# 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/ghtf/final/sg1/technical-docs/ghtf-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/ghtf/final/sg1/technical-docs/ghtf-sg1-n055-definition-terms-090326.pdf | |
| | Medical Device Classification | Principles of Medical Device Classification (SG1/N77: 2012) http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf | |
| | | Principles of IVD Medical Devices Classification (SG1/N045: 2008) http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n045-2008-principles-ivd-medical-devices-classification-080219.pdf | |
| | Principles of Conformity Assessment | Principles of Conformity Assessment for Medical Devices (Study Group (SG)1/N78: 2012) http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n78-2012-conformity-assessment-medical-devices-121102.pdf<br><br>Principles of Conformity Assessment for In Vitro Diagnostic (IVD) Medical Devices (SG1/N046: 2008) http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-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 | |

**Documents of Primary Focus for the 2023 Workshop**

# ANNEX: CORE-CURRICULUM

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| | Essential Principles of Medical Device Safety & Performance | 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 | 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. |
| | Optimizing Standards for Regulatory Use | Optimizing Standards for Regulatory Use (Standards WG/N51: 2018) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf | 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 |
| | Principles of Labeling | 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 | |
| | Clinical Evaluation | Clinical Investigation (IMDRF MDCE WG/N57FINAL:2019) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n57.pdf | |
| | | Clinical Evaluation (IMDRF MDCE WG/N56FINAL:2019) http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n56.pdf | |

# ANNEX: CORE-CURRICULUM

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| | | Clinical Evidence<br>(IMDRF MDCE WG/N55 FINAL:2019)<br>http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-191010-mdce-n55.pdf | |
| 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)<br>http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n15r8-risk-management-principles-qms-050520.pdf | |
| | | Quality Management Systems – Process Validation Guidance (Edition 2) (SG3/N99-10: 2004)<br>http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n99-10-2004-qms-process-guidance-04010.pdf | |
| | | Quality Management System – Medical Devices –<br>Guidance on the Control of Products and Services<br>Obtained from Suppliers (SG3/N17R9: 2008)<br>http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-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/ghtf/final/sg3/technical-docs/ghtf-sg3-n18-2010-qms-guidance-on-corrective-preventative-action-101104.pdf | |

# ANNEX: CORE-CURRICULUM

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| | Auditing/MDSAP | Nonconformity Grading System for Regulatory Purposes and Information Exchange (SG3/N19: 2012)<br>http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n19-2012-nonconformity-grading-121102.pdf | |
| | | Medical Device Regulatory Audit Reports (MDSAP WG/N24: 2015)<br>http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-mdra-audit-report.pdf | |
| | | Competence and Training Requirements for Auditing Organizations (MDSAP WG/N4: 2013)<br>http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf | |
| | | MDSAP Training Modules*<br>1. Introduction to MDSAP<br>Presentation<br>2. MDSAP Management<br>Presentation<br>3. MDSAP Device Marketing Authorization and Facility Registration<br>Presentation<br>4. MDSAP Measurement, Analysis and Improvement<br>Presentation<br>5. MDSAP Medical Device Adverse Events and Advisory Notices Reporting<br>Presentation<br>6. MDSAP Design and Development<br>Presentation<br>7. MDSAP Production and Service Controls, part 1<br>Presentation | *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. |

# ANNEX: CORE-CURRICULUM

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| | | 8. MDSAP Production and Service Controls, part 2<br>Presentation<br><br>9. MDSAP Production and Service Controls, part 3<br>Presentation<br><br>10. MDSAP Purchasing<br>Presentation | |
| | | MDSAP Affiliate Membership Policy Documents**<br><br>MDSAP Affiliate Members Roles and Responsibilities Policy<br>https://www.fda.gov/media/127697/download<br><br>MDSAP Affiliate Membership Application Form<br>https://www.fda.gov/media/127700/download | **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. |
| Postmarket | Adverse Event Reporting | Medical DevicesPost Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (GHTF/SG2/N54R8:2006)<br>http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n54r8-guidance-adverse-events-061130.pdf<br><br>Medical Devices Post Market Surveillance: Content of Field Safety Notices (GHTF/SG2/N57R8:2006)<br>http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n57r8-2006-guidance-field-safety-060627.pdf<br><br>IMDRF terminologies for categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Edition 4) (IMDRF/AE WG/N43FINAL:2020)<br>http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-200318-ae-terminologies-n43.pdf<br><br>Annexes A-G:<br>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexA_2020.05.11_v02.10.xlsx | |

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| | | http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexB_2020.05.11_v02.10.xlsx<br><br>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexC_2020.05.11_v02.10.xlsx<br><br>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexD_2020.05.11_v02.10.xlsx<br><br>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexE_2020.06.12_v02.10.xlsx<br><br>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexF_2020.05.11_v02.10.xlsx<br><br>http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-ae-terminologies-n43_AnnexG_2020.06.22_v01.10.xlsx | |