CDRH Learn – Standards: Resources and Use in Premarket Submissions with Jianchao Zeng

Slide 1
Hello, my name is Jianchao Zeng and I am a Senior Standards Advisor at the CDRH Standards Program. In this CDRH Learn module, I will discuss some resources for FDA recognized consensus standards and how they are used in premarket submissions to CDRH.

Slide 2
In this module, you'll learn how to find and locate standards in the FDA Recognized Standards Database on our website. You'll also find FDA guidance documents specific to the use of standards. You'll be able to identify and decipher the full title of a standard. You'll be able to locate Supplementary Information useful in understanding how FDA recognizes a standard. We'll discuss the two main ways to use standards via General Use or Declaration of Conformity. And finally, you'll understand the elements of a declaration of conformity and how it's used.

Slide 3
To understand which and how standards can be used in premarket submissions to CDRH, it's important to know that not all standards are equal in terms of their use. Some standards are test methods and have pre-specified objective performance criteria, others are guidelines that have choices or pathways to follow with regards to testing requirements, and still others are practices or have a set of suggested options. Knowing the type of standards product that's being used will guide how much information to supply in a submission.

Slide 4
FDA maintains a current repository of recognized standards in a database found at the FDA website listed on this slide. The database is publicly available and each recognized standard contains a Supplementary Information Sheet, or SIS. While not comprehensive, the SIS commonly notes the device type as listed by its product code that is addressed by the standard. The standards contained in this database are recognized by FDA, either completely or in part, and stakeholders may elect to use them with or without making a declaration of conformity.

Slide 5
This slide shows a screenshot of the Consensus Standards Database. From here, you can use the search wizard to find a specific standard of interest, along with its corresponding Supplementary Information.

Slide 6
The search wizard has a number of fields you can use to help with your search. Not all search fields need to be filled out to conduct your search. Search fields include the standards organization, standard designation number, standards title or keyword, specialty task group, and product codes.

Slide 7
This slide shows an example of a search. Here we selected "Cardiovascular" as the "Specialty Task Group Area" and then ran the search to total number of standards in this category. If you look above the table on the left, you'll see the total number of standards associated with the category "cardiovascular." On the right hand side, highlighted in the yellow circle, you can change the number of standards presented per page.

This sort can be downloaded for your convenience, however please check back with the database as we'll refresh it each time a Federal Register recognition list is published. If you click on a standard title, the Supplementary Information Sheet for that standard will appear.

Slide 8
This slide shows an example of an SIS for a particular cardiovascular standard. In this case, this standard pertains to non-invasive blood pressure devices. The standard was published in 2007 but was most recently recognized on January 30, 2014. As a reminder, the SIS is published when FDA recognizes a standard.

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The Supplementary Information Sheet is CDRH's determination of how the standard should be used in a premarket submission or other Center process. CDRH has built-in latitude to support the recognition of a standard even if some aspects conflict with an FDA position and the Center does this by recognizing a standard in part. In this way, the Center may communicate that the standard may still be useful to the rest of the community even if it is not directly useful in premarket review. An example of this would be a practice guideline for how a device would be used in hospitals or by medical personnel.

Slide 10
This slide outlines the type of information included in a Supplementary Information Sheet. The SIS includes the Recognition List number, which is the number on the Federal Register Notice of Recognition, and the date of the publication of the Federal Register. We also include a Recognition number.
Other details, such as the standards developer, its designation number, and the date the standard was published, are also included. The SIS identifies any parallel adoptions, scope and rationale for recognition. Also included are the type of standard, extent of recognition, related product codes or classification, and any published guidances that refer to the standard. At the bottom of the SIS are the FDA technical points of contact and the SDO's address. Finally, if applicable, you'll also find a history of recognition which lists related standards that have been withdrawn (including earlier editions, corrections, amendments, and superseded standards).

Slide 11
On this slide, we break down the anatomy of the full description of the title of a recognized international standard with an example. Starting from the left, underlined in red, we have the standards developing organization, which is IEC for this example. IEC is an international standards organization, which also means this is an international standard. To the right of the SDO, underlined in blue, is the standard's designation number, which is 60601-2-13. The edition, underlined in black, and year of publication, underlined in green, are next listed - in this example, Edition 3.1 of this standard was published in 2009. And we conclude with the full title of the standard, underlined in brown. This is a standard specific to the safety and essential performance of anaesthetic systems.

Slide 12
This slide lists an example of a recognized U.S. national standard. The SDO is the Association for Advancement of Medical Instrumentation or AAMI, which is a U.S. developer. This standard was accredited through the American National Standards Institute, or ANSI. This standard's designation number is BP22 and it was originally published in 1994. You'll next see the letter R in parentheses, followed by the year 2011. This means that the standard was reaffirmed in 2011. And finally, we conclude with the title of this standard, which is blood pressure transducers.

Slide 13
This slide includes an example of a recognized US parallel adoption of an international standard. This is done by combining the U.S. standard developer, AAMI, the US accrediting body, ANSI, and the international standards developer, ISO. Next listed is the standard's designation number, which is 7198. Next are three dates, which are from left to right, the original publication of the standard, the date the standard was adopted in parallel, and the most recent date the standard was reaffirmed. The description then concludes with the title of the standard, which is Cardiovascular Implants, Tubular Vascular Prosthesis.

Slide 14 - Standards Guidances
This slide includes useful links to some standards-related guidances. This is an excellent resource to get more information about the standards process.

Slide 15 - Two Ways to Use a Standard in Submissions
A standard may primarily be used in two ways in a medical device submission: General use or Declaration of Conformity. Over the next few slides, we'll go over both ways so you can decide which approach is most suitable for your submission.

Slide 16
General use of a consensus standard refers to submissions in which a submitter demonstrates conformance to a part of, or an entire consensus standard, but does not submit a Declaration of Conformity. This applies to any standard, whether or not it is recognized. In this situation, the submitter should discuss how the standard was used by providing a full test report. A submitter may apply a general use of a standard to any type of submission.

Slide 17
The second way to use a standard is with a Declaration of Conformity or DoC. In this case, the submitter certifies that its device conforms to all of the applicable requirements of an FDA-recognized consensus standard. The submitter may not deviate from the FDA-recognized consensus standard. Additionally, a submitter may not submit a DoC if the submitter used a consensus standard that has not been recognized by FDA.

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Over the next few slides, I'll outline the elements of a declaration of conformity.
First, provide the name, organization and address of the submitter who is responsible for the declaration. Then, identify the medical device to which the declaration applies. Third, provide a statement of conformity and include, for each standard, the options or choices that were selected. Next, provide a list of FDA recognized standards and the corresponding recognition number for each.

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Next, list the date, address and signature of the responsible person making the DoC. And finally, describe any limitation of the validity of the declaration. For example, a limitation would be that the declaration is valid during a certain timeframe. The order of elements shown in these slides is not prescriptive. You may also choose to create a Declaration of Conformity using the format described in ISO/IEC 17050-1 Conformity assessment - Supplier's Declaration of Conformity - Part 1 General requirements.

Slide 20
The purpose of declaring conformance to an FDA-recognized consensus standard is to meet certain premarket requirements and reduce the amount of supporting data and information submitted to CDRH. Keep in mind, a submitter needs to certify that the device was tested and conforms to the FDA-recognized consensus standard. This is not a future promise to meet the standard upon further testing.

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In some cases, it's sufficient for a submitter to provide a DoC to support the premarket submission. This is because the standard has enough specificity and detail with respect to test methods, test specifications, pass/fail criteria, and/or pre-specified testing requirements or outcomes, so that CDRH doesn't need to review the full test data to understand how conformance was established.

Slide 22
In some cases, however, a standard will need both a DoC and supporting documentation. Examples of these types of standards include guidelines or practices, technical reports or technical information reports. The reason is that these types of standards may include options within the test methods, or lack details such as pass/fail criteria. As a result, the supporting documentation provides this added detailed information.

The ISO standard cited on this slide can be used to help develop the necessary information. I'll go into some detail on this on the next slide.

Slide 23
In cases where the standard provides an option or a choice, document the selection made and the rationale for that choice.

The documentation should describe the test methods. If an option was chosen, or the test method was adapted or modified to fit the device, this should be explained. In some cases, you may need to modify the device in order to complete the testing described in the standard. This would need to be explained.

And finally, was testing conducted on the final finished device? If not, you should explain why this was done and why the results are still acceptable.

Slide 24
In a promissory statement, a submitter indicates that testing on the device has not yet been completed at the time of the premarket submission. In this case, the submitter promises to complete the specified testing prior to marketing. In limited cases, FDA will accept a promissory statement. Keep in mind, however, that a promissory statement is not a declaration of conformity, because the testing has not yet been completed as required by the DoC.

Slide 25
Let's recap what we reviewed in this module. First, we reviewed how to find FDA-recognized standards. We navigated the FDA website to review the specific search features of the standards database. We provided links to relevant guidances on standards.
We also reviewed the anatomy of a standard title using examples of a national, an international standard, and a US parallel adoption of an international standard. Finally, we reviewed elements of a Declaration of Conformity, and discussed where standards may be used, including the use of promissory statements.

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Thank you for your attention to this CDRH Learn Module: Standards -Resources and Use in Premarket Submissions. We hope you found this module helpful. We encourage you to use other industry education resources we've developed especially for you, as shown on this slide. Thanks for watching this program and we'll see you next time.

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