

LABQUALITY DAYS

Complementarity of dual ISO 15189 and CAP lab accreditation in Europe: Insights from a Belgian clinical laboratory.

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Introduction

Accreditation is essential for ensuring high-quality services in laboratories. ISO15189 and the College of American Pathologists (CAP) accreditation are two prominent frameworks that laboratories adopt to enhance their quality management systems. While ISO15189 focuses on the overall high-level quality of medical laboratories, CAP emphasizes detailed, practice-oriented quality assurance and proficiency testing. Traditionally, the focus in Europe is mainly on ISO with CAP not being as well established.

Approach

This case study aims to (1) evaluate the overlapping and unique features of ISO15189 and CAP standards and their complementary nature, (2) assess their combined impact on quality management and performance, and (3) identify the practical synergistic benefits and challenges of dual accreditation for a European clinical lab.

This study was conducted in an already ISO15189 accredited Belgian clinical laboratory that recently implemented and obtained CAP accreditation. As part of a feasibility study a review of the CAP requirements and quality management protocols was performed. An analysis was conducted to identify the coverage of the applicable CAP requirements and the gaps with the existing ISO15189 quality system. The final comparison of the two accreditation standards is based on review of both standards, the gap analysis and the practical implementing experience from the lab, with a focus on required investments regarding resources and financial investment at the stage of implementation and maintaining the additional accreditation.

Outcome and Conclusions

ISO15189 and CAP accreditation exhibit significant complementarity in core areas such as quality management, equipment calibration, quality control, and documentation. CAP accreditation added rigor in specific areas, notably in personnel competence, proficiency testing, inter-laboratory comparisons, and clinical practice guidelines. The pursuit of dual accreditation enhances the robustness of the quality management system and fosters a culture of continuous improvement and staff involvement in quality initiatives.

However, maintaining dual accreditation poses several challenges, including increased workload, the need for continuous staff training to comply with both standards, and additional financial

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investment. Laboratories seeking dual accreditation should strategically plan to manage the increased administrative demands and ensure continuous staff training. Implementing integrated quality management systems that meet the standards of both ISO15189 and CAP can streamline processes and minimize redundancy, enhancing overall efficiency and effectiveness.

In conclusion: although it requires a significant time and financial investment, dual accreditation offers complementary strengths that significantly elevate the quality and reliability of laboratory services when combined. ISO15189 provides a solid foundation in quality management principles, while CAP accreditation adds depth in practice-oriented standards. European laboratories striving for excellence in clinical diagnostics or clinical trials can greatly benefit from pursuing dual accreditation. This holistic approach not only ensures compliance with international regulations (e.g. FDA) but also fosters a culture of best practices, quality and continuous development and improvement, ultimately leading to enhanced patient care outcomes.

¹ College of American Pathologists checklists version 2022.

² ISO 15189:2022 Medical laboratories Requirements for quality and competence.

