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Category	Elements	GHTF/IMDRF Documents
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 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
	Essential Principles of Medical Device Safety & Performance	Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices (SG1/N68: 2012)

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		http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n68-2012-safety-performance-medical-devices-121102.pdf *Pending IMDRF Approval: Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices(IMDRF/GRRP WG/N047)*
	Role of Standards in the Assessment of Medical Devices	Role of Standards in the Assessment of Medical Devices (SG1/N044: 2008) http://www.imdrf.org/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n044-2008-standards-in-assessment-of-medical-devices-080305.pdf *Pending IMDRF Approval:* Optimizing Standards for Regulatory Use (Standards WG/N51(PD))
	Principles of Labeling	Label and Instructions for Use for Medical Devices (SG1 N70: 2011) http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n70-2011-label-instruction-use-medical-devices-110916.pdf *Pending IMDRF Approval:* Principles of Labeling for Medical Devices and IVD Medical Devices (GRRP WG/N52(PD1))
QMS	QMS Requirements and Guidance	ISO13485:2016
		Implementation of risk management principles and activities within a Quality Management System (SG3/N15R8: 2005) 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) 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 – Guidance on the Control of Products and Services Obtained from Suppliers (SG3/N17R9: 2008) http://www.imdrf.org/docs/ghtf/final/sg3/technical-docs/ghtf-sg3-n17-guidance-on-quality-management-system-081211.pdf

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		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
	Auditing	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
		Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part 4: Multiple Site Auditing (SG4/N83R6: 2010) http://www.imdrf.org/docs/ghtf/final/sg4/technical-docs/ghtf-sg4-n83-2010-guidelines-for-auditing-qms-part-4-multiple-sites-100827.pdf
		Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers Part 5: Audits of Manufacturer Control of Suppliers (SG4/N84 R13:2010) http://www.imdrf.org/docs/ghtf/final/sg4/technical-docs/ghtf-sg4-n84-2010-guidelines-for-auditing-qms-part-5-control-of-suppliers-100827.pdf
	MDSAP	Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition (Edition 2) (MDSAP WG/N3: 2016) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160324-requirements-auditing-orar.pdf
		Guidance for Regulatory Authority Assessors on the Method of Assessment for MDSAP Auditing Organizations (MDSAP WG/N8: 2015) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-mdsap-auditing-organizations.pdf
		Medical Device Regulatory Audit Reports (MDSAP WG/N24: 2015) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-mdra-audit-report.pdf

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		MDSAP Assessment and Decision Process for the Recognition of an Auditing Organization (MDSAP WG/N11: 2014) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-assessment-decision-process-141013.pdf
		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
		Regulatory Authority Assessment Method for the Recognition and Monitoring of Medical Device Auditing Organizations (MDSAP WG/N5: 2013) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-assessment-method-140901.pdf
		Regulatory Authority Assessor Competence and Training Requirements (MDSAP WG/N6: 2013) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-assessor-competence-and-training-140901.pdf
Post market	Adverse Event Report,	Adverse Event Reporting Guidance for the Medical Device Manufacturer or its Authorized Representative (SG2N21R8: 1999) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-fd-99-7-reporting-guidance-990629.pdf
		Medical Devices: Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (SG2/N54R8: 2006) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n54r8-guidance-adverse-events-061130.pdf
		Reporting of Use Errors with Medical Devices by their Manufacturer or Authorized Manufacturer (SG2/N31R8: 2003) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n31r8%202003-reporting-errors-medical-devices-by-manufacturer-0302.pdf
		Comparison of the Device Adverse Reporting Systems in USA, Europe, Canada, Australia & Japan (SG2/N6R3: 2002) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n6r3-2002-comparison-device-adverse-reporting-systems-020521.pdf

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	Summary of Current Requirements for Where to Send Adverse Event Reports (SG2 68R3: 2005) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n68r3-2005-guidance-adverse-event.pdf
	Medical Device Postmarket Vigilance and Surveillance: Timing of Adverse Event Reports (SG2/N33R11: 2002) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n33r11-2002-medical-device-postmarket-vigilance-timing-ae-reporting-020927.pdf
	Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices (SG2-N008R4) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n008r4-reporting-guidance-990629.pdf
	Manufacturer's Trend Reporting of Adverse Events (SG2/N36R7: 2003) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n36r7-2003-manufacturer-trend-reporting-adverse-event-030101.pdf
	Post-Market Clinical Follow-Up Studies (SG5/N4:2010) http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n4-post-market-clinical-studies-100218.pdf
FSN	Medical Devices: Post Market Surveillance: Content of Field Safety Notices (SG2/N57R8: 2006) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n57r8-2006-guidance-field-safety-060627.pdf
Data Exchange System Requirements	Universal Dataset for Manufacturer or Authorized Representative Adverse Event Reports (SG2/N32R5: 2002) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n32r5%202002-manufacturer-adverse-event-report-0302.pdf
	An XML schema for the electronic transfer of adverse event data between manufacturers, authorized representatives and National Competent Authorities (based on GHTF/SG2/N54:2006) (SG2/N87: 2012) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n87-2012-xml-schema-electonic-transfer-adverse-event-data-120727.pdf
CAR	Global Medical Devices Competent Authority Report (SG2/N9R11: 2003)

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		http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n9r11-2003-global-medical-devices-competent-authority-report-030101.pdf
	NCAR Program	Post-Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form (Edition 2) (NCAR WG/N14:2017) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-pms-ncar-n14-r2.pdf
		Application Requirements for Participation in the GHTF National Competent Authority Report Exchange Program (SG2/N38R19: 2009) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n38r19-national-competent-authority-report-program-090701.pdf
		Medical Devices: Post Market Surveillance: National Competent Authority Report Exchange Criteria and Report Form (SG2/N79R11: 2009) http://www.imdrf.org/docs/ghtf/final/sg2/technical-docs/ghtf-sg2-n79r11-medical-devices-post-market-surveillance-090217.pdf
	AET	Terminologies for Categorized Adverse Event Reporting: Terms, Terminology Structure and Codes (Edition 2) (AE Terminology WG/N43: 2017) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-aer-n43-r2.pdf Maintenance of IMDRF AE Terminologies (AE WG/N44: 2017) http://www.imdrf.org/docs/imdrf/final/procedural/imdrf-proc-170316-ae-terminologies-n44.pdf
	Registry	Methodological Principles in the Use of International Medical Device Registry Data (Registry WG/N42: 2017) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170316-methodological-principles.pdf Principles of International System of Registries Linked to Other Data Sources and Tools (Registry WG/N33: 2016) http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-160930-principles-system-registries.pdf Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making (Registry WG/N46: 2018)

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		http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-180327-usability-tools-n46.pdf