

# FDA Update

## Transition to ISO 13485:2016

December 5, 2018



# FDA's Intention

*FDA intends to harmonize and modernize the Quality System regulation for medical devices. The revisions will supplant the existing requirements with the specifications of an international consensus standard for medical device manufacture, ISO 13485:2016. The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers by harmonizing domestic and international requirements. The revisions will also modernize the regulation.*

<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201804&RIN=0910-AH99>

NOTE: Proposed rule estimated to be issued in Fall 2019

# Benefits for Adopting ISO 13485



- ISO 13485:2016 is already used by Regulatory Authorities in other countries as a basis for their QMS requirements; therefore, one globally harmonized system will allow for opportunities
  - To work closer with foreign regulatory authorities and facilitate regulatory convergence on QMS
  - For medical device manufacturers to have a more globally harmonized QMS
- Deltas between the QS regulation and ISO 13485:2016 are minor
  - Gain more than we lose
  - More robust QMS principles in many areas
  - Better guidance
  - Stronger ties to risk management principles and ISO 14971

# FDA's Interest in ISO 13485



- FDA has always had an interest in seeking ways to harmonize requirements with ISO 13485 including programs such as:
  - ISO 13485 Voluntary Audit Report Submission Pilot Program\*
  - Medical Device Single Audit Program (MDSAP)

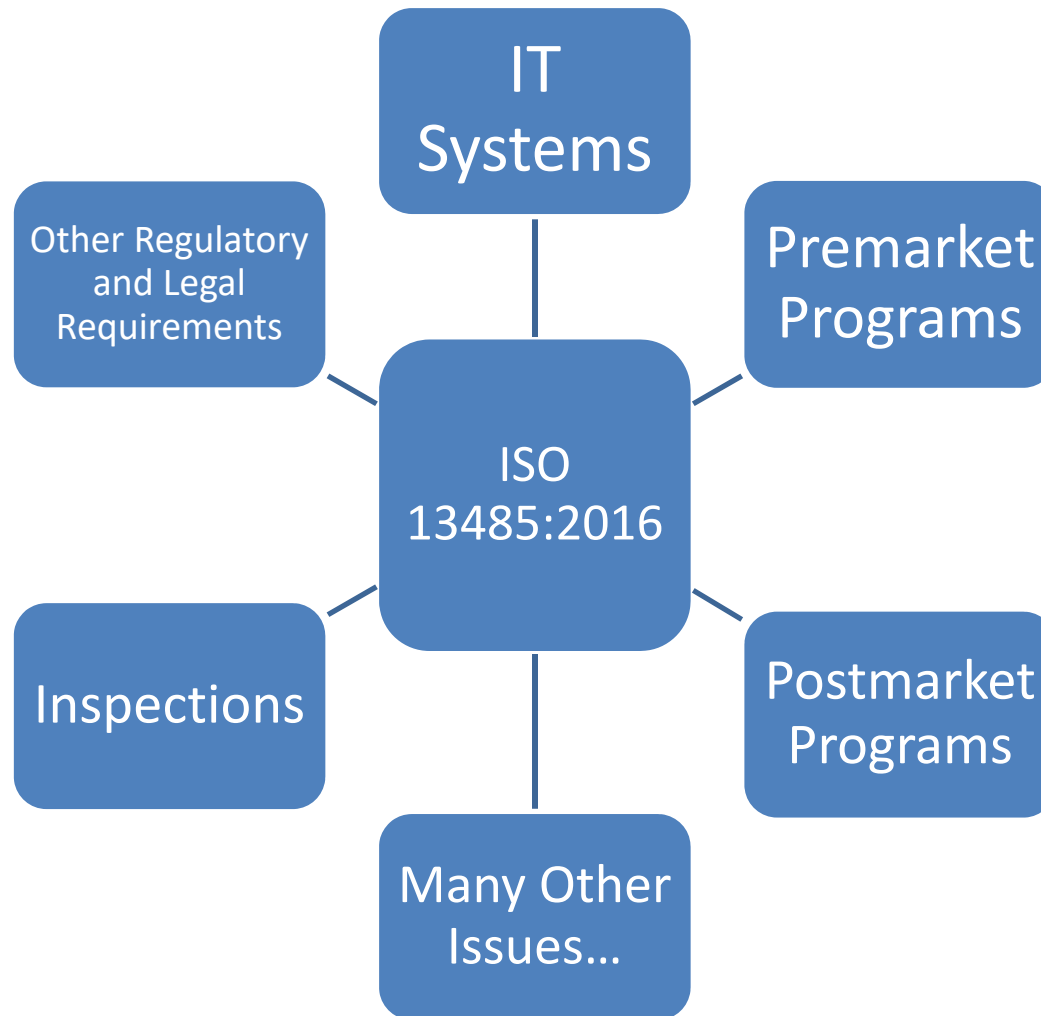
*\*Program no longer in use as it was a precursor to MDSAP*



# Implementation

- We recognize there will be a significant impact on FDA for implementation. For example:
  - Training on ISO 13485 requirements, interpretation, best practices, etc. to CDRH staff and ORA investigators and compliance officers
  - Changes to the inspection model (QSIT)
  - Revisions/updates to numerous documents
  - Changes to IT systems
- Transition period will likely be a few years

# Impacts to FDA





# Current Status

- FDA currently is currently working on the proposed rule which will be issued in 2019
  - A panel committee meeting will be held after issuance of the proposed rule
- Development of an AAMI Technical Information Report (TIR) which outlines the comparative analysis between ISO 13485: 2016 and the QS regulation and vice versa.
  - Developed by AAMI with FDA participation
  - Will be completed in early-mid 2019

