Conformity Assessment for Medical Devices: Medical Device Single Audit Program (MDSAP)

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Medical Device Single Audit Program (MDSAP)

• Development of program began in 2012 by IMDRF

• Participation:
  – Members: Australia, Brazil, Canada, Japan, US
  – Affiliate Members: Argentina and S. Korea
  – Official Observers: EU and WHO

• Allows recognized Auditing Organizations (AOs) to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of 5 participating Regulatory Authorities (RAs)

• Standardized audit model developed by the participating RAs
MDSAP Overview

- Participating RAs perform assessments of the AOs:
  - Formal recognition and monitoring process
    - Using IMDRF Criteria and ISO/IEC 17021: *Conformity Assessment – Requirements for Bodies Providing Audit and Certification of Management Systems*
    - Training and competency requirements for auditors
    - 4-year cycle
- AOs perform audits of medical device manufacturers on behalf of the RAs.
  - Audits conducted using the MDSAP Audit Model
    - Using ISO 13485:2016 and specific quality system requirements from participating RAs’ regulations
  - 3-year cycle
Participating Regulatory Authorities

MDSAP

Audit

Medical Device Manufacturers

Audit Report

Assessment

Independent, Private Sector, For-Profit Auditing Organizations (AOs)

Enforcement

(Per contractual agreements)
Regulatory Authority AO Assessment Focus

- Management (including Impartiality)
- Measurement, Analysis and Improvement
- Competency Management
- Certification Process
- Information Management

Outsourcing
MDSAP Assessment Process to Recognize Auditing Organizations
MDSAP Audit Model

• 90 audit tasks covering
  – All ISO 13485:2016 requirements
  – Relevant regulatory requirements

• Clarifying annexes:
  – Audit of technical documentations
  – Considerations relative to the audit of the controls of the sterility

✓ Verification that the audited manufacturer has defined and implements controls to ensure the safety and performance of medical devices [Quality / Compliance]
MDSAP Audit Cycle

Initial Audit
- Stage 1: Documentation Review
- Stage 2: On-Site Audit

Surveillance Audit
- Stage 1 – (as needed): Documentation Review
- Review of changes, management process, MA&I, registration, authorization, etc.

Recertification Audit
- Stage 1 – (as needed): Documentation Review
- Review audit reports, corrections/corrective actions, other MDSAP audit process tasks, etc.

Special Audit, Unannounced Audit, RA audit
Resources

MDSAP Website
http://www.fda.gov/medicaldevices/internationalprograms/mdsappilot/default.htm

MDSAP Question and Answer Document
Thank You