International Medical Device Regulators Forum (IMDRF) and Medical Device Single Audit Program (MDSAP) Working Group

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Mission

- The mission of the International Medical Device Regulators Forum (IMDRF) is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety.

IMDRF Work Items

Medical Device Single Audit Program (MDSAP)

- The Work Group will develop a standard set of requirements for auditing organizations performing regulatory audits of medical device manufacturers' quality management systems. The document will be applicable to competent authority auditing groups/inspectorates, as well as third party organizations that conduct such audits. This is an initial critical step in establishing a single audit program.

IMDRF Work Items - MDSAP

- **WG (PD1)/N3R2 -** Recognition Criteria for Medical Device Auditing Organizations
- Source Documents
  - ISO/IEC 17021:2011
  - EU Draft Legislation on Requirements for Notified Bodies
  - EU MEDEV 2.10-2 Rev 1:2001 - Designation and Monitoring of Notified Bodies within the Framework of EC Directives on Medical Devices

IMDRF Work Items - MDSAP

- HC - Draft Auditing Organization Recognition Criteria and HC GD 210
- MHLW - Registration Criteria for Medical Device Conformity Assessment Bodies in Japanese Pharmaceutical Affairs Law
- US FDA - Accredited Person Inspection Program Rating Criteria
- IAF MD9:2011 - Mandatory Document for the Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)

IMDRF Work Items - MDSAP

- Draft proposed document
  - ISO/IEC 17021:2011 + Regulatory Authority requirements drawn from the source documents described in the previous slides.
    - Special attention and additional requirements regarding Impartiality, Appearance of Conflict of Interest, Outsourcing Auditing Activities, Arrangements with Medical Device Manufacturers for the Sharing of Audit Information

IMDRF Work Items - MDSAP

- Public comment
- Sub-Tasks from ISO/IEC 17021 requirements and Annexes:
  - Auditor Competency
  - Auditor Maintenance of Competency
  - Code of Ethics
  - Criteria for Special Audits

Future

- Look forward to some exciting areas of progress for regulatory convergence

- Benefit patient health, patient access, and provide a more global view both on short term goals and longer term goals by IMDRF regulators