CDRH Learn: The ASCA Pilot: Streamlining Conformity Assessment in Device Submissions

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Hello, my name is Simon Choi. I am a health science analyst in the Standards and Conformity Assessment Program at FDA. The title of this presentation is "The ASCA Pilot: Streamlining Conformity Assessment in Device Submissions." In this module, we'll introduce you to the Accreditation Scheme for Conformity Assessment pilot program, or ASCA, as it's known for short.

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Testing is a critically important part of device development and manufacturing, and of course, a central aspect of the FDA's review processes. Essentially, the ASCA Pilot establishes an accreditation program for testing laboratories. Test results from ASCA-accredited test labs should enhance device manufacturers' and product reviewers' confidence in medical device testing. This, in turn, should reduce FDA's need to request additional information regarding testing conducted to support premarket evaluation. Ultimately, the ASCA Pilot is designed to enhance FDA's approach to conformity assessment in premarket review.

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We're going to accomplish three things during this session. First, we'll talk about the program itself: what it is and why it will benefit manufacturers and the FDA. Next, we'll go over, step by step, how to prepare a premarket submission which includes testing from an ASCA-accredited testing lab. Finally, we'll close with some helpful tips on how to participate successfully in the Pilot. Before I begin, I should note that we understand that there are different types of organizations that submit their devices for FDA review. For the purposes of this module, I will use the word "manufacturers" throughout to refer to anyone who files device submissions.

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Let's get started with an introduction to the ASCA Pilot and its benefits.

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The ASCA Pilot was developed with input from experts across the medical device manufacturing and conformity assessment communities. It is a voluntary program. It leverages a well-established international conformity assessment infrastructure, and it capitalizes on the use of voluntary consensus standards in device development and review. We are "putting standards to work'" on both an individual submission level as well as on the international level!

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The ASCA Pilot is authorized under section 514(d) of the Federal Food, Drug, and Cosmetic Act and is part of the Medical Device User Fee commitments of 2017. The Pilot was built with the intention of increasing FDA's confidence in the test methods and results in device submissions. That enhanced confidence means that manufacturers should usually see fewer requests for additional information regarding testing methods. This, in turn, helps leads to a review process that is more consistent, predictable, and efficient – which supports CDRH's commitment to a "least burdensome" approach. Finally, at the end of the day, ASCA should help the patients we all serve to have access to safe, effective and high-quality devices.

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Before we go any further, I'd like to distinguish between two important terms in the ASCA Pilot. The first is ASCA Recognition. ASCA Recognition is a formal status that the FDA grants to accreditation bodies who demonstrate the qualifications summarized in the ASCA program guidance. This is not to be confused with the FDA's standards recognition program, though the two are related in that only FDA-recognized versions of standards are included in the ASCA Pilot. The second ASCA Pilot term is ASCA Accreditation. This is the formal status that the FDA grants to qualified testing laboratories that meet ASCA Pilot specifications outlined in the guidance. This is separate from any other accreditation a test lab may have from accrediting bodies.

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ASCA is a brand-new voluntary program for the FDA and manufacturers. In fact, it is the first conformity assessment initiative of its kind using FDA-recognized standards within CDRH and the first time FDA is directly engaging with the conformity assessment community. This slide outlines the pre-ASCA environment: FDA's key interactions were between FDA and industry. Industry worked with test labs, and test labs worked with accreditation bodies. Accreditation bodies interacted with ILAC, which is the international accreditor of accreditation bodies. Those individual, bilateral relationships are depicted by the light blue arrows you see.

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Here you see how the relationships change. The ASCA Pilot introduces new interactions: the FDA is now working with both accreditation bodies and testing labs, and you can see those new relationships in the dark blue arrows. In the future, we anticipate working with ILAC as well, as noted by the yellow dotted arrow. This dynamic community is all coming together to support our shared priorities of improving device review and advancing regulatory science.

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Understanding how those individual entities work together as part of the ASCA Pilot makes this slide a little easier to understand. I won't go into too much detail, because I know your interest lies in how manufacturers are expected to participate, but the process goes like this. First, FDA grants ASCA Recognition to accreditation bodies who meet Pilot specifications. Second, the test labs may apply to the FDA for ASCA Accreditation. Both independent and in-house test labs may participate. Third, device manufacturers select an ASCA-accredited test lab and develop a test plan. Fourth, the test lab conducts testing and sends both the complete test report and a Summary Test Report to the manufacturer. Fifth, the manufacturer sends a declaration of conformity and the Summary Test Report to the FDA with its device submission. And finally, FDA conducts its review according to the ASCA guidance. We'll dive into how all this works in just a moment, but first a little background.

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Three guidance documents outline the parameters of the ASCA Pilot. The first is a program guidance, with general information about the Pilot and how to participate. The other two are standards-specific guidances that outline specifications for the two standards families included in the Pilot: biocompatibility and basic safety and essential performance. How did we go about choosing which standards should be included in the ASCA Pilot? Well, we asked you, and we asked conformity assessment experts. We wanted standards and test methods that were both cross-cutting and product-specific, and ones which would yield good insights into how a conformity assessment program should work.

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The biocompatibility scope in the ASCA Pilot includes the standards listed in the left column and the test methods in the right column. Be sure to check the biocompatibility standards-specific guidance. There is also a button on the ASCA web page called "View ASCA Pilot Standards" that will take you directly to a list of ASCA standards in our Recognized Consensus Standards database. This database is also where you'll find the Supplementary Information Sheets. These contain important information about the version of the standard, extent of recognition and related guidances you should know.

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The basic safety and essential performance standards in the ASCA Pilot are from two families: ANSI/AAMI 60601-1 and IEC 61010-1. There are too many to list here – the Basic Safety and Essential Performance standards-specific guidance and the ASCA web page contain the complete list.

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Now let's turn our attention to how to go about preparing a premarket submission that contains ASCA testing.

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The ASCA aspects of a premarket submission are not complicated and can be summarized in 5 steps. Let's review them one at a time, starting with Step 1.

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This step is straightforward: identify the ASCA Pilot standards to be cited. The important thing about this step is that you should first check the list of ASCA Pilot standards, then go to the Recognized Consensus Standards database to access and review the Supplementary Information Sheets. Be sure to check the extent of recognition – partial or complete – as well as the edition. A quick but important reminder: the manufacturer maintains responsibility for the choice of standards and test methods and appropriate use and application.

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Next up is to develop and agree on a test plan with the ASCA-accredited test lab.
First, select an ASCA-accredited testing laboratory, and then work together to develop and agree on a test plan. Just remember that you, as the manufacturer, are ultimately responsible for the test plan. Keep some things in mind as you develop the test plan. Consult relevant FDA guidance documents, and not just ASCA Pilot guidances. The standards you use must be the FDA-recognized version of the standard – be sure to check the extent of recognition. In cases of partial recognition, the Supplementary Information Sheets will have more information on the rationale for a partial recognition and may also point you to relevant FDA guidance documents to aid in the development of your test plan. All of this information can be found in the Recognized Consensus Standards database. And finally, be sure to check that the test laboratory's scope of accreditation matches the edition or version of the recognized standard you've chosen to use.

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Step 3 is to plan the submission elements. So, what are the ASCA elements of a premarket submission? First is the cover letter of the submission. In the cover letter, you will include a reference to the ASCA Pilot so that we can flag it as an ASCA submission. The other elements are the declarations of conformity and the Summary Test Reports. We'll go into greater detail about these in just a moment,

but it's important to remember that complete test reports generally do not need to be included in the submission.

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Next, the laboratory will conduct the testing according to the agreed-upon plan, and then send you the complete test reports and ASCA Summary Test Reports.

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Step 5 is when it all comes together: you prepare your FDA submission. You'll prepare your cover letter that includes ASCA-specific information, the declarations of conformity, and the Summary Test Reports. Of course, as a reminder, do not modify the Summary Test Reports. Submit them just as they were received from the testing laboratory. And don't forget the non-ASCA related components of the submission! Other submission requirements are not altered by this pilot.

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Now let's turn to a deeper discussion of the three ASCA elements you'll want to include: a cover letter, declarations of conformity and the ASCA Summary Test Reports. We'll review each of these in turn.

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Let's start with the premarket submission cover letter. This is separate from and in addition to the FDA Submission Cover Sheet, or Form 3514. We understand that a cover letter is also commonly included in a submission. We encourage inclusion of a cover letter, because this is where you will identify for the FDA that the submission is ASCA-related. A reference to ASCA in your cover letter is the way to tell us that the submission is ASCA-related. The additional language for the cover letter can be very simple: it should clearly state that the submission contains ASCA Summary Test Reports, it should reflect the ASCA-accredited test lab's information, including its ASCA identification number, and it should list the ASCA standards and test methods being cited.

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Let's move on to the declaration of conformity. Remember that this is the manufacturer's responsibility. It should reflect the test lab's ASCA Accreditation status at the time of testing. We encourage you to check out the example declarations of conformity provided in the two standards-specific guidances.

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The third and final element is the ASCA Summary Test Report provided to you by the test lab. We're going to review one in detail in a moment, but as a reminder there are example Summary Test Reports in the standards-specific guidances: nine for biocompatibility and one for basic safety and essential performance.

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Here are two examples of ASCA declarations of conformity. These examples may be found in the two standards-specific guidances.

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The ASCA Summary Test Report examples were developed in response to feedback to the draft ASCA guidance. We were asked to offer direction on what a Summary Test Report should contain. Note: these are not templates or forms - they are simply advice on what to include. Test labs will likely have their

own format for Summary Test Reports. And while you are not allowed to change anything on the Summary Test Reports that the test lab sends to you, you as the manufacturer are responsible for its contents, so please be sure to check that they contain all the information that FDA expects.

We're going to walk through an example Summary Test Report – in this case, from the basic safety and essential performance standards-specific guidance. The biocompatibility examples will of course be different. The first part addresses three elements. The administrative information, next to the blue arrow, provides details about the testing and the lab. It includes a reminder in #5 that the lab should have that testing or method in its ASCA Accreditation scope. The red arrow indicates the device essential performance characteristics section. It should reflect all those that you as the manufacturer have developed. This section should also indicate if there are any differences between the essential performance identified in the standard and those essential performance characteristics which were considered during the test. The next section, with the green arrow, describes the use environment, reflecting where the device is intended to be used.

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In the Clauses Tested section, next to the blue arrow, the test lab goes into detail about how and what it did and did not test. The test lab will also want to indicate if any modifications were made to the test methods or the acceptance criteria – highlighted there by the red arrow. Recall that some standards allow choices; this is how the lab will note those choices.

The green arrow points out where the test lab would describe any additional testing that was performed, along with its results. And at the bottom of this page next to the yellow arrow, you can see that we would want to understand how the device was configured, including its mode of operation, during all of the testing.

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Finally, we come to the test results section. The test lab is expected to be very clear about any "observations and degradations" during the testing, as seen here by the blue arrow. And if they did find such observations, they should enter only the unexpected ones. In the next section, the red arrow indicates whether the test lab made any modifications to the device. They then describe any identified concerns – highlighted by the green arrow - which would have been clearly communicated to the manufacturer. And finally, the yellow arrow points to where the test lab signs to confirm that the document is accurate and summarizes all original and any retest data. As we mentioned earlier, individual test labs may have different styles or formats for their ASCA Summary Test Report. However, those reports should still reflect the expected content described here and in the guidance documents.

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Let's close with some tips to help you prepare a successful ASCA submission.

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First, ensure that your submission cover letter is complete and that it indicates that it contains ASCA Pilot testing. It should provide the name, location and identification numbers of the ASCA-accredited test labs you worked with, as well as the FDA-recognized standards and test methods used. This will flag the submission so that the FDA reviewer knows to look for an ASCA declaration of conformity and Summary Test Report. Include complete declarations of conformity for all cited FDA-recognized standards.

Submit ASCA Summary Test Reports, as supplied by the testing lab. And finally, but most importantly, please don't hesitate to ask questions. The ASCA Pilot is a new program and we are here to help you in any way we can.

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I'd like to recap what we've shared here today. The Accreditation Scheme for Conformity Assessment Pilot brings together stakeholders from across the device community who contributed to the design of the Pilot, which relies upon and leverages international consensus standards. At the same time, these stakeholders are helping us advance regulatory science. Our shared goal is to enhance the use of conformity assessment in device premarket review.

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ASCA's advantages are potentially significant, for both manufacturers and the FDA. It is designed to increase consistency and predictability in FDA's approach to assessing conformance, which should reduce regulatory burden. Most importantly, we expect that the patients we all serve will benefit from the ASCA Pilot, as safe and effective devices are made available to them without unnecessary delay.

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We reviewed the five steps to preparing a submission with ASCA testing. These are: identify the ASCA standard, agree on a test plan with the ASCA-accredited test lab, plan the submission elements, obtain the test results and summary test reports, and prepare the FDA submission.
And finally, we reviewed the three elements of an ASCA submission: the cover letter with ASCA-specific information, the declaration of conformity and the Summary Test Reports.

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The next few slides include resources for you to use after watching this presentation. On this slide, I've listed the links to the three ASCA Pilot guidance documents we discussed.

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This slide provides some websites that should be helpful to you use standards in your submissions.

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This slide includes two important standards-related guidances: Recognition and Withdrawal of Voluntary Consensus Standards and the Appropriate Use of Voluntary Consensus Standards. As a reminder, the use of standards is voluntary, and these two guidances represent FDA's thinking on these important standards topics. I'd also like to draw your attention to CDRH Learn, which features a series of educational modules on the standards program – these may be found under the "How to Study and Market Your Device" section.

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And of course, we urge you to tap into CDRH Learn and Device Advice for additional regulatory education. You may also contact D-I-C-E directly by phone or email with any general regulatory questions you may have. Useful information is listed on this slide.

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I'd like to close today with your call to action. First, you promote the use of recognized standards in device submissions: among your colleagues, within your firms, everywhere. Second, please participate in

the Pilot! You have a lot to gain – time, efficiency and the confidence that you are contributing to the advancement of regulatory science. Third, contact us with any questions or feedback for the Pilot. And because the best, most regulatory-ready standards are ones built by a broad cross-section of experts, please get involved in standards development. Your insights and contributions are invaluable and will help us at the FDA put standards to work. Thanks for watching!

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