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**Acronyms that may be used during FDLI’s Introduction to Medical Device Law and Regulation**

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| 483 | Form 483/FD-483 Inspectional Observances |
| 510(k) | premarket notification |
| AAA | abdominal aortic aneurysm |
| ABI | Automated Broker Interface |
| ACCME | Accreditation Council for Continuing Medical Education |
| ACS | Automated Commercial System |
| ADE | adverse device event |
| AdvaMed | Advanced Medical Technology Association (formerly known as the Health Industry Manufacturers Association, HIMA) |
| AE | adverse event |
| AHAs | alpha hydroxy acids |
| AHRQ | Agency for Healthcare Research and Quality |
| AI | Additional Information |
| AIMD | active implantable medical device |
| AIP | Application Integrity Policy |
| AKS | anti-kickback statute |
| AMA | American Medical Association |
| ANDA | abbreviated new drug application |
| ANPRM | Advance Notice of Proposed Rule Making |
| ANSI | American National Standards Institute |
| AOC | Affirmation of Compliance |
| APA | Administrative Procedures Act |
| APC | Ambulatory Payment Classification (CMS) |
| ARRA | American Recovery and Reinvestment Act of 2009 |
| ASR | Analyte Specific Reagents |
| BBT | basal body temperature |
| BG | blood glucose |
| BiMo/BIMO | bioresearch monitoring |
| BIS | Bureau of Industry and Security (Dept. of Commerce) |
| BLA | Biologic License Application |
| BPCA | Best Pharmaceuticals for Children Act of 2007 |
| BTA | Public Health Security and Bioterrorism Preparedness and Response Act of 2002, also known as the Bioterrorism Act Blue Book policies of ODE: *CDRH’s Premarket Notification (510(k)) Refuse to Accept Policy* |
| CA | corrective action |
| CAs | competent authorities (EU) |
| CABs | conformity assessment bodies/Compliance Assessment Bodies |
| CAD | control of automated processes |
| CAH | congenital adrenal hyperplasia |
| CAPA | corrective and preventive action (also spelled C&PA) |
| CBP | Customs and Border Protection (DHS) |
| CCR | Commerce Control List |
| C&R | corrections and removals |
| CDC | Centers for Disease Control and Prevention |
| CDER | Center for Drug Evaluation and Research (FDA) |
| CDRH | Center for Devices and Radiological Health (FDA) |
| CE Mark | French phrase for Conformite Europeene |
| CEC | Clinical Events Committee |
| CED | Coverage with Evidence Development |
| CER | Comparative Effectiveness Research |
| CFG | Certificate for Foreign Government/Certification for Foreign Government |
| CFR | Code of Federal Regulations |
| cGMP | current food manufacturing practice |
| CI | clinical investigator |
| CIA | corporate integrity agreement |
| CLIA | Clinical Laboratory Improvement Amendments of 1988 |
| CMC | Chemistry Manufacturing Controls |
| CMD | Contractor Medical Director |
| CME | Continuing Medical Education |
| CMP | civil money penalty |
| CMS | Centers for Medicare and Medicaid Services (DHHS, formerly known as HCFA) |
| CoA | Condition of Approval |
| COI | conflict of interest |
| COE | Certificate of Exportability (also spelled CE) |
| CP | compliance programs |
| CPG | Compliance Policy Guide |
| CPGM | Compliance Program Guidance Manuals |
| CPSC | Consumer Product Safety Commission |
| CPT | Current Procedural Terminology |
| CRA | clinical research associate |
| CRC | clinical research coordinator |
| CRF | case report form |
| CRO | contract research organization |
| CSO | consumer safety officer |
| CSP | coverage with study participation |
| CT | computed tomography |
| CTA | Clinical Trials Agreement |
| CTI | Council on Technology & Innovation |
| CV | curriculum vitae |
| DD | District Director |
| arDEA | Drug Enforcement Administration (U.S. Department of Justice) |
| DEN | Device Experience Network |
| DGI | Directorate General for Industry (EU) |
| DHF | design history file |
| DHHS | U.S. Department of Health and Human Services |
| DHR | device history record |
| DHS | U.S. Department of Homeland Security |
| DICE | Division of Industry and Consumer Education |
| DME | durable medical equipment |
| DMEPOS | durable medical equipment, prosthetics, orthotics & supplies |
| DMR | device master record |
| DOD | Department of Defense |
| DPA | Deferred Prosecution Agreement |
| DRGs | diagnosis-related groups |
| DSMB | Data and Safety Monitoring Board |
| DTC | direct-to-consumer |
| DWPE | detention without physical examination |
| EAR | Export Administration Regulations (U.S. Department of Commerce) |
| ECCN | Export Control Classification Number |
| EEA | European Economic Area |
| EFTA | European Free Trade Association |
| EIA | Environmental Impact Assessment |
| Eid | electronic identification |
| EIR | establishment inspection report |
| EMC | electromagnetic compatibility |
| eMDR | electronic medical device reporting |
| EN | European |
| EPA | Environmental Protection Agency |
| EPI | Essential Prescribing Information |
| ESG | Electronic Submission Gateway |
| ESRD | end stage renal disease |
| EU | European Union |
| EUCOMED | European Confederation of Medical Devices Associations |
| FATA | Federal Anti-Tampering Act |
| FCA | False Claims Act |
| FCPA | Foreign Corrupt Practices Act of 1977 |
| FCS | Food Contact Substance |
| FDA | Food and Drug Administration (DHHS) |
| FDAAA | Food and Drug Administration Amendments Act of 2007 |
| FDAMA | Food and Drug Administration Modernization Act of 1997 |
| FDASIA | Food and Drug Administration Safety and Innovation Act of 2012 |
| FDCA | Federal Food, Drug and Cosmetic Act (also spelled FFDCA/FD&C/FDA Act) |
| FDERA | Food and Drug Export Reform and Enhancement Act of 1996 |
| FIFR | First-In-First-Reviewed |
| FMEA | failure mode and effects analysis |
| FOIA | Freedom of Information Act |
| FR | Federal Register |
| FRCP | Federal Rules of Civil Procedure |
| FTC | Federal Trade Commission |
| FTEs | full time employees |
| FURLS | FDA Uniform Registration and Listing System |
| FY | fiscal year |
| GAO | Government Accountability Office |
| GCP | good clinical practice |
| GGPs | good guidance practices |
| GHTF | global harmonization task force |
| GLP | good laboratory practice |
| GMDN | Global Medical Device Nomenclature |
| GMPs | good manufacturing practices |
| GPPs | good promotional practices |
| GRAS | generally recognized as safe |
| GRPs | good reprint practices |
| HBV | Hepatitis B virus |
| HCFA | Health Care Financing Administration (DHHS; now known as CMS) |
| HCPCS | Healthcare Common Procedure Coding System |
| HCUP | Healthcare Cost and Utilization Program |
| HCV | Hepatitis C virus |
| HDE | humanitarian device exemption |
| HHS | U.S. Department of Health and Human Services |
| HIFU | high-intensity focused ultrasound |
| HIPAA | Health Insurance Portability and Accountability Act of 1996 |
| HMO | health maintenance organization |
| HOPPS | Hospital Outpatient Prospective Payment System |
| HSP | human subject protection HUD |
| IC | informed consent |
| ICD | International Classification of Disease |
| ICH | International Conference on Harmonization |
| ICSR | International Case Safety Report |
| IDE | investigational device exemption |
| IECs | Independent Ethics Committees |
| IFE | Import-For-Export |
| IG | Inspector General |
| IND | investigational new drug application |
| IOM | Institute of Medicine |
| IPO | initial public offering |
| IPPS | Inpatient Hospital Prospective Payment System |
| IRB | institutional review board |
| IRO | independent review organization |
| ISO | International Standards Organization |
| ISRO | independent service and repair organization |
| IUO | investigational use only |
| IVD | in vitro diagnostic product |
| IVMD | in vitro medical device |
| LASIK | laser assisted in situ keratomileusis |
| LCD | local coverage decision |
| LDT | laboratory-developed test |
| LOC | level of concern |
| LS/LS | life supporting/life sustaining |
| MAUDE | Manufacturer and User Facility Device Experience Database |
| MAP | management action plan |
| MCO | managed care organization |
| MDA | Medical Device Amendments of 1976 |
| MDDs | medical device directives |
| MDDRP | Medical Device Dispute Resolution Panel |
| MDDS | Medical Device Data Systems |
| MDMA | Medical Device Manufacturers Association |
| MDP | medical devices program (Canada) |
| MDR | medical device reporting regulation |
| MDUFA | Medical Device User Fee Amendments of 2007 |
| MDUFMA | Medical Device User Fee and Modernization Act of 2002 |
| MDUFSA | Medical Device User Fee Stabilization Act of 2005 |
| MedSun | Medical Device Surveillance Network |
| mHealth | mobile health |
| MI | myocardial infarction |
| MIRA | Medicare Innovation Responsiveness Act of 2003 |
| MMA | Medicare Prescription Drug, Improvement and Modernization Act of 2003 |
| MOU | memorandum of understanding |
| MPA | multiple projects (human subjects) assurance |
| MQSA | Mammography Quality Standards Act of 1992 |
| MRA | mutual recognition agreements |
| MRI | magnetic resonance imaging |
| MS-DRG | Medicare severity diagnosis-related group |
| MTF | medical treatment facility |
| NAAG | National Association of Attorneys General |
| NAF | Notice of Adverse Finding |
| NAI | no action indicated |
| NBs | notified bodies (EU) |
| NBAC | National Bioethics Advisory Commission |
| NCAs | National Competent Authorities |
| NCCLS | National Committee of Clinical Laboratory Standards |
| NCD | National Coverage Decision |
| NCP | nonconforming products |
| NDA | new drug application |
| NDI | new dietary ingredient |
| NEMA | National Electrical Manufacturers Association |
| NF | National Formulary |
| NIDPOE | Notice of Initiation for Disqualification and Opportunity to Explain |
| NLR | No License Required |
| NIH | National Institutes of Health (DHHS) |
| NOC | Notice of Completion |
| NPA | Non-Prosecution Agreement |
| NPRM | Notice of Proposed Rulemaking |
| NSAIDs | nonsteroidal anti-inflammatory drugs |
| NSE | not substantially equivalent |
| NSR | non-significant risk |
| NSRD | non-significant risk device |
| NTIS | National Technical Information Service (U.S. Department of Commerce) |
| OAI | official action indicated |
| OASIS | Operational and Administrative System for Import Support |
| OCI | Office of Criminal Investigations (ORA) |
| OCD | Office of the Center Director (CDRH) |
| OCE | Office of Communication and Education (CDRH) |
| OCEA | Office of Clinical Evidence & Analysis (CDRH) |
| OCP | Office of Combination Products |
| OEMs | original equipment manufacturers |
| OFAC | Office of Foreign Assets Control (U.S. Department of Treasury) |
| OGC | Office of General Counsel |
| OHTI | Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (CDRH) |
| OHT2 | Office of Cardiovascular Devices (CDRH) |
| OHT3 | Office of Gastro-Renal, ObGyn, General Hospital Device and Urology Devices (CDRH) |
| OHT4 | Office of Surgical and Infection Control Devices (CDRH) |
| OHT5 | Office of Neurological and Physical Medicine Devices (CDRH) |
| OHT6 | Office of Orthopedic Devices (CDRH) |
| OHT7 | Office of In Virto Diagnostics and Radiological Health (OIR) |
| OHRP | Office for Human Research Protections (DHHS) |
| OIG | Office of the Inspector General (DHHS) |
| OM | Office of Management (CDRH) |
| OMDRHO | Office of Medical Device and Radiological Health Operations (ORA) |
| OP | Office of Policy (CDRH) |
| OPEQ | Office of Product Evaluation and Quality (CDRH) |
| OPPS | Outpatient Prospective Payment System |
| ORA | Office of Regulatory Affairs (FDA) |
| ORP | Office of Regulatory Programs (CDRH) |
| OSEL | Office of Science and Engineering Laboratories (CDRH) |
| OSHA | Occupational Safety and Health Administration |
| OST | Office of Strategic Partnerships and Technology Innovation (CDRH) |
| OTC | over-the-counter |
| P&PC | Production and Process Controls |
| PA | preventative action |
| PAD | public access defibrillation |
| PAP | patient assistance programs |
| PAS | post approval studies |
| PBM | pharmacy benefit manager |
| PCTs | practical clinical trials |
| PDP | product development protocols/principal display panel |
| PDS | pre de novo submission |
| PDUFA | Prescription Drug User Fee Act |
| PFS | Physician Fee Schedule |
| PHI | protected health information |
| PHS | Public Health Service (DHHS) |
| PHSA | Public Health Service Act |
| PIPEDA | Personal Information Protection and Electronic Documents Act |
| P.L. | public law |
| PLA | product license application |
| PMA | premarket approval application |
| PMAS | premarket approval application supplements |
| PMN | premarket notification |
| PMOA | primary mode of action |
| PMS | postmarket surveillance |
| POS | program operations staff |
| PPACA | Patient Protection and Affordable Care Act & the Health Care and Education  Reconciliation Act of 2010 |
| PPC | production and process controls |
| PPE | personal protective equipment |
| PPO | preferred provider organization |
| PPS | prospective payment system |
| PREA | Pediatric Research Equity Act of 2007 |
| PS | postmarket surveillance |
| PSA | prostate-specific antigen |
| QC | quality control |
| QSIT | quality systems inspections technique |
| QSR | quality system regulation |
| RA | regulatory affairs |
| RAE | Remedial Action Exemption |
| RBRVS | Resource-based Relative Value Scale |
| RCHSA | Radiation Control for Health and Safety Act of 1968 |
| RCT | randomized controlled trials |
| ReGo | Reinventing Government |
| RF | radio frequency |
| RFD | request for designation |
| RPM | Regulatory Procedures Manual |
| RTA | refuse to accept |
| RUO | research use only |
| SAL | sterility assurance level |
| SCGD | special controls guidance documents |
| SE | substantially equivalent/substantial equivalence |
| SEC | Securities and Exchange Commission |
| SG | study group |
| SGEs | special government employees |
| SMDA | Safe Medical Devices Act of 1990 |
| SMO | site management organization |
| SNF | skilled nursing facility |
| SOA | search/service oriented software |
| SOMDs | software-only medical devices |
| SOPs | standard operating procedures |
| SPC | statistical process control |
| SPF | sun protection factor |
| SR | significant risk |
| SRD | significant risk device |
| SSE | Summary of Safety and Effectiveness |
| SSED/SSE | Summary of Safety and Effectiveness Data |
| STED | Summary of Technical Documentation |
| SUD | single-use device |
| TEP | Transatlantic Economic Partnership |
| TMJ | temporomandibular joint |
| TMO | trial management organization |
| TPLC | total product life cycle |
| TRO | temporary restraining order |
| UADE | unanticipated adverse device event |
| UAI | use as is |
| UDI | Unique device identifier |
| UPC | Universal Product Code |
| USC | United States Code |
| USP | United States Pharmacopeia |
| VA | Department of Veterans Affairs |
| VAI | voluntary action indicated |
| V/V | verification/validation |
| WL | warning letter |
| *WLF* | Washington Legal Foundation |