CDRH Learn - How to Use Consensus Standards in Premarket Submissions

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Hello, my name is Scott Colburn, and I am the director of the Standards and Conformity Assessment Program, or S-CAP, at CDRH. Welcome to this CDRH Learn module. In today's presentation, we'll review how to effectively and appropriately use consensus standards in premarket submissions. For the purposes of this module, I will use the terms standards and consensus standards interchangeably.

Before we get into how to use standards, it's helpful to remember why we should use them. Using consensus standards in premarket submissions offers significant benefits.

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First, the use of standards enhances regulatory science and promotes a least burdensome approach to device oversight. Standards introduce efficiencies into the pre-market review process by setting clear expectations for conformity assessment and test reporting. Using declarations of conformity with FDA-recognized standards can increase predictability, streamline premarket review, provide clearer regulatory expectations, and facilitate market entry. And using international consensus standards reduces burdens on device companies by harmonizing expectations across international jurisdictions.

Second, consensus standards promote quality. Crowd-sourcing standards leads to clearer performance expectations. Relying upon input from around the world ensures that we tap into expertise that no one manufacturer or regulator or clinician will have access to. Robust standards development and standards revision processes yield standards that can keep up with technological advances!

Finally, using standards helps ensure that innovative, safe and effective devices are available: by optimizing 'bench to bedside' time, we get life-saving products to the patients we all serve. The appropriate use of consensus standards encourages innovation and competition among product developers by providing a level playing field. With everyone playing by the same rules, or in this case, standards, more and better devices can be introduced into the market!

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What do we hope to accomplish today? We have four objectives: First, we'll explain how to use standards in device submissions, reviewing submission expectations in detail. Then, we'll describe how declarations of conformity can improve the quality of submissions and their positive impact on device review, because much of the benefit of using standards is predicated upon the appropriate use of declarations of conformity! We'll also identify when supplemental documentation is needed and what that documentation should include. And finally, we'll discuss Helpful Tips for using standards and declarations of conformity in medical device submissions.

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Now that I have introduced consensus standards and their important role in the medical device community, I want to focus on how to use consensus standards in a device premarket submission.

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Consensus standards play a key role the pre-market review space. But before we talk more about the specifics, it's important to emphasize the key point that the use of consensus standards is voluntary. FDA strongly recommends using consensus standards, for all the reasons we just talked about. But their use by a manufacturer is voluntary, unless 'incorporated by reference' into a regulation.

If you, as the manufacturer, wish to demonstrate conformity to expectations in other ways, that is your prerogative. Just be prepared to justify your approach! Now, back to business: standards may be cited in any type of submission. If the standard is recognized by the FDA, the declaration of conformity will reduce the need for supplemental documentation, but 'General Use' of a standard is also an option. Just know that additional documentation will be needed. We'll talk more about the General Use of standards in a moment.

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Form FDA 3514 Cover Sheet is an important resource for your device submission. Note that this form would be used in addition to any submission cover letter your company might also include in submissions. Use of Form 3514 Cover Sheet is voluntary, but we recommend it as it helps ensure you have correctly cited standards in your paperwork. I've included a link to it on this slide. Section J of Form 3514 is where you'll go to include your standards' citations. See the section outlined in blue? This is an 'examples' section. It is included to provide some direction on what will go in the form. There are 5 columns in the first box in this section and I'm going to discuss each of these columns in more detail. But before I do, note that the section below outlined in bright red is where you will actually enter your submission's standards information.

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See this button in the bottom right of the Utilization Section, that I've highlighted in red? You'll click on that button for every standard you wish to add to Form 3514.

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I'm going to go from left to right and point out the elements that you will need to enter. The first column on the left highlighted by the dark red box is for the standard's Recognition Number: enter the FDA recognition number – which is found in the Consensus Standards Recognition database at the link provided at the bottom of this slide. This database has tons of valuable information and if you haven't spent time with it yet, please do, as it will really help you as you 'put standards to work.' If the standard is not recognized, which means you are citing it under 'General Use,' write NR in the Utilization section.

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The next column to the right, highlighted in blue, is where you indicate whether you are using a declaration of conformity or if you are submitting under 'General Use.' Select 'Declaration of Conformity' if you are including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use.' In both cases you should note if you have made deviations from the expectations of the recognized or non-recognized standard.

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Moving on, the column in the green box is where you state the Standards Development Organization (SDO), the standard's Designation Number (including the year), and the title of the standard you are citing.

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The last column highlighted in gold tells us where the standard is applied in your submission. Pointing the FDA reviewer to the page numbers helps save a lot of time.

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Now let's take a deeper dive into the declaration of conformity, or DOC.

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So, what is a declaration of conformity? A declaration of conformity is an attestation from the submitter that the device conforms to all the requirements of an FDA-recognized consensus standard at the time of submission. It confirms to the FDA that all normative requirements have been met, that tests have been conducted, and that those tests were performed on a finished device. If the submitter declares conformity to an FDA-recognized standard, a declaration of conformity must be included in the premarket submission. Using a declaration of conformity may reduce the amount of supplemental information needed in a submission. We'll talk more about what we mean by 'supplemental information' in just a bit.

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We at FDA want to encourage the use of declarations of conformity, so we wrote a guidance. Published in 2018, the Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices lays out what a declaration of conformity should contain.
Since the Standards and Conformity Assessment Program also prioritizes a reliance upon international consensus standards whenever possible, this guidance builds upon ISO/IEC 17050-1, cited at the bottom. The Appropriate Use guidance stipulates the following elements: the sponsor's contact information, the device's identifying information, the actual statement of conformity and all the standards being cited - be sure to include their FDA recognition numbers.

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The other elements of a declaration of conformity are the date and place where the declaration of conformity was issued, the signature of the responsible party, any limitations on the declaration of conformity's validity, and finally, any supplemental documentation supporting the declaration of conformity. Let's take a look at an example of a declaration of conformity.

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This is an example of a declaration of conformity. Note that this is not an FDA form. It's an example declaration of conformity adapted from the Accreditation Scheme for Conformity Assessment Pilot. But it contains everything FDA will need to efficiently evaluate your conformance. You may certainly use different formats but be sure to share all of the information we're getting ready to discuss.

Let's go through each of the three following sections so that you can be comfortable using a declaration of conformity. We'll discuss the responsible party and the product or device identification, then the actual statement of conformity and finally the limitations of validity section of a declaration of conformity, as well as the signature element.

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Before I dive into the specific information needed, I urge you to review the Appropriate Use of Voluntary Consensus Standards guidance for an excellent resource, along with standards ISO/IEC 17050 parts 1 and 2. So here in the first section, you can see where to enter the responsible party's information – name and address - and the device identifiers. This includes both manufacturer-specific information like model numbers as well as the FDA procode.

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The actual statement of conformity, the attestation, goes in this section. It looks like a lot of information, but it's very straightforward. The statement should include these details for each standard cited. At the very top, you can see the actual statement of conformity: don't forget to make that statement! Next, enter the standard's title and FDA recognition number. Then you'll enter whether your submission features 'options.' In other words, if a standard provides alternative test methods or conditions and you took advantage of that, you'd note that here. Next is the test lab information, the date testing was conducted and an indication of whether you are including supplemental documentation – we'll talk more about supplemental documentation shortly.

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The last section is where you will list any 'limitations on the validity' of the declaration of conformity. What we mean by limitations on validity is this: we recognize that some standards are very complex and that testing outcomes do not always fit nicely into a box. This is where you will explain and provide your rationale for such a limitation on validity. And finally, you should provide the name and signature of the responsible party.

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Before we turn to a discussion of when and what types of supplemental documentation may be needed, recall that standards are voluntary. That means you may also use other, non-recognized consensus standards. However, since declarations of conformity are not included in these 'General Use' cases, complete test reports should be included as part of your submission. These reports will need review by FDA, adding time to the review process. For more complex standards, like product-specific standards, modifications might sometimes be needed, which would call for complete test reports for that aspect of the standard, though a declaration of conformity could still be used for the rest of the standard.
For a lot more detailed information about the General Use of a standard, visit that guidance I just mentioned: the Appropriate Use of Voluntary Consensus Standards. And remember you can always ask the FDA review team for advice!

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Our shared goal is that standards should – whenever possible – have clear test methods and acceptance criteria built into them. This makes everyone's lives a lot easier – and makes standards 'regulatory-ready.' And that is one reason FDA prioritizes having regulators at the standards development table, so we can remind standards developers of that! But we don't live in a perfect world, so I'd like to share with you how to determine if your declaration of conformity needs to be accompanied by supplemental documentation, and what form that documentation should take.

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This table is taken from the Appropriate Use guidance I keep talking about. It summarizes when and what sorts of supplemental documentation are needed. Let's walk through the different scenarios outlined in the table.

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The first line of the table points out that standards specifying design requirements, even if they have acceptance criteria or test methods, do not need to be accompanied by supplemental documentation.

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As you can see in the red box, sometimes a standard has a test method but not acceptance criteria. In those cases, the complete test report is not needed, but your supplemental documentation should reference the criteria you tested to.

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Below that line outlined in blue is the opposite case: the standard may feature acceptance criteria, but not specify a test method. As in the previous case, a complete test report is not needed, but you should submit supplemental documentation about the testing methods you chose and why you chose them.

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As you can see in the green box, when both test methods AND acceptance criteria are called out in the standard, and you use and apply them as written, FDA doesn't need any supplemental documentation. This is really the best-case scenario, as it can save you and the FDA time. One caveat: sometimes standards offer choices in test methods. When that is the case, you should let FDA know what you chose and why with your supplemental documentation.

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The final line in the table, outlined in yellow, is our worst-case scenario: neither test methods nor acceptance criteria are included in the standard. For those standards, you'd need to submit the complete test reports.

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So you can see that it's pretty clear when supplemental documentation will be needed: when there are not methods or acceptance criteria called out, and when you have applied deviations to the standard. In these cases, FDA should see complete test reports. And if you decide to cite a non-recognized standard under 'General Use' of a standard even MORE documentation will be needed. Let's take a look at a real-world example next: an ANSI/AAMI human factors standard.

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ANSI/AAMI HE75-2009 is a human factors standard. In this case, FDA recognizes most, but not all of the standard. This is known as a partial recognition. We do not recognize Section 9: Usability testing. That is because that section conflicts with Appendix A of the FDA guidance entitled Applying Human Factors and Usability Engineering to Medical Devices. In this example, complete test reports will be needed for usability testing, which is further outlined in the FDA guidance.

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To emphasize: supplemental documentation is NOT needed when citing a design standard. Nor is it needed when test methods and acceptance criteria are specified. For example, ISO 17665-1, a sterilization standard, has both so we can rely on declarations of conformity alone – no supplemental documentation should be needed!

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Let's go over some helpful hints to ensure you are 'putting standards to work' appropriately.

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We've told you a lot of things TO do, what about what NOT to do? Well first of all, take care not to use standards inappropriately. Don't use standards that don't apply to your device, and don't forget to

check the extent of recognition as identified in the Recognized Standards database. If a standard or a section of a standard is NOT recognized, you may not submit a declaration of conformity to it.

Second, avoid inappropriate uses of declarations of conformity. Don't send a declaration of conformity citing a non-recognized standard, or one that is an old version no longer recognized by FDA. Be careful with deviations. As I mentioned earlier, some standards have permissible modifications built in. You are allowed to choose a test method for example, and then you'd share with us why you chose that method. However, if you make a deviation to a method or acceptance criteria that is NOT called out in the standard, you should send supplemental documentation that clearly tells us what you did and why you did it. And in all cases in which supplemental documentation is called for, it goes without saying – please don't forget to include it in your submission.

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Next, don't fall into the trap of thinking that using a recognized standard satisfies ALL questions in a premarket submission. Don't forget to check relevant regulations and FDA guidances for what is needed. And finally, FDA Form 3654 expired in 2018 – please don't use it!

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We've covered a lot of ground here today, and I thank you for your attention. We discussed how to use standards in device submissions, and how declarations of conformity can make regulatory review more efficient. We specified when supplemental documentation is needed, and what form it should take based upon various scenarios.

Finally, we shared some more general tips on how to successfully use standards and declarations of conformity.

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Here are some excellent web sites I encourage you to review. These include the Standards and Conformity Assessment Program's web page, the Recognized Consensus Standards database, Device Advice resources and a CDRH Learn module with more information about standards and device review.

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We always encourage you to become familiar with FDA guidances. Here are two that are relevant to today's module: the Appropriate Use of Voluntary Consensus Standards we've mentioned before and the Recognition and Withdrawal of Voluntary Consensus Standards guidance. Please don't hesitate to write to us at CDRHStandardsStaff@fda.hhs.gov with any questions or feedback. We welcome hearing from you.

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As always, we encourage you to refer to CDRH Learn and Device Advice for additional regulatory education. You may also contact D – I – C - E directly with any general regulatory questions you may have. We are happy to assist you by phone or email. Please refer to the information provided on this slide for our hours of operation.

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I leave you with this call to action: Hopefully we have convinced you to 'put standards to work' by using FDA-recognized consensus standards in your device submissions. And while their use is completely voluntary, if you submit a declaration of conformity, it can save time. Be sure that your documentation

is complete – knowing when and what to submit can help you avoid delays in your device's review. We'd also like to use this opportunity to encourage you to get involved in standards development. Effective use of standards doesn't start and end with citing them in device submissions. Helping standards development organizations write better, 'regulatory-ready' standards that are fit for use in device review is an important priority, one which we hope you share with us. Thank you for watching today!

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