Publicly Accessible Databases to be Used in Preparation of Audits and Assessments

REGULATIONS are accessible on the MDSAP webpage:
https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/ucm453797.htm

Australia = TGA	Main page	http://www.tga.gov.au/
	Recalls (SARA)	http://www.tga.gov.au/recall-actions
	Adverse Event Notifications (DAEN)	http://www.tga.gov.au/database-adverse-event-notifications-daen https://www.tga.gov.au/reporting-adverse-events
	Australian Register of Therapeutic Goods (ARTG)	http://tga-search.clients.funnelback.com/s/search.html?query=&collection=tga-artg
	Reporting a problem such as medical device Medicine Deficiency and Defect including eBS Access Form, etc.	https://www.tga.gov.au/reporting-problems https://www.ebs.tga.gov.au/
Brazil = ANVISA	Main page *(Portuguese)*	http://portal.anvisa.gov.br/
	Product Registration	https://consultas.anvisa.gov.br/#/saude/
	Adverse Events and Quality Issues	http://portal.anvisa.gov.br/alertas
	MD IFU	http://www.anvisa.gov.br/scriptsweb/correlato/correlato_rotulagem.htm

	Recalls, Counterfeit, Suspended products	http://portal.anvisa.gov.br/produtos-irregulares#/
Canada = HC	Main page All about Medical Devices	https://www.canada.ca/en/health-canada.html https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices.html
	Recall main page *(allows you to search for all recalls and safety alerts)* Recall Medical Devices	http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php?_cat=3 http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/search-recherche/simple?s=&plain_text=&f_mc=3&js_en=&page=5&f_mc=3&f_sc=41
	Medical Device Active License Listing (MDALL) main page MDALL query page	https://www.canada.ca or https://health-products.canada.ca/mdall-limh/index-eng.jsp
	Medical Device Establishment Licence Listing (MDEL)	https://health-products.canada.ca/mdel-leim/index-eng.jsp
Japan = MHLW/ PMDA	Main page	http://www.mhlw.go.jp/english/
	How to access/search PDF	http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm570303.pdf
	Recall – Medical Devices in Japan *use Google translator or other*	http://www.pmda.go.jp/safety/info-services/devices/0054.html
	Safety Alert/ Recalls/ Review	http://www.pmda.go.jp/english/search_index.html

	reports/ Package Insert *Once on that link you can copy and paste into Google translator* *https://www.google.com/#q=translator*	*Please refer to "Access to PMDA RA Databases.pdf".*
	Quality Management System Inspection in Japan	http://www.pmda.go.jp/english/review-services/gmp-qms-gctp/0002.html
	Review and related services	http://www.pmda.go.jp/english/review-services/index.html
	Standards for Medical Devices e.g. Device Classification, Certification Standards	http://www.std.pmda.go.jp/stdDB/index_e.html
	List of Foreign Registered Manufacturing Sites	https://www.pmda.go.jp/review-services/drug-reviews/foreign-mfr/0003.html *Please refer to "Access to PMDA RA Databases.pdf".*
	PMD Act (English/Japanese)	http://www.japaneselawtranslation.go.jp/law/detail/?id=2766&vm=&re=
	MHLW MO169	https://www.pmda.go.jp/english/review-services/regulatory-info/0004.html
US = FDA	Main page	https://www.fda.gov/MedicalDevices/default.htm
	FDA webpage Inspection classification	https://www.accessdata.fda.gov/scripts/inspsearch/
	Recall Database Main list for recalls (2013-2017)	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm https://www.fda.gov/MedicalDevices/Safety/ListofRecalls/default.htm

	Medical Device Reporting (MDR) *Set up your Mobile App*	https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm https://www.fda.gov/MedicalDevices/Safety/ReportaProblem/ucm385880.htm
	Medical Device Safety	https://www.fda.gov/MedicalDevices/Safety/default.htm
	MAUDE	https://www.fda.gov/medicaldevices/deviceregulationandguidance/postmarketrequirements/reportingadverseevents/ucm127891.htm
	Device Registration and Listing	https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm
	MDUFA IV	http://inside.fda.gov:9003/CDRH/OfficeoftheDirector/ucm561515.htm
	510(K) search engine	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
	Product Code Builder	https://www.accessdata.fda.gov/scripts/ora/pcb/index.cfm?action=main.pcb
	Import Alert	http://cms.fda.gov/vts/imports/default.cfm
	Other database available see right side table	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
	CFR - Code of Federal Regulations Title 21 search engine *or* eCFR database	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm https://www.ecfr.gov/cgi-bin/text-idx?SID=3ee286332416f26a91d9e6d786a604ab&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl
	ICH Guidelines – 4 categories: Quality, Safety, Efficacy, and Multidisciplinary. Link to FDA, HC PMDA and EU	http://www.ich.org/products/guidelines.html