ORA - A Day in the Life: Consumer Safety Officer
Module 2

Slide 1
Hello, my name is Laureen Geniusz, and I'm a Consumer Safety Officer in the Office of Medical Device and Radiological Health Operations, at the Food and Drug Administration, also known as the FDA. Today, I will be giving a presentation on a Day-in-the-Life of a Consumer Safety Officer.

Slide 2
This is the second module in a five-module series on a Day-in-the-Life within the Medical Device program at the FDA's Office of Regulatory Affairs, also known as ORA. I encourage you to watch the Introduction to give you some background on this module.

Slide 3
Have you ever wondered what an FDA Consumer Safety Officer does on a daily basis? Or what are some things you can do to support inspections and make the process more effective and successful? This presentation will address these questions.

Slide 4
In this presentation, I will cover three objectives. First, I will describe some basic characteristics and responsibilities of the FDA Consumer Safety Officer. Second, I will identify and explain the different types of Medical Device Inspections that we do. And finally, I will describe what happens before, during, and after an inspection.

Slide 5
Let's first start off with some general characteristics and responsibilities of the Consumer Safety Officer.

Slide 6
An FDA Consumer Safety Officer is also called an Investigator or by the acronym, CSO. I'll refer to each of these terms during this presentation. About 140 CSOs work for the Medical Device program, under FDA's Office of Regulatory Affairs, also referred to as "ORA".

Our backgrounds may vary, but most CSOs have a college degree in the sciences, such as: Engineering, Biomedical, or Nursing. Many of us have previous government or industry experience; but some of us come to the FDA directly out of college.

As a new hire to the FDA, we complete a detailed training program focused on basic inspectional and investigational skills. As a Medical Device CSO, we receive additional training from FDA, specific to the work we perform in the Medical Device area.

This training focuses on the Medical Device regulations, inspections, and processes utilized by the Medical Device industry, such as: electronics, plastics, process validation, sterilization, and software validation.

We also obtain basic investigator and Medical Device Certifications. These internal certification programs ensure that our workforce has a standardized education, along with the knowledge and skills needed to perform inspections using the relevant regulations.

Slide 7

Now, let me explain the Core Functions and Duties of a CSO. We routinely conduct Inspections and Investigations, and write Establishment Inspection Reports and Memorandums. We spend about 90% of our time in these areas.

We sometimes conduct Recall Audit Effectiveness checks and follow-up on Consumer Complaints. We periodically attend or conduct trainings and deliver presentations. We also participate in Work Groups, which usually focus on internal process improvements.

Finally, we may have miscellaneous duties like assisting other FDA colleagues and keeping up-to-date on new FDA Policies, Procedures, and Guidance Documents.

Slide 8

You might be wondering: What is the difference between an Investigation and an Inspection? Each has a different purpose. An Investigation is less common and usually involves gathering information. In contrast, an Inspection is more common where we determine compliance with the relevant federal laws and regulations.

We sometimes conduct an Investigation to determine whether an Inspection may be needed. For example, we may conduct an Investigation related to a Consumer Complaint. In this case, we may need to gather information to determine whether we believe there may be a manufacturing or design issue with a medical device. If the answer is yes, we may then proceed with conducting an inspection at that facility.

Slide 9

Let me explain more about Investigations. Investigations are conducted for a variety of reasons. Some examples include: following up on a consumer complaint, dealing with an emergency or disaster situations, potential product tampering, or health fraud.

These Investigations might take place at locations beyond a manufacturing facility, for example, at a retail establishment or a consumer's residence. Some investigations may involve other government agencies. I'll provide some examples later in this presentation.

When conducting an Investigation, we do not typically issue a Form FDA 482, Notice of Inspection, also referred to as the "482". The outcome of an Investigation is summarized in a Memorandum and submitted to our first line Supervisor for Endorsement and any appropriate follow-up. I'll discuss "Inspections" in detail later in this presentation.

Slide 10
As a CSO, I receive training about current trends and processes that I might encounter related to medical devices. Training topics may include: International Standards, sterilization processes, software validation, computer aided inspection techniques, process validation, risk analysis, data integrity, and radiological health.

Slide 11
Not only do CSOs receive training, but we also give back to our community and train others. We may do community outreach or provide training in collaboration with industry experts. We'll also provide internal training and mentoring to new FDA employees and co-workers.

Slide 12
We also work on various internal working groups. These groups work on medical device Program Projects, such as assessing current policies and procedures, streamlining current practices, instituting quality initiatives, and collaborating with compliance activities.

Slide 13
We work with other Agencies as needed. We work with FDA's Office of Criminal Investigations, or OCI, on potential criminal activity associated with FDA regulated products. We also work with the FBI and the Assistant United States attorneys' office, on criminal cases, such as Health Fraud. We work with the U.S. Marshals Service on cases related to product seizures.

We also work with other groups within the Department of Health and Human Services, such as: the Centers for Disease Control, the National Institutes of Health, and, of course, the various Centers in FDA.

Slide 14:
Now I'll discuss the Medical Device CSO's primary responsibility: Medical Device Inspections.

Slide 15
Medical device inspections are "Risk Based", which means manufacturers of high-risk medical devices are identified and prioritized on our annual field work plans.

These work plans are developed both by the Center for Devices and Radiological Health, or CDRH, and ORA. When developing the annual work plans, CDRH and ORA may consider factors like the device classification, post-market data and rapidly-evolving technology. The completed work plan is then used to create inspection assignments for the CSOs within the Medical Device program.

Slide 16
What are the types of Inspections do we do? The most common type is a Routine or Surveillance Inspection. Other types include: Directed or For-Cause, Pre-market Approval, Post-market Surveillance and foreign. We will look at each type of Inspection in more detail in the next few slides.

Slide 17
Let's start with Routine or Surveillance Inspections. These Inspections are usually pre-announced, often 5 days in advance. They cover the current Good Manufacturing practices, or cGMPs. There are two types of Routine inspections: a Comprehensive, Level 2 Inspection, and an Abbreviated, Level 1 Inspection.

Slide 18
Comprehensive, Level 2 Inspections cover the 4 main Quality Subsystems: Management Controls; Corrective and Preventive Action, or CAPA; Design Controls; and Production and Process Controls, also referred to as the P & PC system. Now, Abbreviated, Level 1 Inspections cover just the CAPA System, plus one other System - usually either Design Controls or Production & Process Controls. The selection of this second System may be based upon Quality Indicators found in the CAPA System, such as: Complaints or non-conforming trends, new processes or products, or previous inspectional findings. We may need to expand an Abbreviated Inspection to a Comprehensive Inspection, if we find issues that could be related to multiple sub-systems. In this case, it's important that we obtain a complete picture of the firm's Quality System.

Slide 19
Routine Inspections can also cover other areas, such as: Medical Device Reporting, or MDRs, Corrections and Removals, and "UDI", which is the Unique Device Identifier. How long does an inspection take? Well, this depends on several factors, such as: How complex is the device or manufacturing process? How long does it take for the firm to gather data and respond to questions? Is there a need to follow up on any prior inspectional observations? Does the current inspection identify any new observations? These variables can make it difficult to accurately predict the length of an inspection in advance.

Slide 20

Let's look at an example of a routine type of inspection we'll conduct involving radiological products. We'll refer to these types of inspections as EPRC, which stands for Electronic Product Radiation Control. These are usually Routine Inspections but can be assigned as a "Directed" Inspection if needed. These Inspections determine compliance with specific radiation regulations; but can also cover compliance with the Medical Device Quality System Regulation found in 21 CFR part 820.

Slide 21

Next, I am going to talk about "Directed" Inspections, which are also known as "For Cause" Inspections. These inspections usually have a specific focus area, which is communicated to the CSO when the inspection is assigned. These Inspections can either be pre-announced or un-announced, depending on the nature of the assignment. Some examples of a directed Inspection are: Compliance Follow-up Inspections, and Center-Initiated Assignments to cover specific issues or concerns. We may conduct a directed inspection for Pre-Market or Post Market Assignments. We also follow-up on Trade Complaints that warrant an Inspection, or MDR events that may trigger an immediate follow-up Inspection.

We may also have an assignment to perform a follow-up inspection on a medical device recall action. As you can see, directed inspections usually involve specific concerns that need to be evaluated.

Slide 22

Next, let's review Pre-market and Post market Inspections. These Inspections are generated by a CDRH Assignment and are conducted in accordance to our Premarket Approval Program, also referred to as a "PMA". A PMA Inspection is conducted before a new Medical Device is legally marketed. These Inspections focus on the firm's validation processes. After the new device is on the market for about a year, we'll usually conduct a post-market surveillance inspection. Post-market inspections may cover a variety of areas, however, we generally focus on changes in processes, changes in design, and evaluation of post-market data.

Slide 23

We also conduct "Foreign Inspections". As the name implies, a foreign inspection takes place in countries other than the United States. We do these inspections when a firm wants to import, or already imports a medical device into the United States. These inspections can be conducted as a routine or Surveillance Inspection but may also be directed inspections.

Foreign inspections are always pre-announced well in advance to accommodate the extensive travel logistics required for us to travel abroad. These inspections are conducted as Comprehensive Inspections.

We do not issue the Form FDA 482, "Notice of Inspection" at the start of these Inspections. However, we may issue Form FDA 483, "Inspectional Observations", if observations are found. If significant observations are found, these Inspections may be classified as "Official Action Indicated" and may result in regulatory actions, such as an Import Alert, with or without detention, a Warning Letter, or an Untitled Letter.

Slide 24
Now, I would like to outline what generally happens during the inspection process. I'll describe what happens before, during, and after an inspection.

Slide 25
There are several things we do to prepare for an Inspection before we arrive at the firm. We determine if the firm is participating in the Medical Device Single Audit Program, also known as MDSAP.

If the firm is part of this Program, we only conduct an inspection if the device falls under the EPRC regulations, or if there's an assignment to conduct a directed inspection. To gain a better understanding of the firm were going to inspect, we obtain background information on the firm. We review the firm's current Establishment Registration and Medical Device Listing. We review our internal databases for MDRs and Recalls related to the firm. We review past Establishment Inspection Reports and prior 483 observations. We may also review the firm's website for current marketed products and advertising.

Slide 26
After our prep is complete, we determine if we need to Pre-announce for the Inspection. The Pre-announcement is designed to give companies enough time to ensure they have the proper staffing and documentation readily available once the inspection begins. When we pre-announce the Inspection, we also obtain some general information, such as confirming the firm's operational status, and determining if the firm continues to manufacture or design FDA regulated products. We typically pre-announce 5 days before the anticipated start of the inspection.

During the pre-announcement, we explain the type and purpose of the Inspection, including the expected duration of the Inspection. We may also request some documents at this time, such as the Quality Manual.

Routine inspections are normally pre-announced. Directed inspections may be pre-announced or un-announced. This depends on the urgency of the inspection, or if there are any potential allegations against the firm that may warrant an un-announced visit, such as a complaint allegation. Compliance Follow-up Inspections, where a previous Warning or Untitled Letter was issued, are typically un-announced.

Slide 27

Once we arrive at the firm, we present our FDA Credentials and issue the 482 Notice of Inspection to the most responsible person present at the start of the Inspection. We always attempt to issue the 482 to the President or CEO, but if that person is not present, then we issue to the most responsible person available. Usually, the firm has an Opening meeting and we obtain general administrative and operational information we need, such as: the hours of operation, the size of the firm, the firm's contact information, the number of employees, the percentage of interstate commerce and an overview of the current product lines.

Slide 28

After we obtain general information, we like to get an understanding of the products and the manufacturing operations. A walk-through of the facility allows us to see and better understand the firm's operations. It's also helpful to provide product demonstrations so we can understand how the device is designed, and how it operates. We conduct our routine Inspections using the Quality System Inspection Technique process, also known as QSIT. We follow internal Compliance Programs that provide us with inspectional guidance and objectives. We are also trained to follow leads as they are encountered, which may alter our inspectional strategy to ensure appropriate coverage.

During an Inspection, we may request copies of documents to review further. These documents may include: procedures, validation records, test data, product & design records and training records. We may request these in hard copy and electronic formats. Some records will be used to support violations. Some records will be used during the writing of our reports, and some records may not be needed after our review and may be returned or shredded. It's helpful when requested documents are provided promptly.

Slide 29

So, how can you help us during an inspection? There are few things you can do. Have your medical device available for us to review. Show us how it works. If you have a video, that would also be helpful. Make a team available that understands the Quality System and related document, so they're ready to answer questions we may have.

Retrieve and provide requested documents in a timely manner. It's also important to understand that we may use different terminology than what you use. If you don't understand what is being asked, please ask for clarification. Communication is often one of the biggest obstacles we encounter during an Inspection. Please use this opportunity to have open dialogue with the CSO to determine exactly what is being requested. When answering questions, please give straight-forward, honest answers and try to avoid over explanation. It really is Ok to say, "I don't know" or "I will have to ask". It's far better to wait for the correct answer, rather than providing potentially incorrect answers, which may lead us down the wrong path and lengthen the Inspection process.

Slide 30

Next, let's talk about what happens at the end of the Inspection. Typically, the CSO and the firm hold a close-out meeting at the end of the inspection. The Close-Out meeting is usually attended by both the individuals who participated in the Inspection, and the firm's management. However, the number of the firm's attendees for this meeting is at the discretion of the firm. During this meeting, the CSO discusses all the inspectional findings with the firm.

If Observations are found during the Inspection, the CSO may issue a 483. The 483 communicates our inspectional observations by incorporating both the Regulation and examples of how the firm failed to meet the Regulation. The 483 is issued to the top management official who is present at that time. The CSO will explain both the Observations and the FDA's potential administrative and regulatory options. If the observations are significant and could escalate the inspection to require further regulatory action, we may need to collect additional documents, like interstate records, and we may obtain an Affidavit.

Slide 31

On the next two slides, we'll look a little closer at our Inspectional Observations. All potential inspectional observations should have been discussed with the firm during the Inspection. There should be no surprises when the 483 is issued. Observations on the 483 are typically listed in order of significance. The 483 should be factual, clear and concise. There may be some deficiencies that will be discussed and included in the final Report, but do not appear on the 483. These deficiencies may be significant but may require further FDA Center concurrence prior to placing on the 483.

Some examples include: labeling or marketing issues, lack or incomplete 510(k)s or PMAs, and some Correction and Removal issues. We may also have deficiencies that are minor and not systemic. We may decide to discuss these items with the firm, rather than listing them on the 483.

Slide 32

When we issue the 483, we give the firm the option to "annotate" each observation. These annotations are canned statements the firm can select, with concurrence from the CSO. These annotations are "Reported corrected, not verified"; "Corrected and verified"; "Promise to correct"; or "Under Consideration". If "Promised to correct" is selected, the firm has the option to add a date or a timeframe by which they believe they can correct this observation. The firm also has the option to not provide any annotation.

The CSO will explain how to voluntarily respond to the 483 Observations. The firm's responses are directed to the ORA Division's Compliance Branch. If the firm would like their response to be part of the Compliance Branch review, the firm would need to submit their response within 15 business days from the date the 483 is issued.

Slide 33

We've explained what happens before and during the inspection. Let's wrap up and talk about what we do after the inspection is completed. After the inspection, the CSO writes the Establishment Inspection Report, or EIR.

In addition to writing the EIR, the CSO also proposes an initial recommendation for the inspection classification. These classifications are more commonly known by their acronyms: NAI, VAI or OAI. "NAI", or No Action Indicated, usually indicates that no 483 was issued, or there were no significant verbal discussion items. "VAI", or Voluntary Action Indicated, usually indicates that a 483 was issued. "OAI", or Official Action Indicated, usually indicates that observations found are significant and may warrant regulatory action.

The EIR is routed to the first line Supervisor for review and endorsement. If the CSO recommends a classification of "OAI" and the Supervisor concurs, the EIR is forwarded to the Compliance Branch to determine if further regulatory actions are needed. Observations classified "VAI" are typically followed-up during the next Inspection. After the inspection close-out meeting, the CSO usually does not communicate further with the firm. Any further communication with the firm after the inspection is typically done by the Compliance Branch.

Slide 34

Let's go back and say a few more things about the EIR. The EIR includes the purpose of the Inspection, updated administrative data, and current management responsibility at the firm. We also include any updates to the firm's history of business and operations. We explain what exactly was covered during the inspection.
We also include a section explaining any Observations found, along with the firm's proposed corrections and responses, if available.

The EIR also includes Documents collected during the Inspection to explain a process or to support a violation. These Documents are referred to as "Exhibits". We also can include "Attachments", which are Documents related to the Inspection, but not collected from the firm. Examples include: FDA memorandums with inspection information, Charts created by the CSO, and Trade Complaints received by the FDA. The EIR is entered into an electronic database to be accessed by other groups within FDA, and as an historical record to file.

The time it takes to write the EIR depends on several factors, such as the length of the inspection, the observations found, the complexity of the inspection and the potential inspection classification. If the Inspection is classified VAI or NAI, the first line Supervisor releases a copy of the EIR to the firm. Firms do not receive a copy of the EIR if the Inspection is classified OAI. Also, the firms do not receive copies of the Exhibits or Attachments, regardless of the inspection's classification. The process we follow for releasing a copy of the EIR is directed by the Field Management Directive 145, also referred to as FMD 145.

Slide 35

Here, I'd like to highlight a couple of the most commonly used reference documents related to the inspection process. The first resource is the "Investigations Operations Manual", also known as the "IOM". This is our primary operational guide. It directs the conduct of all fundamental field investigational activities. This manual is publicly available at the website listed on the screen. The IOM is updated at least annually.

CSOs also use the Quality System Inspection Technique Guide, which we refer to as "QSIT" for certain Inspections. The QSIT guide defines and directs the Inspection process for most medical devices. The QSIT guide is also public information and can be found online at the website listed. There are many more FDA Guidance documents and Compliance Programs we may use to conduct Inspections. You can find them on the FDA website.

Slide 36
Let's recap what we reviewed in this presentation. We covered the main responsibilities of a CSO. While the CSO may have a variety of work to complete, the majority of the CSO's time is spend conducting inspections. CSOs conduct a variety of Medical Device Inspections, and each inspection type has a specific purpose. And finally, there is a general sequence of activities that occurs before, during, and after an inspection.

Slide 37
Now that you have a better understanding of what a CSO does, let's conclude with your call to action. Become familiar with the various types of inspections you may encounter. Be responsive to requests during an inspection to facilitate the inspection process. Encourage an open dialogue during your inspection to ensure that everyone involved clearly understands what is being asked. Don't be afraid to ask for clarifications. And view the other modules in this series to learn more about the other Medical Device program staff roles.

Slide 38
Here's the list of the other Medical Device program roles we cover in the separate modules within this series.

Slide 39
Thank you for joining us. Have a great day!

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