WHITE PAPER

EFFECTIVE COMPLIANCE MANAGEMENT IN LIFE SCIENCES MANUFACTURING BY INTEGRATION OF ORACLE AND LABWARE INFORMATION MANAGEMENT SYSTEMS

Abstract

The integration of Oracle E-Business Suite applications with laboratory information management systems (LIMS) presents a flexible solution for the life sciences industry. It enhances efficiency and accuracy in various processes, from sample collection to electronic documentation, streamlining operations while adhering to regulatory standards. This paper highlights the value of LIMS integration while detailing a framework for greater business benefits for organizations in the industry.

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Introduction

The manufacturing segment in the life sciences industry plays an important role in the production of medicines, drugs, and equipment required for medical treatments. It is imperative that each drug product adheres to the quality specifications laid out in the Food and Drug Administration (FDA) guidelines. The manufacturing process must follow the good manufacturing practice (GMP) system to meet the prescribed quality standards and specifications.

In the life sciences industry, maintaining stringent quality specifications and calibration throughout the production cycle is essential. This helps ensure every drug product or active pharmaceutical ingredient (API) meets the required quality standards and regulatory specifications. A strong application architecture is critical to support business operations and efficiently maintain laboratory systems to achieve this end.

Labware Laboratory Information Management System

The pharmaceutical industry needs a robust application to maintain and document quality test results, conduct tests, ensure regulatory compliance, and maintain electronic records.

The Labware laboratory information management system (LIMS) plays a key role in collecting sampling data and ensuring that specifications meet FDA standards. Laboratory stakeholders, including lab managers, quality managers, and scientists, are responsible for conducting various tests on samples, performing calibrations, monitoring sample quantities, and ensuring accurate documentation in an electronic format.

The LIMS application performs the following key functions based on laboratory activities :

- Sample management: Collection of sample data at periodic intervals is an essential activity during the manufacture of drug products. The sample data is recorded and tested on various parameters to ensure that quality standards are met and consistently followed.
- Lot management and release: Lot-based batch transactions are tested and monitored to keep track of the lot through the manufacturing process. The LIMS application also helps perform calibration and sample data tracking.
- Stability study: All raw materials and drug products go through various test cycles to measure potency and stability. The stability study is conducted, and results recorded, to ensure product quality as specified by GMP guidelines.
- Environmental monitoring: Products go through checks for moisture, temperature, and air quality. These checks ensure the maintenance of an environment conducive to product manufacture, storage, and distribution.
- Internal reporting and client reporting: All test sample results are documented and electronically signed for future reference and audit trail purpose. Data from previous years is made available as needed through suitable tracking.
- Increase in user efficiency and reduced resource consumption: The LIMS application helps automate processes, reducing manual handling and eliminating errors in data recording and generation.
- Digital storage of sample data for audit trail: Electronically stored data maintains lot history and sample test results. This reduces manual data error entry and maintains accurate, electronically-signed data. It allows for easy access to data for audit purposes, providing complete visibility of the sample lot.

Solution Approach

Oracle application architecture and landscape

Pharmaceutical companies manage their manufacturing operations using the Oracle enterprise resource planning (ERP) system. Oracle enables seamless business operations across divisions by connecting manufacturing, distribution sites, and financial reporting. Figure 1 depicts Oracle's integration with various applications to complete the pharmaceutical manufacturing activities, ensuring GMP compliance and following standard operating procedures (SOPs) with electronic documentation.

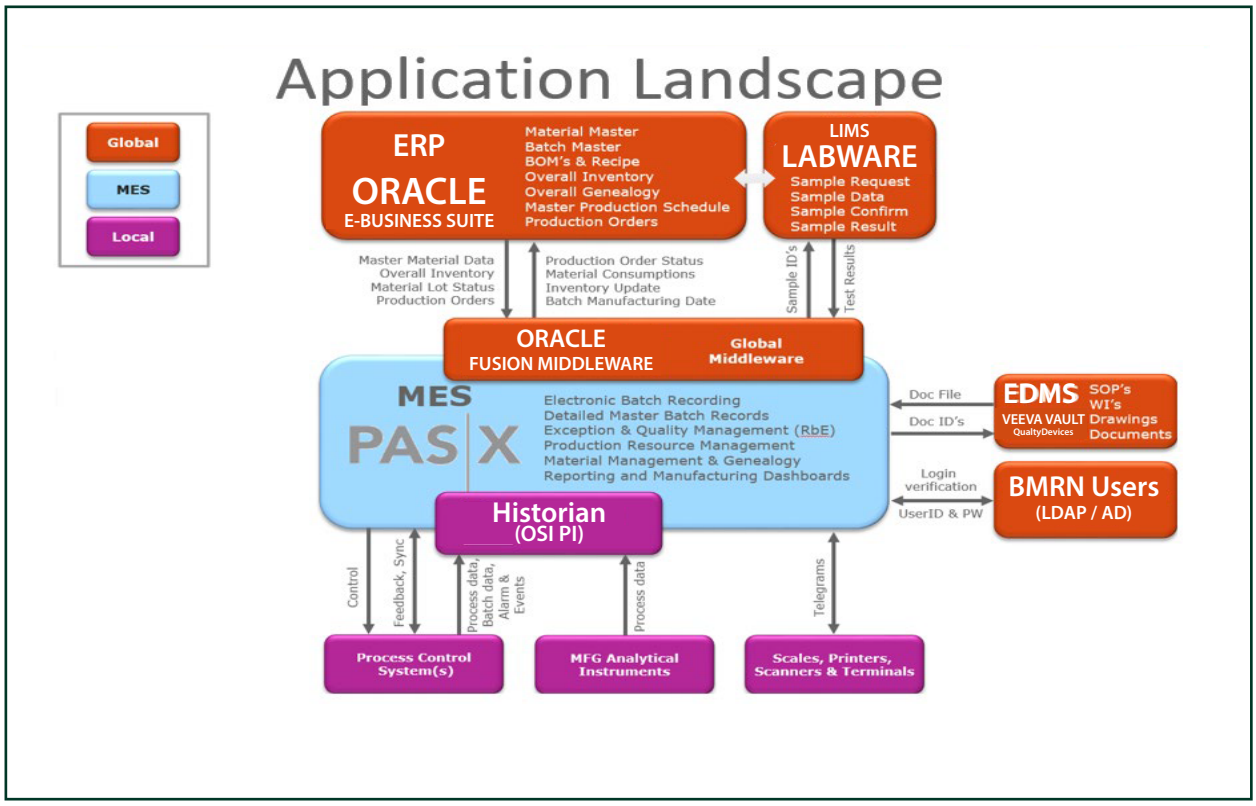

Fig 1: Oracle application landscape

Oracle provides the following range of features to enhance lot traceability and genealogy within pharmaceutical organizations:

- Lot information screen, providing details of transactions, genealogy, elapsed date, and status of lots, offering complete visibility of lot movement in the supply chain
- Oracle Manufacturing Execution System (MES), for weighing and dispensing accurate material quantity for production batches
- Oracle MES process instructions, ensuring each step is accurately followed according to SOP guidelines
- Accurate calibration of process and quality parameters, addressing non-conformance during manufacturing
- Transaction-based electronic signature capture, maintaining electronic signature data for regulatory compliance
- Material movement as per need-based defined roles
- Lot status, driving or restricting material movement based on business needs

Oracle seamlessly integrates with various systems:

- LIMS via service-oriented architecture (SOA)
- MES via SOA
- Laetus packaging via SOA
- Documentation and SOP via Veeva

Integrating Oracle E-Business Suite applications with LIMS

It is vital to establish a robust handshake between the Oracle ERP and LIMS application for timely and accurate data processing.

The seamless integration of Oracle E-Business Suite applications and LIMS relies on a strong connection with the SOA application, making for smooth and easy configuration and scalability. A custom interface is required to support and enable the data transfer between Oracle E-Business Suite applications and LIMS, as represented in Figure 2.

Fig 2: Custom interface facilitating data transfer between Oracle ERP and LIMS

Efficient data transfer between the two applications relies on the identification of the key business events depicted in Figure 3 and explained below.

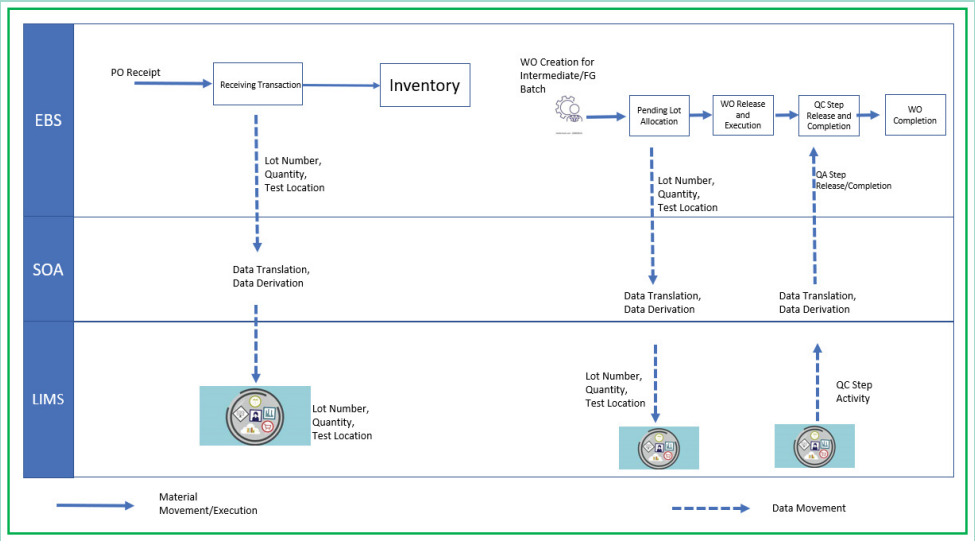

Fig 3: Key business events that aid efficient data transfer between Oracle ERP and LIMS

- Purchase order receipt and lot number generation: Raw material received by the manufacturing plant triggers generation of lot number, with information communicated to the LIMS in real time.
- Intermediate production batch and lot number generation: The creation of intermediate batches and assignment of pending lots are transmitted to LIMS in real time during manufacturing.
- Final drug substance batch and lot number generation: Details on drug substance, drug product, finished goods production batch, and lot information are conveyed to the LIMS instantaneously.
- Batch step planned start and end date changes: Changes in the planned start and end dates of production batches are immediately relayed to the LIMS.
- Quality control (QC) batch step release: QC-initiated sampling and quality checks in LIMS prompt the transmission of batch step release message from LIMS to Oracle.
- QC batch step completion: On completing sampling calibration and analysis in LIMS, a batch step completion message is sent to Oracle from LIMS.

The data mentioned above must be transferred between the two systems in real time, in alignment with the occurrence of the business events. This transfer is essential to carry out quantity and quality checks, sampling activities, and stability tests performed in the laboratory

Table 1 provides a comprehensive list of data elements that must be transferred to LIMS as part of lot information for raw material, intermediates, drug products, and finished goods.

Data Elements	Description
Lot number	Lot number generated for the item
Test site	Site location of lot number creation
Manufacturing organization	Inventory organization
Item	Name of item for which lot number is created
Transaction quantity	Transaction quantity performed
Date received	Purchase order (PO) receipt date
Manufacturer	Name of manufactured item
Batch planned start date	Start date of batch step for manufactured item
Batch planned end date	End date of batch step for manufactured item
Child lot flag	Child flag for parent-child lot items
Batch step release date	QC batch step start activity in LIMS
Batch step completion date	QC batch step completion activity in LIMS

Table 1: Data elements transferred to LIMS as part of lot information

The SOA integrated services support the integration between the two systems, acting as a common platform to connect the ERP and LIMS systems. This connection helps swift configuration, easy deployment, efficiency , and robust integration.

Key features of the SOA-integrated services:

- Data translation between receiver and consumer services
- Data derivation
- Defaulting constant values
- Invocation of APIs
- XML payload generation

LIMS integration with MES

Pharmaceutical companies conduct their routine manufacturing activities using MES implementation, as depicted in Figure 4

Fig 4: MES implementation for manufacturing activities

The primary business drivers for using the MES application are:

- ❑ User efficiency
- ❑ Integration with automation and equipment devices
- ❑ MBR design
- ❑ Integration of weighing scale devices
- ❑ Elimination of paper batch records
- ❑ Improvement in inventory stock
- ❑ Implementation of electronic documentation for audit trails
- ❑ Integration with printers and scanners

Both LIMS and MES have the inherent feature to seamlessly connect applications as well as execute transactions.

The critical bridge interfaces that facilitate data transfer, sampling activities, and the capture of sample results include:

- ❑ Sample request from MES to LIMS: MES sends a request for sample collection to LIMS based on the manufacturing lot in progress.
- ❑ Sample collection request from LIMS to MES: Details such as sample collection, lot number, and reference sample information are collected from LIMS to MES.
- ❑ Sample confirmation: MES confirms the delivery and storage location of the samples to LIMS.
- ❑ Sample results: Various tests, along with their results and calibration information completed in LIMS are sent to MES.
- ❑ Ad hoc messages/sampling: Ad hoc sampling requests, as needed, are processed between LIMS and MES.

Best practices

Establishing a sound integration process involves the following best practices:

- ❑ Defining the business processes and transactions intended for integration
- ❑ Identifying entities such as the inventory organization, test site locations, and item attributes
- ❑ Utilizing middleware application and ensuring compatibility between Oracle E-Business Suite and LIMS applications
- ❑ Compiling a list of data elements and fields to be transferred
- ❑ Ensuring data cleaning for accuracy during the transfer

Business benefits

Following these best practices can provide several business benefits, including:

- ❑ Seamless and robust integration of Oracle E-Business Suite applications with LIMS
- ❑ Enhancement in user efficiency through quality specification and calibration results in LIMS
- ❑ Lot-based transaction processing for test calibration needs
- ❑ Maintenance of electronic data and e-signature activities
- ❑ Ability to meet regulatory requirements and GMP guidelines
- ❑ Enhanced architecture to support businesses in Oracle E-Business Suite applications while adhering to quality standards in the LIMS application

Conclusion

Oracle E-Business Suite applications offer the flexibility and capability to seamlessly integrate with life sciences LIMS to enable the successful completion of essential quality checks, test metrics, and regulatory compliance required by the industry. It empowers organizations to transfer data swiftly and smoothly and enhance user efficiency. The integrated approach supports business processes and helps maintain standards in the life sciences domain.

References

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