REFERENCES

Elements of Regulatory Systems:

Asian Harmonization Working Party Playbook for Implementation of Medical Device Regulatory Frameworks. AHWP, 2014. Retrieved 10/22/2015 from: http://www.ahwp.info/index.php?q=node/497

Essential Principles of Safety and Performance of Medical Devices. Global Harmonization Task Force document GHTF/SG1/N68:2012. Retrieved 10/22/2015 from: http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n68-2012-safety-performance-medical-devices-121102.pdf

Good review practices: guidelines for national and regional regulatory authorities. WHO Expert Committee on Specifications for Pharmaceutical Preparations, Forty-ninth report, Annex 9. WHO, 2015. Retrieved 10/22/2015 from: http://www.who.int/medicines/areas/quality_safety/quality_assurance/Annex9-TRS992.pdf

Review of Information (Manufacturing /Labeling and Performance Studies):

Clinical Evidence for IVD Medical Devices - Clinical Performance Studies for In Vitro Diagnostic Medical Devices. Global Harmonization Task Force document GHTF/SG5/N8:2012. Retrieved 10/22/2015 from: http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n8-2012-clinical-performance-studies-ivd-medical-devices-121102.pdf

Clinical Evidence for IVD medical devices – Scientific Validity Determination and Performance Evaluation. Global Harmonization Task Force document GHTF/SG5/N7:2012. Retrieved 10/22/2015 from: http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n7-2012-scientific-validity-determination-evaluation-121102.pdf

Clinical Evidence for IVD medical devices – Key Definitions and Concepts. Global Harmonization Task Force document GHTF/SG5/N6:2012. Retrieved 10/22/2015 from: http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n6-2012-clinical-evidence-ivd-medical-devices-121102.pdf

Clinical Investigations. Global Harmonization Task Force document GHTF/SG5/N3:2010. Retrieved 10/22/2015 from: http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n3-clinical-investigations-100212.pdf

Clinical Evaluation. Global Harmonization Task Force document GHTF/N2R8:2007. Retrieved 10/22/2015 from:

http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n2r8-2007-clinical-evaluation-070501.pdf

Clinical Evidence – Key Definitions and Concepts. Global Harmonization Task Force document SG5/N1R8:2007. Retrieved 10/22/2015 from: http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n1r8-clinical-evaluation-key-definitions-070501.pdf

Quality System Information-FDA Guidance Document. Quality System Information for Certain Premarket Application Reviews: Guidance for Industry and FDA Staff. Issued February 3, 2003. Retrieved 10/10/2015 from: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070899.pdf

Unique Device Identification (UDI)-FDA Guidance Document. Global Unique Device Identification Database (GUDID). Guidance for Industry and Drug administration Staff. Issued September 24, 2013. Retrieved 10/18/2015 from: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm

Labeling Information. Label and Instructions for Use for Medical Devices. Global Harmonization Task Force document SG1/N70:2011. Retrieved 10/23/2015 from http://www.imdrf.org/documents/doc-ghtf-sg1.asp

Post-Market Surveillance:

Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps. CDRH/FDA, 2013. Retrieved 10/22/2015 from: http://www.fda.gov/downloads/MedicalDevices/Safety/CDRHPostmarketSurveillance/UCM348845.pdf

Post-Market Surveillance of In Vitro Diagnostics. WHO, 2015. Retrieved 10/22/2015 from: http://www.who.int/diagnostics_laboratory/postmarket/150819_pms_guidance_final_version.pdf?ua=1

The Value of Quality Management Systems –IVD Manufacturing Industry:

Quality System Information-FDA Guidance Document. Quality System Information for Certain Premarket Application Reviews: Guidance for Industry and FDA Staff. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070899.pdf

ADDITIONAL RESOURCES AND INFORMATION

DOCUMENTS AVAILABLE FROM THE IMDRF
http://www.imdrf.org/ghtf/ghtf-archives

- **GHTF/SG1/N045:2008,** *Principles of In Vitro Diagnostic (IVD) Medical Devices Classification*
- **GHTF/SG1/N046:2008,** *Principles of Conformity Assessment for IVD Medical Devices*
- **GHTF/SG1/SG1/N063:2010,** *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of IVD Medical Devices (STED)*
- **GHTF/SG1/N68:2012,** *Essential Principles of Safety and Performance of Medical Devices*

DOCUMENTS AVAILABLE FROM THE SAUDI FOOD & DRUG ADMINISTRATION http://www.sfda.gov.sa/en/medicaldevices/regulations

- Guidance for medical device importers and distributors (G1)
- Guidance for medical device authorized representatives (G3)
- Guidance for overseas manufacturers (G4)
- Guidance on marketing authorization procedures (G5)
- Guidance on post-marketing surveillance (G6)
- Implementing Rule on Safeguard Procedures (IR8)