**Application for *ASCA Recognition***

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

* 1. **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
  1. **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).

* 1. **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]](#footnote-1)
* A detailed description of the accreditation body’s approach used to determine technical competency of testing laboratories consistent with ASCA program specifications. This 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.
  1. **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.

1. As discussed at the public workshop titled “[Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards](https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-accreditation-scheme-conformity-assessment-asca-medical-devices-fda-recognized),” biocompatibility testing conducted under the ASCA Pilot will be conducted in accordance with 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations. [↑](#footnote-ref-1)