

Application for ASCA Recognition

A complete application from an accreditation body seeking *ASCA Recognition* includes the following components:

A. Administrative Information

- Organization name and address
- Designated point of contact: first and last name, title, phone number, and email address
- Alternate designated point of contact: first and last name, title, phone number, and email address

B. Scope of ASCA Recognition

Indication of the requested scope of *ASCA Recognition* from the list of FDA-recognized consensus standards and test methods in the ASCA Pilot (more than one standard and test method may be identified).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Pilot.

- Proof of signatory status as International Laboratory Accreditation Cooperation (ILAC) MRA with scope that includes testing: ISO/IEC 17025.
- Confirmation that accreditation body is based in the United States.
- A current list and description of any accreditation services offered for which the scope includes any of the FDA-recognized consensus standards or test methods in the ASCA Pilot.
- An example scope of accreditation that is typically used by the accreditation body, and to what extent it will be modified to address accreditation for the ASCA Pilot.
- A detailed description of the process to accredit testing laboratory applicants to ISO/IEC 17025 and ASCA program specifications to include awareness, training, and accreditation activities.
- A detailed description of the approach to assess procedures and corrective actions as related to the most recent inspection findings noted by FDA Bioresearch Monitoring Program per 21 CFR Part 58 – Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies for testing laboratory applicants with biological evaluation of medical device standards and test methods in their scope of accreditation.¹
- A detailed description of the accreditation body's approach used to determine technical competency of testing laboratories consistent with ASCA program specifications. This

¹ As discussed at the public workshop titled "[Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards](#)," biocompatibility testing conducted under the ASCA Pilot will be conducted in accordance with 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations.

includes a detailed description of the qualifications for technical assessors for the requested scope of *ASCA Recognition*. A description could include resumes, CVs, summary of experience, relevant technical training, etc., from personnel already identified.

- A detailed description of the policy and processes concerning corrective actions and the approach for responding to, investigating, and resolving complaints against testing laboratories.

D. Signed Agreement

Confirmation that the accreditation body has read, understood, and agrees to adhere to all of the following for its ASCA Pilot-related activities:

- Maintain scope of signatory status to International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) that includes ISO/IEC 17025.
- Verify conformance with ISO/IEC 17025 and ASCA program specifications when accrediting testing laboratories for the ASCA Pilot.
- Provide all ASCA Pilot accreditation documentation to FDA upon request.
- Allow FDA to participate as an observer during the accreditation body's ILAC MRA peer evaluation(s).
- Allow FDA to participate as an observer during the accreditation body's assessment of a testing laboratory.
- Commit that all relevant FDA training will be completed by appropriate individuals prior to providing any accreditation to testing laboratories under the ASCA Pilot.
- Establish and maintain appropriate communication with FDA. An accreditation body should not hesitate to contact FDA regarding the ASCA Pilot. FDA expects that appropriate communication includes the following at a minimum:
 - Notification to FDA within five calendar days via email of any changes that may impact the accreditation body's participation (e.g., change to scope of signatory status to ILAC MRA).
 - Notification to FDA within five calendar days via email of any changes that may impact the participation of any of the testing laboratories that the accreditation body has accredited.
 - Attendance at regularly scheduled teleconferences with FDA as requested.
 - Provision of status updates annually or upon request to FDA including the following information regarding the accreditation body's ASCA Pilot activities:
 - Complaint handling;

- Total number and list of testing laboratories the accreditation body has accredited, including dates of accreditation;
 - Number and nature of non-conformities the accreditation body has observed during accreditation or auditing of testing laboratories;
 - Number of suspensions issued by the accreditation body for testing laboratories; and
 - Results of the accreditation body's management reviews.
- Establish and maintain policies and procedures that incorporate feedback from FDA.
 - Acknowledge that FDA maintains complete discretion regarding granting *ASCA Recognition* to an accreditation body. FDA may withdraw *ASCA Recognition* at any time.
 - Confirm, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.