Use of MDSAP - Regulatory Updates (FDA)

FDA QS Inspections

U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health, will accept the MDSAP audit reports as a substitute for FDA routine inspections.

However, all other situations listed under the FDA's Compliance Program Guidance Manual (CPGM) 7382.845, Inspection of Medical Device Manufacturers, still apply.

Types of QS 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	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

Program Development

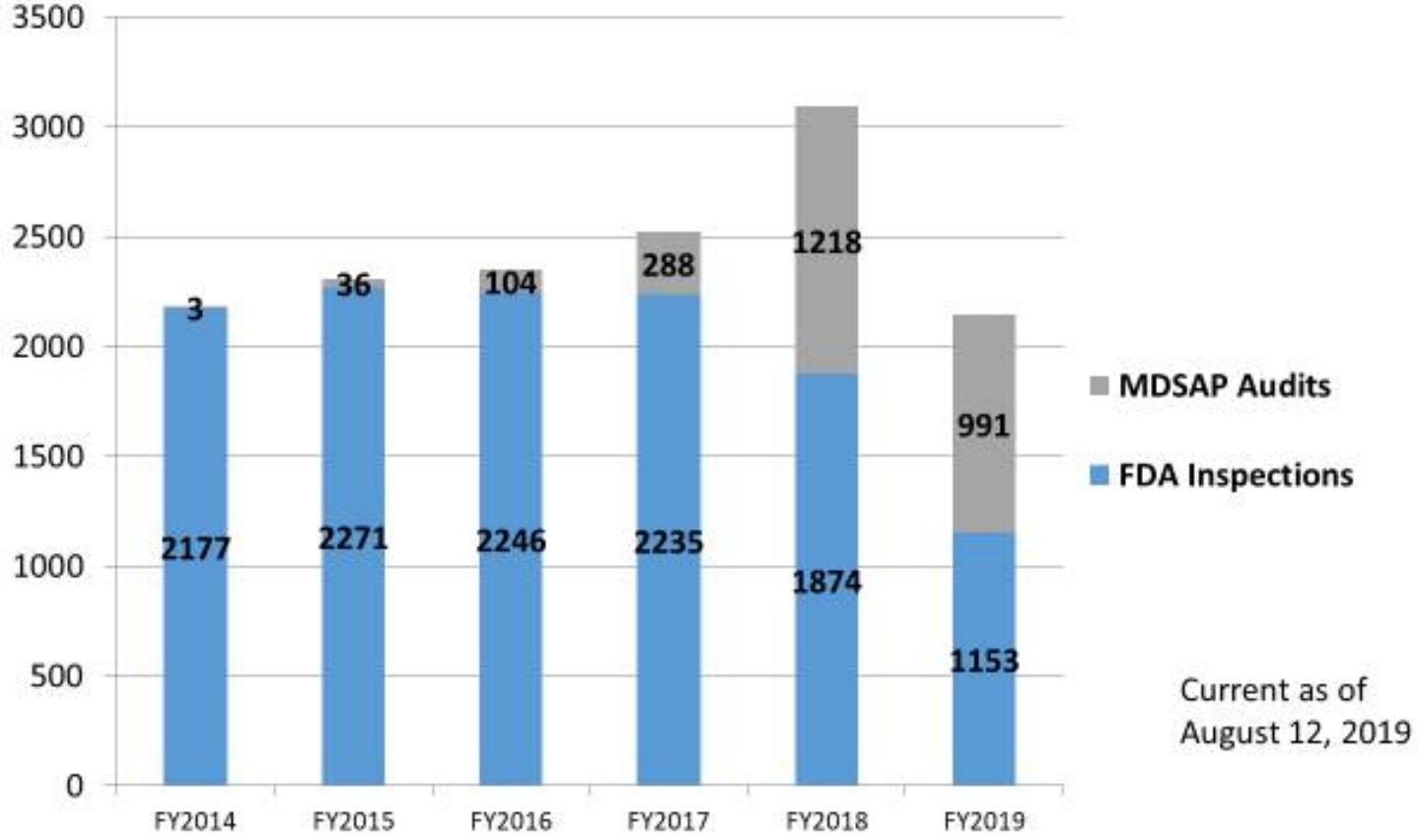
Challenges

- CDRH Reorganization - TPLC
- Resource limitations
- Internal tracking mechanism
- Educating internal stakeholders on the program and benefits to FDA
- Expanding regulatory uses for MDSAP audit reports
- Medical devices regulated by other Centers

Successes

- Consistent source of QS intelligence
- Capability Maturity Model Integration (CMMI) Institute
- Engagement with Auditing Organizations, partner countries and potential affiliate members
- Program implementation and maintenance
- Continual improvement to IT Portal

Medical Device QS Surveillance Inspections and MDSAP Audits



Current as of
August 12, 2019


MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM