



FAQ

About the US FDA's Accreditation Scheme for Conformity Assessment (ASCA) Program

UL Solutions presents the following frequently asked questions (FAQs) and answers to help you navigate the U.S. Food and Drug Administration's (FDA) Accreditation Scheme for Conformity Assessment (ASCA) program. We hope you will find this information helpful in assessing your organization's fit with ASCA and accessing resources and information to streamline the submission process.

Program basics

Q: What is the U.S. FDA's ASCA program?

A: To ensure market availability of safe and effective medical devices and regulated laboratory equipment, the FDA has introduced the ASCA program. This voluntary program provides participating manufacturers with:

- A framework for submitting data to demonstrate the safety and effectiveness of their medical devices
- A list of ASCA-accredited testing laboratories evaluated for competency in the required areas of testing
- Greater confidence that their products will achieve compliance

Q: Is participation in the FDA ASCA program mandatory?

A: Program participation is completely voluntary.

Q: Is the FDA ASCA program exclusively for manufacturers submitting their devices for 510(k) compliance?

A: No. The FDA ASCA program is relevant for many other FDA reviews that manufacturers may need. The FDA ASCA program leverages many FDA consensus safety and biocompatibility standards, including AAMI ES 60101-1, AAMI 60601-1-2, as well as many collaterals and particulars. For IVD devices, the program also includes the IEC 61010-1 standard.

Q: Are all standards related to medical devices covered under the FDA ASCA program?

A: No. The FDA ASCA program only covers a subset of consensus standards that the FDA recognizes. The program currently covers 91 standards, and more are added on an ongoing basis. You can review a list of the latest standards covered [here](#).

Q: What are some benefits of participating in the FDA ASCA program?

A: The program serves to increase manufacturers' confidence in their products' compliance by working with a qualified, ASCA-accredited testing laboratory. The FDA ASCA program helps organize data in a consistent, repeatable format for a more streamlined review and fewer requests for additional information during the review process. Long-term, this may become a precursor to the modernization of the FDA's compliance process and more efficiently position participating manufacturers to follow future compliance processes.

Q: Do we still need to send a full report for FDA submission if we use the FDA ASCA program?

A: No, in most instances a full report will not need to be submitted. One of the key drivers behind the initiative is to decrease the time taken for products to pass through the submission process. An ASCA report is much more streamlined than a standard full format report, which helps reduce review time. For most submissions, the ASCA summary report will be sufficient, and an in-depth review of the full report can be avoided.

Laboratories, testing and reporting

Q: Is developing the test plan the manufacturer's responsibility or the laboratories'?

A: While the FDA initially positioned the test plan as the manufacturer's responsibility, it has revised its position, expecting the test plan to result from a collaboration between the manufacturer and the test laboratory. It is, however, the manufacturer's responsibility to ensure that they agree with the test plan.

Q: What kind of information does a test laboratory require to earn accreditation?

A: The FDA grants ASCA accreditation to qualified testing laboratories that have met ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, as well as additional FDA-identified specifications. Accreditation ensures that the laboratory can perform the test in question and meet other scheme requirements. The FDA assesses laboratories for their ability to produce the data, using a methodology that is repeatable and consistent. A complete list of ASCA-accredited testing laboratories is available.

Once a laboratory has earned accreditation to ISO/IEC 17025 and the ASCA program requirements, with FDA approval, the FDA can then accept the laboratory's application for participation in the program and authorize it to participate.

Q: For complex devices, can testing be conducted at the manufacturer's site so support is available if needed?

A: Yes. In some cases, medical devices can be extremely complex and may require technical support during testing. For this reason, testing may be conducted at the manufacturer's site. Simply coordinate this with your selected ASCA-accredited testing laboratory.

Q: Does the program only accept American test laboratories accredited by American accreditation bodies?

A: Yes, under the program, the accreditation body must be U.S.-based, but the laboratory may be located anywhere.

Q: Are all TS4s forms, reports and declarations the same regardless of the ASCA-accredited testing laboratory chosen?

A: ASCA guidance documents provide examples for summary test reports and declarations of conformance. However, it is the laboratory's responsibility to deliver the final report.

About UL Solutions

UL Solutions can provide manufacturers of medical devices and laboratory equipment with the support they need to participate in the U.S. FDA's ASCA program and also offers other testing and services to help prepare medical devices for launch in markets worldwide. With ASCA-accredited testing laboratories worldwide, we can help streamline your products' compliance with FDA requirements and prepare for market readiness.

Contact us to get started.



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