

## **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.<sup>1</sup>
- A detailed description of the accreditation body's approach used to determine technical competency of testing laboratories consistent with ASCA program specifications. This

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<sup>1</sup> 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.