Design and Implementation of LIMS System for Small and Medium-sized Discrete Manufacturing Enterprise

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Abstract: LIMS refers to the Laboratory Information Management System, which is an integrated system of modern management ideas and computer technology aimed at providing efficient and scientific laboratory operations and information management. This article focuses on a new materials company and studies the development of a LIMS system suitable for small and medium-sized enterprises by analyzing the elements and requirements of laboratory management. The system achieves a good integration of analysis processes and practical applications, and manages and controls the factors that affect the quality of testing in a programmatic way, ensuring the reliability of analysis data.This article provides a detailed exposition on the design and implementation of LIMS, with the aim of providing reference and guidance for other laboratory information management work.

Keywords: LIMS, Quality Management, Functional Design

1 INTRODUCTION

Laboratory Information Management System (LIMS) is a system that integrates modern management ideas and computer technology to provide a platform for efficient and scientific operation of laboratories and the preservation, exchange and statistical analysis of all types of information in laboratories, providing a comprehensive quantification and quality management[4].

At present, a large number of manufacturing enterprises in China have the characteristics of multi-variety small batch production, mixed assembly line production and order-oriented and inventory-oriented production, and the management of their product quality is more complex. For enterprise laboratories, regardless of the size, there are many measurement and analysis data, as well as management-oriented data to maintain laboratory operations. These massive and complex data make each laboratory waste a lot of human and material resources to maintain them, and many basic data are not sound enough, and the low level of information intelligence and traditional management methods lead to many drawbacks such as fine management capability, low production efficiency and high production cost of enterprises[5].

The subject of this study is the laboratory management center of a new material enterprise, which cites the enterprise resource planning management system of German SAP ERP, but the business and quality management process work in laboratory management, such as sample registration application, sample registration, task assignment, analysis data, audit, processing,

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statistics, and query, all rely on manual work, which greatly reduces the production efficiency. Therefore, LIMS digital management work is urgently needed.

2 REQUIREMENT ANALYSIS AND CONSTRUCTION OBJECTIVES OF THE SYSTEM

2.1 System requirements analysis

This paper mainly combines the software SAP ERP can be fully integrated with PIMS, MES, LIMS, etc. LIMS adopts a three-layer logical structure design of application layer, business layer and data layer, in this three-layer structure, the maintenance of each level is independently separated. the main scope of LIMS functional design is designed and developed around the inspection center and quality management department, the inspection center (Technology Center) undertakes the task of inspection, testing and technology development for the whole process of the branch plant from raw materials incoming, production process, environment to products leaving the factory. The quality management of the center's analytical laboratory follows ISO/IEC 17025:1999 and has passed the national accreditation of the laboratory. The Quality Management Department undertakes the tasks of revising and formulating product technical standards, quality indicators for mutual supply materials and internal quality control indicators, analysis operation plans and internal control indicators; quality assessment of the production process, confirmation of factory conformity and issuance of conformity certificates; and management of metrology work.

Therefore, the construction of LIMS aims to improve the standardized management of laboratory operations, improve the implementation of the enterprise's quality assurance system based on the ISO9000 standard and the laboratory accreditation standard ISO/IEC 17025, improve the automation level of the laboratory, complete the integration of LIMS and ERP, and provide timely and reliable support for the enterprise's quality control and production through the timely transfer and sharing of information We can provide timely and reliable support for quality control and production optimization, provide basic data for quality management of ERP, and provide timely and accurate quality data for material balance of MES.

2.2 System construction goals

Based on the full investigation of the enterprise LIMS requirements, the construction objectives of the system were formulated[1].

1.To establish an excellent laboratory automation operation system that follows the requirements of ISO 9000 and ISO/IEC 17025, to programmatically manage and control the elements that affect quality, to minimize the interference of human factors, and to ensure the authenticity and reliability of analytical data.

2.Through the management of samples, standardize the inspection workflow to monitor the specific implementation of laboratory management rules and regulations, and ensure the traceability of the inspection process.

3.To achieve automatic data collection for most of the eligible instruments, automatic processing of data storage, and improve efficiency.

4.Through the system set quality control information and statistical analysis, quickly warn of bad quality changes and prevent abnormalities to improve the quality of inspection, prevent the occurrence of substandard products and reduce production operating costs.

5.By including various forms, reports, templates, workflow, samples, resources, method standards and other customer customization, so that users can easily complete the daily work of change.

6.Through B/S three-layer structure model, it enables managers at all levels or other related units in the branch to access and release relevant data and information quickly through the platform, improves the transmission speed of quality data and the security of the transmission process, and speeds up the response and decision-making speed.

7.To optimize the allocation of human resources in the laboratory through the statistics of personnel workload, production value, error rate and related cost accounting.

8.To reduce the material cost of the laboratory through the management of standard substances, samples, reagents, etc. and the corresponding statistics and analysis of related cost accounting.

3 FUNCTIONAL DESIGN AND IMPLEMENTATION OF THE SYSTEM

The main functions of the LIMS system include business process management, quality management, instrument acquisition, system integration and other parts of the laboratory[4] to realize all types of inspection samples in the production of new materials in this enterprise into the system for management. The system structure of the laboratory information management system is shown in Figure 1.

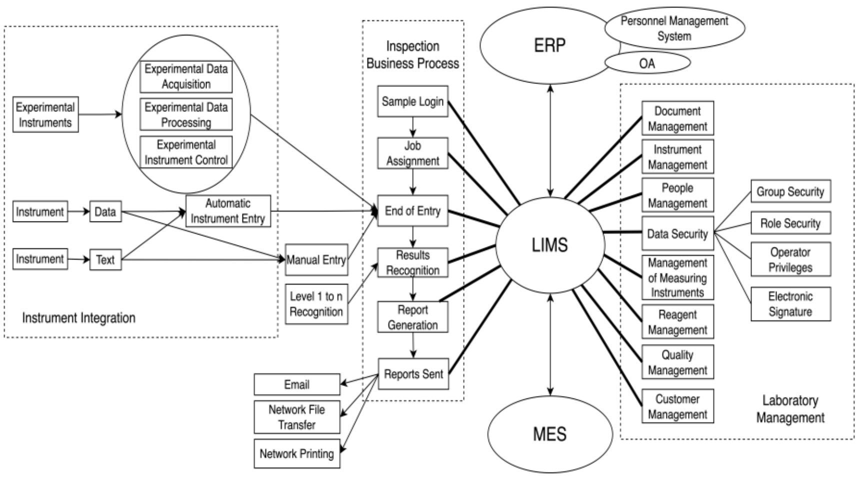

Figure 1 System Structure Diagram

3.1 Network topology

LIMS system to part of the inspection center network expansion, upgrade the switch and increase the number of network nodes. The entire network expansion construction, mainly to indoor twisted-pair construction, basically does not involve the fiber optic part. The inspection center and each production unit boundary area network management center are connected to the information center room by optical fiber (1000M), and the central analysis room and each laboratory are connected to their respective network management center by optical fiber or twisted-pair cable (10/100M)[8].

3.2 The main function design of the system

3.2.1 Analytical business process management

In LIMS, sample management is one of the core elements, which is the management of the whole process (whole life cycle) of sample inspection and analysis. The sample management module uses sample status to control the sample lifecycle, folders to organize the samples, and workflow definitions to control the sample operations during its lifecycle. The designed workflow includes sample registration, test result entry, test self-test, test approval, sample inspection, automatic generation and printing of analysis reports, product qualification, certificate issuance, and Web data publishing so that the person or unit requiring analysis information can directly browse the data open to them using the Web[10].

1. Static data entry

A large amount of static information such as analysis methods, sample templates, sampling plans, devices, sampling points, specifications, users, groups, etc. are set up in the system according to certain coding standards and planned for management.

2.Sample registration

For fixed-frequency samples, in the sample management module, the form of Rule Rule definition is used to map the actual fixed frequency; the mode of running batch login program with regular login is used, and the technique of sampling plan is used for the automatic registration of samples for fixed analysis frequency and analysis items for a complete implementation. The samples are automatically generated by the system backend and the corresponding tests are automatically assigned to the samples[2].

3.Result entry

The system needs to perform automatic input of instrumental data for results and develop interfaces for manual entry that can provide many features to reduce the workload and reduce the error rate of data. The main features include: automatic calculation of all intermediate results, automatic numerical revision processing, automatic formatting of analytical data, automatic display of analytical data overruns, and automatic correction compensation calculation of measurement data.

4.Sample inspection

The inspection and confirmation of the experimental analysis results, sample conclusions and external reporting processes are configured and related extensions are developed according to the domestic quality management process[7]. It mainly includes.

a. Self-checking of tests by analysts

This feature is an extension of the sample management module. The self-test can only be performed by the person who entered the data for that test, with traceability of the data related person.

b. Shift manager approval of tests and samples

c. Shift manager approved samples

d. Sample approval by inspector

Finished samples pass the above checks to achieve three-level review by the analyst, shift manager and inspector. The analysis results of intermediate control samples are audited by analysts and shift leaders at the second level. This process is designed to meet the audit requirements of different products, and it also meets the requirements of ISO/IEC 17025 standard[3].

5. Abnormal business process

When there is an "internal error" or "external error", the system needs to provide a variety of flexible means to deal with the situation under the premise of ensuring traceability, including test self-test, reject and edit the test, cancel the test, reject the sample, cancel the sample, and even resample, etc.

6. Internal query and statistics of samples

In the sample management module internal also define all kinds of sample data query. Such as sample comparison samples, samples with modified records, resampled samples, samples that have been rejected by each shift, and other queries. It also provides comprehensive certificate management functions for quality control department, including issuing certificate of conformity, deleting certificate of conformity, distributing certificate of conformity to workshop, etc.

3.2.2 Transaction management

Transaction management is part of the data management system developed around the reliability of LIMS data and the completeness of the process, combined with the daily management business of the laboratory.

It mainly includes personnel management, instrument and equipment management, measurement apparatus management, sample retention management, material management, and shift log.

1.Personnel Management: The basic information of the management personnel and their induction qualifications are managed, as well as their training plans and training status. This is mainly used to illustrate the quality tracking of the operators of LIMS data.

2.Instrumentation Management: This will mainly manage the management of the use, repair, maintenance and calibration of the instruments and equipment involved in LIMS. This will mainly be used to illustrate the reliability of the instruments used for LIMS data.

3.Instrumentation Management: This is the management of the use and calibration of the instruments involved in the LIMS. This will mainly be used to describe the reliability of the instruments used for LIMS data. It also combines the calibration of the measuring instruments with the sample business process to achieve automatic calibration calculation of the measurement data[9].

4.Sample Retention Management: This is mainly for the documented management of the retention, use and disposal of samples of finished products, raw and auxiliary materials, etc. The development of this module will be a complete business process.

5.Material Management: It mainly completes the material application form, incoming order, outgoing order, inventory count and inquiry of various reports.

6.Shift Log: Develop the format of shift log and realize the electronic shift log in the sample management module.

7.Business management module covers all the internal daily affairs of the inspection center, to achieve management information and procedures.

3.2.3 Quality Management

1. Sample registration management: This function allows lab administrators and technicians to register and manage basic information of samples, such as name, source, quantity, production date, sampling date, etc. Also, this module should be able to record the status of samples and sample assignment in order to track the sample handling process.

2. Assignment Management: This function allows the administrator or quality controller to assign the registered samples to the corresponding lab technicians or testing devices with set deadlines. The technician or testing device can view their assigned tasks through this module and provide progress updates and feedback on results.

3. Data Audit Management: This function is used to audit and approve the test data generated by the lab. Administrators or quality controllers can view data audit records and review, modify and approve the data.

4. Data processing and statistics: This function supports processing, statistics and analysis of laboratory data, such as calculation of mean, standard deviation, correlation coefficient, etc., to better understand the data and support decision making.

5. Quality control management: This function is used to monitor the quality control indicators of the laboratory, such as precision, accuracy, sensitivity, etc., to ensure the quality of laboratory tests and the accuracy of analytical results.

6. Quality Problem Management: This function is used to record and track quality problems or abnormalities found in the laboratory, such as abnormal test results or testing equipment failure. The administrator or quality controller can set the emergency level, responsible person and solution, and track the progress of problem resolution.

3.3 System architecture design

In the platform-oriented construction, the LIMS system was initially constructed by taking into account the overall business process from collection and processing to the overall business process and the architecture system of the application, and its overall technical architecture is shown in Figure 2.

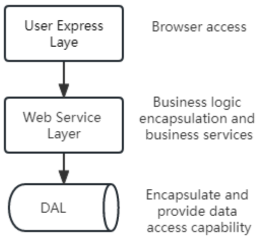

Figure 2 LIMS System Platform Architecture

The LIMS system platform adopts a three-tier browser/Web server/database server J2EE architecture, consisting of a data access layer, a Web service layer, and a user representation layer. Among them, the data access layer extracts and converts data from different sources of instrument interface data, and provides basic support to the platform through microservice calls; the Web server layer is responsible for processing requests sent by the browser layer, sending the requests to the corresponding application components for processing, and returning the processing results to the browser layer. the Web server layer usually consists of a Web server and a Web container. The Web server is mainly responsible for processing HTTP requests and responses, managing the resources of the Web application, and passing data to the database server layer for processing. the Web service layer uses component technology for data standardization modeling, data fusion, encapsulation and processing of business logic, and combining the basic functions in the data layer; the representation layer is responsible for receiving data, encapsulating data, responding to data, and invoking the Web services layer.

In the three-tier J2EE architecture, communication between different layers is generally carried out using HTTP protocol and TCP/IP protocol, business logic processing is achieved through Web components such as Servlet and JSP, and data interaction with the database server layer is achieved using technologies such as JDBC. The advantage of the three-tier J2EE architecture is that the different functions and components of the application are deployed in different layers, making the application more flexible, easy to maintain and extend. Also, by using standard Java technologies, development efficiency and code reusability can be improved. In practice, the B / S architecture design based on a three-tier structure of microservices enables the functional responsibilities of the application to be singularized, easier to maintain and extend modularly, and more efficient to develop and easier to deploy.

4 IMPLEMENTATION OF THE SYSTEM

4.1 Technical selection of the system

This project uses SSM (Spring Boot+Spring+MyBatis) design pattern for the back-end, MySQL for the database, Vue+ElementUI for the front-end, and Vue+ElementUI for the user interface. The front-end and back-end interact with each other by means of interfaces and data in JSON format. The backend uses idea development environment, Spring Boot framework to build the project quickly, and Maven project management to simplify the project configuration and development process and avoid version conflicts caused by third-party dependency packages. Using MyBatis to achieve the mapping between database records and Java objects, through the form of annotations to the automatic assembly of components to improve development efficiency. The front-end layout uses the Vue+ElementUI component library, the icons use the Echarts component library, and the front-end of the business processing module uses the SPA (Single-page Application) single-page application model to design the user interaction interface. request mode. The main interface of the front-end is shown in Figure 3.

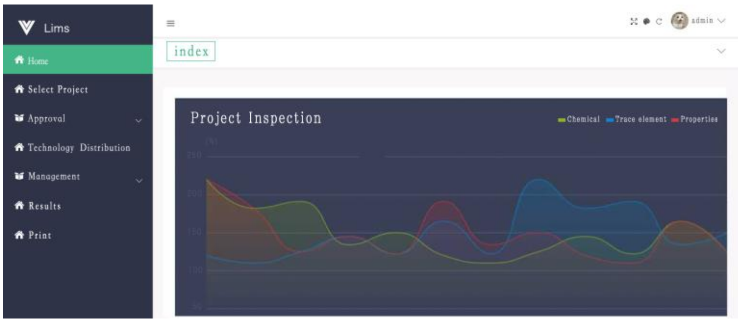

Figure 3 LIMS Back Office Management System

4.2 System testing and validation

To ensure the correctness and reliability of the LIMS, several tests and validations were performed, including functional, performance, security, and user acceptance tests.

By conducting comprehensive functional, performance, security and user acceptance testing and verifying that the LIMS system functions according to user requirements, large volume of data and concurrent user requests, multiple security tests and user acceptance tests, test cases were written to cover all major functions in the system, including sample management, laboratory processes, data management and report generation. The test coverage rate reached 100%. The test results showed that the system functions properly and meets the user requirements.

Through the load tests and performance tests conducted, and using different data sets and test conditions, the test results showed that the system has good performance and stability and can meet most user requirements. The system has good security and confidentiality and is able to prevent malicious attacks and data leakage through several security tests conducted, including network security tests, identity verification and authorization tests, vulnerability tests, and data encryption tests.

The system uses a variety of data formats and data sources, and verifies the integrity and validity of the data. The test results show that the system is able to receive and store data correctly, detect and correct erroneous data effectively, and has good data visualization and report generation functions.

5 CONCLUSION

After this LIMS system was put on line and running, it realized the management of analytical testing business process, transaction management and instrument connection for the enterprise testing center, completed the management of the whole process of sample testing and analysis, realized the informationization and automation level of the laboratory, optimized the laboratory business process, and promoted the standardization and refinement management of laboratory management. It provides quality information to meet the needs of the analysis experiment department, workshop devices and functional departments; the quality information is timely, accurate and reliable. The system is reasonably designed, reliable and easy to operate, and features Web data release as well as report production. In addition, a strict data security, backup and recovery management mechanism has been established to provide a guarantee for the continuous and reliable operation of the system. The entire system business process definition is complete, quality management functions are complete, standardized management of certificates of compliance, timely transmission, timely and comprehensive data release. The implementation of the system plays a positive role in promoting the management of the inspection center and quality management department.

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