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Global Regulatory Guidelines: Medtech Guidance Tracker, July 2016

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Stay up to date on regulatory guidelines from around the world, with *Medtech Insight*'s Guidance Tracker, with documents updated through July 2016.

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[Editor's note: *Check out the complete global Medtech Guidance Tracker with sortable and searchable listings going back to 2014 here.]*

Fifteen new guidance documents on medical device and *in vitro* diagnostics from global regulatory authorities were added to *Medtech Insight*'s *Guidance Tracker* in July. The most guidelines last month came from US FDA, with nine documents, including *two draft guidelines on next generation sequencing*.

Also on the updated list, a draft guideline from Malaysia explaining how change of ownership may impact the device registration process, and a revised final guideline from South Africa outlining essential principles of safety and performance of devices and IVDs.

The July guidance document listing is below, with links to each guideline.

Country	Organization	Document	Status
International	IMDRF	*Competence, Training and Conduct Requirements for Regulatory Reviewers*	Draft
International	WHO	*WHO manual for organizing a national external quality*	Final

		assessment programme for health laboratories and other testing sites	
EU	EC	*MEDDEV 2.1/6 - Qualification and Classification of stand alone software*	Final
Ireland	HPRA	*Guide to Information held by the HPRA* (*Tracked version*)	Final
Malaysia	MDA	*Medical device guidance document: Change of ownership for medical device registration*	Draft
South Africa	MCC	*Medical Devices and IVDs Essential Principles of Safety & Performance*	Final
US	FDA	*Use of Standards in FDA Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases: Draft Guidance for Stakeholders and Food and Drug Administration Staff*	Draft
US	FDA	*Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics: Draft Guidance for Stakeholders and Food and Drug Administration Staff*	Draft
US	FDA	*Principles for Co-*	Draft

		development of an In Vitro Companion Diagnostic Device with a Therapeutic Product: Draft Guidance for Industry and Food and Drug Administration Staff	
US	FDA	*Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI): Draft Guidance for Industry and Food and Drug Administration Staff*	Draft
US	FDA	*Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices: Draft Guidance for Industry and Food and Drug Administration Staff*	Draft
US	FDA	*Adaptive Designs for Medical Device Clinical Studies: Guidance for Industry and Food and Drug Administration Staff*	Final
US	FDA	*Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices: Guidance for Industry and Food and Drug Administration Staff*	Final
US	FDA	*General Wellness: Policy for Low Risk Devices –*	Final

US	FDA	*Guidance for Industry and Food and Drug Administration Staff FY 2017 Medical Device User Fee Small Business Qualification and Certification – Guidance for Industry, Food and Drug Administration Staff and Foreign Governments*	Final

Key:

- IMDRF: International Medical Device Regulators Forum
- WHO: World Health Organization
- EC: European Commission
- HPRA: Health Products Regulatory Authority
- MDA: Medical Device Authority
- MCC: Medicines Control Council
- FDA: Food and Drug Administration