

ANNEX: CORE-CURRICULUM

Category	Elements	GHTF/IMDRF Documents and Standards	Notes
Pre-market	Medical Device Definitions	Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device' (SG1/N071: 2012) http://www.imdrf.org/docs/gh tf/final/sg1/technical-docs/gh tf-sg1-n071-2012-definition-of-terms-120516.pdf	
		Definitions of the Terms Manufacturer, Authorised Representative, Distributor and Importer (SG1/N055: 2009) http://www.imdrf.org/docs/gh tf/final/sg1/technical-docs/gh tf-sg1-n055-definition-terms-090326.pdf	
	Medical Device Classification	Principles of Medical Device Classification (SG1/N77: 2012) http://www.imdrf.org/docs/gh tf/final/sg1/technical-docs/gh tf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf	
		Principles of IVD Medical Devices Classification (SG1/N045: 2008) http://www.imdrf.org/docs/gh tf/final/sg1/procedural-docs/gh tf-sg1-n045-2008-principles-ivd-medical-devices-classification-080219.pdf	
	Principles of Conformity Assessment	Principles of Conformity Assessment for Medical Devices (Study Group) (SG1/N78: 2012) http://www.imdrf.org/docs/gh tf/final/sg1/technical-docs/gh tf-sg1-n78-2012-conformity-assessment-medical-devices-121102.pdf	
Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices (SG1/N046: 2008) http://www.imdrf.org/docs/gh tf/final/sg1/procedural-docs/gh tf-sg1-n046-2008-principles-of-ca-for-ivd-medical-devices-080731.pdf			
Competence, Training, and Conduct Requirements for Regulatory Reviewers	Competence, Training, and Conduct Requirements for Regulatory Reviewers (GRRP WG/N40: 2017) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-competence-conduct-reviewers.pdf		

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<p>Essential Principles of Medical Device Safety & Performance</p>	<p>Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices(IMDRF/GRRP WG/N047: 2018) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf</p>	<p>The intention is to teach the use of essential principles in assessing medical devices and IVDs as part of a regulatory system including how standards may be used to meet the essential principles. The intention is NOT to teach any content on specific standards.</p>
<p>Optimizing Standards for Regulatory Use</p>	<p>Optimizing Standards for Regulatory Use (Standards WG/N51: 2018) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf</p>	<p>The intention of this topic on standards is to reinforce the need to use internationally harmonized standards in the regulatory decision-making process. The intention is NOT to teach any content on specific standards. The only standards that have been included in the core curriculum at this time are horizontal standards listed in the QMS section (ISO 13485 and ISO 14971) because these are widely recognized and accepted medical device industry standards</p>
<p>Principles of Labeling</p>	<p>Principles of Labeling for Medical Devices and IVD Medical Devices (GRRP WG/N52: 2019) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-pl-md-ivd.pdf</p>	
<p>Clinical Evaluation</p>	<p>Clinical Investigation (IMDRF MDCE WG/N57FINAL:2019) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n57.pdf</p>	
	<p>Clinical Evaluation (IMDRF MDCE WG/N56FINAL:2019) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n56.pdf</p>	

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		<p>Clinical Evidence (IMDRF MDCE WG/N55 FINAL:2019) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n55.pdf</p>	
QMS	Quality Management Systems and Risk Management	ISO13485:2016 Medical devices -- Quality management systems -- Requirements for Regulatory Purposes	
		ISO 14971: 2019 Medical Devices - Application of Risk Management for Medical Devices	
		Implementation of Risk Management Principles and Activities within a Quality Management System (SG3/N15R8: 2005) http://www.imdrf.org/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n15r8-risk-management-principles-qms-050520.pdf	
		Quality Management Systems – Process Validation Guidance (Edition 2) (SG3/N99-10: 2004) http://www.imdrf.org/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n99-10-2004-qms-process-guidance-04010.pdf	
		Quality Management System – Medical Devices – Guidance on the Control of Products and Services Obtained from Suppliers (SG3/N17R9: 2008) http://www.imdrf.org/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n17-guidance-on-quality-management-system-081211.pdf	
		Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes (SG3/N18: 2010): http://www.imdrf.org/docs/ghrf/final/sg3/technical-docs/ghrf-sg3-n18-2010-qms-guidance-on-corrective-preventative-action-101104.pdf	

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Auditing/MDSAP

<p>Nonconformity Grading System for Regulatory Purposes and Information Exchange (SG3/N19: 2012) http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n19-2012-nonconformity-grading-121102.pdf</p>	
<p>Medical Device Regulatory Audit Reports (MDSAP WG/N24: 2015) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-mdra-audit-report.pdf</p>	
<p>Competence and Training Requirements for Auditing Organizations (MDSAP WG/N4: 2013) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf</p>	
<p>MDSAP Training Modules*</p> <ol style="list-style-type: none"> 1. Introduction to MDSAP Presentation 2. MDSAP Management Presentation 3. MDSAP Device Marketing Authorization and Facility Registration Presentation 4. MDSAP Measurement, Analysis and Improvement Presentation 5. MDSAP Medical Device Adverse Events and Advisory Notices Reporting Presentation 6. MDSAP Design and Development Presentation 7. MDSAP Production and Service Controls, part 1 Presentation 	<p>*The intention is to provide an overview of the Medical Device Single Audit Program (MDSAP) and the MDSAP Audit Model. These training modules are publicly available and based on GHTF and IMDRF documents as part of MDSAP.</p>

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		<p>8. MDSAP Production and Service Controls, part 2 Presentation</p> <p>9. MDSAP Production and Service Controls, part 3 Presentation</p> <p>10. MDSAP Purchasing Presentation</p>	
		<p>MDSAP Affiliate Membership Policy Documents**</p> <p>MDSAP Affiliate Members Roles and Responsibilities Policy https://www.fda.gov/media/127697/download</p> <p>MDSAP Affiliate Membership Application Form https://www.fda.gov/media/127700/download</p>	<p>**If a Regulatory Authority is interested in the MDSAP Affiliate membership program, the documents provide an overview of the roles and responsibilities of being an affiliate member and the MDSAP Affiliate Membership application form.</p>
<p>Postmarket</p>	<p>Adverse Event Reporting</p>	<p>Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006) http://www.imdrf.org/docs/gh tf/final/sg2/technical-docs/gh tf-sg2-n54r8-guidance-adverse-events-061130.pdf</p> <p>Medical Devices Post Market Surveillance: Content of Field Safety Notices (GHTF/SG2/N57R8:2006) http://www.imdrf.org/docs/gh tf/final/sg2/technical-docs/gh tf-sg2-n57r8-2006-guidance-field-safety-060627.pdf</p> <p>IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Edition 4) (IMDRF/AE WG/N43FINAL:2020) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf</p> <p>Annexes A-G: http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexA_2020.05.11_v02.10.xlsx</p>	

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		<p>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43 AnnexB 2020.05.11 v02.10.xlsx</p> <p>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43 AnnexC 2020.05.11 v02.10.xlsx</p> <p>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43 AnnexD 2020.05.11 v02.10.xlsx</p> <p>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43 AnnexE 2020.06.12 v02.10.xlsx</p> <p>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43 AnnexF 2020.05.11 v02.10.xlsx</p> <p>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43 AnnexG 2020.06.22 v01.10.xlsx</p>	
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