List of term's in alphabetic order.

A

Acceptance Criteria (IEEE) - The criteria that a system or component must satisfy in order to be accepted by a user, customer or other authorized entity.

Acceptance Test (IEEE) - Testing conducted to determine whether or not a system satisfies its acceptance criteria and to enable the customer to determine whether or not to accept the system. See also Factory Acceptance Test (FAT), Site Acceptance Test (SAT).

Aggregation - Aggregation refers to the requirement by the manufacturer to serialise each drug packaging unit (or unit of sale) with a unique identity with the creation and recording of incremental parent-child associations at each subsequent stage of packaging - bundles, cases and pallets. These associations enable single scans of pallets or shipping cases to capture the detail of all units contained within, thereby forming the basis of the e-Pedigree documentation for the batch.

Aluminium Seal - Aluminium seal & "Flip-Off" plastic cap units come pre-assembled, ready to crimp using a required specialty crimper. Colour may be used for vial identification. See also Flip-Off cap.

API - Application Programming Interface. An application programming interface is a set of routines, data structures, object classes and/or protocols provided by libraries and/or operating system services in order to support the building of applications.

Application Software (ISO) - Software or a program that is specific to the solution of an application problem.

Audit (ISO) - Systematic, independent, and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which agreed criteria are fulfilled.

Audit Trail - An unbroken human readable chronological journal to be maintained of all programs, files and data records to which access, or attempted access, has been made for any job or transaction.

Authentication - Authentication is the process of verifying that the product code on the drug package is genuine and originated from the authorized pharmaceutical manufacturer. Authentication uses the unique product serial number information stored on a RFID tag or barcode on a drug's packaging, at the unit of sale level, so that it can used by wholesalers and pharmacies to verify the integrity of the drug package.

Auxiliary code - Used when auxiliary (helping) code or data are used for tracking the pack trough the machine.

B

Batch Protocol (Log file) - Batch related protocol about all system events during a batch including inspection statistics (Total, Good, Ejected), date (Year, Day, Time), configuration (used devices), events (user inputs, error) and other batch related data.

BCR - Barcode Reader (or Scanner). Device used to manually or automatically read a barcode.

Bespoke System (GAMP) - A system produced for a customer, specifically to order, to meet a defined set of user requirements. Also called Custom Built System. Business Continuity Planning (BS 7799-2:1998 Information security management. Specifications for information security management systems). A managed process for developing and maintaining cross-organizational plans to counteract interruptions to business activities.

Biometrics - A method of verifying an individuals identity based on measurement of the individual's physical feature(s) or repeatable actions where those features and/or actions are both unique to that individual and measurable.

BO - Batch Order. The procedure that instructs all the manufacturing lines on how to produce a certain amount of some specific products. Normally it is generated by a Plant Server.

BOM - Bill of Materials. Is the term used to describe the raw materials, sub-assemblies, intermediate assemblies, sub-components, components, parts and the quantities of each needed to manufacture a final product. It may be used for communication between manufacturing partners, or confined to a single manufacturing plant.

Bundle - Set of cartons packed together (e.g. by a carton bundle packer).

C

Calibration (ISO) - The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values of a quantity realized by a reference standard.

Carton - Packaging level of pharmaceutical products

Case - Packaging level of pharmaceutical products

CFR - Code of Federal Regulations (US, book of law)

cGMP - Current Good Manufacturing Practice

Change Control (PDA) - A formal process by which qualified representatives from appropriate disciplines review proposed or actual changes to a computer system. The main objective is to document the changes and ensure that the system is maintained in a state of control.

Closed System - An environment in which system access is controlled to persons who are responsible for that content of electronic records that are on the system.

Commercial Off-the-Shelf Software (IEEE) - Software defined by a market-driven need, commercially available, and whose fitness for use has been demonstrated by a broad spectrum of commercial users. Also know as COTS.

Computer (ISO) - A functional unit that can perform substantial computations, including numerous arithmetic operations and logic operations without human intervention.

Computer System (IEEE) - A system containing one or more computers and associated software.

Computer Systems Validation - (CSV) Confirmation by examination and provision of objective evidence that computer system specifications conform to user needs and intended uses, and that all requirements can be consistently fulfilled.

Customer (ISO) - Organization or person that receives a product. See also User.

D

Data Backup - Procedure to save and restore all variable data like Product Database, Audit Trail and Batch Protocol.

Data matrix code - It is a two-dimensional matrix code consisting of black and white "cells" or modules arranged in either a square or rectangular pattern.

DB – Database. It is a structured collection of records or data that is stored in a computer system

Design (IEEE) (1), ISO (2) - (1) The process of defining the architecture, components, interfaces, and other characteristics of a system or component. (2) Set of processes that transforms requirements into specified characteristics or into the specification of a product, process or system.

Digital Signature - An electronic signature based upon cryptographic methods of originator authentication, computed by using a set of rules and a set of parameters such that the identity of the signer and the integrity of the data can be verified.

E

EFPIA - EFPIA represents 31 national pharmaceutical industry associations and 44 leading pharmaceutical companies operating in Europe.

Electronic Record - Any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

Electronic Signature - A computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Embedded XP - Operating System. Microsoft® Windows embedded is a family of operating systems from Microsoft for use in non-personal computer devices such as specialized industrial controllers.

End User - Economics and commerce define an end-user as the person who uses a product.

e-Pedigree - An electronic pedigree is a legal chain of custody record that traces a drug from the manufacturer to the pharmacy and contains information about all transactions involving that drug.

EPC - Electronic Product Code. It is a family of coding schemes created as an eventual successor to the barcode. The EPC was created as a low-cost method of tracking goods using RFID technology. It is designed to meet the needs of various industries, while guaranteeing uniqueness for all EPC-compliant

tags. EPC tags were designed to identify each item manufactured, as opposed to just the manufacturer and class of products, as barcodes do today.

EPCGlobal - It is a joint venture between GS1 and GS1 US. It is an organization set up to achieve world-wide adoption and standardization of Electronic Product Code (EPC) technology in an ethical and responsible way.

EPCIS - Electronic Product Code Information System

ER/ES - Electronic Records / Electronic Signatures Electronic Records typically are a way of storing digital information. Electronic Signatures are the requirements to show a connection between the stated user and his legitimate identity. Items involved in "21 CFR Part 11" compliance.

ERP - Enterprise Resource Planning. It is an enterprise-wide information system designed to coordinate all the resources, information, and activities needed to complete business processes such as order fulfilment or billing.

F

FAT, (IEEE) - **Factory Acceptance Test.** An Acceptance Test in the Supplier's factory, usually involving the Customer. See also Acceptance Test. Contrast to Site Acceptance Test.

FDA - Food and drug administration (US authority)

Flip-off cap - Coloured plastic cap at vials. Will be applied together with flip-off seal to the vial. Flip-off cap is removed for vial use. Colour may be used for vial identification. The plastic flip-off cap is easily removed to expose the underlying aluminium seal and centre exposed rubber stopper or septa. Ideally suited for filling or emptying vial contents with a syringe.

Functional Design Specification (FDS) - A specification of an actual equipment to be designed in order to fulfil a market need.

Functional Specification (FS) - This specification should clearly and completely describe what the product will do. Should be produced such that objective testing can be subsequently performed.

Functional Testing (IEEE) - Testing that ignores the internal mechanism of a system or component and focuses solely on the outputs generated in response to selected inputs and execution conditions. Also known as black-box testing.

Functional Qualification (FQ) - See also OQ.

G

GAMP - Good Automated Manufacturing Practice.

Good Manufacturing Practice (GMP) - For pharmaceuticals is that part of quality assurance that ensures that products are produced and inspected uniformly in accordance with the quality standards and which conform to their intended use and the approval documentation.

GS1 - Founded in 1977, GS1 is an international not-for-profit association dedicated to the development and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across multiple sectors. The GS1 System of standards is the most widely-used supply-chain standards system in the world.

GTIN - Global Trade Item Number. It is an identifier for trade items developed by GS1. Such identifiers are used to look up product information in a database which may belong to a retailer, manufacturer, collector, researcher, or other entity. GTIN for pharmaceutical market is equivalent to Brand term for tobacco market.

GUI - Graphical User Interface. The user interface is the aggregate of means by which the users interact with the system, a particular machine, device, computer program or other complex tool. In the past the term MMI was used instead (nowadays obsolete).

H

Handheld Scanner - Manually scanning of a bar code or OCR.

Handwritten Signature - The scripted name or legal mark of an individual handwritten by that individual and executed or adopted with the present intention to authenticate a writing in a permanent form. The act of signing with a writing or marking instrument such as a pen or stylus is preserved. The scripted name or legal mark, while conventionally applied to paper, may also be applied to other devices that capture the name or mark.

HMI - Human to Machine Interface. Generic expression for the device providing the platform to operate the GUI software.

H&S Risk – Health & Safety related risk. It may involve: guards not operating correctly, exposed mechanisms causing human harm; open electrical connections; human contamination by API's (active pharmaceutical ingredients).

I

Identification Device - Generic terminology for units identifying parts within packaging process by reading a bar code or any other machine readable identifier.

IEEE - The Institute of Electrical and Electronics Engineers in the USA.

In-Process Control - Checks made during the production of a pharmaceutical product and, if applicable, controlling the process to guarantee that the product conforms to its specification.

Installation qualification (IQ) (PDA) - Documented verification that a system is installed according to written and pre-approved specifications.

ISA - International Society of Automation. ISA Standards help automation professionals streamline processes and improve industry safety, efficiency, and profitability.

ISA 95 Standard – International standard for developing an automated interface between enterprise and control systems. This standard has been developed for global manufacturers. Divided in levels from levels.

Level 4: Plant Production Level (usually ERP from customer)

Level 3: Manufacturing Operation Level (usually MES from customer; Level of S-TTS Plant)

Level 2: Monitoring and automation Control Level (S-TTS Line)

Level 1: Production Process Level (S-TTS Cell)

Level 0: Device Level. Not in all ISA 95 structures!

Island - Set of all the lines that can be controlled by a single Line Computer. This can be defined basing on LAN characteristics, product amount, machine performances and so on.

ISO - The International Organization for Standardization develops and publishes International Standards ensure that products and services are safe, reliable and of good quality.

Item - Smallest unit of sales in pharmaceutical product

K

Key Practices (PDA) - Processes essential for computer validation that consist of tools, work flow and people.

L

LAN - Local Area Network. In T&T systems, the LAN connects all the cells to the Line Computer and the Line Computer to the Plant Server. Also a direct link between one cell and the subsequent one can be implemented.

Line Cluster - Set of physical lines whose cells can work together by aggregating in different flow lines. A line cluster may include one or more islands.

Log File - See 'Batch Protocol'.

M

Marking - Information about the contents and shipment of a package which is printed on or affixed to the surface of the package.

MES - Manufacturing Execution System. It manages and monitors work-in-process on the factory floor including labour and production reporting, as well as on-line inquiries and links to tasks that take place on the production floor. Manufacturing Execution Systems may include one or more links to work orders, receipt of goods, shipping, quality control, maintenance, scheduling or other related tasks.

MRP - Material Requirements Planning. It is a production planning and inventory control system used to manage manufacturing processes.

N

Network (FDA) (1) (ISO) (2) - (1) An arrangement of nodes and interconnecting branches. (2) A system [transmission channels and supporting hardware and software] that connects several remotely located computers via telecommunications.

NHRN – National health care registration number, within GS1 numbering system.

O

OCR - Optical Character Recognition. It is the mechanical or electronic translation of images of handwritten, typewritten or printed text characters (usually captured by a scanner) into machine-editable text. Checking of text but using a specific font of characters.

OCV - Optical Character Verification. Historically used in pharmaceuticals to denote checking of text by 'show and go' operation, without a pre-trained font of characters.

Off-the-Shelf Software (OTS software) - A generally available software component for which the user can not claim complete software life cycle control.

Open System - An environment in which system access is not controlled by persons who are responsible for the content of electronic records that are on the system.

Operating Environment (GAMP) - All outside influences that interface with the computer system,

Operational qualification (OQ) (PDA) - Documented verification that a system operates according to written and pre-approved specifications throughout all specified operating ranges.

P

Palette - Packaging level of pharmaceutical products.

Password - A series of numbers or symbols known only to the individual user, for use in their unique identification to a system.

PDA – The Parenteral Drug Association is the leading global provider of science, technology and regulatory information and education for the pharmaceutical and biopharmaceutical community.

Performance Qualification (PDA) - Documented verification that a system is capable of performing or controlling the activities of the processes it is required to perform or control, according to written and pre-approved specifications, while operating in its specified operating environment.

Periodic Review (PDA) - A documented assessment of the documentation, procedures, records, and performance of a computer system to determine whether it is still in a validated state and what actions, if any, are necessary to restore its validated state. The frequency of review is dependent upon the systems complexity, criticality, and rate of change.

Person - Includes an individual, partnership, corporation, and association.

Predicate Rule - Requirements set forth in the Act, the PHS Act, or any FDA regulation, with the exception of part 11.

Process (ISO) - A set of interrelated or interacting activities which transform inputs into outputs.

Process Parameter (PDA) - A variable that defines or controls a process and can affect the outputs.

Process Validation (PDA) - Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality attributes.

Product (PDA) (1) (ISO) (2) - (1) The intended result of activities or processes. (2) Result of a process.

Product Database - Human readable database for copy of complete system set-up related to a single product name.

Programming Standards (PDA) - Written procedures describing coding [programming] style conventions specifying rules governing the use of individual constructs provided by the programming language, and naming, formatting, and documentation requirements which prevent programming errors, control complexity and promote understandability of the source code.

Q

Qualification (ISO) - The process to demonstrate the ability to fulfill specified requirements.

Quality Management System (ISO) - Management system to direct and control an organization with regard to quality.

Quality Plan (ISO) - Document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product, process or contract.

R

Real-time - It is the study of hardware and software systems that are subject to a "real-time constraint", i.e., operational deadlines from event to system response.

Record Retention (ISO) - Storing and retaining quality records in an established and recorded period of time in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Records may be in the form of any type of media, such as hard copy or electronic media.

Regression Analysis and Testing - A software verification and validation task to determine the extent of verification and validation analysis and testing that must be repeated when changes are made to any previously examined software products.

Regression Testing - Rerunning test cases which a program has previously executed correctly in order to detect errors spawned by changes or corrections made during software development and maintenance.

Reliability - The ability of a system or component to perform its required functions under stated conditions for a specified period of time.

Requirement (IEEE) (1, 2) (ISO) (3) - (1) A condition or capability needed by a user to solve a problem or achieve an objective. (2) A condition or capability that must be met or possessed by a system or system component to satisfy a contract, standard, specification, or other formally imposed documents. (3) Need or expectation that is stated, generally implied or obligatory.

Retail - Sale of products to final consumers (end-user).

Review (ISO) - Activity undertaken to determine the suitability, adequacy and effectiveness of the subject matter to achieve established objectives.

Revision - Document revision. It takes in account different revisions of a certain document, in order to keep a file history. Under our context we assume to use two digits with a leading 0. This suffix should be appended to the file names. Example: TTC MDS Rev03.doc

RFID - Radio Frequency Identifier. It is the use of an object (typically referred to as an RFID tag) applied to or incorporated into a product, animal, or person for the purpose of identification and tracking using radio waves.

RTC - Real-time Computing. A computing that requires real-time constraints.

RTOS - Real-time Operating System. An operating system conceived to deal to real-time constraints.

S

SAP Aii – SAP Auto-ID Infrastructure. Software module by SAP

SAP OER – SAP Object Event Repository. Software module by SAP

SAP PI - SAP Process Integration. Technical integration software to support data exchange between SAP and non-SAP systems

Security (GAMP) - The protection of computer hardware and software from accidental or malicious access, use, modification, destruction, or disclosure. Security also pertains to personnel, data, communications, and the physical protection of computer installations.

Serialization - Serialization refers to a numerical system that assigns a unique number or identification code to each packaging unit. A serialization scheme is built around a code structure that typically identifies the manufacturer, the product type, and each specific item unit.

Site Acceptance Test (SAT) (IEEE) - An Acceptance Test at the Customer's site, usually involving the Customer. See also Acceptance Test, contrast to Factory Acceptance Test.

Source Code (FDA) (1) (IEEE) (2) - (1) Computer instructions and data definitions expressed in a form suitable for input to an assembler, compiler or other translator. (2) The human readable version of the list of instructions [program] that cause a computer to perform a task.

Specification (IEEE) - A document that specifies, in a complete, precise, verifiable manner, the requirements, design, behavior, or other characteristics of a system or component, and often, the procedures for determining whether these provisions have been satisfied.

SSCC – Serial shipment container code, within GS1 numbering system.

Structural Testing (Bluhm, Meyers, Hetzel) (GAMP) - Examining the internal structure of the source code. Includes low-level and high-level code review, path analysis, auditing of programming procedures, and standards actually used, inspection for extraneous "dead code", boundary analysis and other techniques. Requires specific computer science and programming expertise. Also known as white-box testing.

Supplier (ISO) - Organization or person that provides a product.

Supplier Management (GAMP) - The ongoing process of evaluating a supplier against established quality standards, managing noted deficiencies, and working with the supplier to improve the quality of its products or services and documentation.

Supply Chain - A supply chain, logistics network or supply network is a coordinated system of organisations, people, activities, information and resources involved in moving a product or service in physical or virtual manner from supplier to customer.

System (PDA) (ISO) - (1) Equipment, procedures, and other resources required to perform or control a process. (2) Set of interrelated or interacting elements.

System Life Cycle (IEEE) - The period of time that begins when a system is conceived and ends when the system is no longer available for use.

System Qualification (based on ISO) - The process to demonstrate that a system has the ability to fulfill specified requirements.

System Restore - Procedure to rebuild the complete computing system inclusive basic firmware, performed updates and or added options.

T

TCP/IP - Transmission Control Protocol and the Internet Protocol. It is the set of communications protocols used for the Internet and other similar networks. In T&T systems such a protocol is used for transferring messages through the LAN.

Test (IEEE) (1) (ISO) (2) - (1) An activity in which a system or component is executed under specified conditions, the results are observed or recorded, and an evaluation is made of some aspect of the system or component. (2) Determination of one or more characteristics according to a procedure.

Test Case (IEEE) - A set of test inputs, execution conditions, and expected results developed for a particular objective, such as to exercise a particular program path or to verify compliance with a specific requirement.

Test Plan (IEEE) - A document describing the scope, approach, resources, and schedule of intended test activities. It identifies test items, the features to be tested, the testing tasks, who will do each task, and any risks requiring contingency planning.

Test Procedure (IEEE) - Detailed instructions for the set-up, execution, and evaluation of results for a given test case.

Traceability (ISO) - Ability to trace the history, application or location of that which is under consideration.

Track & Trace - Track-and-Trace. It is a system capable of uniquely identify a specific product within the complete supply chain in both the directions (manufacturer to end-user and vice versa).

U

UML - Unified Modelling Language. It is a standardised general-purpose modelling language in the field of software engineering.

User (GAMP) - The person, or persons, who operate or interact directly with the system. The User(s) and the Customer(s) are often not the same person(s), but may be. See also Customer.

User ID - An identity of a user known to the company, such as an employee reference number.

User Requirement Specification (URS) (GAMP) - A requirement specification that describes what the equipment or system is supposed to do, thus containing at least a set of criteria or conditions that have to be met.

V

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

Validation Plan (PDA) - A document which describes the overall strategy and responsible parties for validating a system within its operating environment.

Verification (ISO) - Confirmation, through the provision of objective evidence that specified requirements have been fulfilled.

W

X

XML - Extensible Markup Language. It is a general-purpose specification for creating custom mark up languages. It is classified as an extensible language, because it allows the user to define the mark-up elements. XML's purpose is to aid information systems in sharing structured data, especially via the Internet, to encode documents and to serialise data.

XSD - XML Scheme Document. Set of rules to which an XML document must conform in order to be considered valid according to that scheme.