Medical Device Single Audit Program (MDSAP)

BSI 2015 Medical Device Roadshow
Agenda

• What is MDSAP?
• How does MDSAP work?
• I already have ISO 13485 and/or CE MDD/AIMD/IVDD certificates. How will MDSAP fit into my situation?
Medical Device Single Audit Program (MDSAP)

- Result of one of the 6 Working Groups created by the International Medical Device Regulatory Forum (IMDRF)
- Global approach to auditing and monitoring the manufacturing of medical devices to ensure safe medical devices
- An international coalition to quickly pilot the program
- Objective: to jointly leverage regulatory resources to manage an efficient, effective, and sustainable single audit program focused on the oversight of medical device manufacturers.
International Medical Device Regulatory Forum (IMDRF)

- IMDRF born February 2011 as a forum to discuss future directions in medical device regulatory harmonization.
- Voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF)
- Accelerate international medical device regulatory harmonization and convergence.
International Medical Device Regulatory Forum (IMDRF)

• IMDRF Management Committee (MC) regulators:
  • Australia, Brazil, Canada, China, the European Union, Japan, Russia, and the United States of America

• Observers:
  • WHO - World Health Organization
  • APEC LSIF (Asia Pacific Economic Cooperation Life Science Innovation Forum)

• Affiliate Organizations:
  • Asian Harmonization Working Party
  • Pan American Health Organization

• Working Groups:
  • Standards; MDSAP; Submissions; UDI; NCAR; Software
MDSAP Benefits

• Single Audit by AO would:
  • benefit patient health and patient access
  • leverage regulatory resources
  • minimize medical device manufacturing disruptions due to multiple regulatory audits
  • provide global benefit both on short term goals and longer term goals by IMDRF regulators
How will Regulatory Authorities utilize MDSAP and the 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.

• MDSAP would not apply to any necessary pre-approval or post approval inspections for Premarket Approval (PMA) applications.
United States (continued):

• The FDA will review MDSAP Pilot audit reports with a level of scrutiny commensurate to the significance of audit findings, taking into account the review and follow-up performed by the AO.

• Firms have one month to provide their full response to critical nonconformities (grade 4 and 5) to the AO (as opposed to 15 working days following a FDA inspection)

• FDA will utilize other forms of Advisory Notice, where necessary instead of FDA Warning Letters for MDSAP Audits during the Pilot. Warning Letters will only be considered when the MDSAP audit conclusion reveals an imminent/ unreasonable risk to public health.
Canada:

• Health Canada will operate the current Canadian Medical Devices Conformity Assessment System (CMDCAS) and MDSAP in parallel during the three year pilot.

• Health Canada will accept either an MDSAP certificate or a CMDCAS certificate for the purpose of obtaining a new (or maintaining an existing) Class II, III, or IV medical device license, pursuant to section 32 of the CMDR.

• Upon the successful conclusion of the pilot, Health Canada intends to implement MDSAP as the mechanism to achieve regulatory compliance for quality management system requirements in Canada.
Brazil:

• The Brazilian National Health Surveillance Agency – ANVISA will utilize the outcomes of the program, including the reports, to constitute an important input on ANVISA’s pre-market and postmarket assessment procedures, providing, when applicable, key information that are expected to support regulatory technical evaluation on these issues.
Brazil (continued):

• ANVISA may use MDSAP Pilot audits in lieu of a premarket inspection by ANVISA to grant ANVISA’s GMP Certificate to manufacturers intending to put medical devices of class III or IV on the Brazilian market. Undergoing an MDSAP Pilot audit may accelerate ANVISA’s GMP certification process, which is a pre-requisite to the marketing authorization.

• ANVISA can also use MDSAP Pilot audits to renew ANVISA’s GMP Certificate bi-annually, as an alternative to an ANVISA comprehensive inspection.
Australia:

• The Therapeutics Goods Administration - 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.
MDSAP Pilot

• Pilot started in January 2014 (for 3 years, to Dec 2016)
• Certification Bodies from participating member states can apply to become AO’s
  • Initially CMDCAS (Canada) recognized registrars
• Office audits and witnessed audits required
  • Conducted by Regulatory Authorities
• September 2014 AO’s started conducting audits
• Operational program slated for 2017
How Does MDSAP Work?

Regulatory Authorities
- Assessments
- Reports

Auditing Organizations
- Audits

Manufacturers
MDSAP Operations – Ensuring Consistency

• IMDRF
  • Initial Recognition, Surveillance, and Re-Recognition Criteria for MDSAP Recognized Auditing Organizations
  • Standardized Recognized 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 Information – Official Sources (USA-FDA)

• Pilot Program Announcement (brief description) - link
• Program Announcement (including benefits) - link
• MDSAP FAQs - link
• Eligible Auditing Organizations – link
• MDSAP Audit Procedures & Forms – link
• Website = www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/
Medical Device Single Audit Program (MDSAP) Pilot

The International Medical Device Regulators Forum (IMDRF) recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).

Beginning in January 2014, FDA will be participating in a MDSAP Pilot alongside other international partners. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections.

The MDSAP Pilot is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program.

International partners that are participating in the MDSAP Pilot include:
Audit Cycle

• Three Year Audit Cycle
  • Initial Audit (Stage One & Stage Two)
  • Surveillance Audits (Years 1 and 2)
  • Re-audit (Recertification Audit)
  • Note that not all Regulatory Authorities require “certification” of QMS

• Other Possible Audits
  • Special Audits
  • Audits by Regulatory Authorities
  • Unannounced Audits
MDSAP Audit Procedures

• Audit Procedures & Forms available, e.g., relevant documents
  • Audit Model     AU P0002.002 (56 pages)
  • Companion Document   AU G0002.1.002 (95 pages)
  • Audit Time Calculation Procedure   P0008.001
  • Nonconformity Grading   GHTF/SG3/N19:2012
  • Post-Audit Activities and Timeline Policy   MDSAP AU P0027
MDSAP Audit Model

• Follows the process approach
• Four Primary processes
  • Management
  • Measurement, Analysis and Improvement
  • Design and Development
  • Production and Service Controls
• Three Supporting Processes
  • Purchasing
  • Device Marketing Authorization and Facility Registration
  • Medical Device Adverse Events and Advisory Notices Reporting
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For Manufacturers Currently Holding ISO 13485, ISO 13485 CMDCAS, CE MDD/IVD/AIMD MD Certificates

- Check with current Certification / Notified Body whether capable
- Investigate best plan for the type of MDSAP audit to conduct:
  - Full initial audit or Surveillance audit?
  - Consider current ISO certification cycle
  - Consider business plans (new markets?)
- Note that new marketing authorizations from a Regulatory Authority will require a full audit (rather than a surveillance audit)
- Investigate with CB/NB whether the audit can include CE requirements
BSI Status

- BSI assessed early 2014
- Commenced audits fall 2014
- Continuing through 2015
- Continued & Increasing interest from manufacturers
MSDAP Benefits for Manufacturers

• No additional requirements for manufacturers
• Single audit optimizes time and resources
• Routine audits are scheduled/planned with AO
• Expected to improve predictability
• Expected to add additional Regulatory Authorities
• Some RA’s will use Pilot audit outcomes as alternatives to own inspections to process applications for market authorization
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