COMPLEMENTARITY OF DUAL ISO 15189 AND CAP LAB ACCREDITATION IN EUROPE: INSIGHTS FROM A BELGIAN CLINICAL LABORATORY.

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Background

Accreditation is essential for ensuring high-quality services in medical laboratories. Having been Belac° ISO accredited since 1995, the lab decided to achieve an additional CAP Lab accreditation in 2024. Traditionally, the focus in Europe is mainly on ISO with CAP not being as well established. This case study describes the comparison between these two lab accreditations and the challenges of dual accreditation for a European clinical lab.

°Belgian National Accreditation Body

Differences

ISO15189:2022 vs. CAP

		ISO15189:2022	CAP
PRESENCE		Mainly Europe, Australia, Africa, India, China and Japan	Mainly US, Middle East, Singapore and Hong Kong
REQUIREMENTS		Focus = process (QMS approach accross the entire organisation)	Focus = emphasis on technical and procedural aspects + lab director + safety and hygiene plan
			Detailed, technical (how)
		1 standard for all medical labs	Checklist by department/discipline
		Based on other ISO guidelines	Based on CLIA, FDA, CLSI guidelines, “Best practices”
		Focus on risk management	Focus on safety (e.g. patient, chemical)
		Update: 5-10years	Update: yearly
AUDIT	**Scope**	Selection by lab based on reimbursement	All tests for medical diagnosis/applications within same lab and with same Lab Director
	Frequency	Cfr. Belac guidelines (15 months) By Belac certified auditors	Y0: 2 yearly audit from CAP peer inspectors Y1: 2 yearly self-inspection
	Report	All requirements in scope Conform + non-conform	All applicable checklists ☑ Only ‘citations’ (non-conform)
	Corrective actions	Within 1-6 months	Within 1 month
LAB DIRECTOR QUALIFICATIONS		Clinical biologist (pharmacist) Clinical biologist (MD)	Clinical biologist (pharmacist with PhD) Clinical biologist (MD)
TRAINING & COMPETENCE		Lab’s own training program	6 elements of CLIA + higher frequency
PROFICIENCY TESTING		Acc. to National law and scope(€)	All CAP PT programs scope (€€€)
QA IMPROVEMENT		Internal audits, Risk Analysis, Management Review, feedback	Competence and process control
IMPLEMENTATION			
	Duration	10-12 months	12-18 months after PT participation
	Cost	€€	€€€

Complementary nature and synergistic benefits

Both standards exhibit significant complementarity in core areas such as quality management, equipment calibration, quality control, and documentation. ISO15189 provides a solid foundation in quality management principles, while CAP adds depth in specific practice-oriented areas, notably in personnel competence, proficiency testing, inter-laboratory comparisons, and clinical practice guidelines. The pursuit of dual accreditation forces a critical evaluation of current procedures, enhances the robustness of the quality management system and fosters a culture of continuous improvement and staff involvement in quality initiatives. It increases international recognition (pharma and scientific world) and facilitates regulatory inspections (national, FDA).

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.
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 but also fosters a culture of best practices, quality and continuous development and improvement, ultimately leading to enhanced patient care outcomes.

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