

MITA Perspective on FDA Transition to ISO 13485

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The Medical Imaging & Technology Alliance (MITA), a division of the National Electrical Manufacturers Association (NEMA), is the leading organization and collective voice of medical imaging equipment, radiopharmaceutical manufacturers, innovators and product developers.

We represent companies whose sales make up more than 90 percent of the global market for advanced imaging technologies. MITA is the Secretariat of Digital Imaging and Communications in Medicine (DICOM).

Our mission is to reduce regulatory barriers, establish standards, and advocate for the medical imaging industry.



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MITA strongly supports the proposed transition of the current US FDA 21 CFR Part 820 *Quality System Regulation* to the *Quality Management System Regulation* through incorporation of the International Standardization Organization (ISO) 13485 Quality Management System for Medical Devices



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Benefits of the Transition

- Drives consistency, efficiency, effectiveness
- Eliminates the need to maintain multiple quality systems
- Reduces the burden of compliance and recordkeeping
- Allows for scalability in application



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Benefits of Harmonization

MITA supports global harmonization of regulations and use of international voluntary consensus standards, specifically the transition to ISO 13485

- Many industry members already implement ISO 13485 globally
- Aligns with the MDSAP program
- Supports alignment with the global regulator community and supports additional opportunities for harmonization and reliance
- Adoption and use by FDA of this international consensus standard without modification is an excellent example to global community: linkage to existing national requirements without changing the standard or adding on requirements



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Considerations for FDA

- Clarify to the medical device community that certification to ISO 13485 is not required; guidance regarding how existing certification might be leveraged
- Clarify the transition timeline
- Continue internal training plans for FDA inspection teams and development of educational resources for external stakeholders including small and domestic manufacturers
- Clarify how FDA will conduct inspections – routine, for-cause, EPRC and pre-approval
- Clarify whether FDA's process to inspect other requirements, e.g., Medical Device Reporting, Labeling will change
- Clarify how FDA will update the inspection manual



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MITA offers our support to assist with implementation training and generally as a resource for the FDA.



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Thank You



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