Exploring the US Food and Drug Administration's Accreditation Scheme for Conformity Assessment (ASCA) Program

What is the US FDA's ASCA Program?

In an effort to ensure market availability of safe and effective medical devices or regulatory laboratory equipment, the U.S. Food and Drug Administration (FDA) has introduced its Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program. This voluntary program provides participating medical device manufacturers with:

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

When does the US FDA ASCA Program apply?

All medical devices sold in the U.S. are subject to FDA review and approval. Medical device manufacturers often misunderstand the ASCA Program applies only when submitting for 510(k) compliance. However, it is relevant for many FDA reviews that a manufacturer needs. The FDA ASCA Program leverages many FDA consensus safety and biocompatibility standards, including AAMI ES 60101-1, AAMI 60601-1-2 and many collaterals and particulars. For in vitro diagnostic (IVD) devices, the program also includes the IEC 61010-1 standard.

What is the process?

These are the steps required for participation in the U.S. FDA's ASCA Program to better understand how it works.

Step 1 – Manufacturer selects an official U.S. FDA ASCA -accredited testing laboratory for testing — the FDA's website provides an up-to-date listing of laboratories.

Step 2– U.S. FDA ASCA-accredited test laboratories conduct testing and provide information listed in relevant ASCA Program specifications to the manufacturer.
Step 3 – Device manufacturers include a Declaration of Conformity (DOC) with the ASCA summary test report in the premarket submission to the FDA.
Step 4 – The FDA applies premarket review considerations per the ASCA Pilot.

What are the benefits of the ASCA Program?

While participation in ASCA is completely voluntary, participating offers many benefits.

Increase confidence in test results by selecting an FDA ASCA-accredited laboratory.

Deliver data in your preferred format to reduce add-on requests that can delay the review process.

Enjoy greater predictability of compliance due to comprehensive data submitted in your preferred format for expedited review.

Supplement your internal team by accessing UL's expertise and capabilities in key areas so your team can focus on product development.

How can I streamline the testing and ASCA submission process?

When you thoughtfully prepare for participation in the U.S. FDA's ASCA Program, you can streamline the process and optimize efficiency, saving both time and money. Here are some considerations to help you prepare.

- **Understand the product and usage** – Take time early in the process to outline the product's intended usage, its operation and the technologies required for safe and proper use. Evaluate usage applications. For example, will it be used directly on people, on sensitive areas like breathing pathways, or on the skin? What technologies does it require for proper performance — elements like connectivity, Bluetooth® capabilities, electric power via battery?
- **Determine the appropriate standards** – Applicable testing standards for compliance depend on how and where the product is used. Once you outline the product and its usage, you can identify the appropriate standards for compliance.
- **Select an FDA ASCA-accredited laboratory** – Based on your location, types of devices, needs and other factors, select a U.S. FDA ASCA-accredited laboratory to partner with you for testing and data preparation for submission. The FDA grants ASCA accreditation to qualified testing laboratories that have met international conformity assessment standards such as ISO 17025 and additional FDA-identified specifications.
- **Develop a testing plan** – Collaborate with the laboratory to develop a list of tests required to verify compliance with regulations, then determine which resources will handle which products/testing.
- **Schedule testing** – Submit the appropriate samples or schedule on-site testing if the product is particularly complex and requires on-site technical support.
- **Prepare results for submission** – Work with the laboratory to submit all required documentation as outlined in the DOC and sample submission templates that the FDA provides.

Why UL?

UL can provide medical device manufacturers the support they need to participate in the U.S. FDA's ASCA Pilot Program as well as other testing and services to help prepare medical devices for launch in markets worldwide.

- UL has 15 laboratories around the world that are accredited to perform the testing required for participation in the U.S. FDA ASCA Program. While all laboratories have a broad scope of accreditation, specific laboratories act as centers of excellence, giving UL a total scope of accreditation for nearly all FDA ASCA standards related to basic safety and essential performance.
- UL is part of the technical committees that help develop standards for medical devices and laboratory equipment, giving us a greater, deeper understanding of the standards and criteria involved.
- UL has a seasoned staff with decades of experience in the ever-evolving regulatory landscape for medical devices.
- We strategically develop testing plans to maximize efficiency and resources, recommending approaches that can meet the maximum number of requirements with a single test. We can conduct all or a specific portion of tests to support your compliance initiatives.
- UL is a long-standing, trusted name in testing and third-party certification.

Let us partner with you to help streamline your medical devices' compliance with FDA requirements and position your products for market readiness. Explore our capabilities and contact us to get started.

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