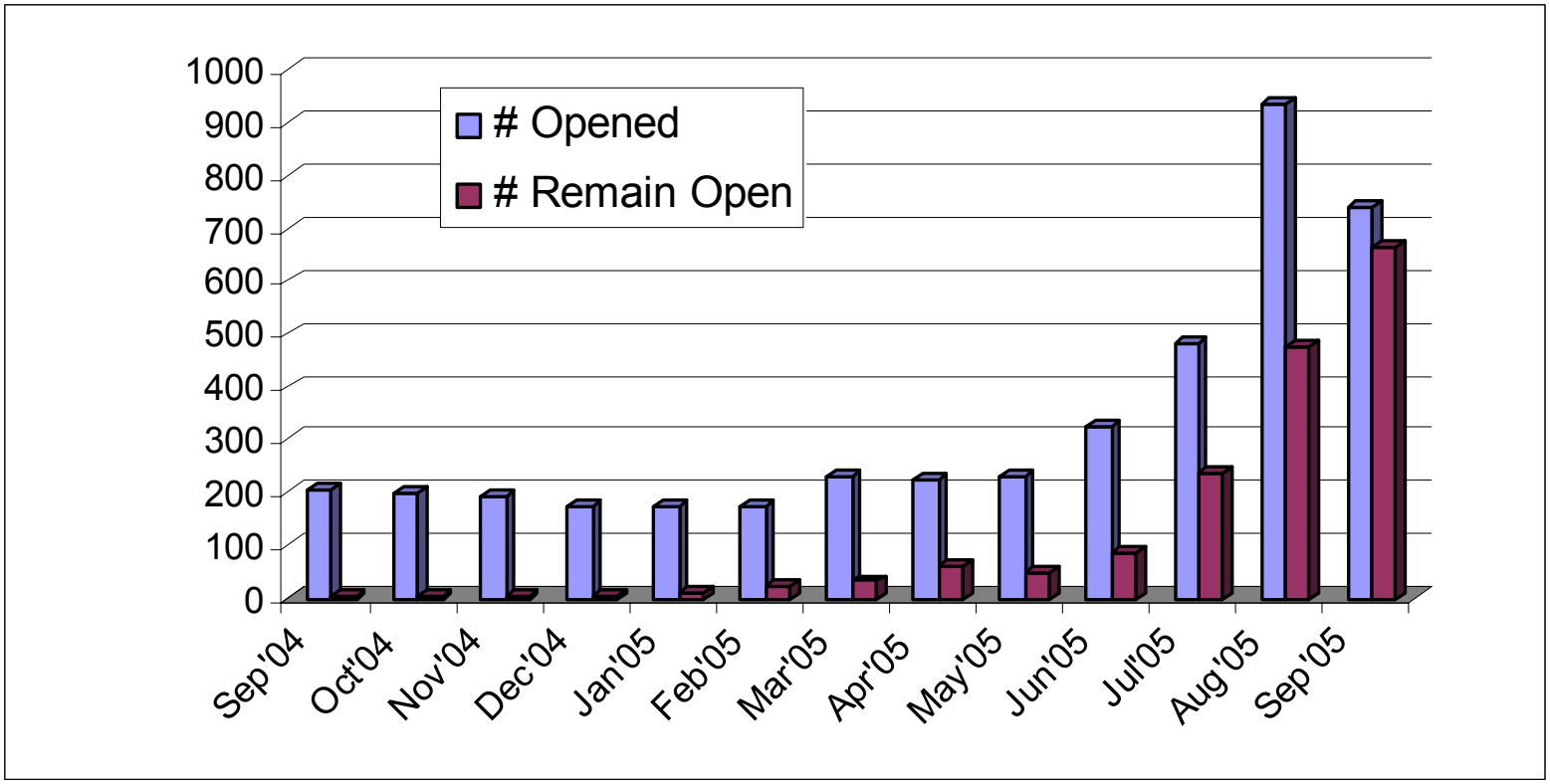
Complaints Open/Closed



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.

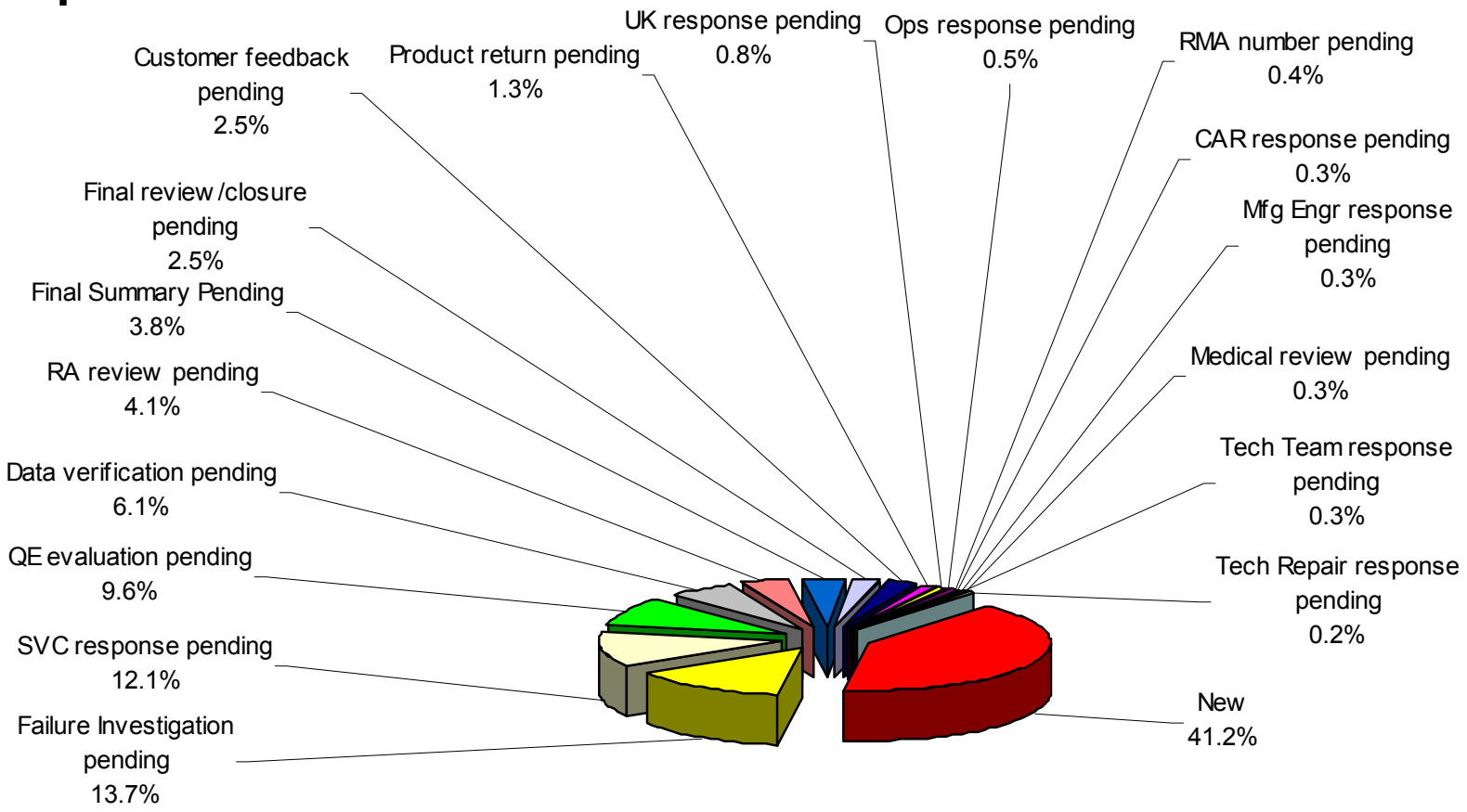
Open Complaints by Month



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.

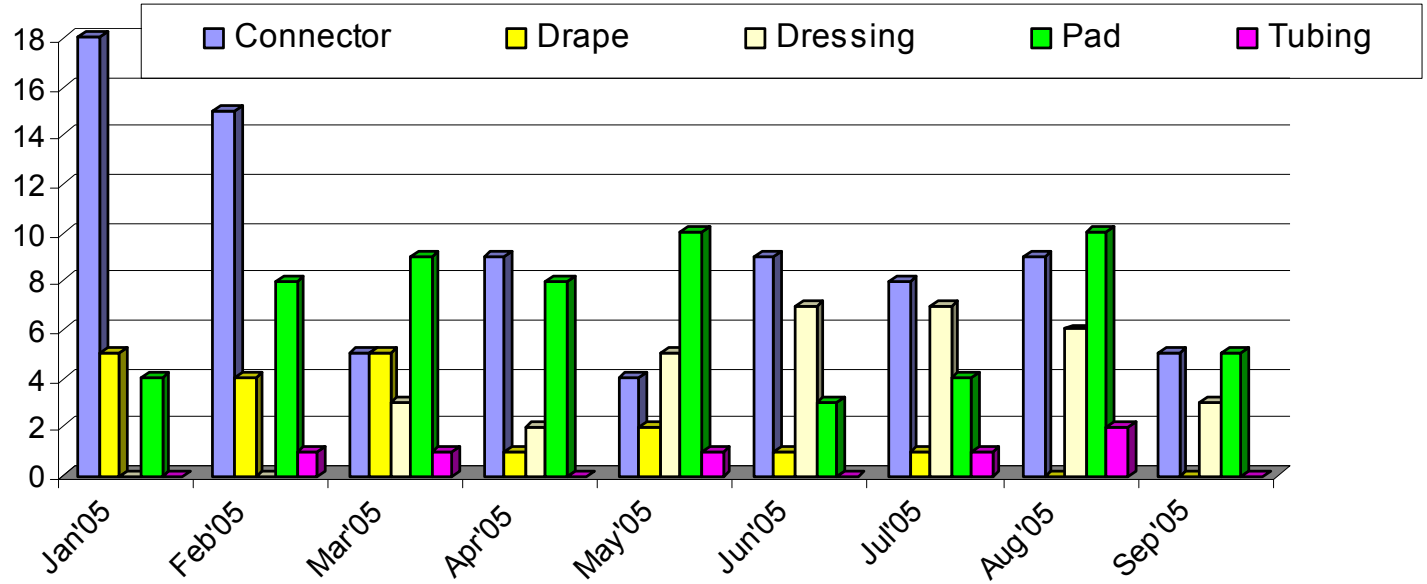
Status of Open Complaints

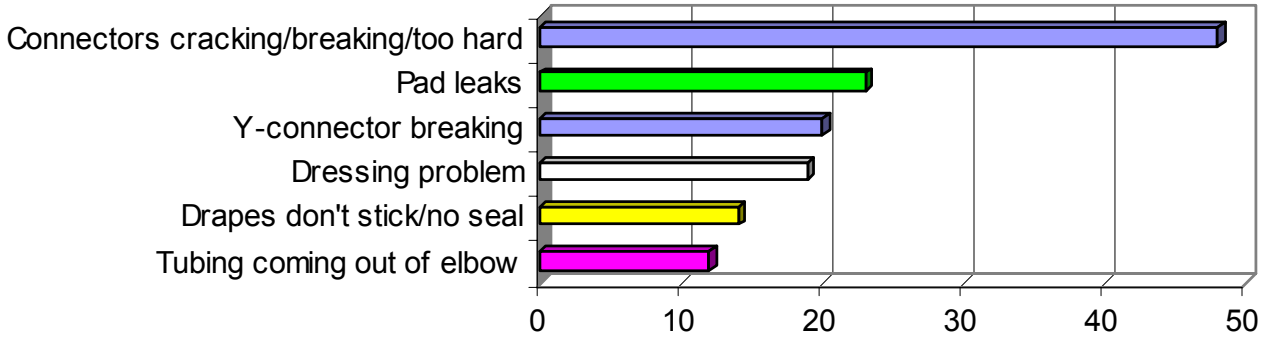


Complaint department's tool for identifying root cause of open complaints.

Disposables – Dressings

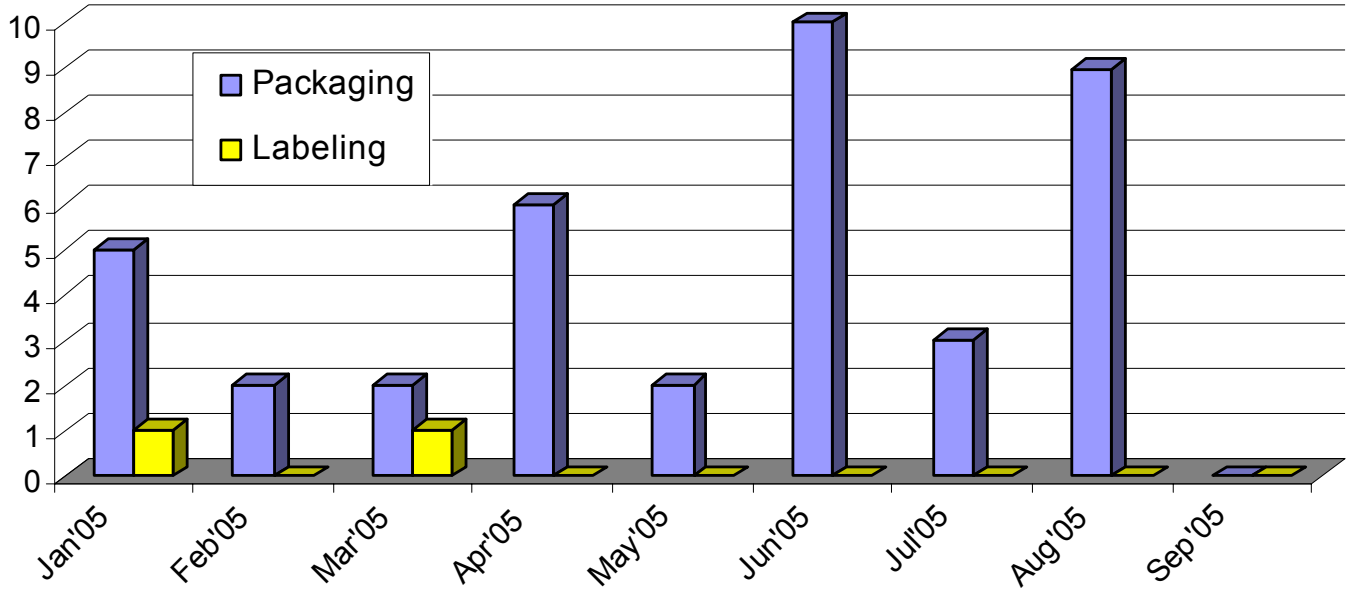
(Sample Presentation of Metrics)

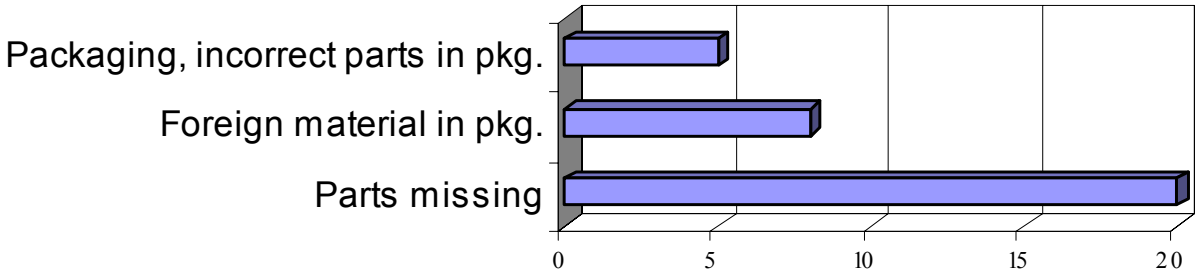




Disposables – Packaging

(Sample Presentation of Metrics)





Questions, Answers, Discussion