ORA – A Day in the Life: Division Recall Coordinator
Module 5

Slide 1
Hello, my name is Cynthia Aycock, and I'm a Division Recall Coordinator in the Office of Medical Device and Radiological Health Operations at the Food and Drug Administration, or FDA. Today, I will be giving a presentation on a day in the life of a Division Recall Coordinator, or DRC.

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This is the fifth of 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 program's operations.

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As a member of industry, have you ever wondered how you can expedite the processing of your recall? Once your recall gets submitted to your Division Recall Coordinator, what does a DRC do? We'll answer these questions for you later in this module.

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In this presentation, we'll cover the following learning objectives: First, we'll describe the basic duties of a Division Recall Coordinator. We'll identify and explain the different classifications of recalls. We'll explain what FDA does with a recall. We'll also describe the interactions between the firm and FDA, up to and including the termination of the recall. Finally, we'll discuss some common issues and questions about recalls.

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First, let's answer the question: "Where do I send my recall?"

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The medical device Recall Coordinators are employed within the FDA's Office of Regulatory Affairs, or O-R-A. ORA is aligned to parallel the regulated commodities for which FDA has regulatory oversight. This allows us to employ dedicated staff in each commodity area, such as drugs, medical devices, food, tobacco, et cetera. ORA has medical device recall coordinators who are solely dedicated to handling medical device recalls.

The medical device program has three divisions: Division 1 in the Eastern portion of the country; Division 2 in the Southeast and Central portion, and Division 3 in the West. This map indicates which states are assigned to which division. Please note that Puerto Rico is part of Division 2, while Hawaii and Alaska are part of Division 3.

The division which will handle your recall is determined by the state in which the recalling firm is located. Each division has medical device recall coordinators as part of their division's compliance branch staff.

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General inquiries about recalls, new recall submissions, status reports, and termination requests should all be submitted to your division recall coordinators.

To contact your DRCs, please send an email to the appropriate division group email address, as shown here. These email accounts are checked regularly. Using this email address is the most efficient method for contacting a division recall coordinator.

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Now that you know where to send your recall, let's discuss what a division recall coordinator does. The DRC is responsible for triaging new recalls. This process includes reviewing the information submitted by the firm and making a recommendation on the potential classification of the recall.

The DRC prepares and submits recall alerts and recommendations to ORA's electronic record system, where the Center for Devices and Radiological Health, or C-D-R-H, can then assess the information and determine the final classification. The DRC communicates regularly with both the firm and CDRH. The DRCs handle the coordination of the recall, which includes reviewing status reports and termination requests for each recall, preparing Classification Letters to inform firms of their recall's classification, and preparing Termination Letters once the recall has been officially closed.

A DRC may also assign audit checks to assess the effectiveness of a recall. So, as you can see, the DRCs are involved with your recall from the time you submit a recall to the time you receive the Termination letter.

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Now that we've had an overview of the DRC's duties, let's go into detail about what happens when you submit a recall to the FDA.

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The DRC may learn of a new recall through the firm's submission via email. Occasionally, the DRC may also learn of a new recall from a consumer safety officer, who notifies the DRC of an unreported recall action they discovered while in the field. We highly recommend emailing us your recall submission, as it is the most efficient way to ensure we receive the submission in a timely fashion.

Ideally, we prefer you notify us before you initiate the recall. Then, we can provide feedback on your customer communication and recall strategy. Please provide us with what you consider the final draft for your customer letter.

We'll review your proposed customer letter and provide feedback. We can also provide a straightforward template for the customer letter in the preferred format that highlights all the necessary information. We strongly advise you to use these templates, because it will ensure that we have all the information we need to submit your recall alert and recommendation. Insufficient information will only delay the classification process.

If you notify the customers first and then notify FDA later, it may be determined that your initial customer communication was insufficient, and you may be asked to re-issue a revised communication. In your initial communication for initiated recalls, clearly state the date the recall was initiated, and the method of notification used. In the initial communication for recalls not yet initiated, please clearly state your projected timeframe for initiating the recall, and specifically ask for feedback on the customer letter. Once your firm initiates a recall, make sure you submit the 806 report within 10 business days.

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Now, if it looks like we may have a Class I recall, there are several things we do. We'll go over the definition of a Class 1 recall in just a few slides. For now, just be aware that Class 1 recalls are deemed as the highest risk.

Please be aware that if the health risk presented by the product issue could potentially drive a Class 1 classification, we will be conservative and treat the recall as a Class 1. This means we'll be operating on an accelerated timeline to prepare and submit the recall for CDRH review. For a Class 1 recall, the timeline for the DRC to submit the Recall Alert is within 24 hours of receiving the firm's notification. For this reason, please supply a complete 806 report with your submission. Any missing or incomplete information will cause delays in preparing the Recall Alert and subsequent Recommendation.

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What happens once we have your recall submission? All recalls must be entered into the FDA Recall Enterprise System, or RES. This duty falls mainly to the Division Recall Coordinator, who reviews each submission and then enters the information into the system. There are two parts to the initial submission.

The Recall Alert has the basic information pertinent to the recall. All required elements of the Alert include information like the recalling firm, the public reason for recall, and the product being recalled. The Alert is entered as soon as possible, after we receive notification from the firm that they are recalling a product. This entry serves as the initial notification to CDRH recall group of a new recall. The second part is the Recall Recommendation, which has more detailed information. This portion is submitted within 5 days after the Alert is submitted. The Recommendation contains the full reason for the recall, including a detailed narrative, distribution patterns, and the recall strategy plan. Both parts are submitted to CDRH for review and classification.

In the event that your submission is incomplete, or clarification is needed, the DRC may contact you for further information. Please help us submit your recall to CDRH in a timely fashion by responding as soon as possible. It's helpful to confirm receipt and to commit to a deadline for submitting the information to the DRC.

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Once the recommendation is submitted, the recall is moved into the queue for CDRH review. In some situations, the reviewing team at CDRH may also contact you if more information is needed to classify the recall. The DRC may also participate in these conversations, which may take place by email or teleconference. CDRH reviews the recall and makes the final classification decision. This decision is then sent to the DRC. The DRC then prepares and sends you a classification letter and instruction on how to submit status reports and termination requests.

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Now, let's go back and review the types of classification. We'll start with Class 1, the recall with the highest degree of risk. These are recalls where there is a reasonable probability that use of, or exposure to, a violative product will cause serious, adverse health consequences, or death. Class 1 recalls take priority in our review and processing, as they have more stringent timelines.

Class 2 recalls involve a lower level of risk than Class 1 recalls. These are the recalls where use of, or exposure to, a violative product may cause temporary, or medically reversible, adverse health consequences, or where the probability of serious, adverse health consequences is remote. Most recalls we receive for medical devices are classified as Class 2.

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Class 3 recalls are the recalls with the lowest degree of risk. They are still called recalls because the product is removed or corrected due to being violative. For example, the product may be mislabeled. However, the use of, or exposure to the product is not likely to cause serious, adverse health consequences.

Class 3 recalls, along with Market Withdrawals and Stock Recoveries, are non-reportable events. If your firm determines your correction or removal is a Class 3 recall, please be sure to document the rationale for this determination. Your documentation should also include a Health Hazard Evaluation, along with the correction or removal activity itself.

If your firm plans to do a correction or removal, and you're not sure if the recall is reportable, please contact your DRC, who can help you evaluate the recall's reportability.

A Market Withdrawal differs from a Class 3 recall because the product being removed or corrected involves either a minor violation that would not be subject to legal action by the FDA, or which involves no violation at all.

A Stock Recovery is the correction or removal of a device that has not been marketed, or which has not left the direct control of the manufacturer.

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Once the recall is classified, CDRH will send the classification to the DRC, who will communicate with the firm. The recall will also be posted on the public FDA website. The DRC will then prepare a Classification Letter that states the classification, level of effectiveness checks to be performed, and expectations for status reports and termination requests. This Classification Letter will be emailed to the Most Responsible Individual identified in your 806 report. If you disagree with the final classification of the recall, you may submit a justification in writing for further review by the Division and CDRH.

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At this point, the DRC may assign recall audit checks for the division's investigations branch to perform. Typically, we will assign recall audit checks if the recall was classified as a Class 1, or if we have reason to be concerned about the firm's ability to ensure that customers are adequately notified. Recall audit checks involve contacting a sampling of consignees, either by phone or by visit. The division staff verify whether the customers have received notification from the recalling firm, and whether the customers have correctly executed the instructions provided in the recall notification. For lower risk recalls, the DRC will ask you to submit a sampling of your documented effectiveness checks for review. While the recall is still ongoing, you'll be expected to submit monthly status reports to your DRC. The DRC receives, reviews, and files the monthly status reports. You may wonder: what goes into a monthly status report?

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There are several expected components to a monthly status report. This includes the number of consignees who were notified of the recall, and the date and method of notification. If there were multiple notifications, please provide the date and method of each communication, and provide the number of products the consignee had on hand at the time they received the communication. Include the number of products returned or corrected by each consignee contacted, and the number of products accounted for. Provide the estimated time frames for completion of the recall. It is acceptable for your projected completion date to move, as long as you keep your DRC updated.

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Your status reports should also include the results of your effectiveness checks. Effectiveness checks are an important part of your recall. Your effectiveness check plan should be part of your 806 report. Essentially, you are answering the following questions about your effectiveness: How are you determining if your recall was effective? How

do you know if your recall notification got to the right person? That they read and understood your communication? and that they took the appropriate action?

Your status reports should also include: the number of consignees who have responded to notification; the number of consignees who have not responded; and an outline of further steps that you'll take for non-responding consignees. Explain if you'll be contacting them again, and by what method.

I would like to further clarify our expectation for consignee responses. We're looking for something more than just a signed delivery confirmation. A delivery confirmation is not accepted as adequate evidence of recall effectiveness. Simply ensuring that someone received a piece of mail is not enough. We strongly recommend that you include a customer response form with your firm's customer letter, and that you ask customers to complete and return the form to you, even if they do not have the affected product on hand. This method verifies that the customer received your notification, read it, understood it, and took any necessary actions. The DRC may ask you for a sampling of your effectiveness checks records. Having a completed, signed customer response form is an easy way to fulfill this request.

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We often get questions about effectiveness checks. The Classification letter will officially inform you of CDRH's expected effectiveness check level. In most cases, we expect a Level A effectiveness check, or in other words, we are looking for confirmation that 100% of customers have been notified. If you believe your recall should not require a Level A effectiveness check, please give a justification in your submission. Your DRC will probably want to discuss this with you.

A common concern we hear from industry is: What if I've made multiple attempts to contact a consignee, but they just won't respond? It's normal for a small percentage of consignees to be non-responsive, which is why it's important to document how many attempts you made to contact everyone. However, we still expect to see an intent to contact everyone, even if, realistically, very few recalls succeed in getting a 100% response rate.

If many of your consignees are non-responsive, the DRC may ask questions about how you normally contact your customers. Who is responsible for contacting your consignees for this recall? Do they have the correct point of contact, like a risk manager or similar role, or are they talking to someone in the sales department?

We've seen cases where the firm's recall notification was sent to the consignee's billing addresses, and as a result, did not reach the actual users. Please check to ensure that you're using the correct contact information for appropriate users when sending a recall notification.

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Your final product disposition plan should be coordinated with your DRC. If you're planning on reworking a product, details on the rework process should be submitted to the DRC for review. If you plan on destroying product, first notify your DRC, in case FDA would like to witness the destruction. If FDA declines to witness the destruction, please submit documentation of the destruction to FDA once it is complete.

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Once your firm has determined that all recall actions have been completed, you may request termination of your recall. The following criteria must be fulfilled before we can consider a recall for termination: all reasonable efforts have been made to remove or correct violative product; the final product disposition, whether it is rework or destruction, must be completed; and all planned preventive actions or corrections need to have been taken.

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You can request termination of the recall by emailing your DRC. Typically, we see termination requests submitted along with the final status report. The DRC will email you if we have any questions or require additional documentation. Termination requests are processed in the order that they're received, so it may take some time to get to any particular request. Once the DRC determines the recall is ready for termination, a termination letter will be prepared and sent to you, again via email, to the Most Responsible Person identified in your 806 report.

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Now that we've reviewed how the DRC interacts with your recall from start to finish, let's go over some common concerns that frequently come up when we're reviewing recall submissions and related materials.

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The DRC will review your customer letter for adequacy. It may be beneficial for you to submit a draft letter to the DRC prior to notifying customers. A common omission we see in customer letters is the lack of a health hazard statement. The customer needs to know the impact the product issue can have on the patient's health. This statement increases the likelihood they will comply with the instructions you supplied.

Speaking of instructions, please make sure you have clear customer instructions. A statement like, "This device may be hazardous," is not very useful to the customer. They want to know what the hazard is and how they can protect themselves or their patients. Draft your instructions with your target audience in mind. Keep instructions concise but clear. The next omission we see is the lack of a response form. We highly recommend including a response form with your customer communication. This form allows you to receive a clear confirmation that your notification reached the right person at the customer's site; that they read and understood your letter; and that they've undertaken the prescribed actions.

Sometimes, I also see customer notifications with the statement, “This is a Class 2 recall.” This practice is discouraged because although your firm may submit a recall with the assumption of a classification, CDRH has the final decision on the recall classification. Stating a classification prior to the final CDRH decision may mislead your customers.

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Now let’s talk about some common issues we see with 806 reports. The 806 report contains the bulk of information about your recall, and we’ve found that they are commonly incomplete. Again, we have templates to guide your submission and to help ensure that we have all the needed information to process your recall in a timely manner.

Common details that are often omitted include things like: labeling; a Health Hazard Evaluation; a recall strategy plan, including the effectiveness check plan; the date of awareness, and manufacturing and distribution date ranges.

Another issue we frequently have is being unable to see or efficiently process your submission, due to file formatting issues. To avoid this issue, please submit text PDF files with searchable text. This format will help us navigate your documents faster. When attaching lists, such as for consignees and for product code lists, please submit these files as excel spreadsheets. Excel allows us to sort and filter the data, so we can easily obtain the information we need.

We cannot access your cloud drive due to FDA network restrictions, so please do not send us cloud file links. The best way to send us files is as email attachments, but please remember to un-protect files before you send them to us! If you have encryption concerns, you can password-protect files before sending to us, and then send us the password in a separate email. Some firms tell us they don’t want to provide consignee information because of concerns surrounding the Health Insurance Portability and Accountability Act, or HIPAA. 45 CFR 164.512 covers Uses and Disclosures of protected health information and provides an allowance for disclosing this information to the FDA. Please reference this document if you have questions about providing consignee information.

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There are a few more issues that DRCs encounter. For example, a firm may tell us that they reworked a product without giving details on how the nonconforming product was reworked. Again, please submit your rework plan prior to executing the rework for your DRC’s review. A firm may submit an effectiveness check plan that is less than Level A 100%. You should always plan to notify all consignees. If you believe that you have a good justification for notifying less than 100%, please include the justification in your 806 report, and be prepared to discuss it with your DRC.

A firm may say they will submit an update by an agreed-upon date, but then they miss the deadline without notice. If you agreed to submit this information by a specific time and date, please be sure to submit it on time, or let us know as soon as you can that you won't be able to make the deadline. We sometimes receive multiple emails or phone calls from the firm in quick succession. If you call or email the DRC, please allow them at least 24 hours to get back to you. While we try to answer your emails and calls as soon as possible, we appreciate the opportunity to respond to your inquiries as our work priorities allow.

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So we covered some concerns that the DRCs may have when handling your recall. Next, let's talk about some common concerns we hear about from industry. Here's a question we often receive. "I thought my recall was a Class II, but CDRH classified it as a Class I. What do I do if I don't agree with CDRH's classification?" When you believe your recall should receive a certain classification, but then CDRH classifies it as something different, it can be confusing, or even alarming. If you'd like to discuss CDRH's rationale for classification, please reach out to your DRC. They can set up a meeting with CDRH for you to learn more about why CDRH decided on that particular classification.

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Another common question we get from industry is: "Is my event really a recall? Or is it just a product enhancement?" The definition of a device enhancement is: "a change to improve the performance or quality of a device, that is not a change to remedy a violation of the Food Drug & Cosmetic Act, or associated regulations enforced by the agency." In other words, the key factor in distinguishing a medical device recall from an enhancement is whether there is a violation.

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We also commonly receive emails and phone calls asking why a firm hasn't heard back from the FDA about their recall submission. Hopefully, I can explain why it can sometimes take a little longer to hear back from your DHC. The Division Recall Coordinators process all the medical device recalls throughout the United States, as we saw in the map at the beginning of this presentation. There are 3 full-time Division Recall Coordinators per division, for a total of 9 DRC's to cover all the medical device recalls nationwide. Annually, these 9 DRCs handle approximately 3,000 recalled products.

We're working hard to process all recalls efficiently, but Class 1 recalls take precedence due to their higher risk. Class 2 and 3 recalls are processed in the order in which they are received. To help us process your recall as quickly as possible, ensure that you have provided all the necessary information. Complete submissions lead to faster processing. We'll let you know if there's anything missing.

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The same concerns apply to terminations. We often receive emails asking about the status of termination requests. The FDA receives a high volume of termination requests, which are processed in the order in which they are received. Often, if you haven't heard back from us, it's simply because we haven't reached your termination in the queue yet. If there is missing information, the DRC will contact you. Once we have all the information and have completed processing your request, we'll prepare and send you a termination letter, which officially closes the recall on our end.

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The next several slides will cover resources you can reference regarding recalls operations.

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This top link will take you to the FDA's enforcement reports. The next two links have information regarding recalls, corrections and removals. The final link is an FDA page for Industry that houses FDA notices and guidance documents.

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The Investigations Operations Manual and Regulatory Procedures Manual both cover how FDA handles recalls in Chapter Seven. 21 CFR Part 7 covers recalls in general, while 21 CFR Part 806 specifically covers medical device recalls and reporting requirements. Links to these documents have been provided for your convenience.

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Let's summarize what we covered in this module. First, the ORA Division Recall Coordinator plays an important role in the coordination and oversight of recalls. Second, FDA classifies recalls into Class 1, 2, or 3 based on its potential for health consequences. Class 1 recalls take precedence over other recalls. Class 2 and 3 recalls are processed in the order in which they are received. And finally, providing complete submissions and timely responses are helpful to processing the recall efficiently.

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Let's conclude with your call to action. First, review Part 806 to ensure that your recall procedures are adequate. Second, be responsive to FDA with requests for information. Third, notify your Division Recall Coordinator of any changes. And finally, please view the other modules in this series, if you haven't already done so, to learn more about some other staff roles in the medical device program.

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This is the fifth and final module discussing the staff roles in the medical device program. We hope that viewing these modules gave you an idea of what a day in our lives may look like.

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Thank you for joining us. Have a wonderful day.