ORA - A Day in the Life: Supervisory Consumer Safety Officer
Module #3

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Hello, my name is James Hildreth, and I'm a Supervisory Consumer Safety Officer in the Office of Medical Device and Radiological Health Operations at the Food and Drug Administration, or FDA. Today, I'll be giving a presentation on A Day in the Life of a Supervisory Consumer Safety Officer, or SCSO. This role is also sometime referred to as a First-line supervisor.

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This is the third module in a five-module series portraying a day-in-the-life of a staff member employed in the medical device program. Please see the Introduction module for general information about our operations.

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Here are the learning objectives for this presentation. First, we'll define what a supervisory group may look like for an SCSO, as well as some of the characteristics of that group. We will outline some of the general responsibilities common to most, if not all, SCSOs. We'll cover some additional responsibilities that may be assigned to SCSOs, but that are either infrequently conducted, or are not common to most SCSOs. Finally, we'll describe the SCSO activities and roles related to an "Official Action Indicated" case, where regulatory action is being recommended.

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Let's start with some background about the group led by a Supervisory Consumer Safety Officer.

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A First-Line supervisor like myself generally oversees 8 to 12 employees, all of who work in the medical device program, including work related to the Mammography Quality Standards Act, or MQSA. The majority of these employees are Consumer Safety Officers, who, among other things, conduct inspections and investigations.

All supervisors manage CSOs in the same commodity area. For example, in my case, this is medical devices. A supervisor's group may also include support personnel, such as Consumer Safety Technicians, who do not generally conduct inspections.

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A supervisor may have CSOs located across multiple states, including multiple time zones, or all within a small geographic area. Currently, most, if not all, supervisors have at least one CSO located in a different office than them. Employees in a group may have different levels of experience and training, ranging from new employees with little knowledge of FDA and program operations, all the way to specialists, who are generally the most experienced and knowledgeable investigators in one or more program areas.

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This is a map of our three division's geographic boundaries. A single SCSO may have staff anywhere within a division. For example, a first-line supervisor for Division 3 may be physically located in Dallas, Texas, but have CSOs stationed in Los Angeles, California.

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Next, we will talk about the core responsibilities of a Supervisory Consumer Safety Officer.

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My responsibilities as an SCSO generally fall into four categories. The first are those activities related to core inspectional and investigational operations, identified here as Field Surveillance Management. I also have a number of responsibilities that are general, uncommon, and infrequent. Let's review each one of these categories one by one.

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Starting with Field Surveillance Management, these activities directly relate to field operations such as medical device inspections by the group. I'm responsible for prioritizing and assigning work to my group, such as inspections and investigations. Prioritization is based on several factors. For example, a preapproval inspection for a Premarket Approval application, or PMA, generally must be completed within certain timeframes and may assume a higher priority than a routine surveillance inspection.

Likewise, follow-up to a complaint alleging a device-related patient death may be assigned a higher priority for completion than other routine work.
Assigning work can take into account a number of factors, such as considerations for the priority and deadline of the operation, the availability of local resources, and the experience or training of a particular investigator. I'm also required to monitor the performance of inspections, such as ensuring operations are completed by the deadline, and reassigning work based on the availability of the investigator and the need to complete higher-priority work.

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Field surveillance work includes providing operational direction and guidance to the CSOs, as needed. I will generally communicate with my direct reports on at least a bi-weekly basis to discuss a variety of operational-related topics. These discussions could include new guidance, new procedures, or best practices. The communications may be in a one-on-one setting or in a group setting, depending on the information being communicated.

For example, general guidance on the use of an FDA-specific database may only apply to a new employee, whereas a newly released guidance document would likely be applicable to the entire group. Depending on the operation, I may need to meet with my staff to discuss the inspection assignment. I'm responsible for arranging communications between the CSO and anyone else necessary, as well as providing necessary assignment information to the investigator. I'm responsible for providing guidance or clarification about the instructions for an assignment, as needed.

During an inspection, my CSOs may reach out to me for guidance on a specific issue encountered. For new hires, these issues may be relatively straightforward and require little investigation to answer. For more experienced CSOs, the issues may be quite complex; in such cases, I'm responsible for reviewing applicable documentation and contacting necessary personnel to obtain the best answer. Although I work hard to get the answer quickly, it may take some time before I can provide a CSO the proper guidance on their inspection.

For an inspection with significant issues found, I may speak with my staff about their observations, and, where needed, involve additional agency components, such as the compliance officer or the involved FDA Center. These communications may help to clarify the issues identified by the CSO, provide inspectional guidance, and ensure the collection of necessary evidence to allow review of the issue post-inspection.
I will very rarely communicate with a firm directly, and even less commonly during an ongoing inspection. Generally, I will provide guidance to the investigator that can then be relayed to the firm.

Post-inspection, I may arrange meetings about findings, evidence developments, and case issues, depending on the nature of the inspection and the specific circumstances. Some guidance I provide may be applicable if the firm, or a similar firm, is encountered in the future. I also review reports, memos, and other work products for completeness, suitability for use, and adherence to applicable policy, procedure, and guidance. These reviews may be simple for an Out of Business memo or could take many hours for the review of an inspection report where significant regulatory action is being recommended. Depending on the experience of the investigator and the work product, it may require multiple drafts by the investigator, and subsequent review by me, before that work product is able to be endorsed.

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I'm responsible for recommending actions based on the information provided by my CSOs, in accordance with various policies, procedures, and guidance. These recommendations are not binding, but they do guide the next steps in processing a work product. For example, review of a memo to put a firm out of business could include notifying administrative personnel to cancel the firm's registration and mark them as "out of business" in our inventory.

For an inspection with significant deficiencies, it could include notifying other parts of the FDA. For example, internal notification may be made to the Compliance Branch that the inspection should be reviewed for the possibility of issuing a Warning Letter, or external notification made to another program if the firm's operations cover multiple product types. Some operations may even warrant communication with other federal agencies, or state or local law enforcement, depending on the circumstances and severity of the issues identified.

I'm also responsible for releasing Field Management Directive-145 copies of inspection reports when the inspection has been classified as No Action Indicated, or Voluntary Action Indicated, and no further actions are pending before the agency. I need to be familiar with the Freedom of Information Act and first-party redaction guidance to ensure appropriate information is released to firms.

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Like a typical manager in any organization, I'm responsible for evaluating and documenting my employee's performance. Where performance is unsatisfactory, I'm responsible for taking actions to address this deficiency. This could include formal or informal performance reviews and actions. Where performance is above average, I try to find ways to recognize, and whenever possible, reward the investigator for good work.

I ensure that new CSOs receive adequate training, whether it be classroom, online, or on-the-job. ORA has a rigorous new-hire training program spanning many months, but I am ultimately responsible for ensuring that new hires complete required training. I arrange discussions with subject matter experts and schedule on-the-job experiences to meet the program's requirements.

I ensure that experienced staff have opportunities to further develop their skills and have more responsibility for more complex products, such as electronic product radiation control inspections. These development activities can be through direct work assignments or training courses.

I provide status updates on specific operations or on certain operational metrics tracked by management and Senior Leadership. I also generally communicate as needed to ensure all supervisory groups are achieving shared goals. Some of these metrics are routinely tracked and requested, others may be requested on short notice or be of a type not routinely tracked, requiring compilation of the data.

As a supervisor, I am responsible for providing information to industry and trade groups as needed. This can take the form of formal presentations such as this one, informal talks, or telephone communications. I also lead, or participate in, various internal work groups. These work groups may include activities like an initiative to improve FDA processes, or developing and reviewing policy documentation. External workgroups could include activities like developing training or certification programs.

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First-line supervisors will also have some infrequent responsibilities, which might be only done a few times a year or once every few years. For example, I may be requested to assist in certain regulatory actions, such as attending a regulatory meeting with a firm at the request of our Compliance Branch. I may need to coordinate disaster response or emergency efforts in my local area or elsewhere in the division; this can include ensuring local firms are either not affected by the disaster, such as a fire or flood, or are taking the proper steps to address any affected product or operations. Disaster response can also include providing staff to assist in the effort, as applicable.

Finally, I'm responsible for auditing the work of my staff. This may include on-site audits of new and experienced CSOs to ensure that the inspections are being conducted in accordance with established requirements. These audits can be less formal, routine checks, or they could be quite comprehensive, as is the case with certification audits which are used to ensure that new investigators are able to perform FDA inspections.

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Some responsibilities may only apply to a limited number of first-line supervisors. For example, I may be asked to review complaints sent to the FDA and determine the need for investigative follow-up. I'll assign any required follow-up by my staff as needed. I may be asked to monitor "Import for Export" shipments, where regulated product enters the US for processing, but is intended only for export to other countries.
In this case, I'll determine whether domestic follow-up at the processing or distribution site is required. Some SCSOs may be delegated to receive requests for checks of recall effectiveness and ensure assignment of those checks to one or more CSOs to meet internal deadlines.

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A Supervisory Consumer Safety Officer may have some uncommon responsibilities. These may include tracking and distributing information about MDSAP participation of local firms. MDSAP stands for the Medical Device Single Audit Program. Where notification is provided that a firm has entered the program, I may need to notify the investigator or their supervisor of the firm's status if a routine inspection is currently planned. When MDSAP participation is discovered during preparation for a routine inspection, I'll typically provide an alternate firm to inspect.

Some states may be contracted to perform FDA inspections. In this case, I monitor these inspections and evaluate the inspection reports before acceptance by the FDA. ORA has small satellite offices called resident posts. Many times, these posts don't have the administrative resources of a larger office.

Responsibility for the operation of these posts may be assigned to a local SCSO to make sure that administrative processes, such as maintenance of the government owned vehicles, are addressed. These uncommon responsibilities are just examples; additional uncommon responsibilities may be assigned to one or more supervisor when needed to ensure that program objectives are met.

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Let's wrap up this presentation with a case study example involving an inspection classification of Official Action Indicated, or OAI.

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OAI is an inspection classification used by the FDA to indicate that significant issues were found during an inspection, and that regulatory action is warranted, such as issuance of a Warning Letter. If a CSO is conducting an inspection that will likely be classified OAI, they will usually contact me during the inspection to explain the findings and discuss any issues with the case. I, in turn, will discuss any next steps needed for the CSO to complete the inspection and submit the report for review.

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After speaking with the CSO, I may contact other offices such as Compliance Branch or CDRH, depending on the nature of the issues and who generated the assignment, to notify them of the potential issues and obtain any further guidance. These contacts may take place during the inspection.

In this case, this may also involve setting up conference calls or other communications between all involved parties. In some cases, the issues the CSO has developed will be shared with other involved personnel for their awareness of the situation prior to completion of the inspection. The exact communications needed are determined on a situation by situation basis, but I'm primarily responsible for reaching out to those contacts.

Depending on the circumstances, I may also ask to review the draft Form FDA 483, inspectional observations, that the CSO is planning to issue to the firm. Once the CSO has completed the inspection and any necessary evidence collection, they will present the 483 to the firm and hold the closeout meeting with management.

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The Consumer Safety Officer then prepares and submits the Establishment Inspection Report, or EIR, to me. I then review the EIR and the evidence collected by the CSO. This review can be very detailed, as the EIR may include hundreds of exhibits in addition to a lengthy narrative report. After I complete my review, I'll work with the CSO until the draft EIR is ready to be endorsed.

Once finalized, I endorse the report with recommendations for classification and action by compliance branch or the FDA Center. After endorsement, the EIR is routed for further review and final classification. The report is routed to Compliance Branch, where the assigned Compliance Officer or CO, further reviews the case, the evidence, and the recommendation. The CO will make the final decision on the inspection classification and process any approved regulatory actions.

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In summary, I discussed how the SCSO manages a team responsible for various field activities, and has a number of responsibilities, including both common and less common. I also discussed the general steps to handling an OAI case, particularly those operations that are the responsibility of the SCSO, such as collaboration and communication with FDA groups.

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Let's conclude with your call to action. First, learn and understand the role of a Supervisory Consumer Safety Officer and how you might interact with this FDA official. And second, please watch the other four modules in this series to learn more about the other staff roles in the medical device program.

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The next modules will focus on the roles and responsibilities of the Compliance Officer and Recall Coordinator. We hope viewing the varied responsibilities of these staff members will give you an idea of what a day in their life may look like.

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Thank you for joining us for this module on Supervisory Consumer Safety Officers as part of the Day in the Life series. Have a great day.