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

Melissa Torres

Associate Director for International Affairs

Office of the Center Director

Center for Devices and Radiological Health

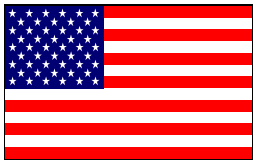
US Food and Drug Administration

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



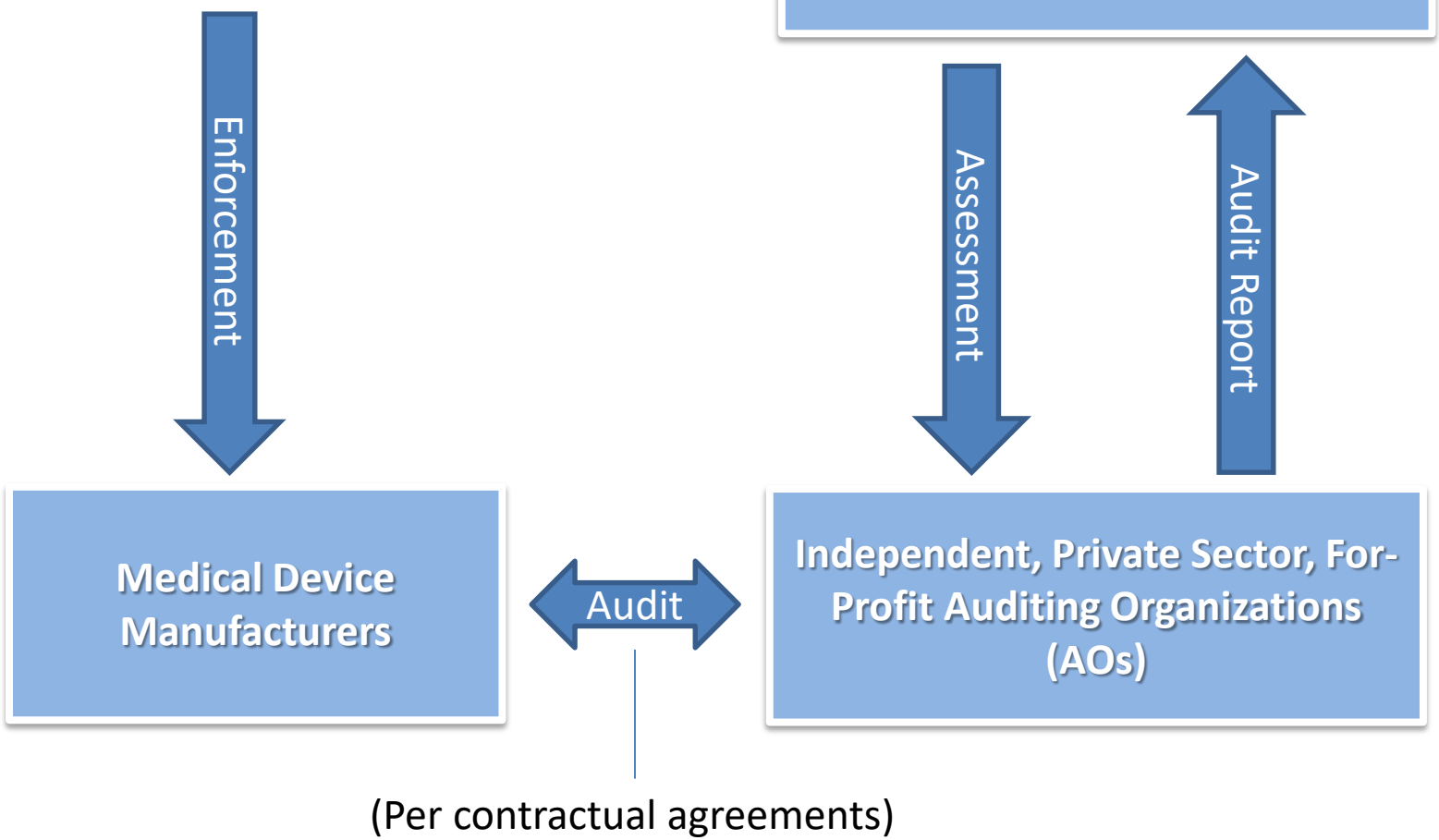




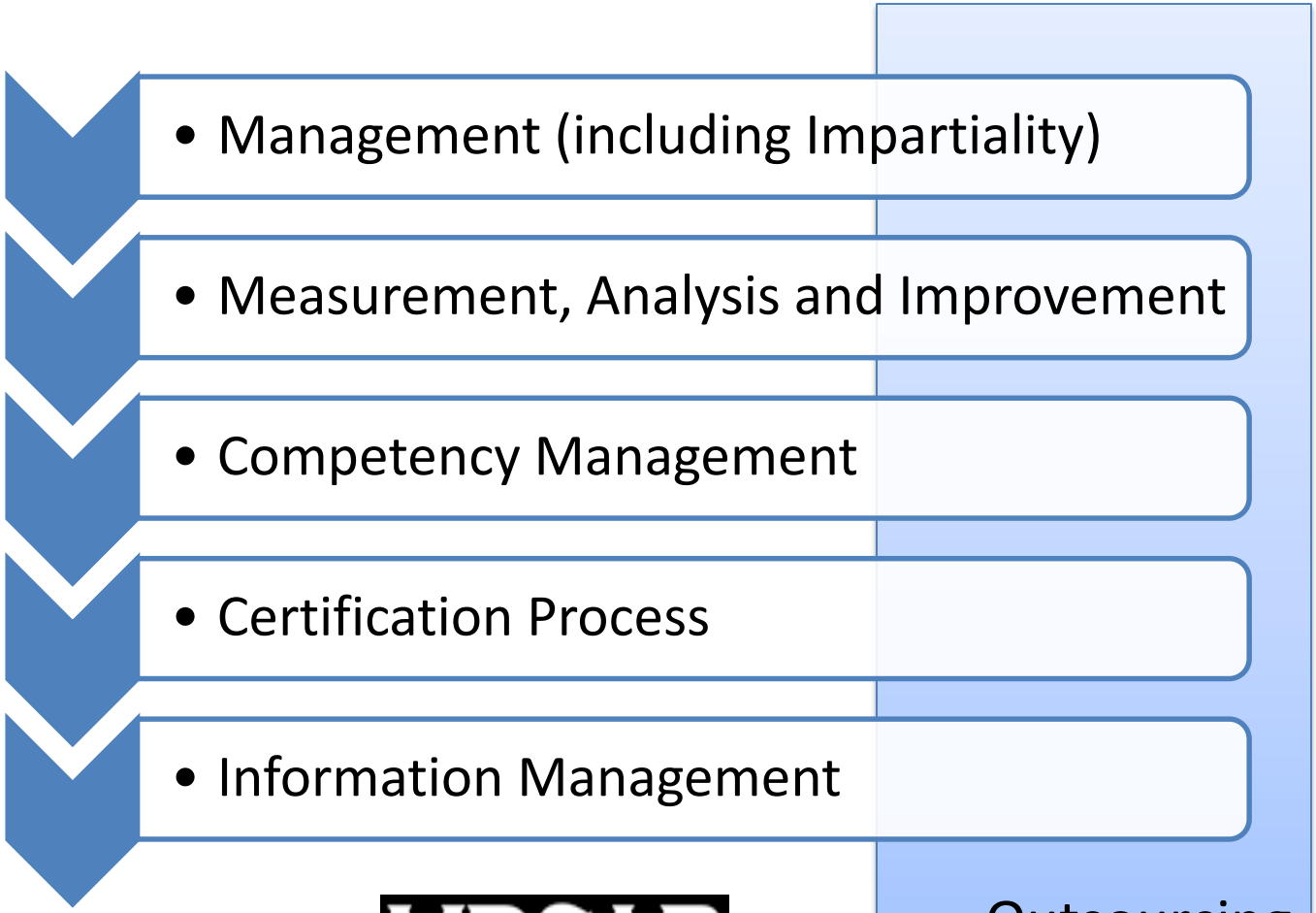
MDSAP Overview

- 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

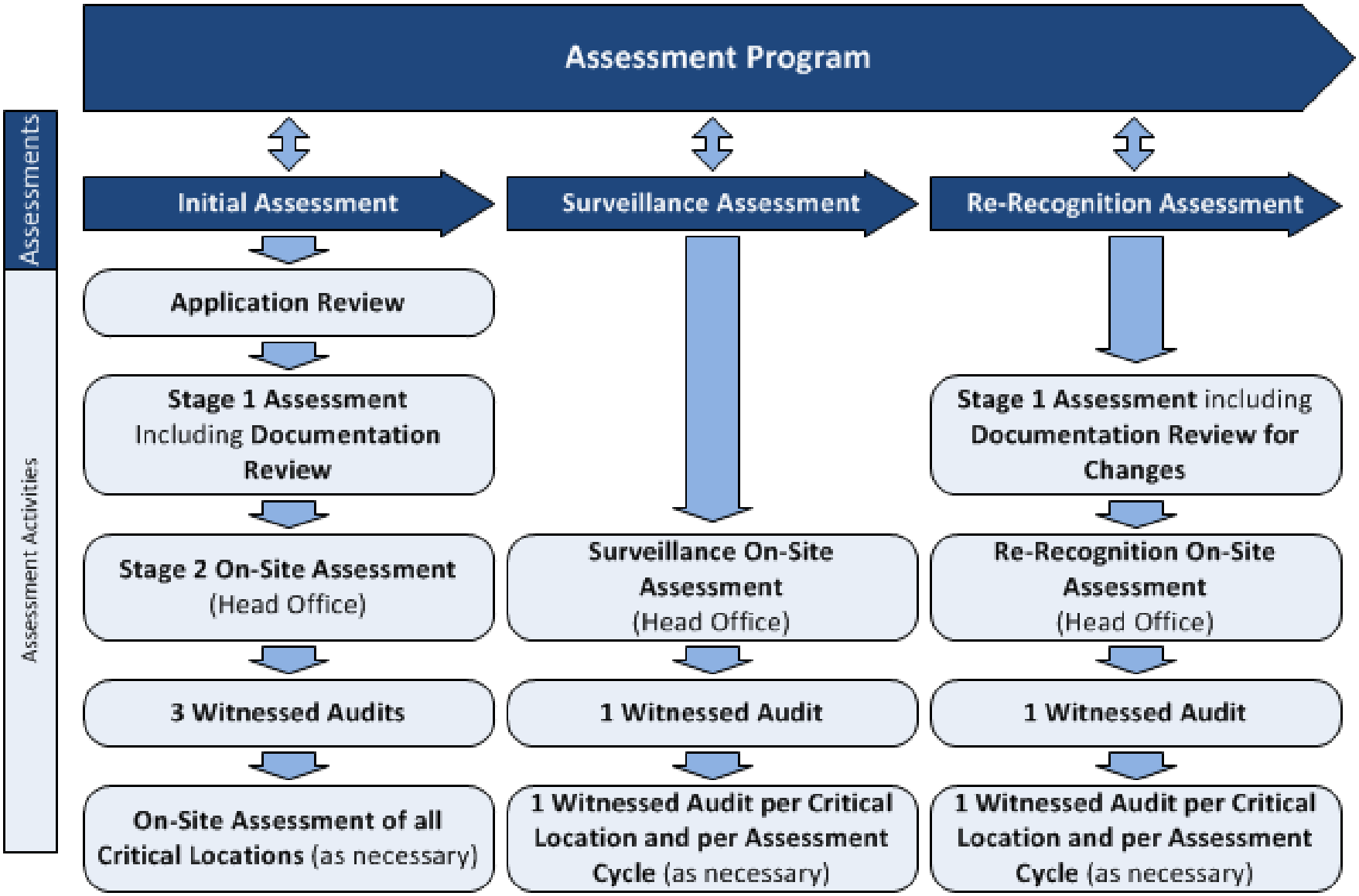


Regulatory Authority AO Assessment Focus



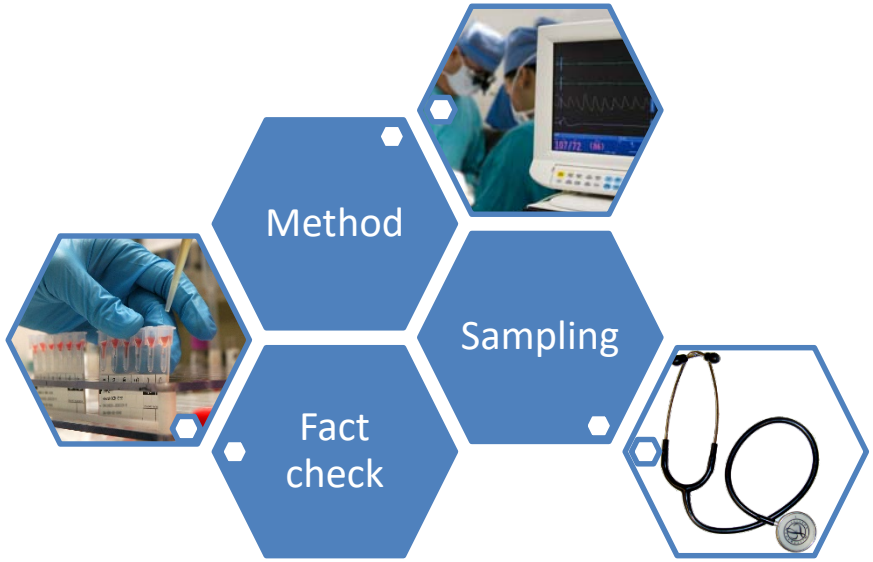
MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

MDSAP Assessment Process to Recognize Auditing Organizations

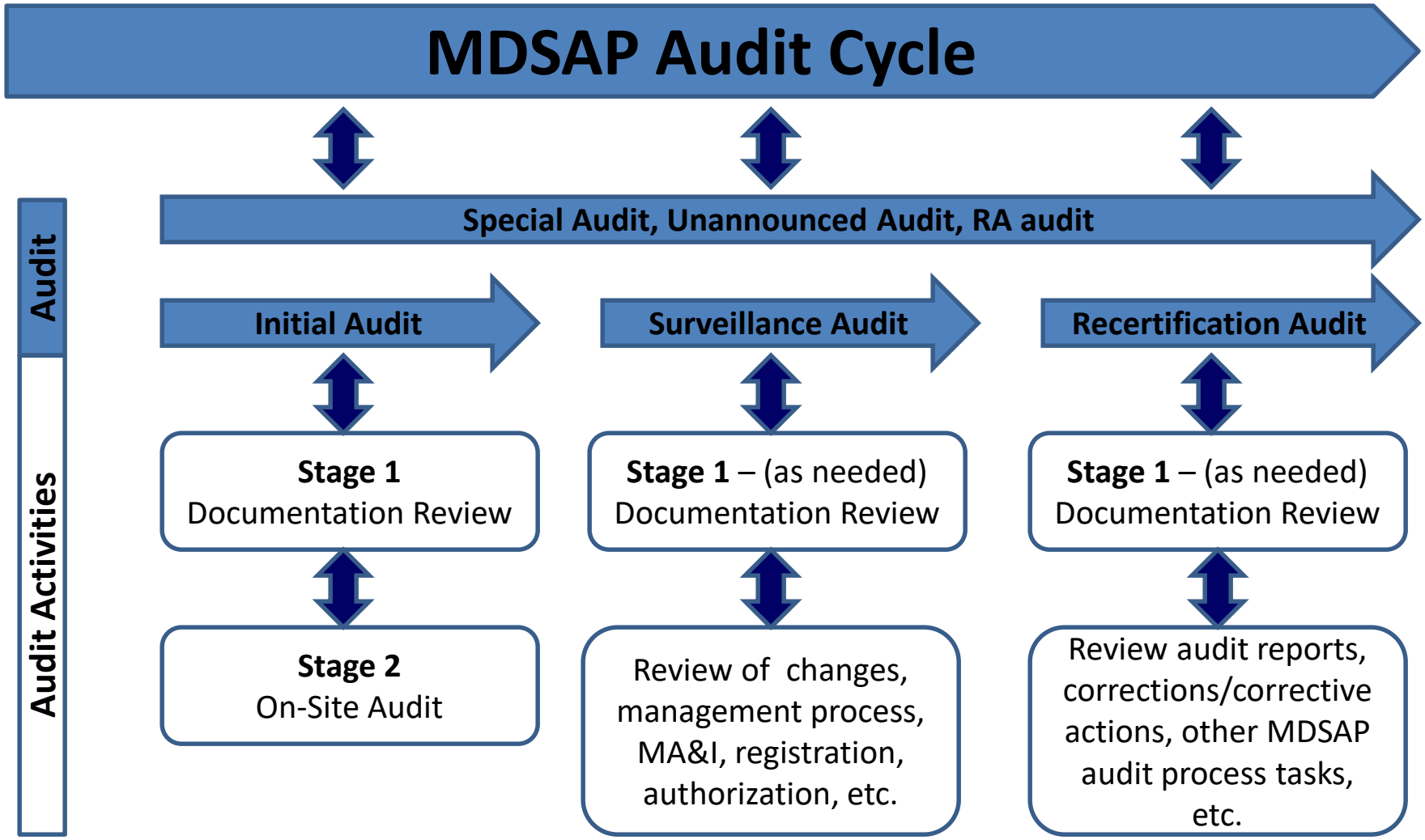


MDSAP Audit Model

- 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
Audit
Audit Activities
Special Audit, Unannounced Audit, RA audit
Initial Audit
Surveillance Audit
Recertification Audit
Stage 1
Documentation Review
Stage 2
On-Site Audit
Stage 1 – (as needed)
Documentation Review
Review of changes, management process, MA&I, registration, authorization, etc.
Stage 1 – (as needed)
Documentation Review
Review audit reports, corrections/corrective actions, other MDSAP audit process tasks, etc.

Resources

MDSAP Website

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

MDSAP Question and Answer Document

http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf

Thank You