# Accreditation Scheme for Conformity Assessment (ASCA) Expansion Workshop

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U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health
Division of Standards and Conformity Assessment


# Topics

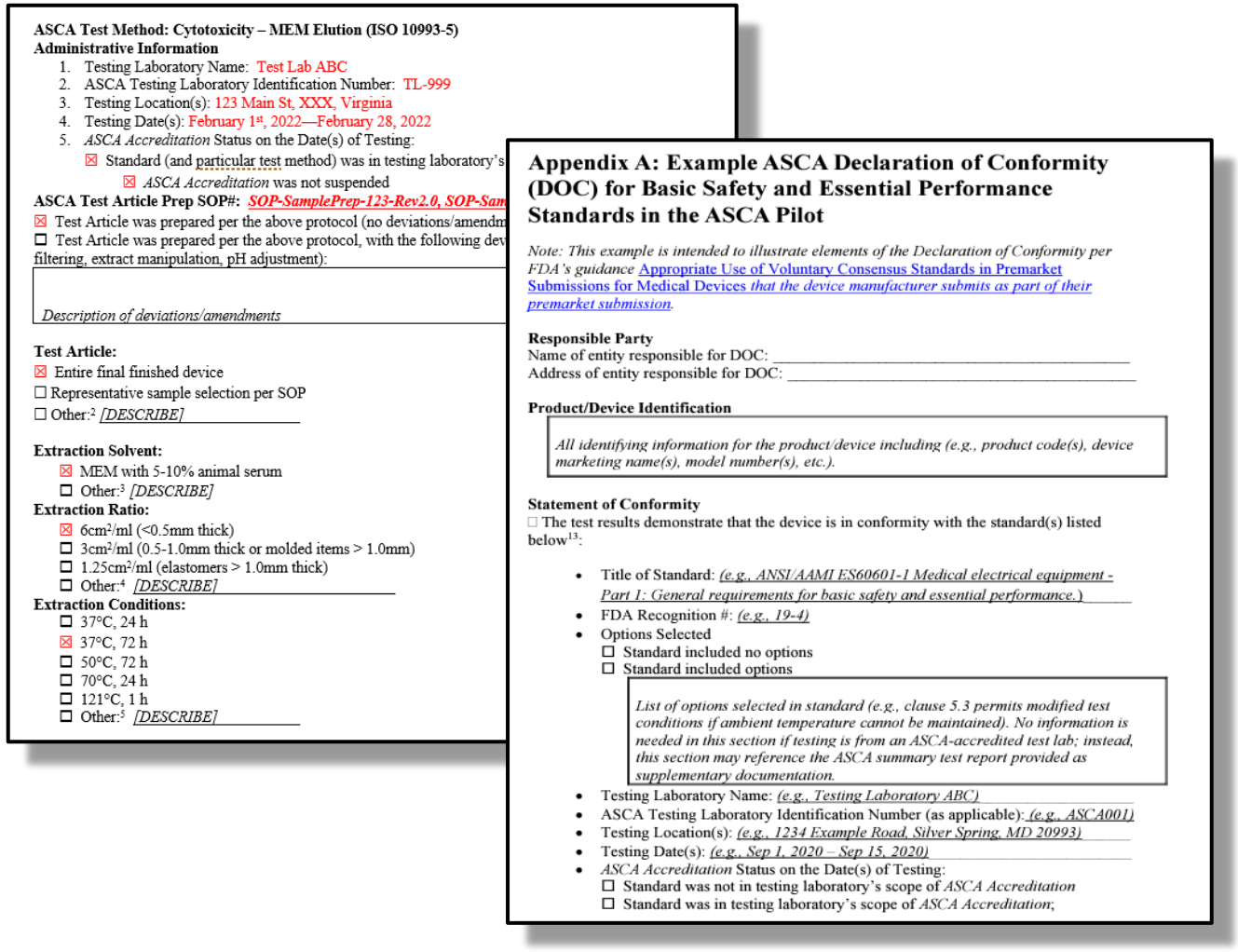
- ASCA Update
- Discussion
  - Aspects of how the current set of ASCA standards worked well or could have worked better during the pilot phase
  - New technical areas appropriate to consider adding to the ASCA program
  - Approaches to consider for ASCA expansion
- Resources

# ASCA UPDATE

# ASCA Goal: Streamline Conformity Assessment in Pre-market Review

## Benefits of ASCA:

- Working with ASCA-accredited test labs removes the guesswork about appropriately using standards
- Specifies supporting documentation needs
  - — ASCA Declaration of Conformity
  - — ASCA Summary Test Report



**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
   - ☒ *ASCA Accreditation* was not suspended

**ASCA Test Article Prep SOP#:** ***SOP-SamplePrep-123-Rev2.0, SOP-Sam***

☒ Test Article was prepared per the above protocol (no deviations/amendm
☐ Test Article was prepared per the above protocol, with the following dev
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]*

**Appendix A: Example ASCA Declaration of Conformity (DOC) for Basic Safety and Essential Performance Standards in the ASCA Pilot**

*Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices that the device manufacturer submits as part of their premarket submission.*

**Responsible Party**
Name of entity responsible for DOC: _____
Address of entity responsible for DOC: _____

**Product/Device Identification**

*All identifying information for the product/device including (e.g., product code(s), device marketing name(s), model number(s), etc.).*

**Statement of Conformity**
☐ The test results demonstrate that the device is in conformity with the standard(s) listed below[13]:

- Title of Standard: *(e.g., ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.)*
- FDA Recognition #: *(e.g., 19-4)*
- Options Selected
  - ☐ Standard included no options
  - ☐ Standard included options

  *List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained). No information is needed in this section if testing is from an ASCA-accredited test lab; instead, this section may reference the ASCA summary test report provided as supplementary documentation.*
- Testing Laboratory Name: *(e.g., Testing Laboratory ABC)*
- ASCA Testing Laboratory Identification Number (as applicable): *(e.g., ASCA001)*
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2020 – Sep 15, 2020)*
- *ASCA Accreditation* Status on the Date(s) of Testing:
  - ☐ Standard was not in testing laboratory's scope of *ASCA Accreditation*
  - ☐ Standard was in testing laboratory's scope of *ASCA Accreditation*;

# *ASCA Benefits, continued*

- 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
- Improves the quality of testing and reporting
  - Increased confidence in device safety
  - Addresses testing issues for which FDA commonly identifies concerns

# ASCA Wound Therapy Device Submission: Basic Safety and Essential Performance Assessment

- Negative Pressure Wound Therapy Powered Suction Pump
  - Device that promotes wound healing
- Basic Safety and Essential Performance ASCA testing:
  - IEC 60601-1
  - IEC 60601-1-2
  - IEC 60601-1-6
  - IEC 60601-1-8
  - IEC 60601-1-11

# ASCA Wound Therapy Device Submission: Basic Safety and Essential Performance Review

| 60601-1 and all collaterals | Complete Test Reports (provided alongside ASCA Summary Test Reports) | ASCA Testing: ASCA Summary Test Reports |
|---|---|---|
| Review staff | | No need for consult |
| Page count | 407 pages total | 20 pages total |
| Estimate of review time | ~ 10 hours | ~ 1 hours |
| Deficiencies identified | | 0 |

# ASCA Lancet Submission: Biocompatibility Assessment

## Contact type

- Limited skin-contacting (<24 h)

## ASCA Biocompatibility Assessment

- Intracutaneous Reactivity Irritation
- Guinea Pig Maximization Sensitization
- MEM Elution Cytotoxicity

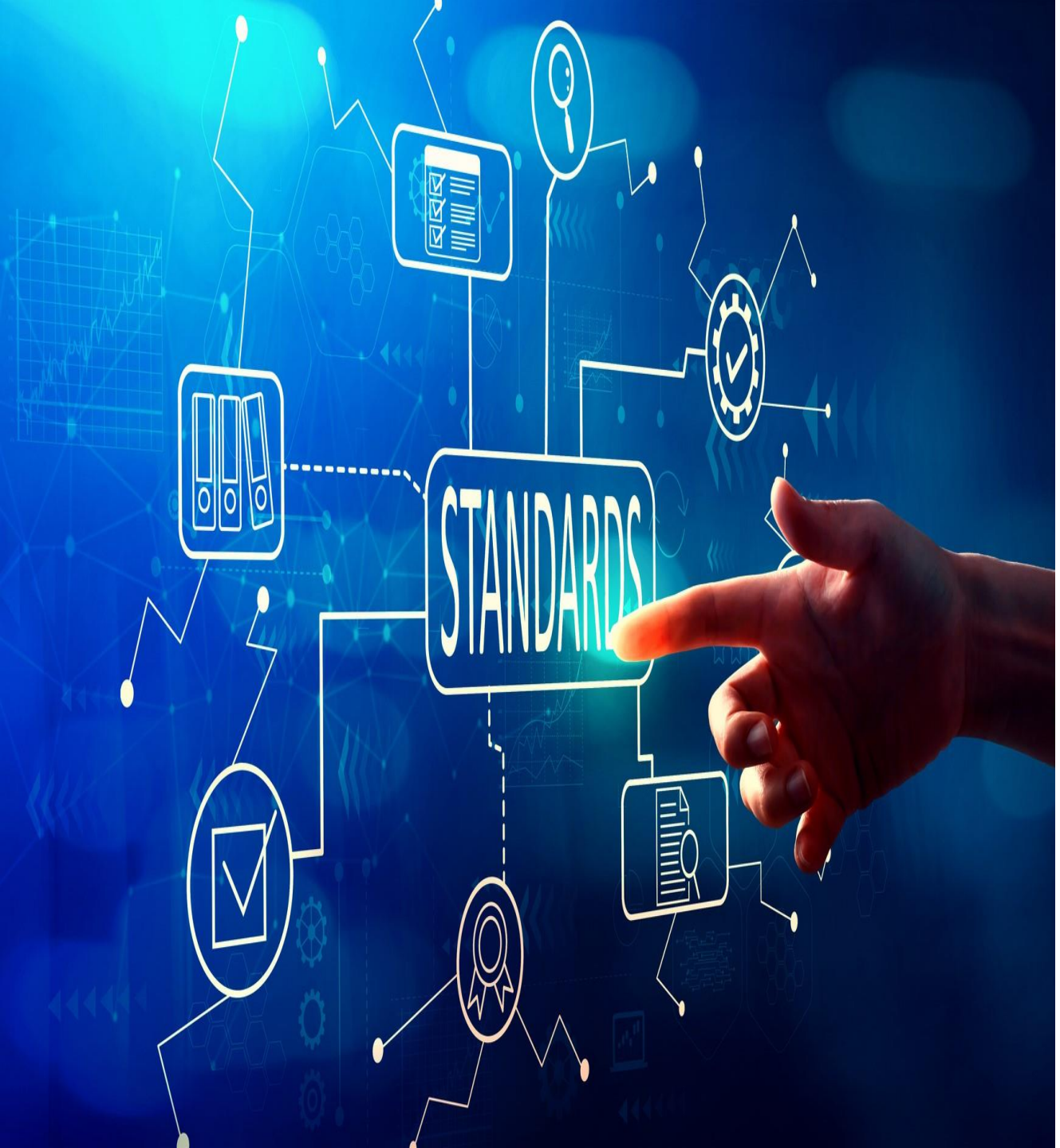
# ASCA Lancet Submission: Biocompatibility Non-ASCA vs ASCA Review

| Biocomp testing 3 methods | Complete Test Reports | ASCA Summary Test Reports |
|---|---|---|
| Number of pages | Would be ~ 60 pages | 8 pages |
| Review time | Would be ~ 5 hours | 45 min |
| Deficiencies identified | | 0 |

# ASCA By the Numbers

| | | |
|---|---|---|
| **80**<br>Standards included in ASCA | **61**<br>Submissions highlighting ASCA | **102**<br>ASCA-accredited testing laboratories |
| **134**<br>Standards tested in ASCA Summary Test Reports | **45**<br>Submissions with ASCA Summary Test Report | **95%**<br>ASCA submissions for which FDA requested no complete test reports |

# 102 ASCA-Accredited Testing Laboratories Around the World




# Future

- ASCA transition from pilot to permanent is complete
- Program improvements under consideration with guidance revisions; watch the *Federal Register* for commenting opportunity
- Expansion under consideration

# DISCUSSION

# Questions and Comments

## To ask a written question, enter it into the Q&A box

## To verbally ask a question/share a comment:

- Raise your hand in Zoom
- Moderator will announce your name and invite you to speak
- Unmute yourself when prompted in Zoom to speak


## When asking a question/sharing a comment:

- Keep question/comment brief
- No questions about specific submissions

## After question/comment is addressed:

- Mute yourself and lower your hand
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# WHAT WORKED WELL? WHAT COULD WORK BETTER?

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# POSSIBLE TECHNICAL AREAS FOR EXPANSION

## *Possible additional biocompatibility methods to consider :*

- Biological Test Methods:
  - MTT Cytotoxicity
  - Neutral Red Uptake (NRU) Cytotoxicity
  - XTT Cytotoxicity
  - Bacterial Reverse Mutation Assay (i.e., Ames Assay)
  - Mouse Lymphoma Assay (MLA)
- Analytical Chemistry

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# POSSIBLE EXPANSION APPROACHES

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# FDA 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
5. **eSTAR Program**
   - https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program?utm_medium=email&utm_source=govdelivery
   - eSTAR Assistance: 510K_Program@fda.hhs.gov
   - Tech Questions/Feedback: eSubpilot@fda.hhs.gov

# FDA Standards Resources

- **Division of Standards and Conformity Assessment (DSCA)**
  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
- **Non-recognized Standards Database**
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm
- **Email us at: CDRHStandardsStaff@fda.hhs.gov**

# Relevant FDA 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

# 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! ASCA@FDA.HHS.GOV**


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