Food and Drug Administration

Center for Devices and Radiological Health

What is ISO 13485?

- International Standard: “Medical Devices – Quality management systems – Requirements for regulatory purposes”
- Recognized by medical device regulatory bodies outside the U.S.:
  - Canada requires ISO 13485 certification
  - EU and Australia recognize ISO 13485 as a means of meeting regulatory requirements
  - Japan harmonized its GMP regulation with ISO 13485

Why is FDA Interested in ISO 13485?

- Risk-based planning and efficient use of FDA inspectional resources:
  - More audits are performed to ensure compliance with ISO 13485 than FDA inspections to ensure compliance with 21 CFR part 820 (QS regulation)
  - ISO 13485 audits are performed domestically and internationally
- Harmonization with other countries

Basis: ISO 13485:2003 Voluntary Audit Report Submission Pilot Program

- Section 228 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated that FDA would accept voluntary submission of ISO reports:
  - "For the purpose of setting risk-based inspectional priorities, the Secretary shall accept voluntary submissions of reports of audits assessing conformance with appropriate quality system standards set by the International Organization for Standardization …"

Manufacturer's submission

- ISO Audit Report from a Conformity Assessment Body certified by a Global Harmonization Task Force (GHTF) Founding Member Regulator*.
  - Must be submitted within 90 days of the audit close
  - Must submit all reports of ISO 13485 audits that were issued during the preceding 2-year period
  - Submitted to the FDA eSubmitter system

*Accepted GHTF auditing systems: 1) Canada; 2) European Union; 3) Australia; and 4) Japan.

Are there specific requirements for the audit and audit reports?

- **The ISO 13485 audit must conform with GHTF SG4 guidance documents**
  - Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers
    - Part 1 General Requirements
    - Part 2 Regulatory Auditing Strategy
    - Part 3 Regulatory Audit Reports

- **The *most recent* eligible audit report must conform with Health Canada's GD 211 Guidance for the content of quality management system audit reports**

Are there specific requirements for the audit and audit reports?

- FDA will require the manufacturer to make an attestation during the FDA electronic submission process that arrangements for conformance to these guidance documents had been made with the regulatory third-party auditor prior to the audit and these guidance documents were adhered to during the audit and the drafting of the audit report that is being submitted to the FDA.

Details …

- The ISO 13485 Audit Report can represent a full assessment of the QMS or a surveillance audit
  - There can only be one FEI number associated with a single ISO 13485 Voluntary Audit Report Submission
- The manufacturer must submit a copy of the most recent ISO 13485 certificate
- Responses and communications between the auditor and the manufacturer regarding correction(s) or corrective action(s) to audit findings can be included in the submission
- The manufacturer must provide requested information required by eSubmitter

What will CDRH and CBER do with the audit reports?

- CDRH and CBER will notify the relevant District Office (domestic establishments) or Divisions of Foreign Field Investigations (DFFI) (foreign establishments) within Office Regional Affairs (ORA)
  - Request that the firm not be inspected for 30 days
- CDRH and CBER will review audit report per Part V of Compliance Program 7382.845 (February 2, 2011)
  - Will determine Situation 1 or 2

  (FDA expects only non-violative reports to be submitted)
- CDRH or CBER will notify the firm (and concurrently the District Office or DFFI) of the outcome of the review within 30 days from receipt.

How is ORA involved in the process?

- Postpone inspections for 30 days after receiving notification that a firm has submitted an ISO 13485 audit report to the program.
  - ORA has the option not to postpone if foreign travel has already arranged and the foreign manufacturer did not make previous arrangements with ORA.

How is ORA involved in the process?

- ORA will receive a copy of the CDRH or CBER letter electronically notifying the firm of the review outcome. Based on outcome, ORA will:
  - Proceed with inspection, or
  - Remove firm from workplan for one year.

The review memo and supporting files will be stored in a FDA electronic database.

How confident is FDA in ISO 13485 audit results?

- **FDA has experience with third-party accredited auditing organizations**
  - Accredited Persons Program
  - Pilot Multipurpose Audit Program (PMAP)
  - Medical Device Single Audit Program (MDSAP)

- **FDA believes that the ISO 13485 voluntarily submitted audit report provides a degree of assurance of compliance with basic and fundamental quality management system requirements for medical devices.**

Important Points to Remember

- The ISO 13485 Voluntary Audit Report Submission Pilot Program does not preclude FDA from conducting:
  - PMA pre-approval inspections
  - For Cause inspections
- One year inspection “pass” would start from the date of the close of the ISO audit.
- Under discussion - how many consecutive years a firm will be allowed to use this process.
  - The conclusion of the Pilot program will help in the determination.

Final details …

- The pilot program is **voluntary**
- FDA *intends* to start the pilot on **June 5, 2012**