Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

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Session Agenda

- Standards & Conformity Assessment Program (S-CAP): Overview
- Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program Draft Guidance
- Questions & Answers
Standards & Conformity Assessment Program (S-CAP): Overview
FDA Standards & Conformity Assessment Program

➢ Enhances the use of consensus standards in the design, development and evaluation of medical devices across their lifespans

➢ Relies upon a collaborative approach to standards development and application

➢ Draws upon expertise from across the medical device and standards communities
  – advances regulatory science;
  – promotes patient safety; and
  – supports a least burdensome regulatory framework
S-CAP core priorities

- Encouraging the appropriate use of standards
- Active participation in national and international standards development
- Recognition program

The numbers

- 17 internal advisory Specialty Task Groups (STGs) in 23 device/scientific areas
- 400+ CDRH staff participating in 600+ national and international standards committees across 29 Standards Developing Organizations
- 1385 currently recognized standards (1268 complete and 117 partial recognitions)
- 5-10% typical increase in requests for new standards development activities each year
- Average of 7 (range of 1-35) standards cited in each 510(k)
Accreditation Scheme for Conformity Assessment (ASCA) Pilot
ASCA: Accreditation Scheme for Conformity Assessment

• ASCA authority
• Goals and benefits
• How the ASCA Pilot would work
• Piloted standards/tests
• Next steps
ASCA Authority

The FDA Reauthorization Act of 2017 – FDARA, which amended Section 514 of the Federal Food, Drug and Cosmetic Act to include a voluntary conformity assessment pilot program, which is also part of the Medical Device User Fee Amendments (MDUFA IV) commitments.
What is the Proposed ASCA Pilot Program?

A voluntary pilot conformity assessment program to improve the premarket regulatory process

– Uses recognized accreditation bodies to accredit test labs to an ASCA scope of accreditation
– Standardized test reports from device sponsors will enhance consistency and predictability
ASCA Pilot Goals

• Enhance confidence in medical device testing
• Promote consistency and predictability in the premarket review process
• Encourage effective use of FDA resources
• Enhance regulatory efficiency
• Support international harmonization
How ASCA Would Work

FDA recognizes qualified ABs for ASCA Pilot participation

TLs receive accreditation from recognized ABs

TLs may apply to participate in the ASCA Pilot

FDA grants ASCA Accreditation to qualified TLs

Device manufacturers may select ASCA-accredited TLs for testing
<table>
<thead>
<tr>
<th>Standard</th>
<th>Standard Title</th>
<th>Test method(s)</th>
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<tbody>
<tr>
<td>ISO 10993-4</td>
<td>ISO 10993-4: Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood</td>
<td>Complement Activation</td>
</tr>
</tbody>
</table>
| ISO 10993-4 and ASTM F756 | ISO 10993-4: Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood  
ASTM F756: Standard Practice for Assessment of Hemolytic Properties of Materials | Direct and Indirect Hemolysis                      |
| ISO 10993-10           | ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization | Dermal Irritation, Intracutaneous Reactivity  
Irritation, Guinea Pig Maximization Sensitization, and Closed Patch Sensitization |
USP <151>: Pyrogen Test | Material-Mediated Pyrogenicity                     |
| ISO 10993-12           | ISO 10993-12: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials | Sample preparation for all test types              |
## Basic Safety and Essential Performance

<table>
<thead>
<tr>
<th>Standard</th>
<th>Standard Title</th>
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<tbody>
<tr>
<td>ANSI/AAMI 60601-1</td>
<td>Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (along with the FDA-recognized collateral and particular standards in the IEC/ISO 60601/80601 family)</td>
</tr>
<tr>
<td>IEC 61010-1</td>
<td>Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (along with the FDA recognized standards in the IEC 61010 family)</td>
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</tbody>
</table>
• Final guidance: in accordance with statutory requirements, FDA must initiate the ASCA Pilot Program no later than September 30, 2020

• Please ‘watch this space’ by monitoring the ASCA Pilot Web page
• Standards & Conformity Assessment Program
  https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm#intro

• FDA Recognized Consensus Standards Database
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

• Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices final guidance

• Recognition and Withdrawal of Voluntary Consensus Standards draft guidance

• CDRH Learn: How to Study and Market Your Device: Standards
  https://www.fda.gov/training/cdrhlearn/default.htm

• ASCA Pilot/draft guidance

• ASCA Pilot Web page
Thank you!

Questions? Please contact:

For recognition/appropriate use: CDRHStandardsStaff@fda.hhs.gov
For ASCA Pilot: ASCA@fda.hhs.gov