Medical Device Single Audit Program (MDSAP) – FDA Use of MDSAP

FDA Small Business Regulatory Education for Industry (REdI)

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Source: [Dilbert by Scott Adams, Tuesday, March 14, 1995]

Learning Objectives

- Review MDSAP Updates
- Discuss COVID-19 Measures and Remote Auditing
- Describe how FDA Uses MDSAP

MDSAP Acronyms 101

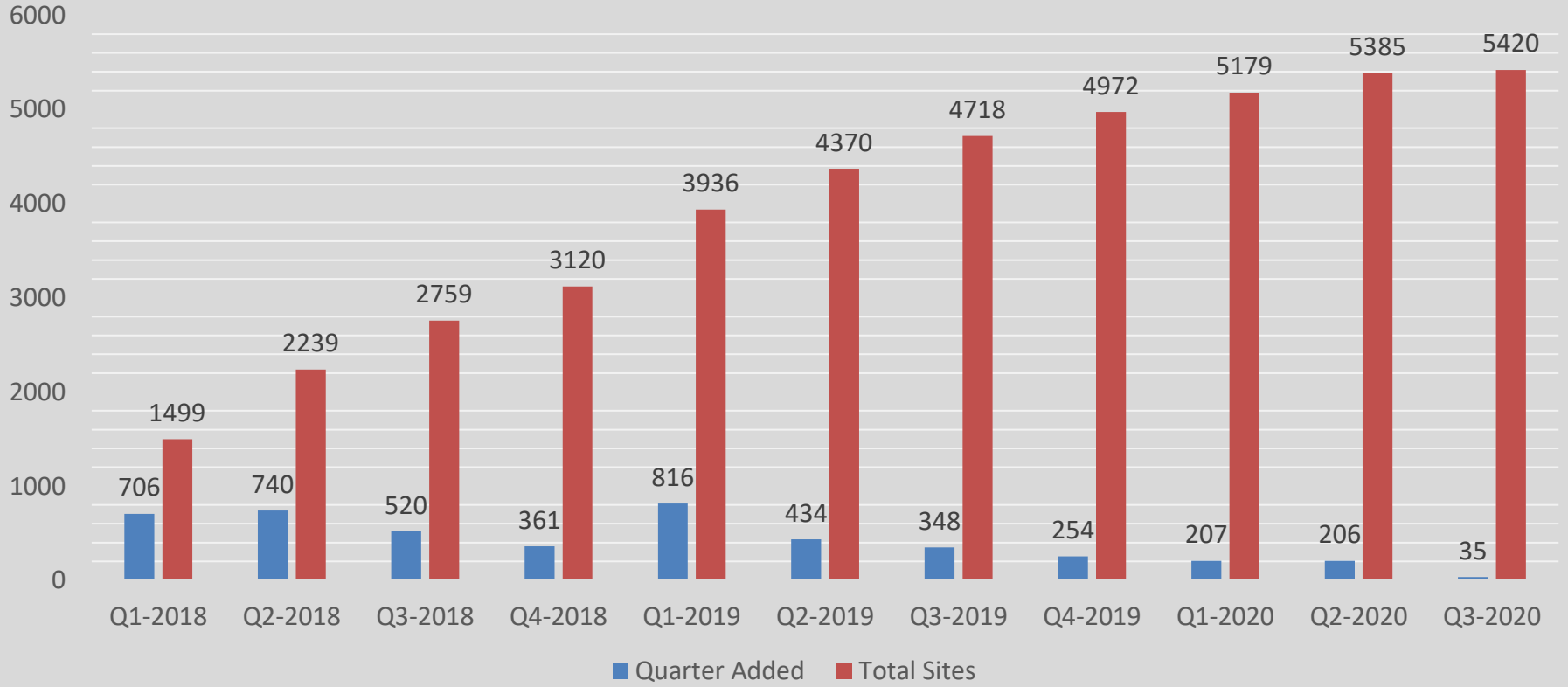
- Medical Device Single Audit Program (MDSAP)
- Regulatory Authority (RA)
- Auditing Organizations (AO)

MDSAP Updates

MDSAP Participation

- CDRH Learn, 10 modules
- Five (5) RAs participating 
- Two (2) Official observers 
- New AOs

Manufacturer Participation



Auditing Organizations

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

Affiliate Membership Program

- Program began June 2019
- Non-participating MDSAP Observer or non-participating MDSAP Regulatory Authority Council RA
- No revisions to MDSAP Audit Model
- Application must describe use of MDSAP

Affiliate Membership Program

- Benefits
  - 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

Changes to MDSAP Audit Model

- Transitioning to the MDSAP Audit Approach
- Combining Audit Model and Companion Document
  - Eliminating the need to maintain two documents
  - Ease of use
- Includes updates from RAs

COVID-19 Measures and Remote Auditing

MDSAP Transmittal Number: 2020-07

- Supersedes MDSAP Transmittal Number 2020-05

Extension and Expansion of Temporary extraordinary measures related to MDSAP audits during covid-19 quarantine orders and travel restrictions – Remote audits

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

Remote Audits and Assessments

- AO's 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

Knowledge Check

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

Use of MDSAP

- Audit reports are mutually accepted
  - Final classification is determined through independent review
- Reviewers utilizing reports as intel for compliance activities
- Issuing Export Certificates

Expanded Use of MDSAP

- Studying an increase to the FDA's threshold beyond the 5-Day Notice
- Discussing ideas to streamline premarket and postmarket activities

Knowledge Check

I am a MDSAP participating manufacturer. Therefore, I am exempted from the FDA's Risk Based Workplan Inspections.

1. True
2. False

Use of MDSAP by other RAs

- MDSAP FAQ, Version 016
  - Question #31: What are the potential benefits to the manufacturer participating, specific to each jurisdiction?
- Stakeholder Day Presentations, December 5-6, 2019

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

Resources

Slide Number	Cited Resource	URL
8	List of Auditing Organizations	https://www.fda.gov/media/137394/download
9	Affiliate Membership Policy, MDSAP P0035.001	https://www.fda.gov/media/127697/download
10	MDSAP Audit Model	https://www.fda.gov/media/88272/download
12	Transmittal 2020-07	https://www.fda.gov/media/136441/download
16	Compliance Program Guidance Manual (CPGM) 7382.845, Inspection of Medical Device Manufacturers	https://www.fda.gov/media/80195/download
21	MDSAP FAQ	https://www.fda.gov/media/90179/download
21	MDSAP Stakeholder Day	https://www.fda.gov/medical-devices/cdrh-international-programs/medical-device-single-audit-program-mdsap

Questions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