Glossary of Acronyms & FDA Regulations

drdg@prodigy.net

21 CFR Part 11 – Electronic Records, Electronic Signatures

21 CFR Part 58 – Current Good Laboratory Practice (CGLP)

21 CFR 210-211 – applies to finished drugs, specifically:

- **21 CFR Part 210** – Current Good Manufacturing Practice (CGMP) for manufacturing, processing, packing, or holding of drugs, general.
- **21 CFR Part 211** – Current Good Manufacturing Practice (CGMP) for finished pharmaceuticals.

21 CFR 820 – applies to medical devices

21 CFR 1404 – GOVERNMENTWIDE DEBARMENT AND SUSPENSION (NONPROCUREMENT)

- Sec. 1404.930 Debarment. *Debarment* means an action taken by a debarring official under subpart H of this part to exclude a person from participating in covered transactions and transactions covered under the Federal Acquisition Regulation (48 CFR chapter 1). A person so excluded is debarred.
- Sec. 1404.1015 Suspension. *Suspension* is an action taken by a suspending official under subpart G of this part that immediately prohibits a person from participating in covered transactions and transactions covered under the Federal Acquisition Regulation (48 CFR chapter 1) for a temporary period, pending completion of an agency investigation and any judicial or administrative proceedings that may ensue. A person so excluded is suspended.
- Subpart E--Excluded Parties List System Sec. 1404.500 What is the purpose of the Excluded Parties List System (EPLS)? The *EPLS* is a widely available source of the most current information about persons who are excluded or disqualified from covered transactions.
- Subpart H--Debarment Sec. 1404.850 What is the standard of proof in a debarment action?
    - (a) In any debarment action, we must establish the cause for debarment by a preponderance of the evidence.
    - (b) If the proposed debarment is based upon a conviction or civil judgment, the standard of proof is met.

483 – An FDA administrative enforcement action following factory inspection, recall or detention requests, notice of refusal of admission of an imported product. Take the form of a written letter describing the issues that facilitated the warning. *See* Consent Decree, and 21 CFR 1404.

510 K – The application filed with the FDA for a new medical device to show that the apparatus is "substantially equivalent" to one that is currently marketed.

Abbreviated New Drug Application (ANDA) – An application filed (with the FDA) for a drug showing that the substance is the same as an existing, previously approved drug (i.e., a generic version).

Adverse Drug Event (ADE) – Post-market adverse drug events consist of an undesired side effect, death, or the lack of a desired effect associated with drugs administered to humans. The reporting system is used to identify adverse effects not detected during pre-market testing of FDA-approved drugs. Vaccine Adverse Event Reporting System (VAERS) is used for issues related to vaccines.

Adverse Event (AE) – in reference to the full spectrum of pharmaceuticals (drugs), vaccines, and medical devices, AE is similar to ADE but more encompassing; ADE is a subset of AE.

ANDA – *see* **Abbreviated New Drug Application**

ANSI – American National Standards Institute

Approval – Once FDA approves the New Drug Application (NDA), the new medicine becomes available for physicians to prescribe. The company must continue to submit periodic reports to FDA, including any cases of adverse reactions and appropriate quality-control records. For some medicines, FDA requires additional studies (Phase IV) to evaluate long-term effects.

ASTM – American Society for Testing and Materials

AZ – AstraZeneca

Bioequivalence – In pharmaceuticals, the demonstration that a drug's rate and extent of absorption are not significantly different from the rate and extent of absorption of an existing drug that is already approved by the FDA.

BMS – Bristol Meyers Squibb

BOM – Bill of Materials

C&PC – Consumer and Personal Care Research

CANDA – Computer-Assisted New Drug Application

CBER – Center For Biologics Evaluation and Research

CDER – Center for Drug Evaluation and Research

CDISC – Clinical Data Interchange Standards Consortium

CDRH – Center For Devices And Radiological Health

CDS – Chromatographic Data System

Center For Biologics Evaluation And Research (CBER) – The branch of the FDA responsible for the regulation of biological products, including blood, vaccines, therapeutics and related drugs and devices to ensure purity, potency, safety, availability and effectiveness. *www.fda.gov/cbe*

Center For Drug Evaluation And Research (CDER) – The branch of the FDA responsible for the regulation of drug products. *www.fda.gov/cde*.

Center For Devices And Radiological Health (CDRH) – The branch of the FDA responsible for the regulation of medical devices. *www.fda.gov/cdrh*.

CFR – ***see*** **Code Of Federal Regulations**

Class I Device – An FDA classification of medical devices. General controls are sufficient to ensure safety and efficacy.

Class II Device – An FDA classification of medical devices. Performance standards and special controls are sufficient to ensure safety and efficacy.

Class III Device – An FDA classification of medical devices. Pre-market approval is required to ensure safety and efficacy, unless device is substantially equivalent to a currently marketed device. (See "510K")

Clinical Data Interchange Standards Consortium (CDISC) – A new standard for exchange and storage of clinical data that has recently been acknowledged by the FDA.

Clinical Research Associate (CRA) – An individual responsible for monitoring clinical trial data to ensure compliance with study protocol and FDA GCP regulations. A representative of either the sponsor or contract research organization (CRO) that is responsible for monitoring the quality of the conduct of the clinical trial.

Code Of Federal Regulations (CFR) – The CFR is a codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government. The code is divided into 50 titles that represent broad areas subject to federal regulation. Title 21 of the CFR covers FDA regulations.

Computer-Assisted New Drug Application (CANDA) – An electronic submission of a new drug application (NDA) to the FDA.

Consent Decree – A punitive action taken by the Department Of Justice on behalf of the FDA. This settlement agreement can involve monetary fines, destruction of product, and stop shipment of products for an indeterminate period of time. This is the most severe penalty that the FDA imposes.

COTS – Commercial Off-The-Shelf (software)

CPT™ – Current Procedural Terminology

CRF – Case Report Form; also Chronic Renal Failure

CRA – Clinical Research Associate

CRO – Contract Research Organization

CRT – Case Report Tabulation

CSV – Computer System Validation

DCS – (process**) Distribute Control Systems**

Device – In medical product development, according to the FDA, an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent or other similar or related article, including any component, part or accessory, that is:
recognized in the official National Formulary or United States Pharmacopoeia or any supplement to them,
intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or animals or,
intended to affect the structure of the body of man or animals and does not achieve any of its principal intended purposes through chemical action within or on the body of man or animals and is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

DIA – Drug Information Association

DMB – Data Monitoring Board

EDC – Electronic Data Capture

EMF – Electro-Magnetic Frequencies

ERP – Enterprise Resource Planning

FAT – Factory Acceptance Test

FCG – First Consulting Group

FDA – *see* Food And Drug Administration

Food And Drug Administration (FDA)- The U.S. government regulatory agency responsible for monitoring and enforcing policies that regulates the manufacturing, testing, and marketing of the drugs and devices. The FDA must approve all drugs and devices prior to their commercial availability.

FRS – Functional Requirements Specification

GAMP – Good Automated Manufacturing Practices (Industry Board or Forum or decided practices, e.g., GAMP3 or GAMP4).

GCP – *see* Good Clinical Practices

GLP – *see* Good Laboratory Practices

GMP – Good Manufacturing Practices

Good Clinical Practices (GCP) – FDA regulations and guidelines that define the responsibilities of the key figures involved in a clinical trial including the sponsor.

Good Laboratory Practices (GLP) – A collection of regulations and guidelines to be used in laboratories where research is conducted on drugs biologics or devices that are intended for submission to the FDA

HL7 – Health Level Seven

HPLC – High Performance Liquid Chromatography

ICD9 – International Classification Of Diseases - Version 9

ICH – International Conference on Harmonisation

IDE – Investigational New Device Exemption

IEEE – Institute of Electrical and Electronic Engineers

IFPMA – International Federation of Pharmaceutical Manufacturers Associations

INDA – Investigational New Drug Application

Investigational new Device Exemption (IDE) – An IDE must be filed with the FDA prior to initiating clinical trials of medical devices considered to pose a significant risk to human subjects.

Investigational New Drug Application (INDA) – An IND(A) must be filed with the FDA prior to initiating clinical trials of drugs or biologics. Application that a drug sponsor must submit to FDA before beginning tests of a new drug on humans. The IND contains the plan for the study and is supposed to give a complete picture of the drug, including structural formula, animal test results, and manufacturing information.

IP – Internet Protocol

IQ – Installation Qualification

IRB – Institutional Review Board

ISO – International Organization for Standardization.

ISP – Internet Service Provider

ISPE – International Society of Pharmaceutical Engineers

IVRS - Interactive Voice Recognition System

J&J – Johnson & Johnson

LAN – (Local Area Network

LC – Liquid Chromatography

LIMS – Laboratory Information Management System(s)

LC –Liquid Chromatography; Logic Controllers.

MDR – *see* **Medical Device Report**

Medical Device Report (MDR) – Medical Device Reporting (MDR) is the mechanism for the Food and Drug Administration to receive significant medical device adverse events from manufacturers, importers and user facilities, so they can be detected and corrected quickly. User-facilities (e.g., hospitals, nursing homes) are required to report suspected medical device related deaths to both the FDA and the manufacturers. User facilities report medical device related serious injuries only to the manufacturer.

MedDRA® – *see* **Medical Dictionary For Regulatory Activities®**

Medical Dictionary For Regulatory Activities® (MedDRA®**) –** Designed to supersede or replace all other terminologies used within the medical product development process, including COSTART, WHO-ART, J-ART, and HARTS.

Major global regulatory authorities (FDA, EMEA, MHW) are adopting MedDRA and moving toward requiring its use. The FDA has already implemented MedDRA within its Adverse Event Reporting System (AERS). European authorities are beginning to use MedDRA as a key component of their electronic database systems. The MedDRA Maintenance and Support Services Organization (MSSO) was established by the ICH to speed and facilitate the adoption of MedDRA by both the regulatory and medical products manufacturing communities. MSSO is also responsible for making sure the terminology is updated regularly and that it remains responsive to user needs.

MRP – Manufacturing Resource Planning Systems

MSSO – Maintenance and Support Services Organization

MedWatch Program – An FDA program designed to monitor adverse events (AEs) from drugs marketed in the U.S. Through the MedWatch program, health professionals may report ADE's (sometimes referred to as AEs) voluntarily to the FDA. Drug manufacturers are required to report all ADE's brought to their attention.

NDA – *see* **New Drug Application**

New Drug Application (NDA) – An application requesting FDA approval, after completion of Phase III studies, to market a new drug for human use in interstate commerce. Clinical trial results generally account for approximately 80% of the NDA.

OIT – Operator Interface Terminals

OQ – Operational Qualification

Orphan Drug – A drug, biologic or antibiotic designated by the FDA as providing therapeutic benefit for an indication (disease or condition) affecting less than 200,000 people in the U.S. Companies that market orphan drugs are granted a period of market exclusivity in return for the limited commercial potential of the drug.

OTC – *see* **Over-The-Counter**

Over-The-Counter (OTC) – Over-the-counter drug products are FDA regulated products that do not require a physician's prescription. Some examples include aspirin, sunscreen, nasal spray and sunglasses.

PDA – Parenteral Drug Association

PDF – Portable Document File

PhRMA - Pharmaceutical Research and Manufacturers of America

PK – Pharmacokinetics

PK/PD – Pharmacokinetic and/or Pharmacodynamic

PLC – Programmable Logic Controller (*also* **Process-programmable Logic Controller).**

PMA – Pre-Market Approval

Post-Marketing Surveillance – The FDA's ongoing safety monitoring of marketed drugs.

PQ – Performance Qualification

Predicate Rule – Requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of 21 CFR Part 11 (since it relies upon predicate rules).

QA – Quality Assurance

QC – Quality Control

QRC – Quality and Regulatory Compliance

R&D – Research and Development

RD&E – Research, Development, and Engineering

RS-232-C – Electronic Industries Association (EIA) standard for connecting electronic equipment. Data is transmitted and received in serial format.

SAE – Serious Adverse Affects

SAS – Database program used in healthcare applications.

SAT – Site Acceptance Test

SCADA – Supervisory Control and Data Acquisition

SCADA - Supervisory Control And Data Acquisition Systems

SDLC – Software Development Life Cycle

SDLC – System Development Life Cycle

SOP – Standard Operating Procedure(s)

SQL – Structured Query Language

TCP – Transfer Control Protocol

TCP/IPTransmission – Control Protocol/Internet Protocol

TMDV – Test Method Development and Validation

Vaccine – A vaccine reduces preventable infectious diseases so that now few people experience the devastating effects of measles, pertussis and other illnesses. Vaccines, as with all products regulated by FDA, undergo a rigorous review of laboratory and clinical data to ensure the safety, efficacy, purity and potency of these products. Vaccines approved for marketing may also be required to undergo additional studies to further evaluate the vaccine and often to address specific questions about the vaccine's safety, effectiveness, or possible side effects.

Vaccine Adverse Event Reporting System (VAERS) – is used for issues related to vaccines; see Adverse Drug Event (ADE).

VAERS – *see* **Vaccine Adverse Event Reporting System**

Validation (...FDA) – Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes.

V&V – Verification and Validation

VPN – Virtual Private Network

WAN – Wide Area Network

WHO – World Health Organization

XML – eXtensible Markup Language