

Medical Device Glossary of Terms

Term	Definition
510(k)	premarket notification for most devices; named for the section of the law that requires these submissions.
Adulterated	FDA term used to describe products whose packaging contains poisonous, deleterious, or banned substances, which are manufactured, shipped, or stored under unsanitary conditions, or which don't comply with the premarket application requirements.
Biocompatibility	refers to the ability of a material to perform its desired function without eliciting any undesirable local or systemic effects on the body of the recipient
BIMO	Bioresearch Monitoring division of CDRF charged with ensuring quality and integrity of clinical data
Business associates	HIPAA term for those that may have access to protected health information (PHI) while working for a covered entity
CAPA	Corrective and Preventive Action
CDRH	Center for Devices and Radiological Health; FDA center in charge of medical device regulation
CE Mark	symbol representing compliance with a European device directive (MDD, IVDD, or AIMDD); products bearing the CE mark may be sold in the EU
CFR	Code of Federal Regulations; US Government regulations; these are divided into titles. Title 21 is for FDA; 21 CFR Parts 800-899 are for medical devices
Combination product	product that includes at least 2 of the following; drug, device or biologic; these products have complicated regulatory pathways
Covered entity	HIPAA term for healthcare providers, health plans, and healthcare clearinghouses that create, store, and manage protected health information (PHI)
DHF	Design History File
DHR	Device History Record
Directive	general name for regulations in the EU; AIMDD is Active Implantable Medical Device Directive; IVDD is In-Vitro Diagnostic Directive; and MDD is Medical Device Directive
DMR	Device Master Record
DTC	Direct to Consumer (a form of marketing)
EMC	electromagnetic compatibility
EMI	electromagnetic interference
EU	European Union
FDA	US Food and Drug Administration
F D & C Act	Food Drug and Cosmetic Act; major law enforced by the FDA
GHTF	Global Harmonization Task Force
GCP	Good Clinical Practices; procedures and processes used during clinical trials
GLP	Good Laboratory Practices; practices, procedures, and processes used during bench and animal testing
GMP	Good Manufacturing Practices; general term for procedures and processes that, when used consistently in production, produce standardized products
HIPAA	Health Insurance Portability and Accountability Act; one section of the law that protects patient medical information from disclosure
IDE	Investigational Device Exemption; application submitted to obtain exemption from misbranding and adulteration while a device undergoes clinical evaluation to support its safety and efficacy
IEC	International Electromechanical Commission; an international standards and conformity assessment organization

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IEEE	originally Institute of Electrical & Electronics Engineers, now simply referred to as "eye-triple E"; professional organization that provides services and resources, and develops voluntary standards
ISO	International Standards Organization; group that develops voluntary standards for many types of products
ISO 13485	Medical Devices -- Quality Management Systems -- Requirements for regulatory purposes; used in Europe (and with additions in Canada) to ensure safe devices; current version published in 2003
ISO 14971	Medical Devices -- Application of risk management to medical devices; standard used in many parts of the world to assess device risks; current version published in 2007
IVD	In Vitro Diagnostics; diagnostic tests conducted outside of the body, usually in the lab.
MDR	Medical Device Reports; submitted to FDA when death or serious injury occurs while using a medical device.
Misbranded	FDA term used to describe products whose information is false, misleading, missing, or lacking in prominence, or whose packaging is misleading or improper
PHI	Protected Health Information; HIPAA term for confidential, personal. Identifiable health information
POC	Point of Care
PMA	Premarket Approval Application; type of submission to the FDA used for high-risk devices
Premarket notification	see 510(k)
QSIT	Quality System Inspection Technique; used by FDA to focus on critical QSR areas
QSR	Quality System Regulation; FDA's term for all procedures and processes that produce and control a medical device from design through distribution; it is broader in scope than GMPs and very similar to ISO 13485
REACH	Registration, Evaluation, Authorization and restriction of Chemicals; EU regulation addressing production and use of chemicals, including chemicals in objects
RoHS	Restriction of Hazardous Substances; EU law restricting use of six chemicals in electronic and electric equipment
SDS	Software design Specification
SRS	Software Requirements Specification
Substantial equivalence	(SE) the heart of 510(k); the argument must show how the device being submitted is SE in intended use and technological features to previously marketed devices
USP	United States Pharmacopeia; sets quality standards for healthcare products manufactured and sold in the US; for medical devices has 6 levels of biocompatibility standards for plastics (USP I - USP VI)
Validation	conducted on initial production lots and focused on the intended use. Answers the question: did we design the right device for the user?
Verification	objective data that answers the question: does it meet specifications? (Or, does it meet design input if done during design?)