Medical Device Single Audit Program

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Objectives

• Introduction to MDSAP
  ➢ What is MDSAP?
  ➢ MDSAP Development Team
  ➢ How does MDSAP work?
  ➢ Assessment vs. Audit

• Benefits
  ➢ Benefits for the Regulatory Authorities
  ➢ Benefits for the FDA
  ➢ Benefits for the Auditing Organizations
  ➢ Benefits for the Manufacturers

• Quality Management System

• Conclusion
MDSAP Development Team*

- **Therapeutics Goods Administration (TGA)**
  - Two (2) members

- **Agência Nacional de Vigilância Sanitária (ANVISA)**
  - Three (3) members

- **Health Canada/Santé Canada**
  - Two (2) current members

- **FDA/CDRH/OC**
  - Five (5) current members
  - One (1) consultant

- **FDA/ORO/ORA**
  - One (1) National Expert Investigator

*Development team governed by eight (8) member Regulatory Authority Council made up of two (2) upper management representatives from each participating regulatory authority*
Formal Statement of Cooperation Regarding the Development of a Medical Device Single Audit Program

Australia
Therapeutics Goods Administration (TGA)

Brazil
Agência Nacional de Vigilância Sanitária (ANVISA)

Canada
Health Canada/Santé Canada

United States of America
Food and Drug Administration (FDA)
The goal of the MDSAP is to provide for more effective, efficient and less burdensome regulatory oversight of the quality management systems of medical device manufacturers.

The implementation of the MDSAP is intended to allow for a single audit to satisfy the regulatory requirements of the Participants.

Source: Statement of Cooperation
The objectives of the MDSAP are to:

Operate a single audit program that provides confidence in program outcomes;

Enable the appropriate regulatory oversight of medical device manufacturers’ quality management systems while minimizing regulatory burden on industry;

Promote more efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among Participants, while respecting the sovereignty of each country;

Source: Statement of Cooperation
The objectives of the MDSAP are to (continued):

Promote, over the longer term, greater global alignment of regulatory approaches and technical requirements based on international standards and best practices;

Promote consistency, predictability and transparency of regulatory programs by standardizing oversight practices and procedures of Participants over third-party auditing organizations, and the practices and procedures of participating third-party auditing organizations; and

Leverage, where appropriate, existing conformity assessment structures.

Source: Statement of Cooperation
MDSAP Current Development Status

✓ Program support infrastructure including IT

✓ Initial Recognition, Surveillance, and Re-Recognition Criteria for MDSAP Recognized Auditing Organizations (IMDRF Lead)

✓ Standardized AO Auditor Competency and Competency Maintenance Requirements

✓ Standardized Regulatory Authority Assessor Competency and Competency Maintenance Requirements

✓ Standardized Audit and Assessment Models
  ✓ Auditing of a Manufacturer by an MDSAP Recognized AO
  ✓ Assessment of MDSAP Recognized AO’s by participating Regulatory Authorities
MDSAP Current Development Status

✓ Standardized Rating System for Manufacturer Audit Findings
✓ Standardized Rating System for Recognized Auditing Organization Assessment Findings
✓ MDSAP Quality Management System
✓ MDSAP Program Communication Strategy (External and Stakeholders)
✓ MDSAP Program Launch Strategy
✓ Training on MDSAP Program
January 1, 2014 Pilot Study

Recognition of initial participating auditing organizations began:

✓ Application assessment of candidate auditing organizations

✓ Assessment audits of candidate auditing organization head office and critical locations

✓ Witness audits of candidate auditing organization auditors performing audits of manufacturers
MDSAP Pilot Audit Process

• Designed and developed to ensure a single audit will provide efficient yet thorough coverage of the requirements of medical devices – quality management systems
  – ISO 13485:2003
  – Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013)
  – Quality System Regulation (21 CFR Part 820)
MDSAP Pilot Audit Process

• AND other specific requirements of medical device regulatory authorities participating in the pilot MDSAP program, such as:
  – Registration
  – Licensing
  – Adverse event reporting
How will Regulatory Authorities utilize the Single Audit Program and resulting audit report/certificate?

- **Australia:** TGA will use an MDSAP audit report as part of the evidence that is assessed for compliance with medical device market authorization requirements unless the medical device is otherwise excluded or exempt from these requirements or if current policies restrict the use of MDSAP audit reports.
How will Regulatory Authorities utilize the Single Audit Program and resulting audit report/certificate?

• **Brazil:** ANVISA will utilize the outcomes of the program, including the reports, to constitute an important input on ANVISA’s pre-market and post-market assessment procedures, providing, when applicable, key information that is expected to support regulatory technical evaluation on these issues.
How will Regulatory Authorities utilize the Single Audit Program and resulting audit report/certificate?

• Health Canada: HC will use an MDSAP audit as part of their Canadian Medical Device Conformity Assessment System (CMDCAS) certification program. Upon the successful completion of the pilot, Health Canada’s intent is to implement the Medical Device Single Audit Program as the mechanism to achieve regulatory compliance for quality management system requirements in Canada.
How will Regulatory Authorities utilize the Single Audit Program and resulting audit report/certificate?

- **United States:** FDA will accept the MDSAP audit reports as a substitute for FDA routine inspections. Inspections conducted “for cause” or “compliance follow-up” by FDA will not be affected by this program. Moreover, the MDSAP would not apply to any necessary pre-approval or post-approval inspections in support of Premarket Approval (PMA) applications.
What Auditing Organizations can apply to the MDSAP Pilot?

- During the pilot, the only Auditing Organizations that will be allowed to apply to the MDSAP for recognition will be the accredited organizations/registrars currently utilized in the Health Canada CMDCAS program. The list of registrars recognized by Health Canada can be found on the Health Canada website.
What Auditing Organizations can apply to the MDSAP Pilot?

• As part of the MDSAP application process, the Auditing Organizations will be required to comply with the following IMDRF MDSAP documents, in addition to other documents approved by the Pilot Coalition Regulatory Authority Council:
  – IMDRF MDSAP WG N3 – “Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition”
  – IMDRF MDSAP WG N4 – “Competency and Training Requirements for Auditing Organizations”
What oversight will Regulatory Authorities have over the Auditing Organizations?

• In accordance with best practices, the Regulatory Authorities involved in the Pilot Coalition have developed a robust plan and schedule of assessing the competence and compliance of MDSAP Auditing organizations to include headquarters office assessments, critical site location assessments, and witnessed audits on an annual basis as part of a four year recognition program.
Assessment vs. Audit

Assessment & Recognition

• Of Auditing Organization By Regulatory Authorities
• Of compliance to the IMDRF Recognition Criteria (including ISO/IEC 17021, GHTF SG3/N19, etc.)
• 4-year cycle
• MDSAP Assessment Model

Audits

• Of Device Manufacturers By Auditing Organization
• Of compliance to ISO 13485 + specific quality system requirements from PRAs’ regulations
• 3-year cycle
• MDSAP Audit Model
What oversight will Regulatory Authorities have over the Auditing Organizations?

• The Regulatory Authorities involved in the pilot Coalition will utilize as the basis of the recognition and assessment process the following IMDRF MDSAP documents, in addition to other documents drafts and approved by the Pilot Coalition Regulatory Authority Council:
  – IMDRF MDSAP WG N5 – “Regulatory Authority Assessment Strategy for the Recognition and Monitoring of Medical Device Auditing Organizations”
  – IMDRF MDSAP WG N6 – “Regulatory Authority Assessor Competency and Training Requirements”
What oversight will Regulatory Authorities have over the Auditing Organizations?

• In addition, IMDRF MDSAP WG N11 is a document being produced to “grade” nonconformities resulting from a Regulatory Authority assessment of an Auditing Organization and to document the decision process for recognizing an Auditing organization or revoking recognitions. When finalized, this document will also be utilized under the Regulatory Authority Assessment program.
Harmonization Efforts for Implementing a Quality Management System within MDSAP

• QMS Framework Model IWA 4:2009(E) Quality management systems – Guidelines for the application of ISO 9001:2008 in local government
Basic Approach

- Document internal processes (i.e., procedures, templates, flowcharts [process mapping])
- Use “Best Practices” approach
- Timeliness, Consistency, Efficiency, and Transparency
- Implement an easy to use QMS Framework, and
- Use the PDCA Approach
  - Do what you say (Do)
  - Say what you do (Plan)
  - Prove it (Check)
  - Improve it (Act)
Benefits for the Regulatory Authorities

• Promotes efficient and flexible use of regulatory resources through work-sharing and mutual acceptance among regulators while respecting the independence of each participating regulatory authority.

• Promotes greater alignment of regulatory approaches and technical requirements globally based on international standards and best practices.

• Moves to create an international coalition of countries dedicated to pooling technology, resources, and services to improve the safety and oversight of medical devices in a more efficient manner that is also less burdensome for industry.
Benefits for the FDA

• Provides confidence in the ability to use third parties through direct recognition and monitoring

• Enables enhanced regulatory oversight of medical device manufacturers’ quality management systems (post marketing phase)

• Does not restrict the ability to inspect per current practices but gives more intelligence on how to best allocate resources
Benefits for the Auditing Organization (AO)

- Single assessment for all jurisdictions
- Reduced burden on AO resources (by reducing the number of necessary regulatory recognitions)
- Standard recognition criteria (i.e. ISO/IEC 17021 + IMDRF N3)
- Common manufacturer audit criteria and audit report template
- Specified auditor competence criteria
Benefits for Manufacturers

• May be acceptable alternative to inspection required for marketing authorization in some countries
• Reduced burden on manufacturer resources (by reducing the number of regulatory inspections/audits from as many as four a year to one a year)
• Common audit criteria capturing the requirements of all participating regulatory authorities to be used by recognized auditing organizations
• Predictability in outcome, based on the use of a standardized non-conformity grading system
How can medical device manufacturers participate?

• As of January 2014, the CMDCAS registrars are allowed to start submitting their application for MDSAP recognition. The MDSAP project plan targets the review of applications every six months for the duration of the pilot.
How can medical device manufacturers participate?

• After a successful assessment, the MDSAP Auditing Organization applicants will be allowed to perform MDSAP audits for medical device manufacturers that will be utilized by the Regulatory Authorities as previously discussed.
How do I find out more specifics on the documents, policies, and procedures that will be utilized in the MDSAP pilot?

• http://www.fda.gov/MedicalDevices/InternationalPrograms/default.htm