Introduction to Medical Device Recalls

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Welcome to CDRH Learn, a resource for multimedia education in the Center for Devices and Radiological Health, or CDRH, at the Food and Drug Administration. My name is Tonya Wilbon, and I'm with the Division of Industry and Consumer Education, or DICE. Hopefully, this module, "Introduction to Medical Device Recalls", will provide clarity on the regulatory requirements for conducting medical device recalls.

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As you can see on this slide, medical device recalls are conducted more frequently than recalls for other FDA-regulated products. Understanding the regulatory requirements for conducting these recalls is paramount in reducing the risk of future action.

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The learning objectives for this module are to review the basic information regarding regulatory requirements for conducting medical device recalls; briefly discuss the classification of recalls; describe the firm's responsibility when conducting a medical device recall; and then finally review CDRH's responsibility in the medical device recall process.

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So, let's begin by reviewing some basic information regarding medical device recalls.

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Most information about recall process and procedures can be found in the Enforcement Policy of Title 21 of the Code of Federal Regulations (or CFR) part 7, which includes Subpart C, titled, "Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities", specifically, 21 CFR subpart 7.40 through 7.59. This subpart provides general guidance for the voluntary recall of products, including those recalls a firm chooses to initiate -whether on its own and or after receiving a request from FDA. In addition, there are FDA regulations that set forth specific requirements for medical device corrections and removals under 21 CFR part 806 titled, "Medical Devices; Reports of Corrections and Removal" and requirements for mandatory device recalls under 21 CFR part 810 titled, "Medical Device Recall Authority". Mandatory recalls of medical devices are authorized by Section 518(e) of the Federal Food, Drug, and Cosmetic Act, also known as the FD&C Act.

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Now let's review a few key definitions, beginning with "recall". Recall is defined in 21 CFR 7.3(g), as the firm's removal or correction of a marketed product that the FDA considers to be in violation of the laws it administers, and against which the agency would initiate legal action, for example, a seizure. Recall does not include a market withdrawal or a stock recovery.

Medical device recalls are usually conducted voluntarily by the manufacturer and involve those devices that if the correction or removal was not done, the device would be in violation of FDA laws and or regulations and the FDA would initiate enforcement action. A recall is an alternative to an FDA-initiated court action for removing or correcting violative products that have been distributed.

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Now let's review the definition of "removal" as it pertains to a medical device recall. Removal is defined in 21 CFR 806.2(j) as the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection. The device is actually moved from the site where it is being used to a different site to address the issue.

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One example of a device removal is when the firm provides a "return material authorization" and as a result, the user ships the device back to the firm because the device does not meet specification. This is a physical removal of the device that is in violation of FDA laws and regulations. Another example is when the firm instructs the user to destroy and dispose of the device. Again, an example of the physical removal of the device. The device did not meet specification and thus was in violation of FDA laws and regulations. These actions are considered recalls.

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The last definition is that of "correction". Correction is defined in 21 CFR 7.3(h) as the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location. Remember these actions are to remedy an issue with the device that constitutes a violation of FDA laws.

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A few examples of a correction to a device that would meet the definition of a recall include an on-site field service correction of a problem with a MRI device, additional monitoring of a patient with an implanted device, and the addition to labeling provided to the user to reduce the potential for a device malfunction. These devices were not physically removed from their location, but corrections were made to address problems with the devices where they were being used or without being returned to the manufacturer. Keep in mind that adjustments to devices that are regularly scheduled for maintenance are not corrections to the device, and thus are not considered a recall.

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It's important to understand that not all correction or removal actions are considered recalls. They include: a market withdrawal, stock recovery, routine servicing, medical device enhancement and a safety alert. These actions are typically taken for specific reasons related to business strategy, quality control, maintenance, improvement, or safety considerations. Only removals or corrections to devices to remedy a violation of FDA laws and against which the agency would initiate legal action fall within the definition of a medical device recall. Only marketed devices can be recalled.

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Medical device recalls can occur in different ways and may be initiated voluntarily by the manufacturer or requested or ordered by the FDA. There are three main types of medical device recalls. They are voluntary recalls that are initiated by the manufacturer; FDA-requested recalls which are reserved for urgent situations and requests for the manufacturer to take action; and an FDA-ordered or mandatory recall where the manufacturer or importer fails to voluntarily recall a device that poses a risk to health.

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Now let's discuss the classification of recalls.

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FDA classifies recalls by evaluating the health hazard presented by the product being recalled or considered for recall based on risk. The FDA classifies recalls into Class I, Class II, or Class III to indicate the relative degree of the health hazard. A Class I Recall is a recall with the highest risk to public health. This is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. A Class II Recall is a recall with a moderate risk to public health. This is a situation in which 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. And finally, a Class III Recall is a recall with the lowest risk of public health. This is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences. While the risk to patient safety is minimal for Class III recalls, manufacturers are still required to take appropriate action to address the violations and ensure compliance.

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Now let's describe the firm's recall responsibilities.

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When a medical device is subject to a recall, it is essential for the firm to understand their responsibilities in the recall process. This includes the manufacturer, distributor, or the importer. 21 CFR 7.40 and 7.41 through 7.59 recognize the voluntary nature of a recall by providing guidance so that responsible firms may effectively discharge their recall responsibilities. A firm's recall responsibilities include identifying the need for a recall and initiating the recall process promptly; ceasing distribution, shipment and/or sale as needed of the recalled product and reporting the recall to the FDA.

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A firm's recall responsibilities include identifying a recall strategy, described in 21 CFR 7.42, to suit the individual circumstances of the particular recall, and consider potential risk to those exposed to the recalled product. The firm's responsibilities include drafting and issuing recall communication promptly to each affected direct account or consignee, informing them of what should be done with respect to the recalled product, and instructions on how to respond to the recall notification.

Additionally, a firm is responsible for notifying the public, when appropriate, by issuing a press release or a notification letter, for example, and finally to conduct follow-up activities including recall status reports. Following a structured approach helps ensure that the recall is executed efficiently, risks are mitigated, and appropriate corrective actions are taken.

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As indicated in 21 CFR 7.42, a recall strategy will be developed by the agency for an FDA -requested recall and by the recalling firm for a firm-initiated recall. An effective recall strategy will consider the following factors: results of risk assessment or health hazard evaluation, ease in identifying the product, the degree to which the product's deficiency is obvious to the consumer or user, the degree to which the product remains unused in the marketplace, and the continued availability of essential products.

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A recall strategy will address several other factors regarding the conduct of the recall. These include the depth of the recall in the distribution chain; issuance of a Public Warning, if needed and how it will issue;

and the method and level of effectiveness checks that will be conducted. The effectiveness checks serve to verify that all consignees at the recall depth specified by the recall strategy have received notification about the recall and have taken appropriate action.

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When issuing a recall communication according to 21 CFR 7.49, the recalling firm is responsible for promptly notifying each of its affected direct accounts about the recall. Communication is very important for the recall process. Its purpose is to inform the direct accounts about the product that's subject to the recall, to indicate to stop using the product immediately, to provide instructions about what to do and, where applicable, to indicate for direct accounts or distributors to notify its customers. Communication can be done by mail, telephone call, email, or other methods. Make sure you document the communication and follow up with those who fail to respond to the initial communication.

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Remember that the recall communication should be brief, to the point, and clearly identify the product subject to the recall - including lot numbers, codes, serial numbers or other identifying factors. The communication should include specific steps to minimize health consequences, the reason for the recall and any associated health hazards, specific instructions on what to do with the product and how to dispose of it as applicable. The communication should also include the method on how to respond to the recalling firm and ensure that the recipient can easily do so, for example, by providing a postage-paid, self-addressed postcard. In addition to the information that should be included in the recall communication, the recalling firm should be equally aware of information that should not be included in the communication. Irrelevant qualifications, promotional material or other statements that detract from the message should not be included in the communication. The recalling firm should ensure that the communication helps the users identify the product and take steps to minimize health hazards. Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm including notifying any other consignees.

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Public warnings are appropriate for urgent situations and are issued to alert the public that a product being recalled presents a serious health hazard. For example, a public warning may be appropriate when a recalled product has been widely distributed, or when the retail level consignee cannot identify to whom the device was sold. FDA generally recommends public warning for recalls that are likely classified as Class I recalls unless specific circumstances indicate that the warning would not be beneficial. Ordinarily, the FDA, in consultation with the recalling firm, will issue such publicity. The recalling firm that decides to issue its own public warning is requested to submit its proposed public warning and plan for distribution of the warning **to** FDA for its review and comment. Public warnings can be disseminated through general or specialized news media, such as professional or trade press and/or to specific populations, such as physicians or hospitals.

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Once a medical device recall is initiated, follow-up activities are necessary to ensure compliance, track progress, and communicate the status of the recall. The recalling firm is responsible for submitting a report of corrections and removals as required by 21 CFR 806, implementing the applicable requirements of 21 CFR 820, submitting recall status reports to the FDA, and requesting a recall termination according to 21 CFR 7.55.

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A recalling firm is required to submit a report of the correction or removal in accordance with 21 CFR 806, Medical Devices, Reports of Corrections and Removals, commonly referred to as an 806 Report, that was initiated to reduce a risk to health, or to remedy a violation of the act which may present a risk to health. The report may be submitted by email or by use of the FDA Electronic Submission Software, or Submitter to the FDA. If foreign manufacturers and importers choose to report by email, they must email the report to the FDA where their US agent is located. The recalling firm shall submit any report required by 21 CFR 806.10(a) within 10 working days of initiating the correction or removal. A report is not required if the information has already been provided to FDA under Medical Device Reporting (21 CFR 803) or under Repurchase, Repairs or Replacement of Electronic Products (21 CFR 1004)). The recalling firm must keep records of those corrections and removals that are not required to be reported to FDA.

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A recalling firm is required to implement applicable requirements of 21 CFR 820 pertaining to the recall. This will help to ensure that corrective actions taken are effectively implemented and documented. Some of the relevant requirements include implementing procedures to address nonconforming product, reviewing associated complaint files, and identifying actions needed to correct and prevent the recurrence of nonconforming product and other quality problems.

This is not all inclusive and the recalling firm is required to ensure all applicable requirements are implemented. Additional information can be obtained by viewing the CDRH Learn modules under the Postmarket Activities section.

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After initiating a recall, a firm is also requested to submit recall status reports to FDA, according to 21 CFR 7.53. throughout the recall process. The reporting interval is usually between 2 and 4 weeks so FDA can assess the progress of the recall. FDA will specify the exact frequency based on the urgency of the recall. The recall status report should contain the number of consignees notified, method of notification and the date notified, and the number of responses received to include the quantity of the devices in hand. It should also include consignees that did not respond to the recall communication. Recall status reports assist in maintaining communication and transparency during the recall process.

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Recall status reports should also include the number and quantity of products returned or corrected, the number and results of the effectiveness checks, and the estimated recall completion timeframe. Recall status reports are to be discontinued when the recall is terminated by the FDA.

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The final follow-up activity for the recalling firm is to request recall termination. FDA recommends that the recalling firm evaluate the recall for termination once all possible customer responses have been received and all possible product subject to the recall are assumed to have been removed and properly dispositioned or the appropriate correction made. A recall termination request can be submitted to FDA in writing, with the final Recall Status Report in accordance with 21 CFR 7.55.

FDA will review the request and determine whether the recall can be officially terminated. The agency will terminate a recall when it determines that all reasonable efforts have been made to remove or

correct the product in accordance with the recall strategy, and when it is reasonable to assume that the product has been removed and proper disposition or correction has been made commensurate with the degree of hazard of the recalled product. If FDA makes this determination, FDA will then issue a written Termination Letter.

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While a recall can be disruptive of a firm's operation and business, there are several steps a firm can take in advance to minimize this disruptive effect. There are a few considerations described in 21 CFR 7.59. In addition, during the recall process, several factors should be considered to ensure a comprehensive and effective recall. A firm should consider the possibility of device shortages because of the recall (which have separate requirements in section 506J of the FD&C Act) and verify that all notifications have been issued and received. A firm should consider which process to implement to ensure all designated product identifiers such as lot, serial, and unique device identifier, or UDI, numbers are included in any communication issued. Also, when conducting the effectiveness check, a firm should consider a process to ensure verification that the right person received the right communication and appropriate actions have been taken accordingly.

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We have described the firm's recall responsibilities. Now let's review CDRH's responsibilities in the medical device recall process.

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During the medical device recall process, CDRH is responsible for evaluating the health hazard to determine the risk to patients and users associated with the recalled products. One way CDRH conducts this evaluation is by completing a Health Hazard Evaluation, or HHE, described in 21 CFR 7.41. CDRH uses this evaluation to aid in the determination of the recall classification and the appropriate actions to ensure the public health. CDRH is responsible for reviewing the firm's recall communication to ensure that it is clear and includes as much identifying information as possible about the recalled product. CDRH is also responsible for reviewing the recall strategy to ensure that it is comprehensive and addresses the appropriate depth of the recall, documents appropriate actions to remediate the violation, notifies appropriate direct accounts and consignees, and documents whether public warning and notification will be issued, among other activities.

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Additionally, CDRH is responsible for evaluating whether a press release is needed to ensure that the public is notified about the recall and obtains instructions on what to do, posting the recall on FDA.gov and in the weekly FDA Enforcement Report, and ultimately terminating recalls.

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In rare instances, where the manufacturer or importer fails to voluntarily recall a device that is a health risk, FDA may issue a recall order to the manufacturer under section 518(e) of the Federal Food, Drug, and Cosmetic Act - and its implementing regulations, found at 21 CFR 810, Medical Device Recall Authority. In exercising this regulatory authority for mandatory recalls, CDRH will conduct a Health Risk Assessment, or HRA, to evaluate the health of patients and users from the affected device, discuss the risk evaluation with the firm, and issue the Cease Distribution and Notification Order. In a Cease Distribution and Notification Order, FDA will provide an opportunity for a regulatory hearing on the actions required by this order, and on whether the order should be modified, vacated, or amended to require a mandatory recall of the device. If FDA determines - after a hearing or agency review of the

Cease Distribution and Notification Order - that a recall is necessary, the agency will issue a Mandatory Recall Order, which includes details for the recall, as well as notification requirements.

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If the recalling firm does not conduct a recall, as required by FDA laws and regulations, or refuses to do so, FDA can conduct more stringent enforcement actions. These include injunction, import alert, Foreign Country notification and/or seizure of the product.

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In summary, the recalling firm should develop and implement a recall strategy that considers the factors in FDA's regulations, and the individual circumstances of the particular recall. The firm should notify consignees about the nature of the recall and provide instructions on what they should do with the product in a timely manner. The recalling firm should report to the Medical Device Division Recall Coordinator for their area and should submit up-to-date status reports and 806 reports if required.

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FDA will review recall information provided by the recalling firm, classify the recall based on the public health risk, post recall information promptly and as needed, and request or order a recall, if needed.

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Here is a list of resources that were applicable to this presentation.

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Here is another list of resources applicable to this presentation as well.

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We in the Division of Industry and Consumer Education provide you with regulatory education in several key formats, so you can choose the most effective way you wish to learn. CDRH Learn consists of over 200 multi-media industry education modules, such as the one that you're watching here. These include videos, webinars, presentations, and various "how to guides." Use your computer, phone, or portable device to click on the link shown here. Now, if you prefer to learn by reading, check out Device Advice! Device Advice consists of several hundred pages of comprehensive regulatory information across the device total product life cycle. And finally, if you have a specific question and wish to ask us directly, I encourage you to call or email us. Our contact information is listed here, and we look forward to speaking with you.

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Let's now conclude with your call to action! Be prepared and plan for your recall. Make sure you properly identify the affected products, problems, and its possible cause. And plan your actions to address the risk related to the recall. Thank you for viewing this presentation.

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