Conformity Assessment and Consensus Standards

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Standards and Conformity Assessment Program (S-CAP)

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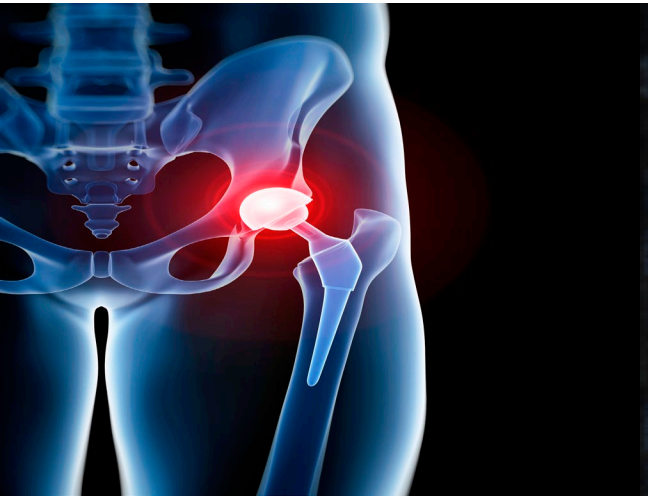
US Food & Drug Administration

Topics

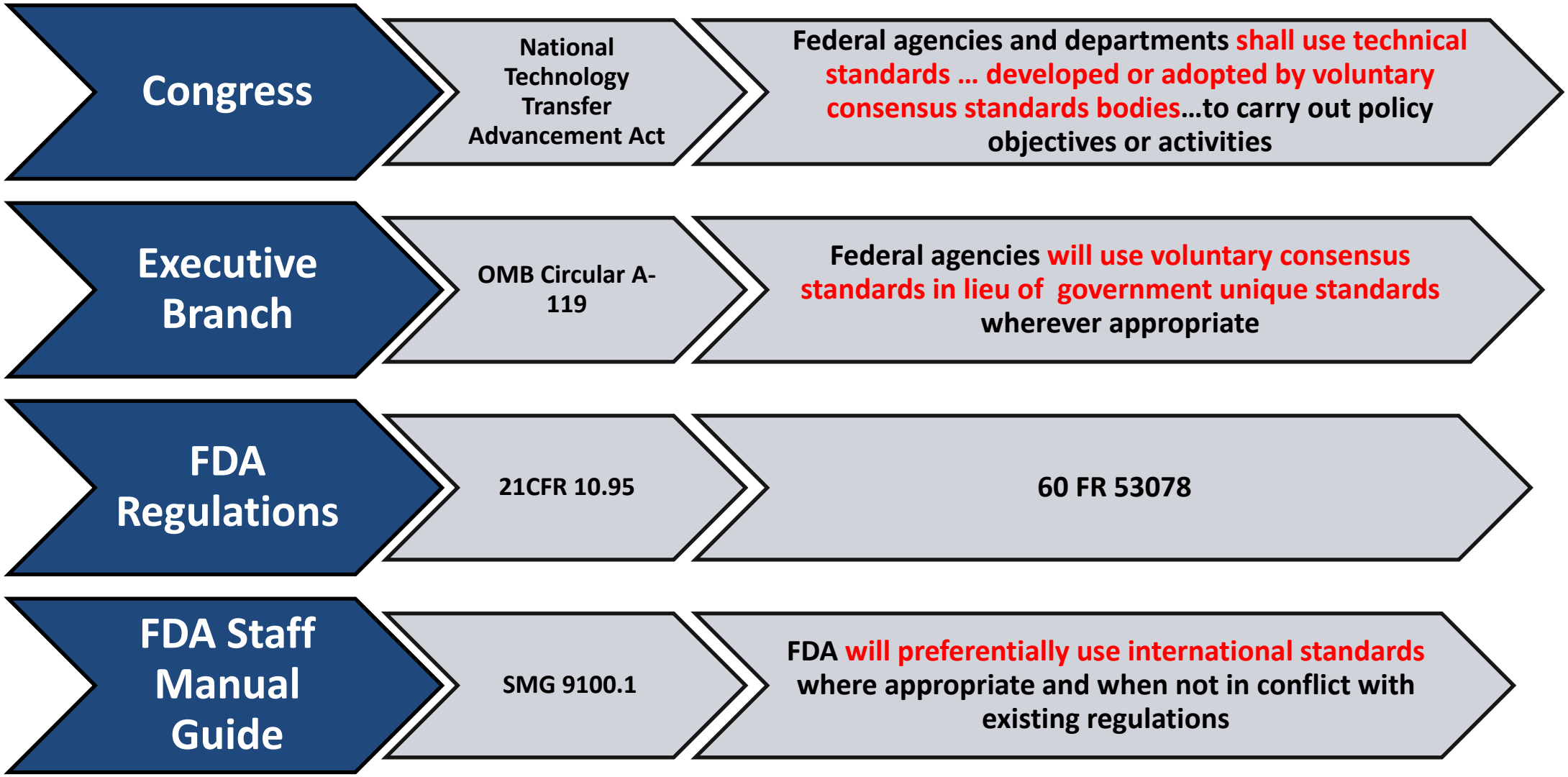
- Why use consensus standards?
- FDA's Standards and Conformity Assessment Program (S-CAP)
- FDA's regulatory use of consensus standards
- Putting standards to work: the Accreditation Scheme for Conformity Assessment (ASCA)



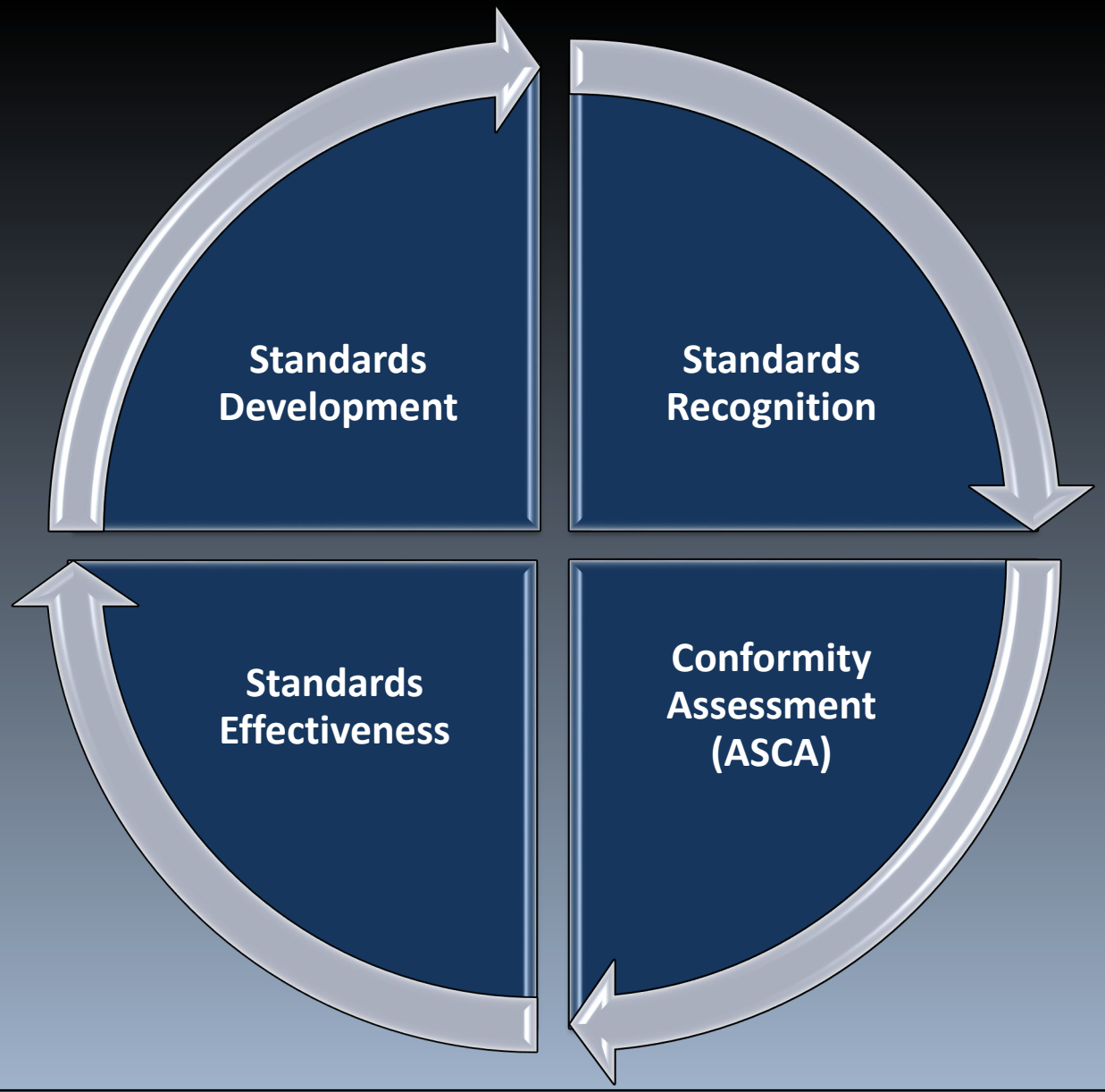
Why Use Consensus Standards?

- Standards benefit from the consensus process, relying upon a broad array of experts and expertise
- Consensus standards preferred over lengthy legal or rule-making approaches
- Encourage innovation and competition among product developers
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions
- Promote regulatory science at national and international levels
- Streamline conformity assessment

US Government Authorities



FDA'S STANDARDS AND CONFORMITY ASSESSMENT PROGRAM (S-CAP)



CDRH's Standards and Conformity Assessment Program

Standards Recognition Program

‘Recognition’: FDA’s formal identification of a standard after determining that it is appropriate for manufacturers to declare conformance (with a declaration of conformity) to meet relevant requirements

- We may recognize all, part or none of the standard
- We publish the decision rationale
- We regularly update databases
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database
- We may withdraw recognized standards, as appropriate

Supplementary Information Sheets (SIS) include:

- FDA Recognition number
- Date of entry into Recognized Consensus Standards Database
- SDO and designation number
- US identical adoption (if applicable)
- Scope of standard
- Extent of recognition
- Is it included in ASCA?
- Rationale for recognition or partial recognition
- Transition period (if any)
- Examples of applicable FDA device product codes
- Relevant FDA guidance documents or other publications
- Relevant FDA Specialty Task Group (STG)
- Name of FDA contact person

FDA’S REGULATORY USE OF CONSENSUS STANDARDS

Using FDA-Recognized Standards

FDA strongly encourages the use of recognized standards in premarket submissions

Declarations of conformity (DOCs) are used with recognized standards, reducing documentation submitted to FDA

A DOC is a communication tool, conveying key information to review staff in a coherent and concise fashion

Using Consensus Standards

- Voluntary
  - Only mandatory if cited in regulation ('incorporated by reference')
- In any type of premarket submission
- With a DOC (recognized standards only) or 'General Use' (any standards, recognized or not)

What is a Declaration of Conformity?

- Attestation that the device conforms with the cited FDA-recognized standard
  - All normative requirements are met
  - All testing has been conducted
  - Testing was performed on finished device or final finished device
- If the manufacturer declares conformity with a recognized standard, a DOC accompanies the submission

**** DOCs support a least burdensome approach by generally reducing documentation needed in a submission ****

Supporting Documentation: Recognized Standards

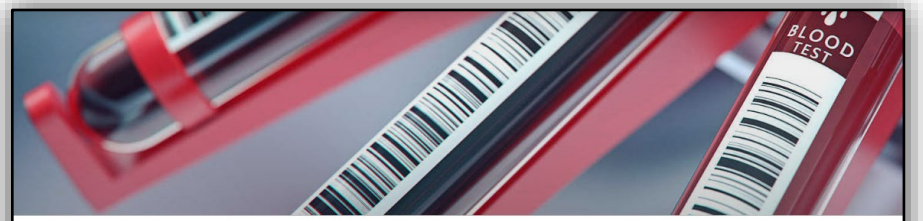
- Information that supports the declaration of conformity
- Needed when the recognized standard:
  - Does not include test method(s)
  - Does not include acceptance criteria
  - Permits modifications
  - Permits options, e.g., for test methods
- Examples: test methods, summary results, ASCA Summary Test Reports

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT ('ASCA')

The Accreditation Scheme for Conformity Assessment (ASCA)

- Voluntary program leveraging a well-established international conformity assessment infrastructure
- Capitalizes on voluntary consensus standards in device development and review
- ‘Puts standards to work’ in conformity assessment

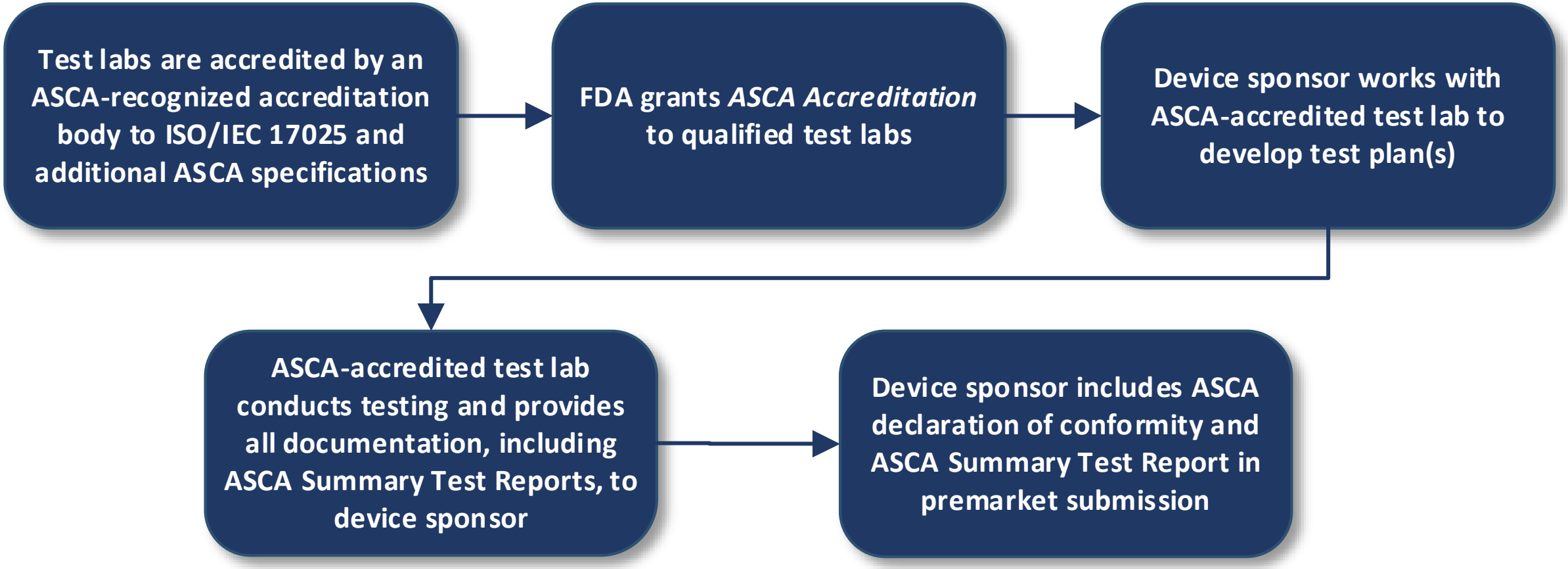
ISO/IEC 17011:2017
Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies



← Popular standards

ISO/IEC 17025
Testing and calibration laboratories

How ASCA Works



ASCA Goal: Streamline conformity assessment in premarket review

- Reduces time needed for the conformity assessment element of device review
  - Less need for Additional Information questions, lengthy internal consults and complete test report review
- Removes the guesswork about supporting documentation needs
  - Provides templates for the only documentation needed:
    - ASCA Declaration of Conformity
    - ASCA Summary Test Report
- Improves the quality of testing
  - Addresses testing issues for which FDA commonly identifies concerns

US Standards Resources

- **Standards & Conformity Assessment Program**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

- **FDA Recognized Consensus Standards Database**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards

- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

- **Contact S-CAP:** CDRHStandardsStaff@fda.hhs.gov

Industry Updates and Education

1. CDRH New

- Sign up at: https://public.govdelivery.com/accounts/USFDA/subscribers/qualify

2. CDRH Learn: Multi-Media Industry Education

- Videos, audio recordings, power point presentations, software-based “how to” modules
- www.fda.gov/CDRHLearn

3. Device Advice: Text-Based Education

- Comprehensive regulatory information on premarket and postmarket topics
- www.fda.gov/DeviceAdvice

4. Division of Industry and Consumer Education (DICE)

- Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: www.fda.gov/DICE

ASCA Resources

- **ASCA Pilot web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA Pilot program guidance**

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA!** ASCA@FDA.HHS.GOV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