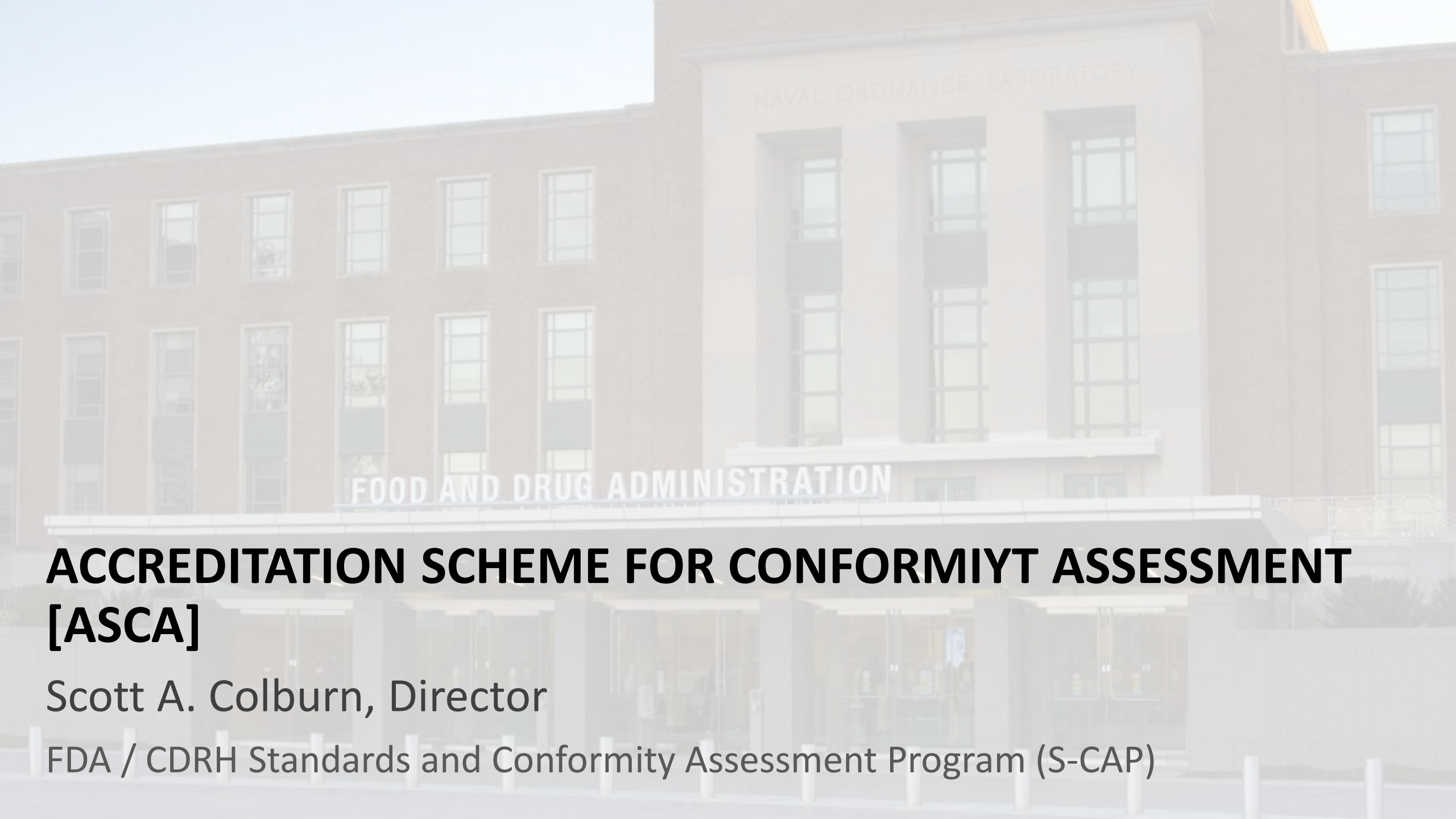


ACCREDITATION SCHEME FOR CONFORMIYT ASSESSMENT [ASCA]

Scott A. Colburn, Director

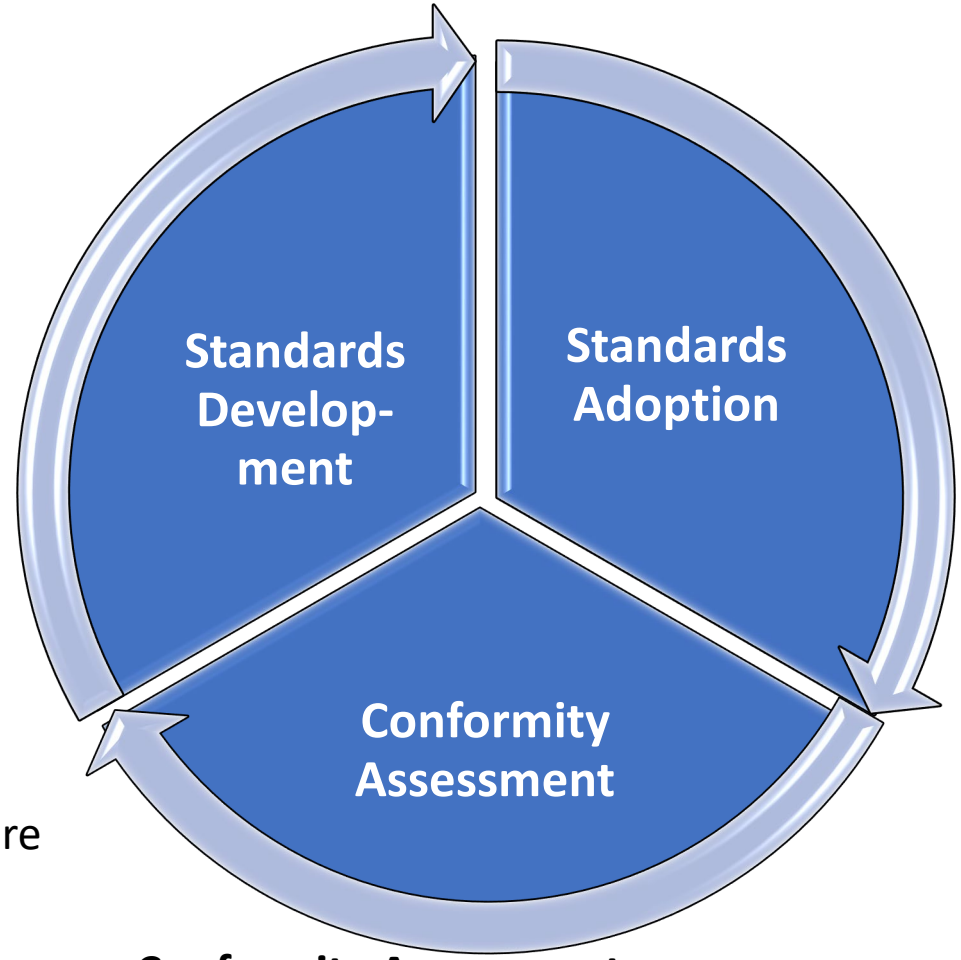
FDA / CDRH Standards and Conformity Assessment Program (S-CAP)

Total Standards Life Cycle

Communication on RA needs/differences during development

Committee make up

Testing V/V during development?



Recognition

- How does recognition enhance the use of the standard?
- What information can accompany recognition?
- Educational needs for stakeholders.

Standards Assessment

- Effectiveness of standard
- Data to support standards future
- Issues with CA

Adoption/Implementation

- Is there a need for Transition for implementation?
- Country/Regional Deviations
- Regulatory challenges

Conformity Assessment

- Do standards lend themselves to adequate Conformity Assessment Reports (e.g. TRFs)
- Enhance the use of declarations of conformity in device submissions

What is ASCA?

- **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 medical device standards to work” in conformity assessment

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

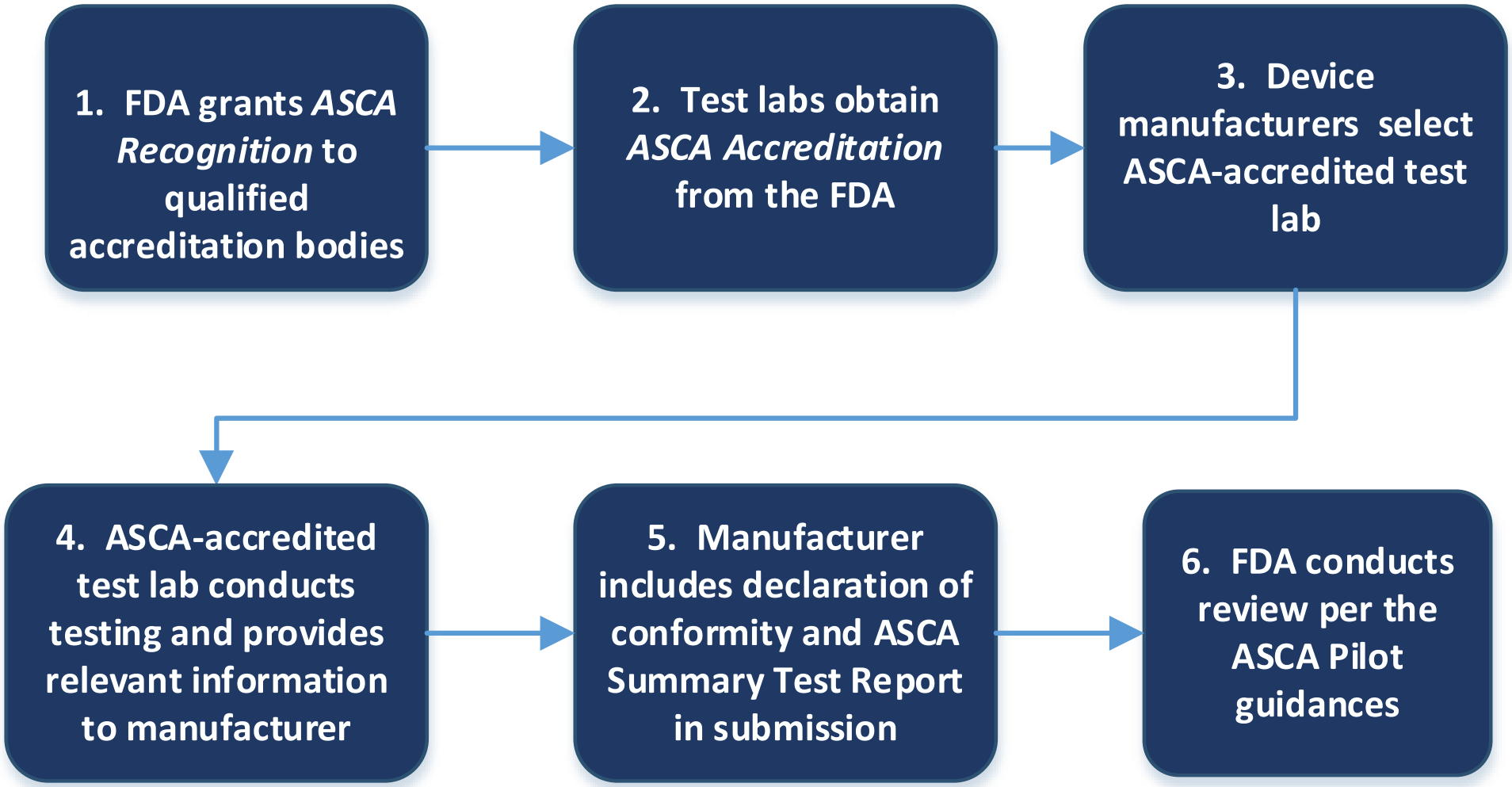
← Popular standards

ISO/IEC 17025
Testing and calibration laboratories

ASCA Goal: Streamline conformity assessment in premarket review

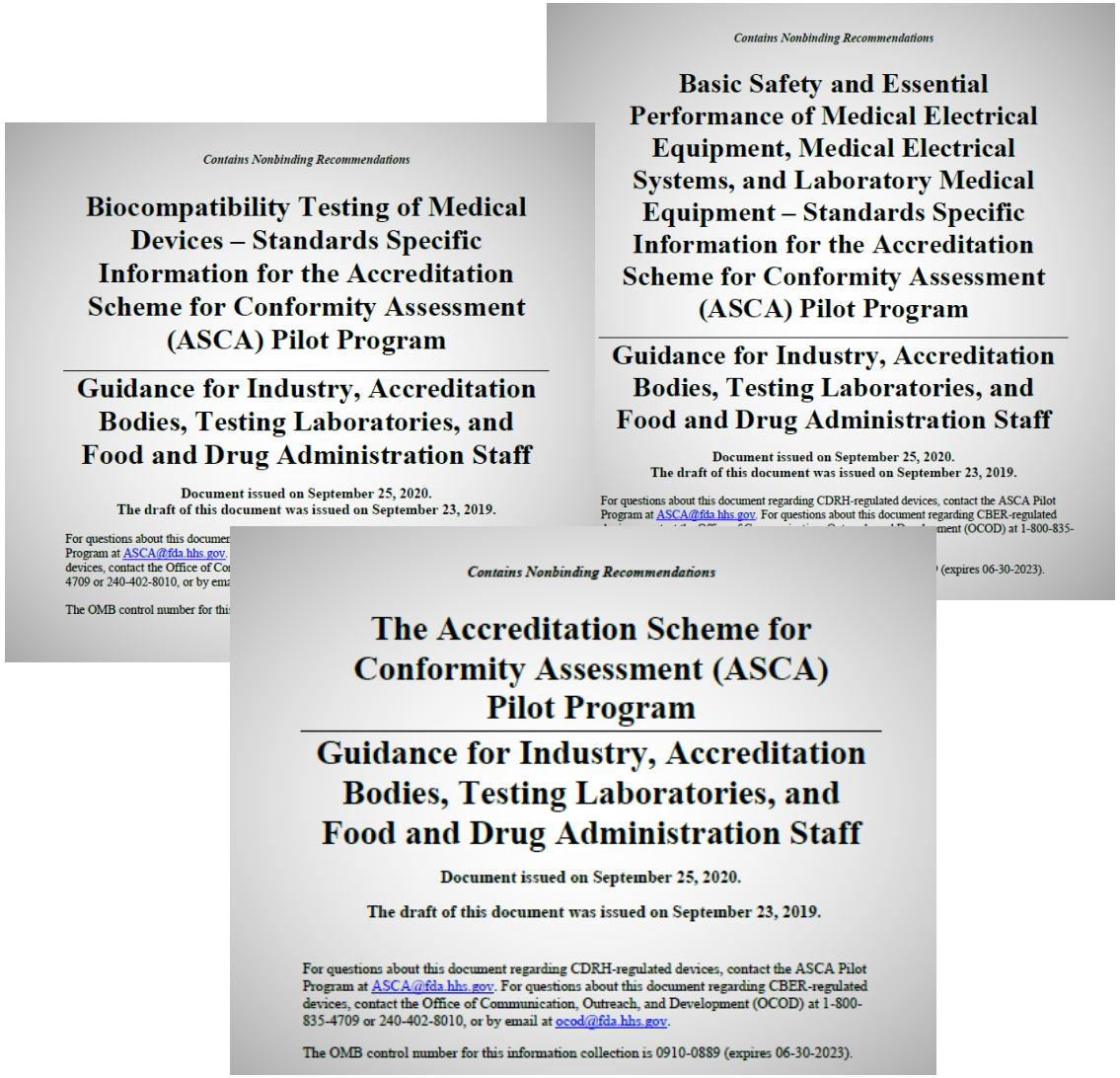
- Communicates expectations on standards use to testing organizations and industry
- Removes the guesswork about supplemental documentation needs
  - Provides templates for declarations of conformity and Summary Test Reports
  - Identifies the minimum documentation needed to accompany a declaration of conformity
- Reduces time needed for the conformity assessment element of device review
  - Less need for Additional Information questions, internal consults and complete test report review

How ASCA Works



ASCA Guidances

- **Program guidance**
  - Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program
- **Standards-specific guidances**
  - Biocompatibility Testing of Medical Devices
  - Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment



Example ASCA Summary Test Report: Cytotoxicity

ASCA Test Method: Cytotoxicity – MEM Elution (ISO 10993-5)
Administrative Information

1. Testing Laboratory Name: Test Lab ABC
2. ASCA Testing Laboratory Identification Number: TL-999
3. Testing Location(s): 123 Main St, XXX, Virginia
4. Testing Date(s): February 1st, 2022—February 28, 2022
5. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☒ Standard (and particular test method) was in testing laboratory's scope of *ASCA Accreditation*
   - ☒ *ASCA Accreditation* was not suspended

ASCA Test Article Prep SOP#: ***SOP-SamplePrep-123-Rev2.0, SOP-SampleExtr-456-Rev3.0***

☒ Test Article was prepared per the above protocol (no deviations/amendments); or
☐ Test Article was prepared per the above protocol, with the following deviations/amendments[1] (e.g., filtering, extract manipulation, pH adjustment):

Description of deviations/amendments

Test Article:
☒ Entire final finished device
☐ Representative sample selection per SOP
☐ Other:[2] *[DESCRIBE]*

Extraction Solvent:
☒ MEM with 5-10% animal serum
☐ Other:[3] *[DESCRIBE]*

Extraction Ratio:
☒ 6cm²/ml (≤0.5mm thick)
☐ 3cm²/ml (0.5-1.0mm thick or molded items > 1.0mm)
☐ 1.25cm²/ml (elastomers > 1.0mm thick)
☐ Other:[4] *[DESCRIBE]*

Extraction Conditions:
☐ 37°C, 24 h
☒ 37°C, 72 h
☐ 50°C, 72 h
☐ 70°C, 24 h
☐ 121°C, 1 h
☐ Other:[5] *[DESCRIBE]*

☒ The test article and extract DID NOT change color, and the extract DID NOT appear turbid or have particles.
☐ There were changes in color/turbidity or particles in the test article and/or extract OR there was swelling/degradation of the test article.[5]

ASCA Test Method SOP #: *SOP-ASCA-MEM-789-Rev2.0*
☒ Test was conducted per the above protocol (no deviations/amendments) and 21 CFR 58; or
☐ Test was conducted per the above protocol and 21 CFR 58, with the following deviations/amendments:[6]

Description of deviations/amendments

Results:[7]

	48 hr Results	72 hr Results	Conclusion
Vehicle Control	Grade 0/0/0	Grade 0/0/0	Performed as expected
Negative Control HDPE	Grade 0/0/0	Grade 0/0/0	Performed as expected
Positive Control Latex	Grade 4/4/4	Grade 4/4/4	Performed as expected
Test Article Extract (100% neat)	Grade 0/0/0	Grade 0/0/0	Non-cytotoxic

I confirm that:
☒ The above summary information includes all original and any retest data; and
☒ I have checked that there are no differences between the complete test report and this ASCA summary test report.

John Standards — 3/15/2022
Name: [TYPED NAME POSITION] — Date

ASCA Submissions: Early Experience

- ASCA Summary Test Reports similar in format to guidance example
- All critical information in the guidance captured in the Summary Test Report
- Internal FDA review checklists use similar format as the ASCA Summary Test Report
- Easy and fast review compared to full test report reviews

Join the Standards Conversation

- Nations (through their 'national bodies' or 'national committees') are ISO and IEC members; they appoint individuals to represent them
- National bodies are responsible for ISO and IEC work within their countries
- National bodies appoint national or 'mirror' committees (called TAGs in the US) whose work mirrors that of the ISO and IEC bodies
  - Develop consensus on issues
  - Review proposals and documents
  - Comment on new standards
- Regulators should participate at both the national (for example, national bodies or mirror committees) and the international levels (ISO and IEC committees)
  - Goal: build regulatory interests into the standards (e.g., test methods, acceptance criteria)
  - Submit effective comments

International Resources

- **IMDRF *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices: 2018***
  http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf
- **IMDRF *Optimizing Standards for Regulatory Use* guidance:**
  http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf
- **International Electrotechnical Commission (IEC)**
  http://www.iec.ch/about/activities/standards.htm?ref=home
- **International Organization for Standardization (ISO)**
  https://iso.ch/home.html
- **ISO Conformity Assessment tools to support public policy: the CASCO Toolbox**
  https://www.iso.org/sites/cascoregulators/02_casco_toolbox.html
- **ISO/IEC Directives Parts 1 (Ed. 13, 2017) and 2 (Ed. 7, 2016)**
  https://www.iec.ch/members_experts/refdocs/iec/isoiecdir-1-consolidatedIECsup%7Bed13.0%7Den.pdf
  https://www.iso.org/sites/directives/current/part2/index.xhtml
- **GHWP WG8 - AHWP/WG2-WG8/F002:2014 Role of Standards in the Assessment of Medical Devices**
  http://www.ahwp.info/sites/default/files/2017-07/Final_GHWP_WG2_WG8_F002_2014.pdf

International Resources, cont'd

- **ISO/IEC Guide 59, ISO and IEC recommended practices for standardization by national bodies 2019**
  https://www.iso.org/standard/71917.html
- **ISO/IEC Guide 63:2012 Guide to the development and inclusion of safety aspects in International Standards for medical devices**
  https://www.iso.org/standard/50729.html
- **ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment**
  https://www.iso.org/standard/42635.html
- **ISO/IEC 17050-1:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 1: General Requirements**
  https://www.iso.org/standard/29373.html#:~:text=ISO%2FIEC%2017050%2D1%3A2004%20specifies%20general%20requirements%20for,irrespective%20of%20the%20sector%20involved.
- **ISO/IEC 17050-2:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 2: Supplemental Information**
  https://www.iso.org/standard/35516.html
- **ISO 14971:2019 Medical devices – Application of risk management to medical devices**
  https://www.iso.org/standard/72704.html
- **Society for Standards Professionals**
  https://www.ses-standards.org/page/A2?
- **World Health Organization WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices 2017**
  https://apps.who.int/iris/handle/10665/255177
- **World Trade Organization Agreement on Technical Barriers to Trade 1994**
  https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

FDA Relevant Guidances

- **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
- **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff**
  https://www.fda.gov/media/113230/download

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

Email: CDRHStandardsStaff@fda.hhs.gov

FDA ASCA Resources

- **ASCA web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA 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! Email: ASCA@FDA.HHS.GOV**

Industry Education

1. **CDRH Learn: Multi-Media Industry Education**
   - Over 200 modules
   - Videos, audio recordings, power point presentations, software-based “how to” modules
   - Mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/CDRHLearn

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - 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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