A Day in the Life: Compliance Officer
Module #4

Slide 1
Hello, my name is Charles Chacko and I am a Compliance Officer at the Office of Medical Device and Radiological Health in Division 3. This presentation will explain the roles and responsibilities of an ORA Compliance Officer. I'll highlight what a Compliance Officer does on a day-to-day basis to protect and promote public health.

Slide 2
This infographic provides a description of the functions of ORA's Compliance Branch and Compliance Officers. As the great 20th century world leader, Winston Churchill, famously said, "All I want is compliance with my wishes, after reasonable discussion." This statement briefly characterizes our main goals: First, we aspire to do the right thing within the regulatory framework. Second, we care about making differences in the lives of people by protecting and improving their health and well-being. And, finally, we believe in the value generated from meaningful discussions, decisions, and compliance actions.

Slide 3
This is one of five modules as part of the "Day in The Life" presentation series, presented by FDA's Office of Regulatory Affairs. I'll share the perspective of a Compliance Officer during this module.

Slide 4
This slide highlights the learning objectives of this presentation. I'll describe the responsibilities of a compliance officer. I'll then explain what happens after FDA completes an inspection. I'll discuss the various regulatory actions FDA may take, and the factors used to guide which ones we use. I'll identify various tips for effective communication between a firm and FDA involving a regulatory action. And finally, I will be showing a hypothetical compliance case example to help translate our learning objectives in a practical way.

Slide 5
I'll begin by describing the daily roles and responsibilities of a Compliance Officer.

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A Compliance Officer has various responsibilities. For example, I'll review and evaluate evidence and findings from an inspection. My evaluation will also include reviewing the firm's inspectional and compliance history, consumer complaints, voluntary recalls, and Form FDA 483 responses, in addition to the information from the current inspection. After my review, I'll determine the most suitable course of action. I'll prepare recommendation memos which describe the inspectional findings, violation charges, history, firm's response, and other key elements for recommending a regulatory action. I'll recommend regulatory actions to the responsible FDA Program Center.

These recommendations could include issuing Warning Letters, holding Regulatory Meetings, and recommending product seizures or injunctions to address serious violations.
Also, I may confer with FDA's Center for Device and Radiological Health, or CDRH, for concurrent review and approval when needed. I'll monitor and manage regulatory and enforcement actions such as Warning Letters, Seizures, or Injunctions. Compliance Officers will often work with the firm to provide clear agency expectations of the firm's progress toward compliance. I'll also interact with division, district or center office FDA officials often to coordinate cross-cutting work across these offices.

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I meet and collaborate with firm representatives during various types of meetings and conferences to provide regulatory education and insight. **I** ensure establishments in nonconformance bring their operations and practices into compliance. I answer inquiries from federal, state, and local agencies. If there are cross-agency tasks to be completed, FDA will work with the responsible agencies to accomplish this work. And, finally, I handle inquiries from internal and external stakeholders related to consumer complaints, FDA policy guidance, and establishment inspections.

Slide 8
Next, we will look at what happens after an inspection is completed. I'll highlight the typical post-inspection process at FDA's Office of Regulatory Affairs.

Slide 9
Here is a short flow diagram to explain what happens once the inspection is complete. After an inspection is complete, the FDA investigator begins writing the establishment inspection report, called the EIR. The EIR documents the facts and information obtained from the completed inspection along with any inspectional findings. The supervisory consumer safety officer, called the SCSO, reviews the EIR to determine if the facts and evidence associated with the findings and the inspectional summary match with the observations made during the inspection.

If significant findings are identified and documented on the Form FDA 483, the supervisory consumer safety officer will notify the Compliance Branch, so both branches can agree to an appropriate course of action.

The Supervisory Consumer Safety Officer endorses EIR and recommends the inspection be classified as Official Action Indicated. Next, the Director of Investigations Branch, called the DIB, will review the OAI, or Official Action Indicated, inspection report. This final review is conducted by top management in the Investigations Branch to determine if the inspection warrants compliance review and regulatory action by the Compliance Branch. The inspection is then sent to the Compliance Branch to evaluate if the firm is in violation of the FD&C Act or other statutes.

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Once the inspection has been classified as OAI, Compliance Branch will review the EIR, Form FDA 483 observations, and related documents to determine if the evidence and findings warrant further action. A Compliance Officer will be assigned to review the inspection report and all supporting documents. We maintain all our case work in an electronic system called Compliance Management System, or CMS. CMS is a legal file repository application for Compliance Officers to keep track of all documents and records associated with the case and to monitor the case to completion. The compliance review process includes review of the completed EIR and its related exhibits and attachments.

A Compliance Officer also must consider benefit/risk of the products, current establishment inspection history, regulatory history, Form FDA 483 observations, firm response and corrective actions. All these elements are carefully assessed to determine an appropriate compliance decision and regulatory strategy.

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Compliance Officers typically spend a majority of their time on OAI cases, determining whether a regulatory action is warranted and monitoring such actions. However, another task we perform is by reviewing the firm's Form FDA 483 responses and acknowledging them via our response letter. An acknowledgement letter is issued to the firm confirming receipt of firm's response and providing general feedback and comments.

Slide 12
Next, we will outline the process for supporting a regulatory action. We use regulatory actions to achieve our primary goal of voluntary firm compliance.

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Compliance Officers base their recommendation on several factors. Let's look at each of these determining factors now. First, I'll determine whether the observed violations pose a risk to public health, and whether the significance of the violation warrants regulatory action. Next, I will review the evidence.

The evidence and facts observed need to correspond and support the recommended charges. For example, filth and insanitary conditions charges are directly associated with adulteration. False or misleading labeling and inadequate directions for use charges are directly related to misbranding. Evidence of Quality System Regulation or Good Manufacturing Practices violations are associated with adulteration charges.

If the evidence supports a violation, I'll determine if the firm did or did not correct the deficiencies during the inspection. Also, I will look for repeat deficiencies of the same or similar problems from previous inspections. Finally, any documentation of prior warnings to the firm and the firm's promised corrections are also evaluated as possible support for a regulatory action.

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The Compliance Branch's Regulatory Procedures Manual, or RPM, provides guidance on factors needed to support a regulatory action. These are the general factors we consider. First, the evidence needs to show that a firm, product, and/or the individual is in violation of the law or regulations. The evidence also needs to show a failure to achieve adequate and prompt correction. This lack of correction may result in consideration of an enforcement action.

Next, the violation needs to be of regulatory significance and the issuance of a Warning Letter is appropriate. Finally, there needs to be a reasonable expectation that the responsible party will take prompt corrective action.

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The Compliance Officer also reviews more specific factors to ensure the case warrants regulatory action. I'll research if any prior compliance actions were taken against the firm in relation to violations of the law. I'll determine if those violations impact the problem at hand and any products that have been distributed. I'll decide if we need to discuss the need to voluntarily recall products from the market.

If the firm has conducted a prior recall, I will determine if the current violation is related to recalled finished product or components. I will also review any documentation related to the correction and removal process to ensure the correction was effective. Next, I'll consider the benefits and risk associated with the product. We may need to conduct a risk-based assessment to determine the benefit and risk of the product.

I'll assess the firm's corrections and/or corrective actions and their reported timeframes. To be clear, corrective actions will not prevent the FDA from issuing a regulatory action based on evidence of observed violation. Finally, I'll determine if firm's corrective action produces compliance with applicable laws and regulations.

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If the firm has already completed their corrective actions, I'll review those corrective actions to determine their adequacy and effectiveness. Any ongoing or planned corrective actions does not prevent consideration for issuing a regulatory action. The Compliance Officer may use an acknowledgement letter to communicate the results of their review to the firm. This letter acknowledges the agency's receipt of firm's response to the Form FDA 483 observations. This letter also provides feedback on the firm's corrections. If corrections are determined to be inadequate, unresolved observations will be summarized and additional or specific information needed will be requested for review. Additionally, these correction actions will be reviewed and verified for adequacy during future inspections.

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Finally, one remaining factor to consider is the verification of correction actions. I'll determine if firm's correction is adequate using the firm's verification process. We may schedule an accelerated or routine compliance inspection at the firm to determine the completeness and effectiveness of the corrective actions.

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This slide is a general case flow diagram which describes the stages of a compliance case starting from the end of an inspection until the case is closed. This diagram illustrates two possible outcomes for a compliance case.

Both outcomes start with the end of the inspection and a recommendation to classify the inspection as OAI. Then, the Compliance Branch receives the inspection, completes their compliance review and produces a recommendation memo. After the recommendation memo, there are typically two paths the case could take. The first path shows a regulatory action against a firm followed by a re-inspection or compliance follow-up at the firm to verify that corrections have been implemented. Then, the action is closed. The second path occurs when no regulatory action is taken against the firm and the case is downgraded to a lower classification.

The Compliance Branch will then notify the Investigations Branch of the downgraded classification. The Compliance Branch will also notify the affected firm via an acknowledgement letter. Then, the action is closed.

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Now that we have covered the compliance review process, let's take a closer look at some of the commonly used compliance actions available to FDA. We'll look at each one of these in more detail in the next slides. The FDA has been given the authority to utilize these compliance actions based on evidence and inspectional findings. The agency uses firm warnings and advisory actions to bring the firm into compliance and prevent a public health risk.

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One of the most commonly used regulatory actions is the Warning Letter. A Warning Letter is an official letter from the FDA to a manufacturer or other organization that has violated the law in a federally regulated capacity. Warning Letters are issued to achieve prompt voluntary compliance, to ensure the scope and seriousness of the non-compliance is understood by the firm and to list Food Drug & Cosmetic Act violations, including their descriptions.

These specific Warning Letter elements have originated because of precedent cases like Dotterweich & Park Case Law, where the premise of the case law stipulates that we always issue our Warning Letters to top management.

The Warning Letter is specifically addressed to the top management official because if the firm fails to take appropriate action, we may need to take additional regulatory action.

Under the FD&C Act, civil or criminal actions may be pursued without proof of either intent or awareness of wrong doing by the defendant. Since the agency does not need to prove intent, the Warning Letter provides prior notice to the firm for any other type of potential action in the future.

For some situations, like novel technologies, approvals, and labeling claims, a Warning Letter may also require CDRH's concurrence. For other situations like Good Manufacturing Practices violations, Warning Letters may be issued directly from ORA. The device program management has direct reference authority for issuing Warning Letters without CDRH's concurrence in these cases.

Since Good Manufacturing Practices violations are developed with work done solely within ORA, the case can be processed from inspection to Warning Letter entirely within ORA. All FDA-issued Warning Letters are redacted and then posted on FDA's Warning Letter webpage. The public can obtain a copy directly from the website. If the Warning Letter is not yet posted, you can request a copy from FDA through a Freedom of Information Act request.

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As stated previously, Warning Letters are the most common regulatory action taken in Medical Device Program area. On an average, approximately 30 domestic and 40 foreign Warning Letters are issued per year. Warning letters are frequently issued for Quality System Regulations violations. In fact, 7 out 10 Warning Letters issued for Quality System Regulations are for violations in the two subsystems of Production and Process Controls and Corrective and Preventive Actions.

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Another option that Compliance Officers may consider when reviewing an OAI inspection is to have a Regulatory Meeting with the firm. A Regulatory Meeting is to inform the firm and its responsible individuals that one or more of the firm's products, practices, or processes are in violation of the law.

The intent of the meeting is to have a real-time dialogue concerning these issues and to work with the firm in obtaining prompt voluntary compliance. The meeting is also to provide prior notice of potential future action, to review the deficiencies, to review FDA Form 483 responses, to outline expectations for adequate corrections, and to discuss next steps. If a violative situation does not present a danger to health or does not constitute intentional, gross, or deliberate violations, this meeting affords individuals and the firm the opportunity to voluntarily take prompt corrective action prior to the initiation of enforcement actions such as Seizure, Injunction or Civil Money Penalties.

During a Regulatory Meeting, we typically inform the attendees that FDA personnel are not consultants. We typically recommend the firm seek consultants or outside resources, if they need assistance achieving compliance. We would also inform the firm that they are obligated to review the applicable regulations to determine the best way to meet that regulatory expectation.

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FDA has several other regulatory actions that we use infrequently. The purpose of a seizure is to remove specific violative goods from commerce. It is intended to take quick control over the violative product by placing it under the possession or custody of the court. FDA may seek an injunction against an individual and/or a corporation to prevent them from violating or causing the violations of the FD&C Act. If an establishment has a continuing pattern of significant deviations despite past warnings, an injunction may be recommended.

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We also may consider prosecution against an individual. Misdemeanor convictions, which do not require proof of intent to violate the FD&C Act, can result in fines and imprisonment up to one year. Felony convictions, in the event of a second violation or intent to defraud or mislead, can result in fines or imprisonment up to three years.

We may impose Civil Money Penalties. Such penalties are used to eliminate the profit from violative activity and/or provide non-compliant individuals or firms with the financial incentive to correct violations.

Finally, we may issue an Administrative Detention Order. This order broadens the FDA's ability to ensure the safety of regulated products for U.S. consumers by removing the product from the marketplace.

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Next, we are going to walk through a hypothetical compliance case example associated with a firm that manufacturers an anesthetic gas analyzer device. I'll explain how a Compliance Officer would typically conduct a review and make final decisions of an incoming compliance case.

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The next few slides will highlight how a case flows through the compliance process. In this example, the device is an Anesthetic Gas Analyzer. The device is used to monitor airway gases and/or assisted respiration. It is used in a fixed location such as an Operating Room or Intensive Care Unit to monitor patient's blood levels of gases such as Oxygen, Carbon Dioxide, Nitrogen Dioxide, and other anesthetic agents, during a medical procedure that involves the use of general anesthesia.

During the Pre-Inspectional Preparation**, t**he Investigations Branch would determine through their annual workplan if an FDA inspection is required at the firm that manufactures this product. The FDA investigator would start preparing for the inspection by determining the type of establishment inspection required, reviewing associated files for the firm, reviewing the firm's inspectional/compliance history and reviewing FDA's guidance documents.

There are multiple FDA guidance documents that the investigator reviews, including the Investigations Operations Manual, or IOM, the Compliance Program Guidance Manual, or CPGM, and other related procedures that will help the investigator during the inspection.

Once the pre-inspectional preparation is complete, the FDA investigator will begin the inspection by issuing the Form FDA 482, Notice of Inspection upon arrival at the firm.

The authority to enter and inspect a firm is dependent upon the investigators showing their credentials and issuing an originally signed 482 to the top management official or it's designee for a domestic inspection. Foreign inspections do not require the issuance of a 482. However, the investigator's credentials are still presented to top management officials or it's designee.

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Once the inspection is completed, a close-out meeting is conducted at the firm. The investigator will discuss the progress of the inspection and any inspectional observations identified during the inspection. If the inspectional findings are significant and the firm is not in compliance with the regulations, the Form FDA 483, Inspectional Observations is issued to the highest management official or it's designee.

In our examples, the Good Manufacturing Practices observations are read and issued on the 483 to the firm. The option to annotate the 483 is offered to the firm. If the firm has promised and/or completed a corrective action for the 483 observations prior to the completion of the inspection, the 483 will be annotated with a standard list of options such as reported corrected, not verified; corrected and verified; promised to correct; and/or under consideration. The FDA will generally allow firms 15 business days to respond to the 483 observations.

Any firm responses received within the 15-business day window will receive an acknowledgement letter and will be considered during the compliance review to determine whether to issue a regulatory action. However, responses received after the 15-business day window may not be received in time to be part of the compliance review. Additionally, the FDA acknowledgement letter may not include feedback on the apparent adequacy of the firm corrections since a regulatory action may already be in progress. If the response is late, we typically evaluate the response along with any other written material submitted after the regulatory action has already taken place.

Once the establishment inspection report is endorsed by our Investigations Branch with a recommendation to be classified as OAI, the case will be referred to the Compliance Branch. The Compliance Branch will review any inspections observed to violate the quality system regulations and any inspectional observations cited for significant deviations from the FD&C Act.

In this example, the assigned compliance officer will review the inspection and all evidence on the identified significant Good Manufacturing Practices, lack of 510(k) notification and labeling claim observations with this medical device manufactured at firm ABC.

When considering a regulatory action, the compliance officer also reviews the firm's inspection and compliance history, types of high-risk devices covered during the inspection, lack of 510(k) premarket notification, the Form FDA 483 observations, significance of the violations, non-conforming products on the market, and any other available information.

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The Compliance Officer will then review the firm's corrective actions for the violations identified in the firm's Form FDA 483 response and determine if adequate corrections have been taken or if the firm has agreed to provided planned corrections. If a decision is made not to pursue further regulatory action because adequate corrective action has been taken, an alternative form of communication like a response letter or an acknowledgment letter will be issued to the responsible individual at the firm.

This letter will supplement the record of the violations and reflect the agency's decision to rely on the firm's actions and/or promises. However, in our example, a Warning Letter is recommended for firm ABC, based on the compliance review and the regulatory significance of the violations. We consider a Warning Letter as the agency's principal means of achieving prompt voluntary compliance with the FD&C Act.

When issuing a Warning Letter, we outline several factors. First, we detail whether the evidence shows that a firm, product, and/or the individual is in violation of the law or regulations. Second, we state the firm's failure to achieve adequate and prompt correction may result in consideration for an enforcement action.

Third, we outline the regulatory significance of the violations and the issuance of Warning Letter in accordance with agency policy. Fourth, we state the FDA has a reasonable expectation that the firm will take prompt corrective action. And finally, we request the firm submit their Warning Letter response within 15 business days. Once the Warning Letter has been issued, the firm is responsible for reviewing the Warning Letter and responding to the agency in a timely manner by completing corrective actions.

The firms are not required to work with consultants, but they can use consultants if assistance is needed to bring the firm into compliance.

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The overall completeness and effectiveness of the corrective action is verified during the next inspection. The timing of the inspection may be either accelerated or routine, based on the determination of the involved office and the Compliance Officer. A regulatory meeting with the firm may be held to discuss the need to adequately and promptly correct the observations.

After review of the firm's response, the involved office can request that the firm attend an on-site or remote meeting to discuss inspectional findings and the firm's corrective actions. There may also be discussion with the CDRH on subject matter review and 510(k) regulatory submissions.

In our example of the investigator observing 510(k) Clearance or Pre-Market Approval issues with the Gas Analyzer, CDRH would likely join the meeting to discuss regulatory submission requirements or technical information associated with the medical device or quality problem. The Compliance Branch is concerned with protecting the public health by giving individuals and firms an opportunity to take voluntary and prompt corrective action. Our expectation is that individuals and firms will voluntarily comply with the law. However, if the violation continues at firm ABC, FDA has the authority to initiate enforcement action if needed to protect the public health.

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Our next section will offer a few tips to effectively respond to regulatory actions.

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First, it can be helpful to know exactly what requirements apply to your product. Knowledge is the first step to following the requirements for marketing a medical device and establishing a robust quality system. But where do you start?
You can start by determine which federal regulations classify your device and how your device is classified. Next, research if your product requires a premarket submission before getting to market. This information will allow you to determine the correct regulatory submission path, for example, 510(k), PMA, DeNovo, or Humanitarian Device Exemption, or HDE.

You should be aware of the level of regulatory control applied to your product to ensure the safety and effectiveness of a given device. The next questions you should answer are related to the reporting requirements for your device. The requirements may vary based on the type of establishment and if you are considered a specification developer, manufacturer, or distributor of the product. You should determine if you must comply with Medical Device Reporting and the Quality System regulation.

You should research which regulations apply. The most common medical device regulations are Parts 803, 806, 807, and 820. Finally, you should research what labeling and claim requirements apply to your product under the law. The labeling for a device must be written according to regulations and included in your pre-market submission for approval.

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Once you understand the regulatory requirements for your product, it will be easier for you to respond to the FDA. Here are some tips for developing effective firm responses. If you agree to address the issue during the inspection, ask for the correction to be noted through the annotation process.

This annotation documents your willingness to promptly correct the observation. Your correction will either be verified during the inspection or at a future inspection. Ensure you address each noncompliance identified in the 483. Determine the root cause for any non-compliance. You must correct both the identified issues and any contributing systemic issues.

Remember to include any available data to support your corrective activities and decisions. Your corrective action needs to be comprehensive and accurate. Simply identifying the problem and having a plan for correction is not enough to prove resolution. You need to address the issue by identifying the problem and providing the solution through an evidence-based approach. Be sure to provide supporting documents that will facilitate the Compliance Officer's review.

When a CAPA observation is cited, you need to identify the corrective actions and implement them through an effectiveness check process. The corrective action should be verified and/or validated to determine its effectiveness and reproducibility throughout all the affected processes.

Corrected forms, procedures, labeling, memos and any other supportive documentation should be included with your response to provide evidence of corrective actions. Provide applicable procedures and records showing original and revised versions. Compliance Officers are looking for confirmation the firm understands the violations and are addressing them appropriately and systemically.

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It is important to set realistic dates, provide a timetable and meet your proposed timeframes. We understand that some corrective actions are not quick fixes - for example, if you need to do process revalidation. You may also need additional time to complete all promised corrective actions. In those instances, we would prefer updates to show that you are progressing and will alert us of any delays. The Compliance Officer is willing to work with you. We are willing to help you resolve problems that affect the protection of public health. We can point you to resources from the FDA website to use as guidance. If you need assistance and hire a consultant, please let us know.

Inspection findings that have been verbally discussed with you should also be corrected. Any uncorrected items may become a 483 observation during a future inspection. The Compliance Officer's review of a firm's response may include any pre-market issues, for example, a question regarding the need for a new 510k discussed with the FDA investigator during the inspection. We may review how you addressed the premarket issues and consult with our CDRH reviewer for feedback and approval.

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Here are some medical device resources available on the FDA website that can help you. These resources include guidance and advice on marketing your device products, following inspectional regulations and searching for official guidance documents. We also have contact emails to our Division of Industry and Consumer Education, or DICE, and Ombudsman groups who can help answer any questions and help you better understand FDA's regulations and policies.

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So, let's summarize what we reviewed in this module. First, a compliance officer is critical to protecting the consumer by assessing violations of the law and by assessing corrective actions to protect the public health.

Second, ORA issues advisory and enforcement actions as based on the product's health risk and violation of the law. Third, ORA's Compliance Branch communication strategies and risk-based enforcement actions help to reduce and prevent patient harm. And finally, Compliance cases aim to ensure a positive public health outcome.

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So, let's conclude with a call to action. You can make interactions with the FDA easier if you understand your regulatory responsibilities. It's also helpful to stay informed and use various FDA resources. You can also view the other modules in this series to learn more about the other individual OMDRHO staff roles covered in this series.

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This concludes the compliance officer module. Thank you for watching.

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