Medical Device Single Audit Program (MDSAP)

FDA Small Business Regulatory Education for Industry (REdI)

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Learning Objectives

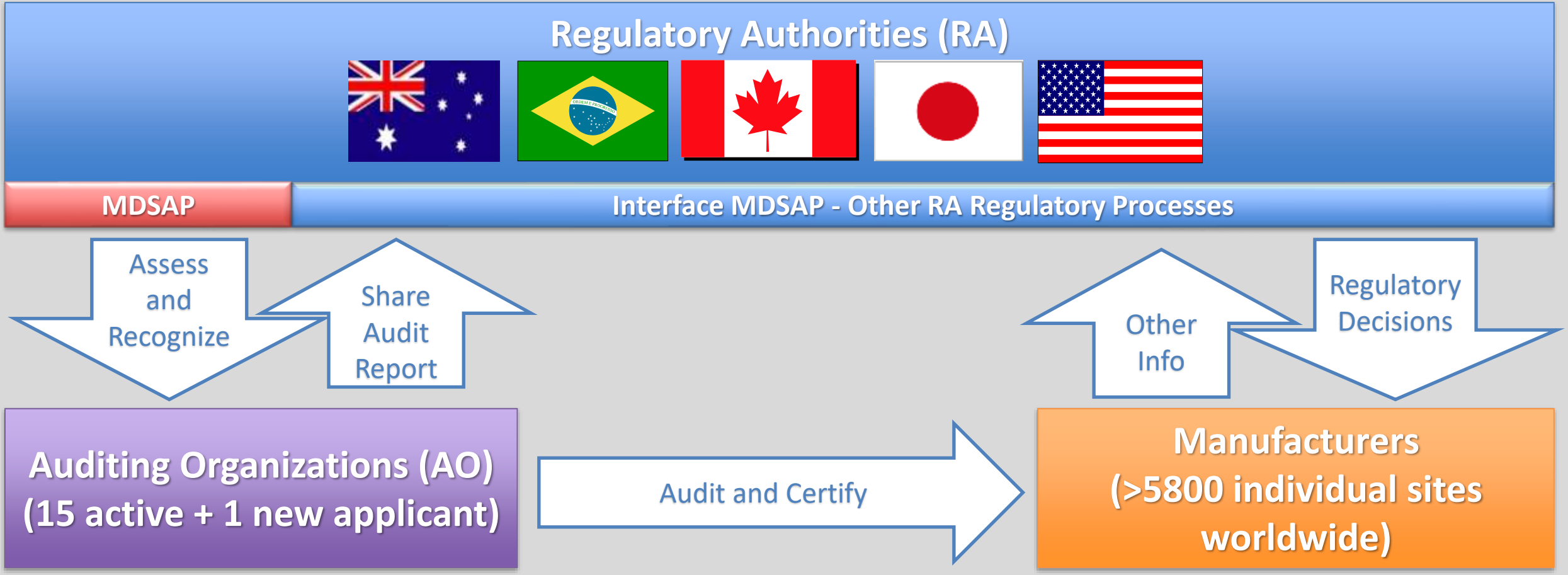
- Review MDSAP Updates
- Describe how FDA Uses MDSAP
- Discuss Extraordinary Measures and Remote Auditing

MDSAP Acronyms 101

- Medical Device Single Audit Program (MDSAP)
- Regulatory Authority (RA)
- Auditing Organizations (AO)

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Medical Device Single Audit Program (MDSAP)



MDSAP Participation

- CDRH Learn, 10 modules
- Five (5) RAs participating
- Three (3) Official observers
- Three (3) Affiliate members
- 15 AOs

Affiliate Membership Program

- Non-participating MDSAP Observer or non-participating MDSAP Regulatory Authority Council RA
- Training, information exchange and meeting obligations
- Affiliate Members:

Argentina's National Administration of Drugs, Foods and Medical Devices (ANMAT)

Republic of Korea's Ministry of Food and Drug Safety

Singapore's Health Sciences Authority

MDSAP Updates

Manufacturer Participation

Auditing Organizations

Authorized	Recognized	Application Received
QMI SAI GLOBAL NCC Lloyd's Register LRQA MEDCERT Certification. Medical Only.	TÜV USA Member of TÜV NORD Group bsi. DQS MED TÜVRheinland SGS TÜV SÜD UL intertek Total Quality. Assured. DEKRA LNE G MED NSAI National Standards Authority of Ireland Údarás Um Chaighdeáin Náisiúnta na hÉireann	Presafe A DNV GL COMPANY

Knowledge Check #1

I am marketing and distributing medical devices in a MDSAP Affiliate Member's jurisdiction. The Affiliate Member can obtain MDSAP audit reports and/or MDSAP certificates through the MDSAP Database.

1. **True**
2. **False**

FDA Use of MDSAP

FDA Quality System Inspections

- FDA accepts MDSAP Audit Reports as a substitute for FDA routine surveillance inspections.

- Other inspection levels listed in the Compliance Program Guidance Manual (CPGM) 7382.845, Inspection of Medical Device Manufacturers, still apply.

MDSAP Participants:
Types of FDA Quality System Inspections

Inspection Level	Type of Inspection	Guide to Inspections
1 (Routine)	Abbreviated	QSIT – Two subsystems; Corrective and Preventive Actions (CAPA) plus Production and Process Controls (P&PC) or Design Controls (PAC 82845A)
2 (Routine – Initial)	Comprehensive	QSIT - The four major subsystems; Management Controls, Design Controls, CAPA and P&PC (PAC 82845B or 82845P or 82A800)
3	Compliance Follow Up	Follow-up* As directed by inspectional guidance and elements of QSIT (PAC 82845C)
Special	For Cause	As directed by inspectional guidance and elements of QSIT (PAC 82845G)
Special	Risk Based Work Plan	As directed by CDRH inspection assignment and elements of QSIT (PAC 82845H)
Pre/Post Market	Comprehensive or Abbreviated	Process used by FDA to review and evaluate the safety and effectiveness of Class III medical devices. (PAC 83001, 83001A)

Exempted

Not Exempted

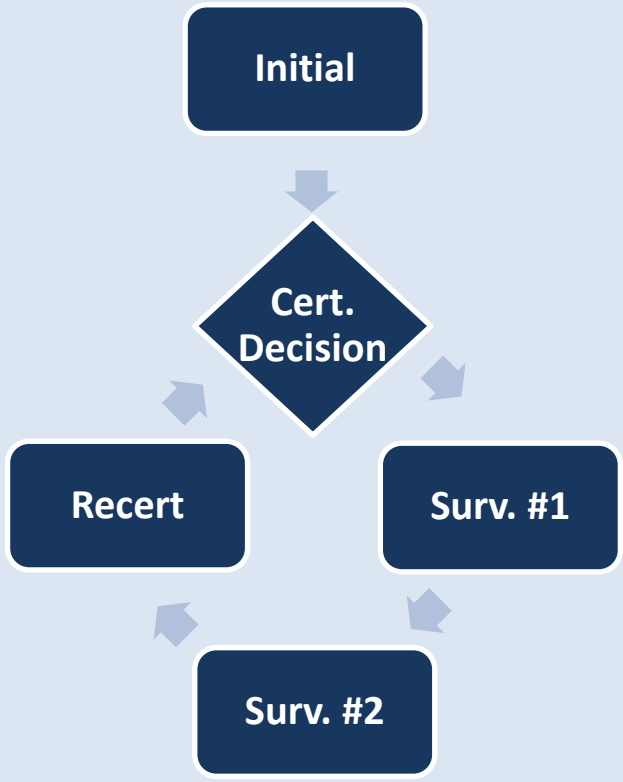
Types of Inspections and Audits

FDA Inspections

- Pre-approval
- Post-approval
- Surveillance
- Compliance follow-up
- For-cause
- Risk-Based

MDSAP Audits

- 3-year cycle of annual audits
  - Initial
  - Surveillance
  - Recertification
- Special
- Unannounced



MDSAP Audit vs FDA Inspection

MDSAP Audit

- ISO 13485:2016 plus RA requirements
- Voluntary Program (in the U.S.)
- Third Party Auditor
- MDSAP Audit Approach
- Routine Inspection Equivalent: Initial, Surveillance, Re-certification
- MDSAP Audit Report and NGE Form
- Multiple Regulatory Authorities

FDA Inspection

- 21 CFR 820, 803, 806, 807, etc.
- Mandatory
- FDA Investigator
- Quality System Inspection Technique
- Baseline, Abbreviated, EPRC, For Cause, RBWP, etc.
- EIR, FDA-483, Exhibits
- FDA, few RAs (firm-provided)

Knowledge Check #2

I am a MDSAP participating manufacturer. Therefore, I am exempt from FDA Inspections.

1. **True**
2. **False**

Extraordinary Measures and Remote Auditing

MDSAP Transmittal Number: 2020-10

- Supersedes MDSAP Transmittal Number 2020-07

Extension and Expansion of Temporary extraordinary measures related to MDSAP audits during quarantine orders and travel restrictions – Remote audits

- Describes the interim measures to address challenges.
- Remote audits as a substitute for on-site audits.

Alternative Audit Types

- **Desktop Audit:** performed remotely by reviewing documentation
- **Remote Audit:** performed off-site using information and communication technology (ICT)
- **Hybrid Audit:** partially performed off-site using ICT, while at least one MDSAP qualified auditor is simultaneously on-site during a portion of the audit
- **Surrogate Audit:** partially performed off-site using ICT, while at least one non-MDSAP qualified auditor is simultaneously on-site during a portion of the audit

Remote Audits and Assessments

- AOs are performing remote audits
- RAs performing remote witness audits and head office assessments
- Challenges:
  - Technology
  - Time zones
  - Travel Restrictions
  - Resource and personnel availability
  - Uncertainty of pandemic

Summary

- MDSAP allows a single regulatory audit that satisfies the requirements of multiple regulatory jurisdictions
- Audits are conducted by Third Party Auditing Organizations
- Results from MDSAP audits are factored into compliance activities
- Addition of Affiliate Membership Program and three Affiliate RAs
- Extraordinary measures implemented due to travel restrictions

Resources

Slide Number	Cited Resource	URL
7	Affiliate Membership Policy, MDSAP P0035.001	www.fda.gov/media/127697/download
10	List of Auditing Organizations	www.fda.gov/media/137394/download
13	Compliance Program Guidance Manual (CPGM) 7382.845, Inspection of Medical Device Manufacturers	www.fda.gov/media/80195/download
19	Transmittal 2020-10	www.fda.gov/media/144883/download
	MDSAP FAQ	www.fda.gov/media/90179/download

Questions


FDA
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ADMINISTRATION