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Laboratory Information Management System

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Abstract

LIMS is an abbreviated form of Laboratory Information Management System, which is widely used in the Pharmaceutical Industry. It is a software system which is used to save and secure the data and documents by reducing manpower. This paper is to document the current state of the LIMS software and conceive to determine the number of the downfalls of the current technology. This article will review the implementation, cost, and efficiencies facing Pharmaceutical firms. These include in-house development system to user friendly interface. This paper describes the capabilities, advantages, disadvantages, benefits, of LIMS in the Pharmaceutical firms and also the standards effecting LIMS.

Keywords: LIMS; LIS; Information/data management; Technology

Introduction

LIMS (LABORATORY INFORMATION MANAGEMENT SYSTEM) aka LIS (laboratory information system), LMS (laboratory management system) could be a software-based laboratory system developed by the organization to enhance the data operation, which gives a set of key features that support a modern laboratory operation. In Pharmaceutical firms, managing documentation and securing of information is important thus by using LIMS software system it is a lot easier to secure, save information and documents by reducing manpower. Key features include workflow, data trailing, data exchange interface, data management, data processing, data analysis, good data exchange, versatile design, and integration. Pharmaceutical firms use LIMS in a totally different manner, some laboratories of LIMS holds sample information however that information stored varies a lot between different user organizations. Some laboratories store finish results of the analysis only. Some laboratories use LIMS completely by connecting them to the instruments and transferring and documenting all the required data electronically between the instrument and LIMS. LIMS software system is employed in QA, QC and R&D departments in pharmaceutical industries. The aim of LIMS is to integrate sub-processors and delivery them along and consolidate potential the efforts of many peoples and consequently speed up the complete method. LIMS can save a considerable amount of your time. It's not a tedious technique. The modern laboratory exists in an associate environment that produces a large quality of information with the arrival of recent technologies, each the quality and quantity of information's are increasing exponentially. LIMS should facilitate give the documentation and confirm that a laboratory and its operations exist in compliance. LIMS is used for twenty years and also the technology has been considerably evolved throughout the period [1-4].

Functions of LIMS

The functions of LIMS are mainly divided into the following:

- Reception and login of a sample and associated data.
- Assignment, scheduling, following of the sample and also the associated analytical work.
- Processing and quality control related to the sample used instrumentality and inventory.
- Storage of information related to the sample analysis.
- Review approval and compilation of the sample data for reporting and/or further analysis.

LIMS also helps scientists to manage their significant employment, provides a platform to support growth and accomplish the objective of optimum efficiency. LIMS offer superior capabilities by delivering real-time analysis and reports facilitating regulatory compliance and products quality, integrating with the company's broader network and provides secure access to key knowledge throughout the organization. In the modern world, LIMS functionality has unfolded even further beyond its original purpose of sample management.

History

In late 1970's management of laboratory samples, associated analysis and reportage was a time intense manual method with manual errors. It helped the organizations to streamline the collection of data and its way of reporting. A few individual laboratories developed a custom in-house solution, while some enterprising entities at the same time seeking to develop a more commercial reporting solution in the form of special instruction based systems.

In 1982 the 1st generation of LIMS was introduced which offered laboratories the 1st opportunity to utilize automated reporting tools in the form of a single centralized minicomputer.

By 1988 the second generation commercial offerings were sound into a computer database to expand LIMS into an additional application. At that point, specific territory and international LIMS conference were full swings.

By 1990's the third generation of LIMS emerged into the market and took advantage of the developing client/server architectures. This LIMS allows laboratories to implement better data processing and exchange.

Web-enabled LIMS was introduced in 1996 with wireless computing capabilities, whereas in 1997 due to USFDA CFR part 11 rules on electronic records and signatures LIMS started with the new electronic signature function.

Web-enabled Global Positioning Satellite (GPS) technologies for georeferencing sample location at the time of sample collection were introduced in LIMS in the year 1998 and also XML recommended in industry as application specific markup languages, such as chemical markup language (CML) 1st application service provider(ASP) introduced in LIMS in 1999 that could be purchased on a monthly basis and accessed over the internet *via* a secure line from the LIMS vendor and 1st completely XML-based LIMS on Microsoft's. Net platform was introduced in 2002.

For managing the personnel, facilities, equipment, and instruments RDLIMS (relational database laboratory information management system) was developed during 2003. Different LIMS were available in the market till 2004; however, they could not fulfill all requirements regarding flexibility and process connectivity.

LIMS developed in 2005 had used open-source software, PHP, and MYSQL.

PHP is a hypertext processing language that is well suited for a web-based approach.

MYSQL forms the backend of LIMS to manage the associated information.

In 2006 the requirement for LIMS with secure, flexible open database connectivity was needed to build a complete protected electronic tracking system and to maintain records. LIMS available during this time were implemented in a Java Program and Postgres SQL database. In 2007 LIMS represent the workflow layer of hierarchical operation automation with open system architectures to offer client/server capabilities and enterprise-wide access to lab information. In 2008 LIMS were implemented in Java, Platform-neutral open-source software and developed on the Microsoft Windows's Platform tested with Windows XP and SUSE Linux operating systems.

In 2009 the focus was on a more user-friendly interface of LIMS and likewise, many other fields started using it as a facilitator to their technology.

In the year 2010 LIMS focused on providing a user-friendly and integrated data management solution for effective management of the laboratory.

As on 2017 LIMS is numerous in quality and adoption but not the *de facto* standard, as the costs and daunting nature associated with vendors transitioning legacy products and with companies trying to integrate a modern based LIMS into a complicated environmental growth [2].

LIMS Cost and Efficiencies

LIMS reduces cost and improves efficiencies. About from twenty years of the drug development and cost are approaching $2 billion, pharmaceutical firms are progressively in search of a process which will facilitate them systematically deliver a comeback on investment throughout the patent lifetime of a drug. Firm's level laboratory information management system (LIMS) is key contributors to the current effort. Delivering advanced functionality that's specific to every stage of the drug development method, sophisticated purpose, designed LIMS streamline process and costs and present organizations with distinctive integration opportunities. This LIMS provides superior capabilities by delivering time period analysis and report, facilitating regulatory compliance and product quality, disintegrating with the company's broader network and providing secured access to key information throughout the organization. [5,6]

Standards Affecting LIMS

A LIMS developed and use is affected by standards such as;

- Title 21 CFR parts 11
- ISO 17025
- ISO 15189
- GOOD LABORATORY PRACTICE

Title 21CFRpart 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) [7,8]. Part 11 as it is commonly called, defines the criteria under which electronic records and electronic signatures are considered trustworthy, reliable and equivalent to paper records (Title 21CFR part 11 sections 11.1(a) [9].

ISO17025 was 1st issued in 1999 by the international organization for Standardization (ISO) and the international electrotechnical commission (IEC). It is the single most important standard for calibration and testing laboratories around the world. Laboratories that are accredited to this international standard have demonstrated that they are technically competent and able to produce precise and accurate test and/or calibration data [10,11].

ISO15189 Medical laboratories – requirements for quality and competence is an international standard that specifies the quality management system requirement particular to medical laboratories. The standard was developed by the international organization for Standardization's Technical Committee (ISO/TC 212) [12].

GLP is a set of principles that are intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies. GLP specifically refers to a quality system of management control for research laboratories and organization to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemicals, non-clinical safety tests from physiochemical properties through accurate to chronic toxicity tests [13].

Advantages

- Avoiding the workload and stress.
- Elimination of human error.
- Volume and capability increase.
- Real time saving and time tracking.
- Increase revenue.
- Consumption-based inventory alert.
- Increase in productivity occurs when the system is properly integrated into the daily routine of laboratory operations.
- Makes ergonomic for individuals working in a laboratory.

Disadvantages

- Adequate validation to ensure data integrity.
- A limited interface between lab and field computer system.

- The substantial cost of knowledge acquisition and knowledge maintenance.
- Loss of data due to a damaged disk or system crash cannot be tolerated and the backup system will be critical.
- Physical restriction.

Capabilities

- Producing Accurate, Reproducible Results.
- Faster and more Reliable Documentation.
- Store, Track and Assess over time.
- Automate Workflow.
- Integrate Instruments.
- Manage Samples and Associate Information.
- Improve Operational Efficiency.

Benefits

Efficiency, Accuracy, Productivity, Client satisfaction.

Efficiency

- Generate and send reports
- Eliminate lost data
- Generate invoice
- Access archived data

Accuracy

- Reduce errors
- Enhance quality control
- Verify data at the input
- Avoid missed deadlines
- Avoid the embarrassment of false results

Productivity

- Track productivity
- Increase Throughput
- Document lab output
- Spend time effectively
- Interact directly with LIMS developer

Client satisfaction

- Electronically notify customers
- Invoice customers for a good job done
- To meet customers' needs it configures reports

Implementation of LIMS

The key factors of implementing LIMS in Pharmaceutical Industry: LIMS is that the set of software tools that facilitate automate the gathering associate management of the data generated in an exceedingly laboratory. Many of these products' data is stored in firm's usually used information which they're in an associated interface with analysis instrumentation to collect experimental data. Complete LIMS, implementation, additionally, support data gathering, deciding, calculation, review, and release into the work. Effective use of information might be a key task for each laboratory. LIMS systems that effectively serve pharmaceutical and life sciences analysis and development endeavors ought to give a versatile set of options that adapt quickly to a dynamic method, material, and analysis. Configurable templates facilitate to modify the advancement of the workflow furthermore because of the creation of sample records, the assignment of testing and the collection of results, even in a dynamic atmosphere.

LIMS in Pharmaceutical Industry

Pharmaceutical Industry is exclusive in many ways. Various laboratories, regulative constraints, advanced batch management and testing desires, all are the challenges that are being featured by the Pharmaceutical Company during this current economic session. For all these challenges the firms desire a sophisticated and enterprise level data system. The foremost vital issues that determine the necessity for the common data system is that the wide diversity of laboratories of an organization in an exceedingly country. Combinatorial chemistry, clinical, bio analysis, analytical chemistry, and screening, preclinical, producing R&D, production of quality control all have distinctive desires in another part of the company. In some cases, this might work however a lot of usually than not the result is a failing implementation and loads of unhappy (potentially unproductive) users. The Pharmaceutical firm additionally faces intense pressure from the regulative Authorities than the others. Any potential resolution ought to satisfy the issues of both internal and external auditors. This includes the flexibleness to support the wide variable review and approval progress for both static information like product specifications and study protocols and dynamic information like test results and batch disposition. Finally, the bulk of pharmaceutical firms are being challenged to become a lot economic.

Discussion

Challenge

A major pharma company faced changing requirements to observe and capture different types of data in its *in vivo* animal studies program. The customer wanted to collect typical single point data analyses from the standard range of treatment and subject body weight, toxicity, Pharmacokinetic, and bioavailability. In addition, they wanted to conduct and capture animal observations from behavioral studies, including text and other non-numerical descriptors across time course experiments that might run for weeks or months. The company's original data capture and management system were built in-house based on spreadsheets. The system lacked consistency and hampered communication between the researchers and technicians in the multiple departments involved, including animal care, animal handlers, and bio analysis staff.

Solution

The Pharma team configured its core platform to incorporate these new data types and schedules and include them in an extended data model. The system also manages and captures output from all downstream testing such as bio analysis, toxicology, pathology and flow cytometry and tracks samples and parent/child lineage [14].

Challenge

An international Pharma company wanted to move beyond spreadsheets and disparate data stores and selected core to manage its *in vivo* and *in vitro* bioassay systems. The pharma company's key requirement was for the new assay management system to access and remain in synchronization with the existing small molecule and

peptide registry system. The chemical registry was developed in-house and had a unique data model. The system contained the structures and registration numbers of the compounds to test in the assays. The team wanted to ensure that they leveraged their existing investment in the chemical registry and that users only had to input data once, allowing them to maintain data integrity and process efficiency.

Solution

Stakeholders from Pharma Company worked with the core team to configure the core system to match their proprietary bioassay data model. They initially focused on *in vivo* study management, as it provided the most complex and variable type of data to be captured and managed. The core system flexibility configurability convinced the customer that the system met their requirements and could be extended to other, simpler *in vitro* assay types [15,16].

Conclusion

The present paper explain about LIMS and its scope in Pharmaceutical companies as a part of their informatics solution and its benefits regarding lower cost, risk, and time is explained. Using LIMS enterprises can enable secure storage and efficient management of samples and the dependable transmission of information between the laboratories within a firm.

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