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Short communication

Enhancing secondary reference standard management through LIMS

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Introduction

Standards serve as reference points to ensure accuracy, consistency, and reliability in analytical processes. According to ISO Guide 30:2015, reference materials are homogeneous and stable materials fit for their intended use in measurement processes.

In the pharmaceutical context, reference standards are highly characterized materials used for the identification, assay, and purity testing of drug substances and products (USP General Chapter <11>). Reference standards are frequently necessary to achieve adequate quality control of pharmaceutical substances and preparations (European Pharmacopoeia 12.2, Chapter 5.12).

Secondary reference standards are widely used in routine quality control laboratories and require effective tracking to ensure proper usage and traceability. Their role is essential in supporting the generation of reliable analytical results and analytical procedures in pharmaceutical quality control laboratories, in accordance with the principles described in ICH guideline Q2(R2) The use of the inventory management module within a Laboratory Information Management System (LIMS) enables systematic control and monitoring of key parameters, including available quantities, standard consumption, bottle opening records, storage location, issuance history, expiry dates, potency, and certification.

Materials and methods

Prior to implementation, the management of secondary reference standards was performed using paper-based records and forms. The implementation was carried out using LabWare LIMS (version 8.0) and its Inventory Management module. The configuration process included establishment of master data, definition of suppliers and corresponding SAP codes, creation of stock templates, and setup of storage and operational locations including refrigerators, receiving areas, and issuing locations.

For secondary reference standards, stock templates were configured using the Standard and Reagent Template. Predefined test lists were assigned to enable automatic creation of analytical samples during inventory record creation. These samples were used for recording analytical parameters such as potency and loss on drying/water content. In addition, inventory records were configured to support management of standard quantities, usage records, storage locations, expiry dates, potency values, certificates of analysis, and electronic label generation.

User access rights, audit trails, electronic records, and review/approval workflows were configured in accordance with internal quality requirements and GMP expectations described in EudraLex Volume 4, Part I, Chapter 6 (Quality Control).

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Results and discussion

Management of secondary reference standards before LIMS implementation

Prior to the implementation of the LIMS, the management of secondary reference standards was performed using paper-based forms. These included evidence list for issuance of the reference standard, evidence list for consumption of reference standards, evidence list for consumption of reference standards of narcotic and psychotropic substances, and evidence list for checking the quantities of secondary reference standards, as well as dedicated lists for standards stored under specific conditions, such as refrigerators. The use of multiple documents required manual data entry and cross-referencing, which increased the risk of inconsistencies and made tracking of standard usage, storage, and stock status more complex and time-consuming.

Master data setup

Before the go-live phase, a comprehensive master data setup was performed in the LIMS. This included the entry of suppliers of secondary reference standards together with their corresponding SAP codes, as well as the creation of stock templates based on inventory type. Storage and operational locations, including refrigerators, receiving and issuing areas, were defined in the system.

For specific categories such as secondary reference standards, the stock templates were configured using the *Standard and Reagent Template*. This template includes a predefined test list consisting of specific analyses or groups of analyses, enabling assignment of one or multiple analyses to a sample simultaneously. Additionally, during the creation of new inventory records, the system automatically generates a corresponding analytical sample with predefined tests and acceptance limits.

These automatically generated samples are used for entering key analytical parameters, such as standard potency and loss on drying or water content, which are essential for further calculations and proper application of the reference standards in analytical procedures.

Management of secondary reference standards in LIMS

Following the implementation of LabWare LIMS and its inventory management module, all previously separate records were consolidated into a single, centralized system. The digitalized approach enabled real-time tracking of quantities, consumption, usage history, storage locations, expiry dates, potency, certification data, and stock levels.

In addition, electronic label generation directly from the LIMS ensured consistency and accuracy of labeling, while audit trails enhanced traceability by recording all data entries and modifications. Overall, the implementation of LIMS significantly streamlined the management of secondary reference standards by improving data visibility, reducing manual workload, and strengthening control over inventory and usage.

Conclusion

Centralization and digitalization of the management of secondary reference standards through the LabWare LIMS system significantly enhance the efficiency and control of laboratory processes. The implementation of the inventory management module enables accurate tracking of standard quantities, usage, and critical attributes, reducing the possibility of human error and improving data reliability. Reduced paper-based documentation contributes to environmental sustainability. Overall, this approach ensures greater transparency, supports data integrity, and facilitates more efficient and compliant management of secondary reference standards in pharmaceutical quality control laboratories.

References

European Pharmacopoeia 12.2 (01/04/2026), 5.12. Reference standards;

EudraLex, The Rules Governing Medicinal Products in the European Union, 2014. Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Part 1, Chapter 6 : Quality control

ICH guideline Q2(R2). Validation of Analytical Procedures.

ISO Guide 30:2015. Reference materials — Selected terms and definitions

USP General Chapter <11> – Reference Standards