

## Summary of Complaint Handling Survey

In February of 2006, Compliance-Alliance sent out a survey on how medical device firms are setting up their complaint handling procedures. This is what we found.

### Demographic Information

- 232 industry representatives completed the survey
- 37 firms manufacture Class I devices
- 145 firms manufacture Class II devices
- 50 firms manufacture Class III devices

### Number of FTEs Processing Complaints

The number of FTEs processing complaints was related to the size of the firm

- 0 - 100 employees: 1 FTE processes complaints
- 101 - 10,000 employees; 2 - 5 FTEs process complaints
- 10,001 - 50,000 employees: 6 - 10 FTEs process complaints

### Interesting Insights

- 85% of firms screen service calls to see if they meet the definition of a complaint.
- 62% routinely send an acknowledgement to the complainant.
- 34% always send a letter to the complainant following closure of a complaint.

### Commercial Software Applications

23% reported using a commercial software application to process complaints.

### Firms generally like the following features in their software applications

- Easy to use
- Effective in capturing consumer and product information, automatic response generation, tracking, and reporting
- Global system: all of the divisions can use the same system
- Powerful search capabilities; easy to sort types of complaints
- MDR and Vigilance Reporting forms are built into the database

### Firms generally dislike the following features in their software applications (i.e., questions that firms should ask when evaluating a web-based system):

- Long configuration time
- Training employees is a challenge
- Difficulty in generating reports
- Annual cost of updates and maintenance
- Difficult to modify the program to meet firm's needs

### Firms used these tactics to motivate customers to report complaints:

- Make communication easy (toll free #, web site, receptive sales reps.)
- Let customers know you are trying to solve the problem
- Provide technical assistance to facilitate proper device use
- Go beyond the reported complaint to ensure total customer satisfaction
- Make it easy for the customer to obtain a free replacement for a defective device

### Firms used these tactics to motivate in-house personnel to report complaints:

- Have management reinforce the business value of effective complaint handling
- Design a simple reporting form and provide training on its use
- Publicize actions taken in response to issues raised by complaints
- Recognize those who report, analyze and take action on complaints

**Many firms (65%) had difficulty getting devices back from their customers.**

**Tactics used to motivate people to return the device:**

- Be responsive: Have a courier or a salesperson personally pick up the product
- Provide free shipping and product replacement or credit
- Continue to follow up with the customer until the firm gets the product back
- Tell customers about how their feedback improves product quality
- Provide information on corrective and preventive actions

**Reasons for not investing complaints:**

- Complaint is for a product not manufactured by the firm (55%)
- The compliant failure mode has already been investigated (55%)
- Corrective action is already open for the same failure mode (52%)
- A failure investigation is already open for the same complaint (39%)
- Complaint is not a failure of the device, labeling/packaging to meet specs (35%)
- Firm is unable to obtain the device for analysis (21%)
- (The preamble to the QS Regulation contains information regarding making a "good faith" effort to recover devices. An investigation can include, for example, testing similar devices (e.g., same lot), reviewing DHRs and complaint historical data.)

**Criteria used to determine when a complaint is officially closed:**

- A corrective action has been initiated or no action is required (42%)
- A corrective action is reported (23%)
- A failure investigation has been completed (20%)
- A corrective action has been completed (1%)
- Other (14%)

**Goal for Closing Complaints**

Firms reported the following time frames as a goal for closing complaints:

- Less than 30 calendar days (37%)
- 31 - 45 calendar days (18%)
- 40 - 60 calendar days (23%)
- More than 60 calendar days (1%) (These are probably the firms who close complaints after the corrective action is implemented and closed.)
- 16% Other