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

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