

## Complaint Files

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Hello, my name is Stanley Liu, and I'm a Consumer Safety Officer in the Division of Industry and Consumer Education. I worked in industry for many years, and know how difficult it is to compete and manufacture medical devices in the United States. Working at FDA, I also understand the "big picture" regulatory framework that helps ensure quality. I hope to bring a balanced picture from both perspectives to my discussion today on Complaint Files.

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Complaint Files are a key, but often neglected, aspect of the Quality System for medical device manufacture. It's human nature to focus on getting a task accomplished, in this case, getting a device marketed and manufactured. But what comes afterwards is oftentimes forgotten or neglected. However, what occurs after a device is released for distribution can be just as important as premarket and manufacturing activities. When Complaint Files are properly handled and coupled with other corrective action systems, the result is a mechanism that can be used to learn from past mistakes. This can result in successful product longevity, increased market share, and consumers will ultimately benefit from a better, safer, and more effective product.

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Today, I will be focusing on the following three Learning Objectives: One - Understand the context of Complaint Files within the overall Quality System and Corrective and Preventive Action, or CAPA, subsystem. Two - Learn about the mechanisms of Complaint Files and their continual Postmarket role, and Three - Understand the contribution of Complaint Files to Quality and Safety. These three key objectives will give you a firm start in understanding the role, function, and importance of Complaint Files.

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What is the CAPA subsystem? It's a key component of the Quality System, and is itself comprised of three parts. This is articulated in this simplified and generalized table – Nonconforming Product, which functions primarily during Manufacturing; CAPA, which functions during both Manufacturing and After Distribution; and Complaint Files, which generally functions After Distribution. I'll be focusing today on Complaint Files, as highlighted in bold.

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Complaint Files, in turn, comprise seven sections, labeled "a" through "g," as listed here. However, you can think of them as being divided into "procedural mechanisms" – "a" through "d," and "record-keeping requirements" – "e" through "g." We will go through each of these groups in greater detail as I progress through my discussion.

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Now that we've taken a brief look at how Complaint Files are laid out, let's explore the procedural mechanisms. We'll start with the formal definition of a Complaint. What is a Complaint? It is 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's released for Distribution. In other words, a Complaint is any communication alleging an issue with a device after it's been released for Marketing and Distribution.

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All complaints must be processed in a specific manner, as defined in the first Complaint Files subsection, General Requirements. Manufacturers must Establish and Maintain procedures for receiving, reviewing, and evaluating complaints by a Formally Designated Unit. This Unit must ensure: processing of complaints in a uniform and timely manner; documentation of oral complaints upon receipt; and evaluation to determine if a Failure Investigation and/or a Medical Device Report, or MDR, is required.

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Some devices may require servicing after distribution. And during this servicing, complaints may arise. What do you do with servicing reports with potential complaints? Well, there are many different solutions, and I will describe two common ones. First, manufacturers may train servicing personnel to identify possible complaints and flag them for the formally designated unit to subsequently review. Second, manufacturers may have the formally designated unit itself review all servicing reports and records for possible complaints. Each solution has its advantages and disadvantages. Manufacturers have the freedom to find a solution that meets both the regulatory requirements as well as their own needs. Please note that these examples focus solely on Servicing as they relate to Complaint Files, and we won't be discussing Servicing beyond this limited scope.

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Once an alleged complaint has been received, manufacturers must review and evaluate complaints to determine if an investigation is necessary. If you determined that an investigation isn't required, then accountability information such as the reason and responsible individual must be documented.

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Any alleged complaint involving the possible Failure of a device and/or its labeling and packaging to meet specifications must be Reviewed, Evaluated, and Investigated. The exception to this would be when an investigation has already been performed on a similar complaint. Please note, though, that a similar complaint may not require an investigation under Complaint Files, but it may require a Corrective and Preventive Action investigation due to recurrence. I'll discuss CAPA referrals later in this presentation.

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Let's briefly discuss a specialized form of complaint known as a Medical Device Report or MDR. All MDRs are a form of complaint; however, not all complaints are MDRs. Our discussion will focus strictly on MDRs within the context of Complaint Files. When MDRs are received, they must be promptly reviewed, evaluated, and investigated by designated individuals, just like complaints. However, MDRs must also be maintained in a separate part of the Complaint Files or be otherwise clearly identified. Additionally, investigation records must be kept indicating: whether the device failed specifications; any use in treatment/diagnosis; and the relationship of the device to the reported incident. Additional information on MDRs can be found in 21 Code of Federal Regulation, CFR, 803.

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Now, let's look at a very basic, simplified diagram of how the three CAPA subsystems function, focusing on After Distribution mechanisms on the right. Corrective and Preventive Action is in the middle, spanning both Manufacturing and After Distribution. Complaint Files and Medical Device Reporting are in the lower and upper right, respectively, within After Distribution. Complaints enter from the lower right. Note that complaints initially go to Complaint Files. From this point, they may be handled locally, or referred to CAPA. MDR Complaints are fed into the MDR system, which can also potentially lead to CAPA.

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With a basic understanding of how a Complaint Files System is established and maintained to review, evaluate, and investigate Failures and MDRs, I'll now turn my focus to two common questions that are asked of the FDA. The first is, "Why are Investigations necessary?" Isn't it enough to simply catalog and note complaints and failures? The answer is, "no." Based on statistical probability, the likelihood that a product line will eventually have a Failure or MDR increases as time passes. Such a Failure can conceivably impact everything from manufacturing to design. A robust investigative system ensures responses/reactions are: accurate, appropriate, and timely. Complaints are captured, reviewed, evaluated, investigated, and corrections made. The end result is a better, safer, and more effective product.

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The second common question is, "Why are there no specifics on how to conduct an Investigation?" On first glance, the Regulation does not appear to be that complicated or specific. There are a multitude of variables and reasons for this. These include: the heterogeneous nature of devices and complaints; risks involved; severity of issues; frequency of complaints; and many other factors, including conditions and context. Therefore, a set of prescriptive requirements governing all possible variables and situations is simply not feasible. Consequently, the Regulation is flexible.

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The FDA recognizes that it cannot foresee every potential situation or contingency. As a result, the Regulation is not vague; rather, FDA has given manufacturers the freedom to define their own circumstances. Manufacturers must understand their own product, associated risks, the conditions and context for use, and apply the regulatory requirements to make their own Complaint Files System work. The result is that manufacturers must decide upon their own details.

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Manufacturers are responsible for the details of their own Compliant File system. These would include: Definitions, Actions, and Investigation Thresholds. For Definitions, this means defining Failures of devices and labeling/packaging, MDRs, and "other" or "non-complaint" communications. For Actions, the manufacturer must establish criteria for what constitutes an Investigation, as well as what happens with "other" activities such as "non-complaints" and similar complaints. Finally, there needs to be provision for Investigation Thresholds, specifically, when should complaints be handled locally under Complaint Files or referred to CAPA. This last topic – Thresholds - is something we'll now examine in more detail.

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Corrections should be handled locally under Complaint Files if they meet the following general criteria: easy/specific correction; isolated incident, minor issue; not a design issue; and not a Manufacturing issue. I have provided illustrative examples in the next 5 slides.

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Easy/specific correction - a device was mishandled during shipping and is dented or scratched.

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Isolated incident - a minor malfunction occurred when it was used once outside the intended/indicated uses in an unanticipated way.

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Minor issue - a part became loose or unattached but was not damaged.

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Not a design issue - the plastic casing cracked when accidentally dropped.

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Not a Manufacturing issue - the Instruction Manual got lost during unpacking.

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Complaints should be referred to CAPA if they meet the following general criteria: no easy/specific correction; recurring problem; severe issue; a design issue; and a Manufacturing issue. Again, I have provided illustrative examples in the next 5 slides.

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No easy/specific correction - complaints of short battery life.

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Recurring problem – a large amount of product frequently dented or scratched during shipping over time.

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Severe issue – a device caught on fire or exploded.

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Design issue - reports of frequent, specific malfunctions in a high E.M. area.

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Manufacturing issue - mold was found inside packaging.

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In deciding on specific threshold parameters, balance is key. Too many failures handled under Complaints may fail to address systemic issues. Generally, Complaint File issues should be simple, specific, and contained. Conversely, too many complaints referred to CAPA will overwhelm that system. Generally, CAPA handles more complex, ambiguous, and systemic issues. I hope my previous examples help to illustrate the general type of line that needs to be drawn.

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Now let's view a final assembled diagram of how Complaint File investigations work. Note that this is again simplified for illustrative purposes. Complaint Files are in the center, while Corrective and Preventive Action and Medical Device Reports are in the upper and lower right side, respectively. Complaints enter from the left side. An initial complaint is received, reviewed, and evaluated. If it is not a complaint, then it is either closed or dealt with in another manner. If the complaint requires further investigation, as in the case of device failures, then it proceeds to the investigation phase. MDRs are identified or separated and dealt with separately, which may include forwarding to CAPA. Failure investigations are examined to determine whether they are to be handled within the Complaint Files system or referred to CAPA for further action.

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Now that we've examined the basic procedural mechanism for the Complaint Files System, let's switch gears to focus on the second part of the Regulation regarding Complaint Files, record keeping for the actions that we've discussed. Complaint File Records must be maintained to capture: the device name; date the complaint was received; unique device identifiers; complainant contact information; nature or details of the Complaint; results and dates of the investigation; Corrective Action taken; and the response to the Complainant.

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In cases where a designated complaint unit is located off-site, and/or outside of the U.S., records must be reasonably accessible to the manufacturer and the FDA at either the U.S. location where the records are regularly maintained, or with the initial distributor or importer. Such records must comply with all other Quality System Records requirements as per 21 CFR 820, Subpart M.

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Additional information on the Quality System, its Preamble, and the FDA Inspection Guide can be found at the links on this slide.

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In concluding this presentation, I now ask you to take on the following Call to Action:  
Use your Complaint File system to learn from mistakes, they can impact everything from quality to design to manufacturing. Know that Complaint Files are a gateway mechanism for CAPA and postmarket activities. And leveraging a robust Complaint File system, to avoid repeating mistakes, can allow you to improve the quality and safety of your product.

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We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Of note, for comprehensive regulatory information, please contact CDRH's Division of Industry and Consumer Education. We look forward to helping you.

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