CLEARING COMPLAINT BACKLOGS: A GUIDE TO EFFICIENT COMPLAINT MANAGEMENT

THE FDA GROUP LLC

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INTRODUCTION

Many FDA-regulated manufacturers find themselves without the resources or processes to efficiently manage product complaints. When the resulting backlog isn't cleared quickly and completely, the issue can compound into serious safety and compliance problems.

In terms of safety, the problem backlogs present is clear. They keep companies blind to product problems, thereby putting patients at risk.

In terms of compliance, the problem can be less apparent and more complex. Complaints stuck in queue can easily fail to meet the closeout deadline required by FDA, opening your entire quality management system up to intense scrutiny from regulators. Conversely, rushing to eliminate backlogs can result in critical details going unnoticed and unaddressed—again leaving the door open to massive (and potentially invisible) compliance problems in the short and long term.

This guide presents the common causes for complaint backlogs and generalized strategies for remediation. These scenarios were compiled by Alan Greathouse, a regulatory compliance expert with extensive experience identifying the causes of complaint backlogs and working to develop efficient and effective ways to remediate them in companies large and small, all over the world.

Contact us today to get expert complaint handling and/or backlog reduction assistance from an experienced regulatory consultant, or **learn more** about our Postmarket Surveillance Auditing & Remediation services.

WHAT CAUSES COMPLAINT BACKLOGS AND WHERE TO LOOK FOR PROBLEMS

INTAKE

- ***Problem #1: Under-trained or under-experienced intake personnel miscategorizing genuine complaints from field incidents.***

  While those receiving complaints from the field are typically experienced complaint handlers, those submitting complaints from the field should also be able to accurately discern genuine complaints from field incidents. When too many field incidents enter your intake disguised as complaints, valuable time and energy is robbed from those triaging and investigating these issues.

> ***Solution:*** *Ensure the field technicians pushing complaints into the system have sufficient training in the basics of complaint investigation and are capable of identifying and resolving issues associated with the specific devices they commonly interface with. Technicians should be able to identify problems when they encounter them and separate complaints from field incidents using indicators in the field.*

- ***Problem #2: Inadequate or incomplete service records.***

  Thorough complaint investigations rely on good thorough recordkeeping. When field technicians fail to capture the information needed, time is wasted tracking that information down. Worse still, serious problems can fly under the radar due to improper processing. A "broken hose," for example, isn't useful as an entry when the device has twenty hoses attached to it. The level of detail provided must be appropriate to the complexity of the specific device in question.

> ***Solution:*** *Determine whether or not reports from the field are being submitted with complete, useful information and consider hands-on training around specific devices to ensure field technicians know which details are critical to include. Everyone must understand what information is needed to make a complaint actionable.*

Pay special attention to the areas that typically go under-explained:

- A detailed description of the failure
- A detailed description of what specifically occurred
- A detailed description of what was done to correct it (if it was corrected in the field)
- A detailed description of how that correction remediated the problem

- ***Problem #3: Improperly handling devices with problems.***

  In the medical device space, malfunctioning or damaged equipment must be returned to the manufacturer to conduct a physical investigation of the unit. Too often, though, under-trained field technicians unknowingly sabotage the complaint process from the start by disposing of problematic devices on-site, making it impossible to investigate.

> ***Solution:*** *Analyze complaint problems resulting from insufficient information from the field to determine if improper handling or other lapses can be dealt with by improving processes, training, or both. Review all processes related to collecting damaged or malfunctioning products to ensure equipment isn't being disposed of or altered further.*

"When it comes to complaint intake, there has to be a fluid interchange between those in the field and those back home assessing the complaint. In many cases, field techs should have a background in complaint investigation. That way, they truly understand the problem and can determine whether or not what they're seeing in front of them is a genuine complaint or just a field incident."

– Alan Greathouse, The FDA Group

INVESTIGATION

- ***Problem #1: Avoidable translation from one language to another.***

  Products present in several markets must be supported by a complaint management system free of translational hiccups. Companies extending their reach around the world have to bring their processes along for the ride. A complaint handling group used to processing complaints in one language can't be expected to be as effective when they're asked to process complaints from three or four.

  Physical problems compound this. When problematic devices are returned to somewhere other than where the complaint handling group resides, for example, another group—sometimes in a different country—must step in to provide the complaint handlers the information they need. This extra step, while likely convenient from a logistical standpoint, only invites inefficiency elsewhere, leading to a possible backlog in addition to missed information.

  > ***Solution:*** *Every preventable step of translation should, in fact, be prevented. Ideally, this is accomplished by localizing the complaint management group to the region the devices are located in. English complaints should be handled by fluent English speakers. Chinese complaints should be handled by fluent Chinese speakers. Nuance and detail—two things that are critical in handling complaints—are often the first things lost in translation. Recognizing this and being willing to act on it can have a massive impact on complaint process efficiency.*

"I worked with a company with a backlog that was, in part, due to a complaint group in Europe that was handling complaints about devices they didn't even manufacture. Those handling them had very limited knowledge of that device. More importantly, when the device was returned, it was returned to a site in the United States. This kind of problem makes for a very poor process. You're asking people, one, 'you have to translate it from English to German' if they don't read and write English. Then, before it gets put into the U.S. system, it has to be translated back. That's a massive opportunity for error."

– Alan Greathouse, The FDA Group

- ***Problem #2: Poor complaint handling procedures lead to user error, incomplete data, and friction.***

  It's a hard question for internal teams to answer objectively (and why they often hire consultants to answer it for them): Are there adequate procedures for those handling complaints to follow? More precisely, can someone pick up the procedure, read it, and actually perform the process without having to work from memory?

  Solution: *If the answer to these questions is anything but a resounding "yes," it's time to put the procedure under the microscope. While it's impossible to give concrete advice as to what a complaint handling procedure should contain, let's discuss four essentials common among the most effective:*

  1. ***Identify what information needs to be included, tab-by-tab in your software application.*** *In general, complaint handlers should be walking through each tab of the complaint within their software system, detailing the specific information that should be included in critical areas.*
  2. ***Appropriately evaluate, document, and assign risks.*** *Complaints should be ranked by risk and/or assigned a risk priority number. This is mission-critical to medical device complaint handling and should be spelled out in clear and complete detail within your procedure.*
  3. ***Categorize complaints by examining analytics.*** *Designate how a complaint handler should properly categorize a complaint as a mechanical failure, software failure, etc. This shouldn't be subjective. It should be the result of a clear assessment of the data in front of them.*
  4. ***Make accurate, consistent MDR determinations.*** *Reporting high-risk issues to FDA with an MDR write-up should be covered in a single procedure, not multiple procedures. Keep in mind that "reportable incidents" are any that have caused serious harm or death, or have the potential to cause serious harm or death should a similar incident happen again. This includes user error.*

CLASSIFICATION & PRIORITIZATION

- ***Problem #1: Inadequate training for risk assignment and ranking.***

  Complaints should be assigned a risk number and prioritized accordingly. However, many complaint handlers are not qualified to perform the level of analysis required for this task. Assigning risk accurately and consistently typically requires the expertise of a product engineer who has a thorough understanding of how to use the software that assigns risk numbers, as well as the factors that software is analyzing to arrive at its answer.

> ***Solution:*** *Develop the training needed to make complaint handlers experts in risk. This should include a thorough understanding of the software used to assign risk numbers and the process the software uses to do so. Common software issues and user errors should be presented with solutions and mitigation strategies during the training. Product engineers should be tapped as subject matter experts to ensure the training is adequate and actionable.*

- ***Problem #2: Improper classification.***

  Improperly classifying complaints can spark a cascade of compounding problems. It skews complaint analytics, tracking, and trending. It's also something regulators make a point of looking for (and routinely issue observations for) as it can result in MDRs not getting filed when they need to be. Improper classification not only causes backlogs but can create a barrier to eliminating them by introducing the tedious task of re-opening and re-investigating closed files.

> ***Solution:*** *If a backlog currently exists, evaluate a sample of complaints to understand whether or not classification is an issue and the extent of remediation required to resolve the problem in full. In general, revisit the decision-making process for complaint classification to ensure handlers are considering all important data points and making decisions consistently.*

"In one backlog remediation project, we were told that none of the 2,500 complaints needed an MDR. That didn't turn out to be true. We found complaints that were two or three years old that never had MDRs filed. The industry expectation is 30 days to file. Not only were there MDRs to file, but we also ended up having to go back and open closed complaints to fill out additional supplemental documents and do further investigation. In some cases, complaints were just misclassified. The risk was inappropriately assigned. So, we had to go in and fill out what's called supplemental forms, which, as you can imagine, that's like a whole other investigation in itself, so you're doing double and triple the work when you do improper investigation up front."

– Alan Greathouse, The FDA Group

- ***Problem #3: Inefficient closure due to long wait times for cross-functional input.***

  Poor alignment between cross-functional teams can let complaints sit partially completed as they wait for someone's input. When complaints aren't prioritized by a critical function, a few complaints can lead to a lengthy backlog by bottlenecking the entire process.

  > ***Solution:*** *Evaluate weak links in the chain of cross-functional input. Are complaints stalling in a particular area? Reexamine the organizational structure and offer guidance on priorities for teams who let complaints lag behind.*

OTHER EXPERT TIPS FOR POSTMARKET SURVEILLANCE & COMPLAINT HANDLING

Review and document your field service program consistently and completely.

"A lot of companies should look at their field service program—how that's documented, where it's documented, and the accuracy of that system. You have to be extremely careful about what your technicians in the field are documenting. What happens is—you attach those service records, or the SAP entry, or whatever the case may be, but the documentation practices change when it gets back to the group. I've seen companies get themselves in a world of hurt here. For example, the auditor picks up some complaints, finds that they're incomplete (they don't include the SAP number, or the field service record number, for instance) so they say, 'well, we want to see them.' Now it takes take a day and a half just to find them. Then they come back and say 'well, this is inadequate or insufficient, let me see some more.' This is not a good situation to find yourself in."

– Alan Greathouse, The FDA Group

Properly assess, investigate, and handle returned goods

"Another area companies may not realize they have an issue in is their returned goods area. Any time goods are returned, they need to be quarantined and held in a separate area. Oftentimes, they get returned, and then they just 'hang out' somewhere. Look into that area and how it's managed. Also look into the disposition of those returned goods. How does that process work? After a product is returned it has to be assessed or inspected and then dispositioned. Is it scrap? Can you rework it? Is it completely fine?"

– Alan Greathouse, The FDA

Look for other issues if problems aren't observed.

"Sometimes customers file a complaint, products get returned, and there's nothing wrong with them. They might not have known how to work it due to poor instructions for use. That's something you may not realize is a problem until you start looking at postmarket surveillance. Say you're working on an injection pump and you start getting a lot of complaints citing faulty equipment. But you're getting equipment back and the engineer's finding there's nothing wrong with it. This is when you should start looking for poor processes or a lacking IFU."

– Alan Greathouse, The FDA Group

THE CONSEQUENCES OF INACTION

When discovered by regulators, the first and most obvious consequence of a complaint backlog is a written observation. This could cite improper investigation and, in some cases, inadequate quality oversight.

Like any observation, expect this to trigger much more digging. Regulators will likely examine your processes and the backlogged files themselves to determine what is causing the delay. Complaints indicating missed MDRs or unknown patient risks will very likely lead to critical observations and/or warning letters or other serious enforcement action.

HOW THIRD PARTY EXPERTS SOLVE THE PROBLEM, QUICKLY AND COMPLETELY

After rigorously reviewing the details of the problem to ensure the expert assigned to resolve it is a perfect fit, The FDA Group works alongside internal stakeholders and subject matter experts to plan and execute a comprehensive backlog remediation project summarized step by step below.

1. Perform a gap assessment & statistical sample analysis

Backlog remediation typically begins with a thorough gap assessment, led and conducted by an experienced postmarket surveillance professional. Unlike a standard gap assessment, a statistical sample of the backlog files is taken and analyzed to understand the true magnitude of the problem as fast as possible.

If you take a statistical approach, you can pull a statistical sample size, look at those files, and determine the quality of investigations performed and where you need to start. Is everything in place and you just need to process them through the last couple of phases? That's a very different project compared to one where investigations are lacking, or not there at all. This needs to be figured out as soon as possible."

– Alan Greathouse, The FDA Group

2. Craft a custom remediation plan

A remediation plan is developed based on the individual circumstances at hand. As much as possible, internal approaches are incorporated to ensure every step is as easy, efficient, and familiar as possible. The project is scoped in terms of resources, hours, and other factors—all pointed at one goal: getting back into compliance as quickly and effectively as possible.

3. Develop sustainable processes and procedures

With a remediation plan positioned and underway, we get to work clearing the backlog while developing sustainable processes as we go. This includes training, SOPs, staffing, and more.

"Part of the solution includes not only get rid of the backlog but providing improvements that will ensure compliance to meet not only today's but tomorrow's regulatory expectations."

– Alan Greathouse, The FDA Group

CLEAR YOUR BACKLOG AND IMPROVE YOUR PROCESSES ALONGSIDE A POSTMARKET SURVEILLANCE EXPERT.

We recognize the challenges of developing and managing an effective postmarket surveillance program under the watchful eye of regulators in a quickly-changing landscape. Our professionals draw on years of experience, highly specialized skills, and best practices developed through work in the field to ensure objective, accurate, and actionable recommendations are made each step of the way.

Our proprietary talent selection process brings together a diverse array of skill sets, experience, and expertise to offer a truly unique opportunity for companies interested in receiving personal and professional attention.

> ***Contact us online*** *or call us today to clear your backlog and improve your postmarket surveillance processes today.*
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