# Comprehensive LIMS Glossary & Acronyms

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# Contents

# 21 CFR Part 11

Title 21 CFR Part 11 is the part of Title 21 of the Code of Federal Regulations that establishes the United States Food and Drug Administration (FDA) regulations on electronic records and electronic signatures (ERES). Part 11, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable, and equivalent to paper records.

# Accreditation

Act by which an authoritative body grants a credit or recognition to an institutional body or person competent to carry out specific tasks maintaining guidelines for quality standards.

# Accreditation (and Certification) Body

An organization or agency authorized to inspect a facility and provide written evidence of its compliance (certification) and competence (accreditation) with a standard.

# Audit

Systematic, independent and documented verification process of LIMS sample data.

# Audit Trail

Audit trails are documented evidences to series of activities occurring at any given point of time, specific operation or event ever since they are first recorded. As part of 21 Code of Federal Regulations Part 11 (21 CFR Part 11), it's a mandate for diagnostics, biobanks and CROs to preserve their records in chronological order for traceability purposes. Information recorded in the audit trail typically includes operator code, case number, amount and quantity prior to change, notes etc.

# Billing Management

A system managing tracking of bills for consumables/ reagents and financial transactions such as payment processing, quotes, expenses within a LIMS set-up.

# Biobanking Information Management System (BIMS)

A system that ensures efficient tracking of biospecimen lifespan, from its receiving, storage, tagging their physical and clinical annotations while processing, associating physical locations till its final disposition.

# Biobank

A biorepository which includes a large collection of biological data and tissue samples for research purposes.

# Biosafety

Prevention or maintenance check on safety conditions for microbial contamination, their integrity, infection or toxic reaction leading to hazardous incidents to protect humans and environment.

## Code of Federal Regulations (CFR)

Set of rules and regulations laid down by the agencies of the US federal government to govern and regulate organizations categorized into 50 titles representing broad subject areas.

## Chain of Custody (CoC)

Chronological record or evidence to safeguard the identity and integrity of the data for sample repositories or biobank. Barcodes, inventory management, and configurable security roles all play a major role in maintaining chain of custody.

## Certificate Of Analysis (COA)

An authenticated document issued by the lab's regulatory or quality assurance authority to its clients, verifying the adherence to product specifications and standards of production.

## Cloud Based LIMS

A cloud based LIMS is a lab information management system that contains all the data on a remote server, known as the cloud. A cloud based LIMS allows diagnostic labs to upload and download all their clinical data to the cloud. It is a hybrid of the thick- and thin-client architectures.

## Cloud Computing

Also referred as a Cloud, it is a type of Internet-based computing technology that provides shared processing resources and data to systems and other devices on demand.

## Commercial Off The Shelf (COTS)

Commercially available products that are ready-made and can be purchased, easily installed and integrated with internal systems at minimal or zero customization costs.

## Content Management System (CMS)

Collection of tools designed by open source community allowing the creation, modification, organization, and removal of content to aid in managing software/ website development in a collaborative manner.

## Cloud Privacy Threat Modeling (CPTM)

It is a modeling approach for securing privacy protection when using cloud to store sensitive data.

## Clinical Trial Management System (CTMS)

A software system used to manage clinical trials in clinical research.

## Data Encryption

Conversion of electronic data into a form that can be deciphered only by the authorized parties for confidentiality of digital data stored on a computer, network or transmitted via internet.

## eClinical

A term used within the biopharmaceutical industry for referring a trial automation technology.

## Electronic Data Interchange (EDI)

It is an electronic communication method that provides standards for exchanging data via any electronic means.

## Electronic Health Record (EHR)/ Electronic Medical Record (EMR)

This refers to a systematic collection of patient and population health information stored in a digitized format.

## Electronic Laboratory Notebook (ELN)

An electronic lab notebook is an application designed to replace paper notebooks used by scientists, research students and technicians to document research, experiments and procedures performed in a laboratory. The features of ELN allow import of data captured from other sources, recording of texts, images or tables, interlinking between records, storage of records in a secured database format to maintain their integrity etc.

## Good Automated Laboratory Practice (GALP)

Set of standard practices that provide guidance regarding usage of automated equipment and instruments in the laboratory. These guidelines ensures integrity of data gathered, processed and archived by a laboratory information management system (LIMS).

## Good Automated Manufacturing Practice (GAMP)

Both, a technical sub-committee of International Society for Pharmaceutical Engineering (ISPE) and set of guidelines for producing quality automated instruments following a life cycle model.

## Good Clinical Practices (GCP)

A set of guidelines provided by ICH which can be transposed into regulations by the government and must be strictly adhered to in any clinical trials involving human subjects to ensure their safety.

## Good Manufacturing Practice (GMP)

Set of regulations, governed by the law, that requires manufacturers for pharmaceutical, medical devices and food products meet quality standards to ensure that their products are completely safe for consumers. These regulations allow companies to minimize errors responsible for contamination.

## Good Practice (GxP)

A general term used in a casual manner for Good Practice quality guidelines and regulations. These are used in many fields, including the pharmaceutical and food industries. The purpose of

these guidelines is to ensure that a product is safe and meets its intended use.

## HIPAA

Acronym for Health Insurance Portability and Accountability Act, enacted by the US Congress a law in 1996, provides security and data privacy to safeguard personal health information. These are a group of rules and regulations for contending fraudulence and abuse in healthcare and insurance.

## International Society for Biological and Environmental Repositories (ISBER)

International forum that provides support for biorepositories and biobanks creating opportunities and innovations for evolving challenges. It addresses quality standards, legal, ethical principles and management of repositories responsible for biological and environmental specimens.

## Inventory Management

A software system that allows managing, maintaining and tracking stock supplies, laboratory consumables and reagents. An advanced inventory management system can easily track usage and expiration of reagents, prompt notification alerts and schedule reordering events when supplies are depleted or are about to expire.

## Laboratory Information System (LIS)

A software system that records, manages, and stores data for clinical laboratories. It supports workflow and data tracking, has a flexible architecture, and interfaces for data exchange allowing its use in regulated environments. It performs similar functions as a Laboratory Information Management System (LIMS) used in the laboratory for management of samples, laboratory users, instruments, standards and other laboratory functions such as invoicing, plate management and work flow automation.

## On-demand Computing

It is a model for enabling ubiquitous, on-demand access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications and services) which can be rapidly provisioned and released with minimal management efforts.

## Patient Portals

Patient Portals are healthcare-related online applications that allow patients to interact and communicate with their healthcare providers, such as physicians and hospitals.

## Personal Health Record (PHR)

It is a medical record carried by an individual which comprises health data, its history and other relevant information.

## Platform as a Service (PaaS)

It is a category of cloud computing services that provides a platform allowing customers to develop, run, and manage applications without the complexity of building and maintaining the infrastructure typically associated with developing and launching a software.

## Quality Assurance (QA)

Quality assurance of a LIMS involves a set of predetermined, systematic activities which are required to maintain a level of necessary quality across many of the functions in a laboratory. The functions include quality control charts and reports, instrument maintenance, certificates of analysis (COA) etc.

## Quality Control (QC)

Quality Control is a regulatory inspection process to compare actual performance with standards. This operation verifies that the requirements for quality of LIMS or clinical trial-related activities are duly fulfilled.

## Regulatory Compliance

Set of influential standards, rules or regulations required for managing LIMS and systems responsible for handling and storing data. Compliance-based standards, and regulations include 21 CFR part 11, HIPAA, GALP etc.

## Software as a Service (SaaS)

A software application delivery model, also referred as “on-demand software”, where a software is hosted over the internet and accessed by clients using a thin client, normally using a web browser. SaaS is generally considered as a low-cost way for LIMS labs to obtain the same benefits of a commercial license, without the associated complexity of IT infrastructure and high initial cost.

## Sample Management Software

A software designed to automate the management of samples right from registering the newly arrived sample by assigning barcodes, designating a particular freezer location, tracking chain of custody till the final disposition of a sample.

## Sample Tracking

Sample tracking is a process that helps laboratories identify and trace the locations of a sample that have just arrived or stored over a period of time. It even allows the laboratory to rapidly identify the patient information or any tests being carried out on the stored sample.

## Thick-client LIMS

A thick-client LIMS is a more traditional client/server architecture, with some of the system residing on the computer or workstation of the user (the client) and the rest on the server.

## Thin-client LIMS

A thin-client LIMS is a more modern architecture which offers full application functionality accessed through a device's web browser. The actual LIMS software resides on a server (host) which feeds and processes information without saving it to the user's hard disk.

## Web-based LIMS Software

An application designed for LIMS that is not installed on a computer, but rather is hosted on a server and accessed via a web thin-client.

## Web-enabled LIMS

A web-enabled LIMS architecture is essentially a thick-client architecture with an added web browser component.