

## Getting a Handle on Complaints

Industry continues to be deficient in complaint-handling procedures despite FDA having made those a priority for a long time. A new survey aims to help change that.

By: Erik Swain

### Q & A

Complaints about a medical device's performance or safety are a strong indicator of whether a firm's manufacturing process is in control. Handling those complaints in a way that fixes problems without creating others goes to the very essence of protecting the public health. As such, FDA takes complaint-handling issues very seriously. Failure to define, document, or implement a complaint-handling system and failure to follow up on complaints about medical devices are among the most frequently cited observations on FDA-483s.

Richard DeRisio and Nancy Singer have made great efforts to ensure that firms understand the value of a proper complaint-handling system and how to comply with FDA's complaint-handling regulations. Their collaboration on this topic began in 2000 when AdvaMed created the Medical Technology Learning Institute and conducted a seminar on complaint handling. Before that, the matter had rarely been discussed publicly. Most recently, DeRisio and Singer conducted a 30-question survey on the topic. It drew responses from 236 firms. The firms answering the survey manufactured Class I, II, and III medical devices and had from 10 to 50,000 employees. DeRisio and Singer hope to use the results to benchmark best practices and gauge how much education is still needed.

Q: How did the idea for the survey come about?

Richard DeRisio: I was preparing a presentation on complaint handling for an MD&M Minneapolis panel that Nancy was chairing, and we thought a survey would be a great way to benchmark best practices. My contribution was to ensure that the questions addressed the biggest challenges that quality assurance (QA) management faces in establishing a highly effective and fully compliant system. Responding to customer complaints is a key element of an effective quality system.

Q: Why should a firm strive to excel in this area?

**Sidebar:** [Meet the Experts](#) [5] DeRisio: There are a few reasons. One is customer satisfaction—offering an easy means for customers to provide input, both good and bad, on one's products, and then using that information to improve current devices and next-generation or completely new products. Then there are product safety issues. An effective system can provide an early alert on possible hazards associated with the use of a device. Good vigilance can prevent the hardship of a patient or user injury and minimize a company's product liability exposure.

Third is regulatory compliance. At MD&M Minneapolis last fall, I was amazed to hear during a presentation by an FDA supervisory investigator that her analysis of Turbo-483 observations indicated that the most frequently cited deficiency was complaint handling. I find this surprising given that the industry has been thoroughly and repeatedly inspected in this area for almost 30 years.

Another is bottom-line performance. When a firm has effectively and efficiently integrated complaint management with its processes for failure investigations and corrective and preventive actions [CAPA], it has the ability to rapidly eliminate product nonconformance's that increase the cost of poor quality. Sources of waste include customer returns, loss of goodwill, scrap, rework, stock outages, and line stoppages.

Q: Why is complaint handling such a common deficiency?



Nancy Singer



Richard DeRisio

DeRisio: FDA investigators are always disappointed when they find a firm is not properly looking into a complaint. Many companies simply don't have adequate procedures for complaint handling, or if they do, they're not following them.

Nancy Singer: It seems that a complaint about a product goes to the heart of the quality system. Complaints are a good way to find out whether a device is meeting its specifications. FDA will look at a firm's complaints, how they follow up on them, and what corrective actions they take to make sure the firm is operating in a state of control. FDA is charged with protecting the public health. If there are a lot of complaints, it's an indication that the device is not doing what it's supposed to do. FDA is obligated to step in and force the firm to correct the problem.

DeRisio: Some firms may not be aware that they have to review, evaluate, and investigate any complaints that involve the possible failure of a device, its labeling, or its packaging to meet any of its specifications. The only exceptions are if you've investigated the issue already or you can justify that an investigation is unnecessary. I think firms are not properly documenting their decisions not to investigate problems. Another issue is failure to close complaints in a timely manner. Most companies close a complaint once they open a corrective action. Some won't until they start a failure investigation. There must be documented reasons for not closing a complaint. Perhaps there was not a successful investigation. Related to this is how firms manage adverse events. A firm could be cited for not promptly processing a complaint that falls under the medical device reporting (MDR) regulation. When an adverse event report is submitted as an MDR, the firm must open a complaint file. And an area related to that is the monitoring of service experience. It is a requirement to open a complaint file if there is a service issue that, upon investigation, results in the filing of an MDR.

Q: If complaint-handling procedures have been a significant part of FDA inspections for almost 30 years, why are some firms still unprepared?

Singer: Until recently, firms have considered their complaint-handling systems to be proprietary and they didn't want to talk about them in public. When AdvaMed created the Medical Technology Learning Institute in 2000, it located consultants and other regulatory professionals who agreed to talk about their systems and share best practices. Before 2000, that information wasn't really available.

DeRisio: Another reason is resources. Sometimes firms don't realize that they aren't funded and staffed sufficiently in this area. As a result, they cannot be highly systematic when it comes to complaint handling.

Q: Nancy, you have analyzed warning letters about complaint handling. What are some examples of citations that you have seen?

Singer: A common citation is failure to establish and maintain adequate complaint-handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and failure to ensure that all the requirements of 21 CFR 820.198(a) through (e) are met. Another is failure to have complete complaint-handling procedures to ensure that all complaints are evaluated to determine whether the complaint should be filed as an MDR, as required by 21 CFR 820.198(a) and (d).

Q: Dick, in your experience, what issues have been likely to trigger FDA-483 observations?

DeRisio: First, not having established—defined, documented, and implemented—procedures that meet the letter of the regulations. It is easy to miss subtle requirements for evaluating, investigating, and closing complaints.

Second, not following procedures consistently and not maintaining adequate complaint files. For example, unless an investigation has already been performed for the same issue, the regulation requires that any complaint reflecting a failure to meet specifications must be investigated. Companies need to be consistent in this area.

Third, not processing complaints in a uniform manner as required by the regulation. A firm cannot operate effectively and efficiently if its approach is not uniform. Moreover, inconsistent complaint-handling criteria, unreliable screening for potentially reportable adverse events, and a lack of timeliness will be obvious to a compliance auditor.

Fourth, not processing complaints in a timely manner as required. If a firm has not established metrics to track complaint-handling performance, it will be difficult to manage to a complaint closure goal and to ensure that there are no old, uninvestigated complaints that contain important performance or safety information.

Fifth, overlooking the fact that an adverse event that results in an MDR filing must have a complaint file associated with it. Also, a complaint file must be opened for any service report that results in an MDR being filed.

Q: What is the best way for firms to learn about the requirements?

Singer: First read 21 CFR 198 line by line with a cross-functional team. Then read the preamble to 21 CFR 198, which is contained in the March 17, 1996 Federal Register. (it's also located on FDA's Web site at [www.fda.gov/cdrh/fr1007ap.pdf](http://www.fda.gov/cdrh/fr1007ap.pdf).) Verify that every requirement is supported by an established procedure.

Q: How can a company build an effective complaint-handling system?

DeRisio: Manufacturers need to set up a designated unit and establish procedures for receiving, reviewing, and evaluating complaints. The procedures need to ensure that all complaints are processed in a uniform and timely manner, oral complaints are documented upon receipt, and complaints are evaluated promptly to determine whether they represent an event that must be reported to FDA under the MDR regulation.

Q: What should happen when a firm receives a complaint?

DeRisio: Upon receipt, the complaint unit verifies that the report meets the definition of a complaint, and that the listed device is manufactured or distributed by the firm. Concurrent with this, the report will be reviewed to see whether it meets the definition of a potentially reportable adverse event. If so, the complaint should be fast-tracked for investigation by the departments (for example, medical and regulatory) that typically conduct these reviews. By the way, 21 CFR 803 requires that reports of adverse events received for another manufacturer's device must be forwarded to FDA.

The next step is for the complaint unit to review and evaluate the report to determine whether an investigation is necessary. As I stated earlier, it is important to note that 21 CFR 198(c) requires that firms investigate the possible failure of a device, labeling, or packaging to meet any of its specifications. The exception is if an investigation has already been performed for a similar complaint. Then another investigation is unnecessary. Firms need to define investigation. At the stage in which a firm is conducting its initial evaluation, to me the investigation pertains to the complaint report, not a failure investigation or analysis of the device. That comes later. Complaint investigation refers to the investigation of the details of the complaint: speaking with the complainant, trying to obtain the device for analysis, looking at device history records for evidence of similar issues during manufacturing, reviewing complaint files for similar complaints, and so on.

Q: What should firms do if they determine that a complaint doesn't relate to the failure of the device to meet its specifications?

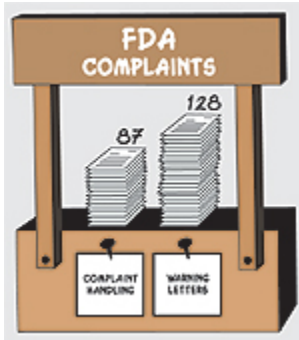
DeRisio: Even if firms don't investigate, they still need to maintain a record that includes the reason that no investigation was made and the name of the individual who was responsible for making the decision not to investigate. This is an area where a company needs to have clear criteria upon which this decision is based.

For example, it is typical practice for a firm to state in its procedures that it does not have to investigate a complaint if a corrective action is open, as long as the corrective action can be shown to be addressing the exact failure mode of the reported complaint. The corrective action might be open or closed; what is relevant is whether the complaint was for products produced before or after the correction was implemented. It's pretty simple to visualize. When a company says: "Here's another report of the x-y-z widget cracking; let's tell the engineer who's handling the corrective action," that is probably a good rationale for not investigating further and using resources for something more worthwhile. And, if a corrective action had already been implemented for "widget cracking," the engineer should confirm that the widget was not manufactured after implementation of the corrective action.

Q: Staffing seems to be an issue. According to the survey, about how many employees do companies devote to complaint handling?

Singer: It depends on the size of the company, but most respondents reported that their firms had between two and five people handling complaints.

Q: Is that adequate?



DeRisio: It depends on the complexity of the products, the quality of the people, and how the job is structured. Firms should consider establishing a standard, like 60 minutes per complaint, which factors in corollary activities such as reporting and running weekly focus group meetings. That helps us justify hiring. Also in my company, some portions of the complaint investigation are handled by members of the quality engineering department. If a complaint produces a reportable adverse event, our regulatory and medical departments will be involved in the investigation.

Q: What would you consider the most important key to establishing a successful complaint-handling process?

Since January 1, 2005, FDA has issued 128 warning letters to device manufacturers, and 87 of them cited complaint handling as a deficiency. Source: FDA Web site.

DeRisio: I know this will sound predictable, but it's true. The most important key to success is companywide support from senior executive management on down. If the top level of management doesn't support it, it's just not going to happen. Let me explain further. Our complaint manager at KCI says that she has the best job in the whole company because she is helping people. She has management support because we have been able to staff her department with individuals who have a high level of education and experience. Part of their job satisfaction evolves from seeing their output—namely clearly trended, product-specific data—being

effectively used by quality engineers to analyze the root cause of nonconformance's, which leads to effective corrective actions, which in turn leads to product and process improvements. Given the company's support of the CAPA program, complaint department personnel see that their efforts are not wasted. The complaint management team knows that their contribution is valued and that is reflected in their terrific attitude. Also, the company has recently invested in a state-of-the-art quality management software application that will further enhance the team's ability to process and report data. We would not have been able to staff adequately, maintain staff morale, and purchase the software solution without top management support.

Our senior executive management sends a strong message through the establishment of a senior executive quality council that meets monthly to monitor complaint trends and the adequacy of our corrective actions. Another key is routine management reviews of quality system data.

Q: What are some other keys to establishing and maintaining an excellent complaint management system?

DeRisio: One element is to have an easy-to-use means of harvesting customer input, and that includes both internal and external customers. Some companies use their labeling and sales force to encourage feedback on product performance. Providing a toll-free number is essential. A feedback form on the company's Web site could be useful as well. Internal customers such as sales and service personnel should have an effective means for reporting customer complaints as well as their experience with the product. It's important to respond to field employees who report complaints as much as it is to external customers. It's not enough to gather data. Sources of quality input must be mapped to ensure an efficient work flow process. KCI trends and acts on service data under our CAPA system.

Another key to success is having an easy method for customers and field-based employees to return products to the company's home office for analysis. Making a good-faith effort to retrieve devices is mentioned in the preamble to the quality system regulation (QSR), and a company cannot improve its products if it doesn't accurately assess the root cause of failure. In addition, knowledge of lot numbers of devices and key components is often needed to determine the scope of a problem.

Singer: The survey produced a terrific response to the question of retrieval, reflecting the fact that many respondents recognize the challenge in getting devices back for analysis. In fact, this was the biggest challenge cited by about 80 respondents, or 37%.

They cited a number of effective techniques. One is to make it really easy for customers and field personnel to obtain a material return authorization. Optimally, the complaint department or whoever takes the call from the complainant should be able to authorize a return and a replacement product. When possible, for example with disposable devices, provide sales representatives and high-volume device users with postage-paid, self-addressed packages for device returns. These packages should include all information needed for safe return, including instructions for disinfection and handling, packing materials to protect the device from damage, and so on.

Follow-up with the customer is standard practice and is done nowadays primarily by e-mail and telephone. It is essential to convey the message that the customer's return of the device has great value in improving the product's performance for that customer in the future and for others who use the device. Be responsive by having a courier or salesperson pick up the product. Provide free shipping and a product replacement or credit. And educate customers on the firm's corrective and preventive actions.

Q: What were some other big challenges reported?

Singer: Other challenges included obtaining sufficient detail about the event from firm's sales or service personnel. This was cited by 56 respondents, or 28%. To encourage the firm's sales or service personnel to obtain sufficient details about the device, respondents suggested getting commitment from top management and having a simple reporting form. They also emphasized training employees how to use the form, making sure they understand the benefits of finding out information from its use, and providing positive and negative reinforcement for compliance.

Firms also experienced challenges such as obtaining sufficient details about the event or malfunction from the device user. That was cited by 74 respondents, or 36%. Another was obtaining commitment from other departments to conduct a failure investigation or initiate a corrective action in a timely manner. That was cited by about 60 respondents, or 28%.

Q: Were there any answers that surprised you?

Singer: I was interested in the number of firms that used Web-based solutions. There are so many software vendors out there. About 100 respondents, or 42%, reported using a commercial Web application. The features that respondents liked included easy to input data, excellent paper trail, the availability of the data, ongoing support, and the linkage to MDR forms. Unfavorable characteristics included lack of flexibility, long configuration times, cost of annual updates, lack of customization, and the fact that the system was not linked to the CAPA system.

DeRisio: I was surprised by the responses that dealt with sending an RSVP to every complainant. Seventy percent said they always send a response to the customer after a complaint investigation. And 86% said they sent an acknowledgement upon receipt of a complaint. On the other hand, 56% responded that they rarely tell complainants about what they are actually doing in light of a failure investigation or corrective action. But 42% said they always respond with what they're doing. That's quite a disparity. Some take it quite seriously, but almost all the others don't usually provide details about their company's actions.

Singer: It is always good practice to send an acknowledgment letter whether the complaint was received from someone who uses the device or from an internal employee. A follow-up letter indicating what action was taken and providing some insight into the root cause of failure demonstrates a firm's commitment to investigating and correcting problems. However, some firms may be reluctant to send such a letter because of a concern for exposure to product liability actions.

DeRisio: I particularly want to stress the following. Always send a response (and, if appropriate, contact the complainant by telephone) if there is any indication that the complaint or adverse event resulted from the device not being used properly or not in accordance with the approved indications for use. This is particularly important if the clinician is in a position to train others on the use of the device.

It is not necessary to send a letter in response to all routine complaints, and it might not be possible for firms processing a high volume of complaints. When a response will be appreciated by the customer who

is interested in a firm's responsiveness, and who wants the assurance that the firm has a handle on the root cause and its correction, then follow-up correspondence should be sent. And firms need to remember that, although 21 CFR 198 does not require that a letter be sent to a complainant, if one is sent, a copy must be included in the complaint file.

The new quality management software that my firm is installing will help with responding to customers, because it can be programmed to generate automatic acknowledgments and customized follow-up responses.

Singer: Another surprise came from responses about complaints resulting from the device being used improperly. When asked for reasons that their firm doesn't investigate some complaints, 23% said they don't investigate in cases when the device wasn't properly used. That's surprising because it speaks to deficiencies in the labeling and in the human factors interface. This presents a problem because not only is the firm not taking the opportunity to educate people about misuse of their device, but they are also enabling professionals to train others on it improperly, which could lead to future complaints and adverse events.

Q: How many complaints should it take to trigger a failure investigation?

Singer: When there is a safety or effectiveness issue involved, 82% of respondents said only one. We would like to see that at 100%, and one has to ask what goes on with the other 18%. Most of the rest said two to four complaints. For situations without an effect on safety or effectiveness, 39% said one and 22% said two to four. If there is a safety issue, the regulations require that the firm conduct an investigation of the complaint. It's important that firms realize that any failure of the device to meet product specifications must lead to an investigation. They must drill down the problem and follow it up. Look at the device history record to see whether there were any nonconformance issues during production of that lot, and look at the service records if it's durable medical equipment. Try to recover the device. Once that's done, there may not be a reason to start a failure investigation or a corrective action. But at least you have the right people analyzing your decision to investigate the root cause of failure.

Q: What are the most common methods used to communicate complaints about devices?

Singer: The most popular method was for customers to call a designated number for complaints, and 98 respondents, or 42%, received most of their complaints in this manner. Other firms' primary method for receiving complaints was when the customer called a general number and the operator referred the customer to the complaint division. This method was cited by 58 respondents, or 25%. Customers also reported their complaints to field personnel. There were 74 respondents, or 35%, who cited this as the most popular method. Less-popular methods for receiving complaints were the use of the general Web site or a specific page on the Web site. The data indicate that people like to share their experiences with a live person rather than communicate electronically.

Q: How is that done at KCI?

DeRisio: We have trained all our employees who have contact with customers calling KCI to be aware of communications that could reflect a product issue meeting the definition of a complaint or an adverse event. The groups involved are not limited to those requesting products or service. We have provided training on complaint reporting to personnel in departments that assist customers on payments, the technical service staff, and other groups that could become aware of complaints or adverse events. We have another pathway for field sales, clinical, and service personnel. They have a toll-free number to a group called Customer First that handles all "compliments, concerns, and suggestions." Field employees are trained to use this number as soon as they become aware of a complaint or adverse event that a customer has reported or about which they have otherwise become aware. Another direct route to Customer First for field service personnel is an icon in their service software tracking system that is used to pull up a form that automatically populates fields with customer information and a device description, and which has fields for reporting the product performance issue.

Q: Who provides the most complaints to firms?

Singer: We found that the people reporting the most complaints to medical device firms were healthcare professionals, and about 80 respondents, or 40%, received complaints in this way. User facilities were the next most frequent source of complaints for medical device firms. There were 59 respondents, or 25%, who reported receiving complaints in this manner. Other firms, 43 respondents or 18%, reported receiving most of their complaints from service representatives.

Q: What categories of information were the most popular for trending?

Singer: The most popular information to trend was the number of complaints received per period, for example by month, quarter, etc., and this was cited by 205 respondents, or 87%. The second most popular information to trend was the number of complaints per device type, and 199 respondents or 84%, reported trending this information. Trending the number of complaints per product model was cited by 79%, and trending the number of complaints per product family was cited by 74%.

DeRisio: In my personal experience, firms trend on the categories that Nancy just described, as these are the expected metrics for routine reports and management reviews. We have established product-line-specific focus groups that meet weekly to discuss complaint trends and review the corrective actions associated with each. The complaint analyst who attends these meetings brings a chart showing specific failure modes both as reported and as confirmed by failure analysis.

Also, firms typically trend information that assists in managing the complaint-handling process. I recommend a 12-month rolling trend of the total number of complaints opened and closed in a given month. That speaks to the group's activity. Another good tool is a 12-month bar chart that shows, for each month, the total number of complaints opened and closed. That graph indicates whether a firm has any complaints still open in months past. Another typical chart is a graph of total complaints open by month and the average days to closure for each month.

Singer: One could argue that a firm's products aren't as good if its complaint numbers are up, but it could just mean that the problems are no different from before but more are being reported now. That's not a bad thing. You need to make every effort to get feedback.

Q: So when should a complaint be considered closed?

Singer: We asked this in the survey. We found that the most prevalent practice was for firms to consider a complaint to be closed when corrective action is initiated or if it has been determined that no action is required. This was the system reported by 100 respondents, or 42%. Other firms, 48 respondents or 24%, reported that their firms considered a complaint to be closed when a failure investigation is completed.

We also inquired about firms' goals for closing complaints. Less than 30 calendar days was the most popular goal, cited by 37% of respondents. The next most popular goal was 40–60 days, reported by about 23%. Lastly, 31–45 calendar days was cited by 18%.

DeRisio: Consistent with survey results, we consider a complaint closed when a corrective action has been opened for a root cause that is the same as that for the complaint sample. Our complaint manager is extremely strict about this. She requires the quality engineer's documented rationale as to why the corrective action is applicable. We can also close a complaint for reasons such as the report does not meet the definition of a complaint, or the device was not manufactured by KCI, and so on.

Q: The relationship between complaints and corrective action is important. Do firms use one system or two?

Singer: Most firms, 182 respondents, or 75%, reported that their firms initiated corrective actions through a process that was separate from the complaint management system. However, 53 respondents, or 25%, reported their firms had their corrective action system as part of their complaint management system.

DeRisio: I have seen it work both ways. My preference is to separate the complaint handling and corrective action systems into two separate functions. There are a number of reasons for this. One is that each has its own discrete policies, procedures, and work flow processes, and I am concerned that trying to integrate these into one system could make the overall system difficult to manage, measure, and control.

Firms should establish a seamless flow between the areas of complaint management, failure investigation, and CAPA. All three systems should share a common method of prioritizing their handling of an issue whether received as a complaint, investigated for root cause, or managed as a corrective action. Also, focus group meetings and CAPA meetings need to involve members responsible for these quality system elements, so communication and tracking are important.

Q: Now that the survey is complete, what are the next steps?

Singer: We plan to conduct more surveys and to develop educational programs on this topic. Clearly, it's an area that has great benefits for a firm and its customers when done well, and, somewhat surprisingly, it's an area that still is the subject of numerous FDA-483 citations. There really isn't any downside to making complaint handling as good as it can be.