U.S. FOOD & DRUG
ADMINISTRATION

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) CONSOLIDATED PILOT FINAL REPORT AND 2023 ANNUAL REPORT

Center for Devices and Radiological Health

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US Food and Drug Administration

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SECTION I: INTRODUCTION

The Center for Devices and Radiological Health's (CDRH) Division of Standards and Conformity Assessment (DSCA) encourages medical device sponsors to use FDA-recognized voluntary consensus standards in their product submissions, as conformity to relevant standards both reduces regulatory burden and fosters quality. To promote the utilization of consensus standards in device development and review, the FDA implemented the Accreditation Scheme for Conformity Assessment Pilot (ASCA) in September of 2020, initially as a pilot program.

ASCA's objective is to enhance the use of declarations of conformity (DOCs)[1] and promote greater consistency and predictability in FDA's approach to assessing conformance to standards in medical device review by enhancing FDA's confidence in the testing laboratories' test methods and results.

ASCA has been designed with input from stakeholders across the medical device community, including industry and conformity assessment bodies. Insights about the scheme parameters and types of standards appropriate for the Pilot were gained from a public workshop in 2018, public webinars, conference presentations and comments submitted to the ASCA guidance documents docket.[2] ASCA operated in 'pilot mode' from its initiation in 2020 to 2023, during which FDA gathered and analyzed information on device submissions that contained ASCA testing.

Amendments made to section 514 by section 2005 of the FDA User Fee Reauthorization Act of 2022[3], part of the Medical Device User Fee Amendments of 2022 (MDUFA V)[4], direct the FDA to conclude the ASCA pilot phase and transition to a sustained program. MDUFA IV commitments, expressly updated in MDUFA V commitments, call for a final report on the ASCA Pilot Program. MDUFA V commitments also continue to require an annual report on the progress of the ASCA Program. This consolidated report serves both purposes. It provides a report on the performance of the ASCA Pilot Program (as specified in the MDUFA V Commitment Letter), while also providing a summary of 2023 ASCA activities.

The report proceeds as follows: Section II Parts A and B comprise the final report for the ASCA Pilot Program, outlining program background, metrics and conclusions. Section III Parts A and B provide the 2023 ASCA annual report, including the summary of progress in 2023 and steps FDA intends to take in 2024.

SECTION II: ASCA FINAL REPORT

Part A: Background

ASCA is authorized under section 514(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[5] In accordance with amendments made to section 514 by the FDA Reauthorization Act of 2017 (FDARA),[6]

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[1] Refer to *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,' Guidance for Industry and FDA Staff* available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

[2] The docket may be accessed at https://www.regulations.gov/docket/FDA-2019-D-3805

[3] *See* Pub. L. 117-180, Division F: "FDA User Fee Reauthorization Act of 2022" (FDAUFRA)

[4] Information about MDUFA V, including access to the MDUFA V Commitment Letter, may be found here: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2022-mdufa-v

[5] 21 U.S.C. 360d(d)

[6] *See* Pub. L. 115-52

and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV),[7] FDA was directed to issue guidance regarding program goals and implementation of the ASCA Program in a pilot phase.[8] FDA has concluded the ASCA pilot phase[9] and has established an ongoing ASCA Program, in accordance with amendments made to section 514 by section 2005 of the FDA User Fee Reauthorization Act of 2022, part of MDUFA V.[10]

ASCA design

Under the ASCA Program, qualified accreditation bodies may apply to FDA for *ASCA Recognition*. ASCA-recognized accreditation bodies accredit testing laboratories using *ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories*[11] and the ASCA program specifications outlined in the standards-specific ASCA guidance documents.

Testing laboratories may then apply to the FDA for *ASCA Accreditation*. After review of a testing laboratory's application, the FDA grants *ASCA Accreditation* to organizations who meet the ASCA qualifications outlined in the program and standards-specific ASCA guidance documents. If a device manufacturer chooses to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to FDA, the device manufacturer includes an ASCA declaration of conformity, an ASCA Summary Test Report and a cover letter that notes the submission contains ASCA testing. For testing conducted under ASCA, FDA will have confidence in the testing laboratories' test methods and results and does not intend to request additional information regarding testing methodologies.

Three ASCA guidance documents provide direction and program specifications: one program guidance and two standards-specific guidances. They were published in September of 2020.[12]

- ASCA program guidance**:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance* [13]
- Basic Safety and Essential Performance standards-specific guidance: *Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment - Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* [14]

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[7] *See* also MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download
[8] *See* section 514(d)(3)(B) of the FD&C Act.
[9] *See* FDA' webpage entitled Accreditation Scheme for Conformity Assessment (ASCA), available at: https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/accreditation-scheme-conformity-assessment-asca
[10] *See* Pub. L. 117-180, Division F: "FDA User Fee Reauthorization Act of 2022" (FDAUFRA)
[11] *See* https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[12] Note that while the ASCA pilot phase ended in September 2023 and the program has transitioned to an established program, it is still currently being implemented through the three ASCA Pilot Program guidances published in 2020. ASCA Program guidances (revisions) are in development and our intent is for these to publish by the end of FY24 (*See* https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2024fy2024).
[13] The ASCA program guidance can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
[14] The basic safety and essential performance standards-specific guidance can be found here: 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: *Biocompatibility Testing of Medical Devices-Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*[15]

Standards included in ASCA

ASCA includes FDA-recognized consensus standards and related test methods across two scopes: the biocompatibility scope (Table 1) and the basic safety and essential performance scope (Table 2). These standards were selected because they address critical safety and performance issues and are used broadly across different device types. In addition, their use is frequently associated with FDA requests for additional information and often require additional resources in premarket review. Please see the CDRH Recognized Consensus Standards Database for more information about these standards.[16] These are the same standards that were identified in the 2022 ASCA Annual Report.

Table 1: List of ASCA standards and test methods: Biocompatibility [17]

FDA-Recognized Standard	Test method(s)
ISO 10993-4*	SC5b-9 Complement Activation using a U.S. marketed ELISA kit
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10**	Closed Patch Sensitization
ISO 10993-23**	Dermal Irritation, Intracutaneous Reactivity Irritation
ISO 10993-10** and ASTM F720	Guinea Pig Maximization Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediated Pyrogenicity
ISO 10993-12	Sample preparation for all test types

* See also ISO/TS 10993-20 for information on when complement activation should be considered for anaphylaxis (Table 2, Hypersensitivity Column).

** ISO 10993-10:2010 split into ISO 10993-10:2021 and ISO 10993-23:2021

[15] The biocompatibility standards-specific guidance can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

[16] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

[17] *See* the biocompatibility standards-specific guidance for a full listing of biocompatibility standards and test methods included in ASCA: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

Table 2: List of ASCA standards series: Standards from the basic safety and essential performance of medical electrical equipment; safety requirements for medical electrical systems, and laboratory medical equipment scope[18]

Standard	Standard Title
60601/80601	*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (along with certain FDA-recognized collateral and particular standards in the IEC/ISO 60601-80601 series)*
61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (along with certain FDA-recognized particular standards in the IEC 61010 series)*

Part B: ASCA Pilot Evaluation

The MDUFA V Commitment Letter[19] specifies the criteria by which the ASCA Pilot should be evaluated for purposes of this final report. The Commitment Letter states:

> *'In Q2 of FY 2024, FDA will provide a report on the performance of the ASCA Pilot Program (to replace the report specified in the MDUFA IV Commitment Letter, Commitment IV.D.8.a). In the report, FDA will provide at least the following information:*
>
> a. *Adequacy of the standards selected to support confidence by FDA and industry in the methods used and results reported by ASCA-accredited testing laboratories;*
> b. *Testing laboratory participation in the training and ASCA program, and areas where any nonconformities were observed*;
> c. *Number of submissions containing the ASCA Summary [Test] Report;*
> d. *Summary [Test] Report acceptance rate by FDA reviewers; and*
> e. *Summary of commonly cited deficiencies regarding the Summary [Test] Report.'*

The ASCA team evaluated each device submission with ASCA testing received from program launch through November 17, 2023. This date was chosen as the cutoff date for the Final ASCA Pilot Report and the 2023 ASCA Annual Report considering simplicity principles and to accommodate clearance for this report. FDA determined if ASCA submissions met the criteria outlined in the MDUFA V Commitment Letter. Below, each specific criterion is quoted from the Commitment Letter, after which FDA describes how it approached the measurement. This is followed by the data itself and conclusions as to whether ASCA achieved the measure. A 'Final Conclusions' section appears at the end of Section II.

Criterion I*: 'Adequacy of the standards selected to support confidence by FDA and industry in the methods used and results reported by ASCA-accredited testing laboratories'*

[18] See the Basic Safety and Essential Performance Standards-specific guidance for a full listing of basic safety and essential performance standards included in ASCA, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and

[19] Information about MDUFA V, including access to the MDUFA V Commitment Letter, may be found here: https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2022-mdufa-v

The FDA measured the adequacy of the selected standards at the scope level (biocompatability and basic safety and essential performance). The criteria for adequacy of the consensus standards were published in the MDUFA IV Commitment Letter[20] and include the following:

- *'cross-cutting/horizontal and/or device-specific areas'*
- *'at least one of which will be device-specific'*
- *'with well-established endpoints/acceptance criteria built into the standard'*

As of November 17, 2023, a total of 80 standards are included in the ASCA program: 9 in the biocompatibility scope and 71 in the basic safety and essential performance scope. This list contains 19 cross-cutting (horizontal) standards, e.g., IEC 60601-1 and ISO 10993-12, which apply to many medical devices, and 61 product/device specific (vertical) standards such as IEC 60601-2-54, which applies to X-ray equipment and IEC 60601-2-56 for thermometers.[21] The ASCA standards were chosen for their ability to accommodate conformity assessment considerations, which means that they feature clear acceptance criteria and/or testing methods. Conclusion: the standards included in the ASCA Pilot exceeded this criterion.

Criterion II*: 'Testing laboratory participation in the training and ASCA program, and areas where any nonconformities were observed'*[22]

This criterion calls for two measures. The first is testing laboratory participation, for which the FDA counted both the number of testing laboratories who were granted *ASCA Accreditation* as of November 17, 2023 and the number of ASCA-accredited testing laboratories who had actually conducted ASCA testing and for which ASCA Summary Test Reports have been received by FDA in ASCA submissions:

- Number of ASCA-accredited testing laboratories: 104[23]
- Number of ASCA-accredited testing laboratories who have conducted ASCA testing and for which ASCA Summary Test Reports have been received by FDA in ASCA submissions: 16[24]

[20] *See* also MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download

[21] *See* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start_search=1&sortcolumn=st&ascapilotyn=on&pagenum=5. Note that recognitions can change over time or consensus standards may also have transition periods associated with them.

[22] The expectations for testing laboratory participation in the ASCA Program are identified in the signed agreement (*Appendix B of the ASCA Program Guidance available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program*. To date, regular meeting attendance and ASCA Summary Test Reports (as summarized in response to Criteria V) are the areas where nonconformities have been observed.

[23] For an up-to-date listing of ASCA-accredited testing laboratories and their respective scopes of accreditation, please see the following FDA website: https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/asca-accredited-testing-laboratories. The current status and historical record for each testing laboratory's scope of *ASCA Accreditation* are available in the tabular summary.

[24] Additional ASCA-accredited testing laboratories have reported to FDA that ASCA testing is underway for devices whose marketing submissions have not been compiled (or submitted to FDA) yet.

The second measure in Criterion II asks for areas in which ASCA-accredited testing laboratories did not conform to ASCA program expectations. One of the ASCA program guidance expectations where nonconformities have been observed is that participating testing laboratories agree to attend all training events.[25] For this measure, FDA identified the following:

- Basic safety and essential performance testing laboratories: Of the 99 ASCA-accredited testing laboratories with the basic safety and essential performance scope, 74% attended 60% or more of the training programs and 87% attended half or more of the training programs.
- Biocompatibility: A total of five ASCA-accredited testing laboratories for the biocompatibility scope have received *ASCA Accreditation*. The ASCA-accredited testing laboratories for biocompatibility received accreditation relatively late in the Pilot. Since they are fewer in number, the ASCA team conducted trainings on a one-on-one basis with each testing laboratory. ASCA-accredited testing laboratories for the biocompatibility scope attended all trainings scheduled with the FDA.

Conclusion: The number of ASCA-accredited testing laboratories is sufficient to effectively conduct the ASCA program with the current scope of standards. Some laboratories did not fully meet the ASCA program expectations for attendance in all training sessions. As a corrective action, the ASCA team will continue to monitor participation in training, notify testing laboratories whose training is delinquent, direct them how to complete training requirements and document performance.

Criterion III: *'Number of submissions containing the ASCA Summary [Test] Report'*

This criterion asks for the number of submissions that contain at least one ASCA Summary Test Report.[26] For this measure, FDA counted the number of submissions to FDA in which an ASCA Summary Test Report was included. In addition, FDA counted the number of ASCA submissions that inappropriately included a complete test report or reports (generally only the ASCA Summary Test Report should be sent to FDA). FDA also examined the ASCA submissions for the appropriate inclusion of a mention of ASCA in the submission's cover letter (the ASCA public web pages feature instructions on how to compile an ASCA submission[27]). These data include submissions received through November 17, 2023, the cutoff date for purposes of analyzing submissions for this report.

- Total number of ASCA submissions (including Q-submissions): 44
    - Q-submissions: 7
    - 510(k)s: 30
    - De Novos: 1
    - IDEs: 5
    - PMAs: 1

- Number of ASCA submissions that included ASCA Summary Test Reports: 35

[25] To date, the only other area where nonconformities, i.e., deficiencies, have been observed is in ASCA Summary Test Reports (as summarized in response to Criteria V).

[26] As of November 17, 2023, all of the data provided in this report are for ASCA submissions to the Center for Devices and Radiological Health. No ASCA submissions have been received by the Center for Biologics Evaluation and Research.

[27] See the 'Manufacturers: How to Participate in ASCA' web page for details on how to correctly compile an ASCA submission at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/manufacturers-how-participate-asca

(Note: Of the 44 ASCA submissions, 7 were Q-submissions that indicated an intent to use ASCA testing, and thus did not contain an ASCA Summary Test Report. In addition, 2 ASCA non-Q-submissions did not contain an ASCA Summary Test Report. Thus, 35 ASCA submissions are analyzed for the purposes of Criterion IV.)

- Number of ASCA submissions with complete test report (not requested by FDA): 21 of 35
- Number of ASCA submissions that failed to mention ASCA in the cover letter: 30 of 35

Conclusion: While FDA is encouraged by the submissions received to date, it will continue to promote ASCA to device manufacturers as well as through co-promotional programs with ASCA-accredited testing laboratories to increase the amount of ASCA testing in device submissions. FDA also intends to offer additional education to device sponsors to reduce the incidence of complete test report submission and increase the mention of ASCA in submission cover letters.

Criterion IV: *'Summary [Test] Report acceptance rate by FDA reviewers'*

For Criterion IV, FDA measured how many ASCA Summary Test Reports reflected deficiencies associated with the reports and/or data therein. FDA also investigated how often FDA review staff requested complete test reports for ASCA submissions.

- Number of submissions for which FDA requested complete test reports: 2 of 35
- Number of ASCA Summary Test Reports with issues or deficiencies: 13 of 35

Conclusion: The number of ASCA Summary Test Reports for which FDA requested complete test reports are the minority of cases. In addition, the majority of the submissions did not result in any deficiencies and streamlined the review of the ASCA Summary Test Report as intended with the ASCA program. An analysis of the deficiencies appears below, associated with Criterion V.

Criterion V: *'Summary of commonly cited deficiencies regarding the Summary [Test] Report'*

For Criterion V, FDA distinguished between administrative deficiencies and technical deficiencies in the 13 of 35 ASCA Summary Test Reports with deficiencies received by November 17, 2023. A summary of the deficiencies appears below:

- Four administrative deficiencies. Examples include:
  - Absence of a declaration of conformity
  - Testing to an older version of a standard that is no longer included in ASCA
  - ASCA Summary Test Reports lacking a testing laboratory signature
  - Erroneously checking a box that indicated a failing result when the result was acceptable

- Ten technical deficiencies. Examples include:
  - Essential performances either poorly or not defined
  - Absence of safety testing, necessitating labeling mitigations and/or justification for the lack of testing
  - A reference to risk management with insufficient detail
  - Lack of clarity about content in the ASCA Summary Test Report; for example, questions about device configuration during testing and whether the device tested was the final, finished version

- Mismatch of information between the ASCA Summary Test Report and the provided complete test reports

Conclusion: Administrative and technical deficiencies are present in a minority of ASCA submissions. Corrective action included discussions with the testing laboratories about how to avoid these deficiencies associated with the ASCA Summary Test Reports in the future. FDA plans to continue to educate manufacturers and testing laboratories on how to ensure that ASCA Summary Test Reports are administratively, technically and factually accurate.

Final conclusions

FDA has determined that the ASCA Pilot met and in some cases exceeded program expectations. For example, while the Pilot called for the inclusion of 5 consensus standards, the program includes 80 recognized consensus standards at this time. Recognized consensus standards currently included in the ASCA program are widely used and reflect areas in which accurate conformity assessment is critically important. ASCA-accredited testing laboratories are sufficient in number to offer manufacturers the ability to order ASCA testing. The ASCA-accredited testing laboratories for the most part meet program expectations, though FDA will direct consistent participation in future training sessions.

While the number of ASCA Summary Test Reports has not yet reached the levels FDA expects to review, only a minority of those that have been submitted contain deficiencies. FDA will continue to offer educational events and resources to address deficiencies, to reduce the number of complete test reports that inappropriately accompany ASCA submissions, and to increase the number of ASCA submissions whose cover letters make a reference to ASCA testing.

Finally, FDA intends to continue to monitor program performance to identify areas where enhancements can be made and expects to revise the ASCA guidance documents to reflect programmatic improvements. These initiatives should further demonstrate the value of the program, including promoting consistency in testing methods and results and streamlined conformity assessment in device review.

SECTION III: ASCA ANNUAL REPORT

Part A: ASCA Progress in 2023

Administrative progress

- As of December 2023, FDA has granted *ASCA Recognition* to 5 accreditation bodies[28] and *ASCA Accreditation* to 104 testing laboratories, 99 for the basic safety and essential performance scope and five for the biocompatibility scope.[29] All 5 ASCA-recognized accreditation bodies renewed their applications in 2023.

[28] The list of ASCA-recognized accreditation bodies may be found here: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-recognized-accreditation-bodies
[29] The list of ASCA-accredited testing laboratories may be found here: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories

- *eSTAR*[30]: The ASCA team provided significant improvements to the eSTAR program that facilitate citing recognized consensus standards in ASCA submissions. For example, as with recognized standards, an ASCA declaration of conformity is automatically generated through eSTAR, eliminating the need to separately create and attach a declaration of conformity.

- *ASCA quality framework metrics*: The ASCA Program Quality Management Framework, which conforms with the Center's overarching approach to quality management[31], outlines ASCA's processes, services and management and incorporates the Center's commitment to quality management. In 2023, the ASCA team continued to track its performance on program operations across several measures. For example:

    - Average number of calendar days to decision for testing laboratory *ASCA Accreditation* applications: 49 (goal: 60 calendar days)
    - Average number of calendar days to publish *ASCA Accreditation* updates, e.g., to scopes: 52 (goal: 60 calendar days)
    - Accreditation body audits: three accreditation body audits were completed in an average of 75 calendar days (goal: 75 calendar days)
    - Testing laboratory withdrawal: a testing laboratory request to voluntarily withdraw from the ASCA program was completed in 9 calendar days (goal: 15 calendar days)

External outreach and audits

Accreditation Bodies

During 2023, the ASCA team led eight virtual meetings with all five ASCA-recognized accreditation bodies. The purpose of these meetings was to provide direction and answer questions about the *ASCA Accreditation* requirements to which the accreditation bodies evaluate testing laboratories. In addition to these meetings and multiple email communications, approximately twenty teleconferences with individual accreditation bodies were held to support their efforts to successfully evaluate the testing laboratories interested in *ASCA Accreditation*.

The ASCA team initiated audits of all five ASCA-recognized accreditation bodies during 2023. These audits entailed a review of general ASCA documents, an evaluation of training and quality systems programs and an assessment of ASCA-specific standard operating procedures. The audits also included records review for a sample of their ASCA-accredited testing laboratories to determine how the accreditation body assessed and documented testing laboratory performance. Three audits were finalized and deemed acceptable during 2023 and two are expected to be finalized in 2024.

Testing Laboratories

Communications with testing laboratories in 2023 emphasized two priorities: how to compile complete *ASCA Accreditation* applications and how to work with industry to conduct and report testing according to the ASCA program specifications. This included hundreds of emails, dozens of formal virtual meetings,

[30] For more information about the eSTAR program, visit: https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program

[31] See https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-quality-management-program

monthly 'Office Hours' opportunities for testing laboratories to check in with FDA, four presentations to the testing laboratory community and a co-promotional event with a multi-site testing laboratory.

Industry

In 2023, the ASCA team continued to focus its efforts with industry on promoting the program's benefits and how to use ASCA testing, including how submissions with ASCA testing should be compiled. The ASCA team delivered eleven presentations to industry, five to professional societies and standards development organizations, and four to testing laboratories and their customers.

Internal outreach: Staff training

Internal FDA Staff Training

The ASCA team utilizes multiple approaches and venues to conduct training on how to assess ASCA testing. Training initiatives in 2023 included the following:

- CDRH Training, including internal rounds, town halls and focused training:
    1. Targeted formal instruction to OPEQ review staff for reviewing ASCA Summary Test Reports
    2. Standards Town Hall: Training on how to conduct reviews for submissions with ASCA testing
    3. ASCA training included in formal eSTAR staff training to OPEQ review staff
- Center for Biologics Evaluation and Research (CBER): formal instruction to review staff for evaluating submissions with ASCA testing
- Partnered approach to ASCA submissions: ASCA technical experts paired with scientific reviewers for hands-on training to evaluate ASCA testing in real time
- Enhanced internal-facing *ASCA Reviewer Resource Page*

Part B: ASCA Next Steps

Programmatic improvements

The ASCA guidance documents are currently under revision to reflect lessons learned during ASCA's pilot phase. The revised draft guidances for the ASCA Program are expected to be published for comments during 2024.

In 2024, the FDA plans to begin routine testing laboratory audits.

ASCA expansion

The ASCA team plans to give careful consideration to how and when to expand the ASCA program. A public workshop is scheduled for April 17, 2024[32] to discuss with stakeholders approaches to expand the ASCA Program.

[32] Please see more about the virtual public workshop here: https://www.fda.gov/medical-devices/medical-devices-news-and-events/virtual-public-workshop-accreditation-scheme-conformity-assessment-expansion-april-17-2024-04172024?utm_medium=email&utm_source=govdelivery

External outreach

The ASCA team intends to prioritize educational programs to encourage participation in the ASCA Program, including at conferences and stand-alone events. The ASCA team also expects to advance additional co-promotion initiatives with ASCA-accredited testing laboratories.

Internal outreach: Staff training

Ongoing training will continue for CDRH and CBER review staff and management on how to review ASCA device submissions and appropriately evaluate associated testing. This includes working one-on-one with review staff assigned to ASCA submissions.

ASCA Annual Report

The ASCA team intends to publish an annual report on ASCA's 2024 progress by the end of January 2025.