FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Biocompatibility and Basic Safety & Essential Performance

Welcome and Introductions

Presenter/MC
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Kelli Ramos is currently pursuing her Master's in Public Health from Central Michigan University. She joined PJLA in December of 2019 as a technical program manager of medical and general testing. Since her start at PJLA, she has helped launch the FDA ASCA Pilot program and worked closely with our ISO 15189 medical assessment team. Kelli is a lead assessor for ISO 15189 and ISO/IEC 17025:2017 where she specializes in QMS. Kelli previously worked in a clinical laboratory setting where she worked in processing and collecting samples.

Presentation Overview

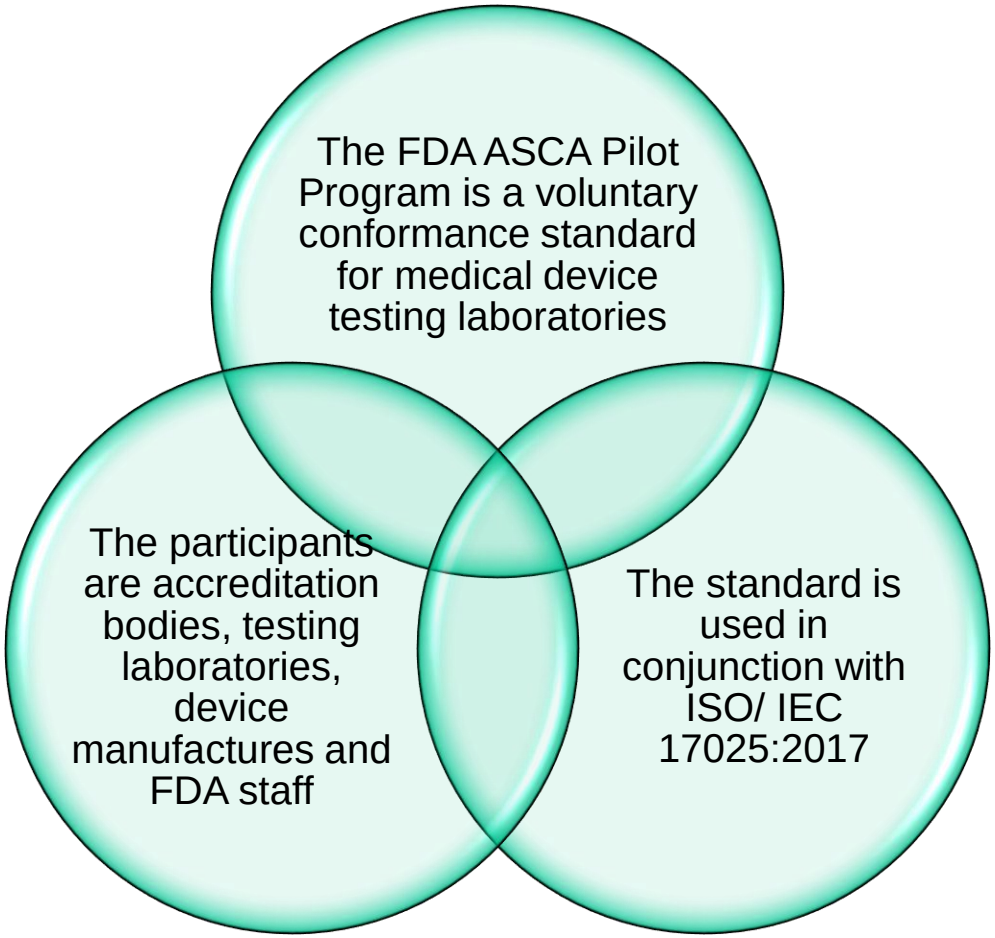
- What is ASCA? Accreditation Process
- The Accreditation Process
- Additional Requirements
- *Benefits of ASCA*

Webinar Housekeeping

This webinar will be recorded and available on the PJLA website shortly after the conclusion.

All attendees are muted. Please utilize the question tool bar to type in your questions to be answered at the end.

FDA ASCA Pilot Program



Steps to Accreditation

A TESTING LABORATORY SELECTS AN ASCA RECOGNIZED ACCREDITING BODY.

THE ASSESSMENT INCLUDES AN ASSESSMENT TO ISO/IEC 17025:2017 AND ASCA PILOT SPECIFICATIONS.

THE LAB THEN APPLIES TO THE FDA FOR ASCA RECOGNITION. (THERE IS SUBMISSION OF MATERIALS SUCH AS PJLA ASSESSMENT REPORT, TEST PROCEDURES AND SOP'S, TEST REPORT).

ONCE APPROVED BY THE FDA THE LAB IS GRANTED RECOGNITION AND PUBLISHED ON THE FDA WEBSITE.

Consensus Standard Methods

There are 91 standard methods recognized in the ASCA Pilot Program.

FDA Database for a list of consensus standards.

There is specific guidance for biocompatibility and basic safety and essential performance.

- Biocompatibility: Testing on how medical devices effect the body; direct and indirect hemolysis, cytotoxicity and skin sanitization.
- Basic safety: Electrical testing of medical equipment.

ISO/IEC 17025:2017 Conformance

All laboratories must obtain ISO/IEC 17025:2017 accreditation.

Must comply with all PJLA policies including proficiency testing

PL-1

Perform PT on 1 scope item per year

Perform PT on entire scope over a 4-year period

Types of PT: third party, inter-lab, intra-lab, and repeatability

PJLA requires approval for intra-lab and repeatability studies before the accreditation can be granted

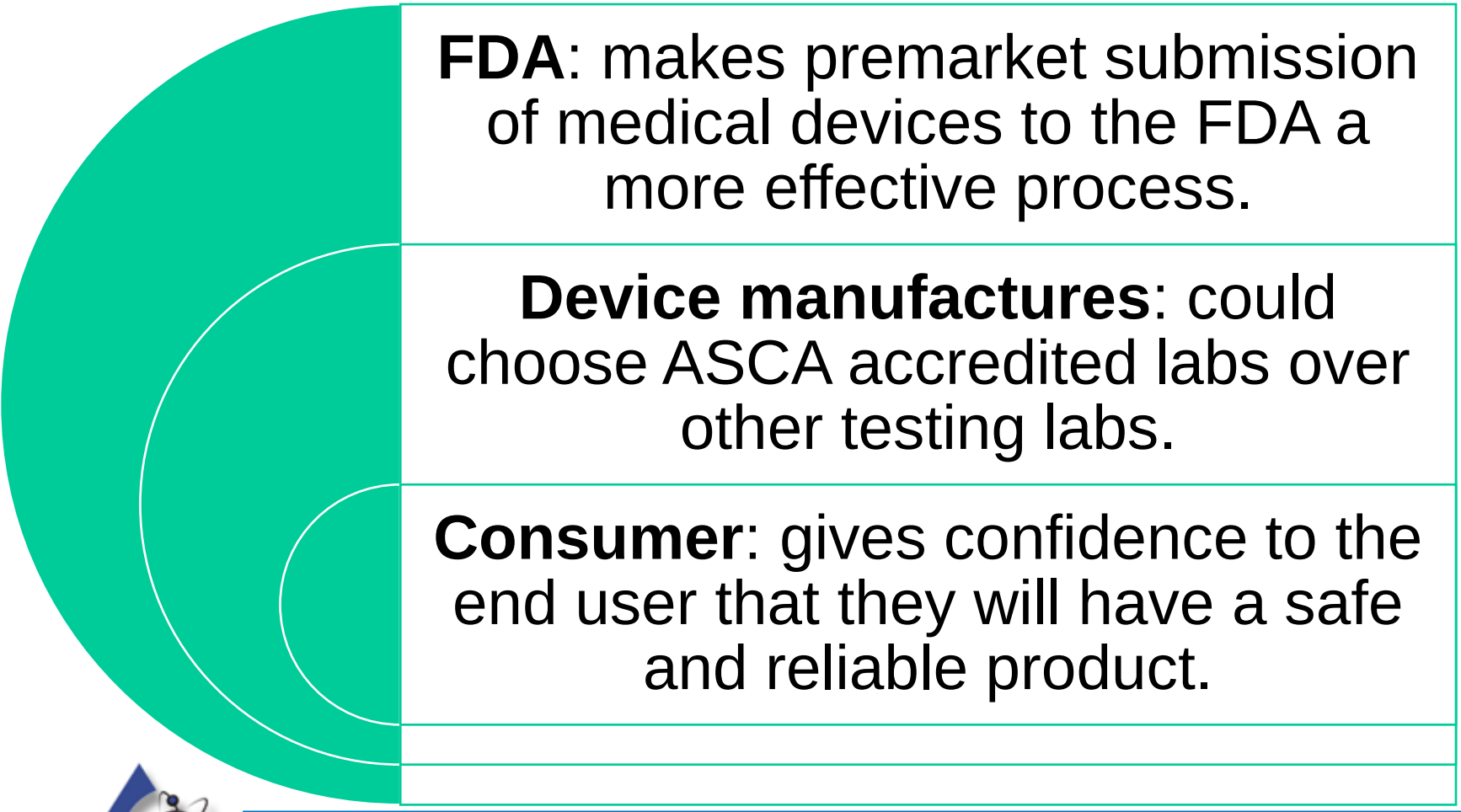
ASCA Pilot Additional Requirements Biocompatibility

- sample preparation
- personal training and qualifications
- positive and negative control criteria
- test reports

Additional requirements form 21 CFR 58:

- Testing facility management 21 CFR 58.31
- Study director, per 21 CFR 58.33
- Quality Assurance Unit, per 21 CFR 58.35
- Animal care 21 CFR 58.90 (vivo studies)
- Standards Operating Procedure 21 CFR 58.81
- Conduct of a nonclinical laboratory study 21 CFR 58.130
- Storage and retrieval of records and data 21 CFR 58.190

ASCA Goals


FDA: makes premarket submission of medical devices to the FDA a more effective process.
Device manufactures: could choose ASCA accredited labs over other testing labs.
Consumer: gives confidence to the end user that they will have a safe and reliable product.

ASCA References and Information

https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-recognized-accreditation-bodies

https://www.pjlabs.com/accreditation-programs/asca-pilot-program

https://www.fda.gov/media/75891/download

Time for Questions

Join us for our Next Webinars

Wednesday, October 20 – 1:00pm EST
Overview of Key Requirements of ISO/IEC 17020:2012 “Inspection”

Wednesday, October 27 – 1:00pm EST
ISO 17034:2016 General Requirements for the Competence of Reference Material Producers

Contact Information

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Thank You!