CDRH Portal Overview and Feature Walkthrough

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[Andrew Sprau] Hello. Welcome to CDRH Learn, our program series for multimedia education for medical devices and radiological health products. In this module, we'll provide an overview of the CDRH Portal and walk through of some of its features. Your presenter for this module is Nelson Anderson, CDRH Portal platform owner from the Office of Regulatory Programs in the Office of Product Evaluation and Quality within the Center for Devices and Radiological Health.

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[Nelson Anderson] The medical device industry has been asking for a way to electronically submit their applications to us. And we have heard that and created this CDRH Portal, which allows both electronic upload of submissions and tracking of some of those same submissions.

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Please note that the CDRH Portal is an evolving program and continually is enhanced throughout the year. So, some of the information in this presentation may be somewhat out of date by the time you view it. If you want the most up-to-date information, please see the Portal Help articles that are inside the portal itself.

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Our objectives today are to describe the purpose of the CDRH Portal, to discuss what submissions can be uploaded through the portal, and to discuss which submissions can be tracked in the portal.

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So first of all, what is the CDRH Portal? The CDRH Portal, otherwise known as the Customer Collaboration Portal, is a secure website that allows the medical device industry to upload CDRH-led pre-market submissions directly to CDRH and allows them to track the progress of supported pre-market submissions.

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So first, we're going to talk about uploading files through the portal.

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We frequently get the question, well, what can we upload through the CDRH Portal? And the answer is pretty straightforward. Anything that is typically mailed to the CDRH Document Control Center, otherwise known as the DCC, can be uploaded through the portal. That makes it simple and straightforward.

Also, our uploads are limited to a size of 4 gigabytes. Now, if you're concerned about whether that 4 gigabytes might be a constraint, please consider the current average size of an upload through the portal is right around 55 megabytes. And to date, the last roughly quarter of a million submissions that have come to CDRH, which is about 10 years' worth, 99.9% of those submissions have all been lower than 4 gigabytes. So, this size restriction should not be a problem for most of our submitters.

Nothing physical needs to be sent in for a file uploaded through the portal, which hopefully is fairly logical. Our eCopy guidance does currently specify that if you send an eCopy through the mail, you do have to print off a cover letter and sign that cover letter, but that only applies to the ones that are sent

through the mail. If you upload an eCopy through the portal, you do not need to include the printed cover letter.

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However, speaking of cover letters, they are still very important for uploads through the portal. So, unless it's an eSTAR format, which includes information in it, everything else should have a cover letter attached in PDF format somewhere in that upload. The cover letter is used by our DCC to determine the purpose of the submission and how it should be processed. If they do not have a cover letter and the DCC is not clear on what that upload is, it could cause delays in the processing of that submission. And it may not get to the reviewers or to whomever it's supposed to get to in an expedient manner. So, providing a PDF format and cover letter in your eCopy is very important for making sure your things occur efficiently.

And while there are no file name requirements for file uploads through the portal, logical file names are another thing that help our DCC identify the file and process it quickly. For example, if you name your submission K23####AIresponse.zip, as soon as the DCC sees this, they are going to know this is related to this specific 510(k). It's an AI response, so I know it's going to be a supplement. So, before they even open it and get to the cover letter, they know what to do with it, and that's just going to help them be more efficient.

Now, this last point is really important. So, some users presume that, as soon as they upload something to the portal, it has been received by FDA. And we have certain workflows, say additional information response to a 510(k), that have a response due date. And so potentially, a user might say, hey, today is the response due date, but it's before midnight, as long as I upload my file before midnight, I have met the response due date.

Well, that is not correct. So, we have a cutoff time every business day for when any file that is received in the portal will be processed. And that is 16:00 Eastern. For example, if you upload something at noon Eastern time on Friday, it will be processed on Friday. The DCC will get it. They'll process it. It will be officially received by CDRH on Friday. However, if you upload that same submission at 18:00 Eastern, it has missed the 16:00 Eastern cutoff point and will not be processed on Friday. It will be processed the next normal business day. Well, of course, the DCC does not work on weekends. So, it will not be processed on Saturday. It will not be processed on Sunday. It will be processed on Monday, unless, of course, Monday is a federal holiday and then it will be processed Tuesday morning. So potentially, by missing this cutoff date on a Friday, your submission may not be officially received by CDRH until Tuesday morning Eastern time. So please keep this in mind when you are uploading. Don't wait until the last minute to upload something to us. Do it ahead of time. Do it the day before. Then you don't have to worry about missing the cutoff time.

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For the most part, all submissions through the portal should be a single file. So, you should be either uploading one single ZIP file for an eCopy or one single PDF for an eSTAR. Now, there are some circumstances, third party eSTAR, where you have the eSTAR and the third-party documentation, or potentially an eSTAR that also has statistical data, or has a bunch of proprietary images that have to be sent separately, that can't be attached. So, there are sometimes when you actually need to split it up.

We have instructions in the portal on how to do that, and I'll show you that later. But for the most part, your submission should be one single file that you're uploading. You shouldn't be breaking it up into multiple pieces. Just one ZIP file or one PDF. And this is a reminder that, starting on October 1st, 2023, all 510(k)'s must be submitted in eSTAR format and they should come through the portal as long, of course, as they are under 4 gigabytes.

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Now, we're going to switch over to talking about tracking submissions. So, currently in the CDRH Portal, it supports the progress tracking of traditional, special, and abbreviated 510(k)s, as well as all pre-submissions. There are only two types of pre-submissions, which is written feedback and meeting request.

The tracking of a submission is initially only available to the official correspondent on record. And if you're wondering who the official correspondent is, there is a help article inside the portal that describes exactly how we determine who the official correspondent of record is. But initially, again, that submission can only be tracked by the official correspondent. But the official correspondent can share the progress tracking with other portal users. For example, if there is a consultant who is the official correspondent on a 510(k), they can then share that tracking information of the 510(k) with the sponsor of the 510(k), presuming, of course, that the sponsor has self-registered for a portal account.

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Next, we're going to talk about where you can get help or more information about the portal.

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So, the primary place to find out more information about the portal is in the Portal Help System, which, of course, is inside the portal itself. It has answers to many of the common questions that we get, and it has a What's New section that includes instructions on how to use all of the newly added features, such as the progress tracking share with others that I mentioned.

You don't need any sort of invitation to get a portal account. You can self-register for it. And to find the links to the portal, or to the self-registration that I just mentioned, simply do a web search for “FDA Send and Track”. Generally, the very first search result will be our web page and you can use the links right off of that web page.

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Now, we're going to go ahead and take a look at the portal itself. So, what you see here is the home screen of the portal. This is what you see when you log in and the first thing I'm going to mention is the Portal Help, of course. Portal Help is the question mark down in the lower left-hand part of the screen there and

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that will give you a new tab, and as I mentioned previously, there are two sections, the Common Question sections, which has answers to the most common questions, of course, and the What's New section that will tell you new features as they come out. It'll also give you instructions on how to use those new features.

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Going back to the home screen, this top portion here is the Progress Tracking section of the CDRH Portal, and it is going to list all of the 510(k)'s and/or pre-subs for which you are the official correspondent or have been shared with you. And there's a little bit of information that is shown here just to give you a summary, so you know what that submission is, its general progress, and the goal date, how many days are left. Just here from your dashboard. So, you can see this 510(k), which is listed is On Hold. It is a traditional 510(k) and the goal date, which is June 20th, 2023, is the date by which I need to respond to CDRH because they asked me questions. So, it's saying, hey, your response due date is in 84 days. So, that's what I can get just off of looking at the simple bit of information. If I want the details, I can click on the 510(k) number here and that will move me to a details screen.

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So here we are in the details screen, and up here in the left corner, we see that, again, this notes it's a traditional 510(k) and gives the 510(k) number. Below that, we have some general administrative information; we have the company name, the device name, and then we have where in the FDA that this is being reviewed, including the office, the division, the team, and the lead reviewer name. The lead reviewer name will also generally include their email address listed under it.

In the top status section, we have a quick status statement, reviewing. We are reviewing this medical device. so that's just to let you know it's not on hold, it's under review. The progress bar gives you a general sense of how far through the review this submission is. And in this case, this is just a day count, so a traditional 510(k) generally takes 90 days, is the MDUFA commitment. This is on day 28, so this bar is roughly one third full. It notes the FDA start date, and it notes the FDA presumed MDUFA decision date. So, this is a predicted date for the MDUFA decision, which again should be by 90 days. So, it's just predicting this should happen by 90 days. It's not a guarantee it will, it's just when it should happen.

Next, we have a couple of statements up here at the top. The important one I want to mention here is all records are updated overnight. So, the portal does not track in real time, it just gets nightly updates.

So don't log into the portal multiple times a day trying to see if something has changed or if the status has somehow been updated because it won't. It's only going to update once per night. The other thing to mention about that is if you receive an email from CDRH with an official recommendation. Say we've sent you an SE on your 510(k), that is not going to be reflected on the portal until the following day. So, if you get the SE letter today and you go into the portal, it will not show the SE decision, but if you check the portal tomorrow, it will show the SE decision.

Then below that, we have milestones here. So, this just gives you a sense of what has occurred with a submission from when we receive it to future predicted dates. So, the substantive interaction is in the future we are predicting when that should occur. And the final decision, again, estimated, this is a MDUFA date in the future, so we give some predictive dates in the future as well.

Now, we have service time here. This is generally the time that has passed for the submission. In this case, it's pretty straightforward since it hasn't been on hold, it's been under review for 28 days and it has 62 days left to meet the 90-day MDUFA commitment. And then the last section is just the official correspondence contact info.

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Now, back to the home page of the portal, this next section is for the uploads or the sent submissions. And in this case, you see it says you haven't sent anything yet. So, this particular user has not uploaded anything to CDRH.

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If something had been uploaded, you would see it listed on screen similar to this. So, under the Your Sent Submissions, it's going to list the file name that was uploaded, it's going to list the format type, so whether it's an eCopy or eSTAR, and then it's going to list the date and time that it was sent to the FDA.

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So, how do you send something using the portal? Well, you can either click on Send a Submission, those words there. Or after you send something, that wording will disappear, and you'll need to use the plus sign over here on the left-hand side. Now, clicking on either of those is going to open a new tab in the portal. And that will be the Upload Workflow.

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So here, we have our Send a Submission tab, and first, you'll note that over on the right is an info panel. And this information panel gives you some extra information that might be relevant to your first-time sending submission. So, if you're not familiar with eSTAR, we have a link to the eSTAR home page, and then the instructions I mentioned previously about sending an eSTAR and another file, say a statistical CDISC package, third party memo, some DICOM images, something like that, if you click on View More, that would give you the instructions on how to go about that. Those same instructions are also in the Portal Help articles as well.

For eCopy, we have a link to the eCopy guidance, in case you're not familiar with how to format something in the eCopy format. We have some additional resources, such as FDA Device Advice and some contact email addresses. So, for general questions, you'd want to contact DICE. For submission-specific questions, you'd contact OPEQ Submission Support. And for anything related to the portal itself, CCP@fda.hhs.gov. Now, if you don't need this information panel, you can just click on the arrows up in the right-hand corner, and it will happily go away.

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Now, of course, if you want that information panel to come back because you need an email address or something, you can just click on the “I” up there in the corner and the information panel will slide back out. So, let's go ahead and talk about actually sending the submission. So first, you're going to decide what format you're going to use, and that's going to be either an eSTAR or an eCopy. We're going to select eCopy today.

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So, you can see here it says, Send Your eCopy. So, it knows that we're sending an eCopy. And I'll note, as mentioned earlier, this has the send a submission before 16:00ET. It has the cutoff message. So, you'll see this on most of the screens, just to remind you what that cutoff time is.

Now, for the file selection, obviously, you have to upload your own file. So, you can drag and drop it directly here in this box or you can browse for it. Clicking Browse will open the typical Windows Explorer window, and then allow you to select some ZIP file. Now, it's not going to allow you to select other file

types because, of course, this is an eCopy, it only allows ZIP files. Once you select that, it's going to switch and start uploading.

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So here, you can see we're on the upload process, and it shows the progress as the upload continues. And the only option you have while you're uploading is to stop the upload. So, say you realize, oh wait, this is a compendium of all my pet cuttlefish photos, not my 510(k), I should stop this upload, you have a way to stop the upload and then you can select a different file if you need to.

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Once the upload is complete, you'll see this confirmation screen and it shows you the file name that was uploaded. And now, you have a couple of different options here. You can cancel the submission. So, if you realize, wait, this is, we need to change something in our 510(k), I don't want to upload it all right now. Canceling the submission allows you to close that tab, you're done with uploading at that moment. Again, if you realize, wait, I just uploaded my cuttlefish pictures, I need to select the actual 510(k), you can select a different file, but if everything looks good, then you just click on Send.

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And that takes you to the sent to FDA confirmation screen. Now, you'll notice, again, as I mentioned, it says sent to FDA, not received by FDA. And it gives you the date and time stamp and the file name that you uploaded. It also gives you some general expectations of what should come next.

So as the uploader, you'll get an email that notes the same information, file name, date, and time of upload. And then the official correspondent, which may or may not be the same as the uploader, will get another email from the document control center when this submission is processed. This is what the email looks like that the uploader would get, again containing the file name and the date and time of the upload.

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So, in summary, the CDRH Portal can be used to track the progress of 510(k)s and pre-submissions, and any submission that is generally mailed to the CDRH Document Control Center can also be uploaded to them directly through the CDRH Portal. Thank you.

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Let's conclude this module with your call to action. First, use the CDRH Portal to upload your submission. No need for you to mail your eCopy or eSTAR. And second, track the progress of your submission by using the Progress Tracker. This is a great way to get almost real-time status of your submission. Thank you for your attention to this CDRH Learn module, CDRH Portal overview, and feature walkthrough. We'll see you next time.

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