Accreditation Case Study

ViVitro Labs

American Association for Laboratory Accreditation

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Case Study

Imagine you're the president of a testing organization with two separate labs. Each lab has its own quality management system (QMS), is accredited by different accrediting bodies (ABs) in two different languages, and there's a nine-hour time difference between them. Operating these labs separately, yet simultaneously, has led to increased operating costs, double the quality management efforts, and inconsistencies in requirements for each lab.

For three years, this was the case for ViVitro Labs, an organization with one lab in Victoria, British Columbia, and the other in Marseille, France. However, in 2019, Karim Mouneimne, President and General Manager, had a desire to simplify operations, reduce costs, and harmonize the system. This case study will share how ViVitro Labs successfully merged two QMSs and earned ISO/IEC 17025 accreditation from A2LA.

About ViVitro Labs

Founded in 2009, ViVitro Labs offers engineering solutions to assess the functional performance of passive, implantable cardiovascular devices under real, physiological, and accelerated conditions.

Their philosophy is to be a trusted partner to their customers by offering pre-configured test equipment solutions, and modular and versatile components and accessories that meet a wide variety of test applications and requirements throughout development, from research and design to verification and validation.

"We want to empower medical device engineers to become self-sufficient using reliable test methods that fit medical device innovation and research requirements," said Karim Mouneimne, President of ViVitro Labs. "It's important for us to transfer that knowledge to them."

By leveraging their ISO/IEC 17025 accreditation, they increase the reliability of medical device performance testing as well as patient safety at the pre-clinical level. Their extensive experience guides their customers as they navigate the complexity of in-vitro testing. In addition, they are active participants in several ISO and ASTM working groups, remaining on the forefront of innovation and regulation.

A Complex QMS Merger

To successfully merge their two quality management systems into one overarching system, they first had to determine which existing QMS would serve as their model for the new system. By selecting one of the existing systems as a template, the ViVitro team could update, adjust, and streamline the two systems into a single framework that would work for them, without starting from scratch.

"It was a very difficult and complex decision," said Karim. "What really drove the decision was the amount of activity we had in each lab. We had a bigger group in France working on contract testing services, with more equipment, more test procedures, and a broader expertise, so we chose to adapt to the QMS in France."

The team would also have to decide which of the two accrediting bodies to continue working with for its ISO/IEC 17025 accreditation—Cofrac, the accrediting body in France, which accredited the lab in Marseille, or A2LA, one of the largest accrediting bodies in the United States, which accredited the facility in Victoria, B.C. Since there were varying requirements between the accrediting bodies, their choice would also guide them in the creation of their new QMS.

Ultimately, ViVitro Labs decided to continue working with A2LA because of the strong partnership they had built over the years. They also liked the fact that A2LA has a positive reputation and is well-known within the medical device testing industry.

> *"A2LA always takes a collaborative approach throughout the accreditation process," said Farzad Ziaee, ViVitro's Quality Assurance Manager. "If I had one word to describe A2LA staff and assessors I had the opportunity to work with, it would be 'professional.'"*

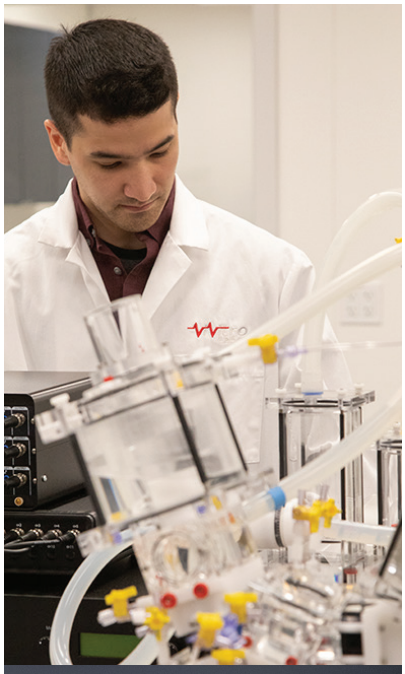
Karim added, "They are very pragmatic. They understand the operational reality of the laboratory environment. They're not just working from pure theory. There's an industrial reality to the people we work with and it's very refreshing."

Process Challenges

Many challenges emerged, some foreseen and others unforeseen, as the team at ViVitro began to merge the two quality management systems. These challenges included adding and removing AB-specific requirements, determining the structure of the QMS, and even translating portions of the French QMS into English.

"One of the main challenges during the merger was removing Cofrac specific requirements from our quality management system, including procedures and forms, and aligning it with A2LA requirements," said Farzad. "There was a huge documentation clean up that had to happen."

In addition, changes had to be made to the system's structure. The QMS for the lab in Marseille was originally structured to meet the requirements of ISO 13485, the standard for quality management systems for the medical device industry. It had since been updated to meet the requirements of ISO/IEC 17025 for mechanical testing, but many aspects of the system were inherited from former versions.



"During this process, we did not abandon the teachings of Cofrac and ISO 13485," said Karim. "On the contrary, this expertise was integrated into all our operating procedures which helped us build a unique QMS specially adapted to meet the needs of our customers."

Moreover, because the quality management system for the lab in Marseille was written in French, the team also had to take the time to translate portions of the system into English. Considering the technical language often used in laboratory management principles, it was a new challenge for the team to undertake.

Around the time of the merger and assessments, the ViVitro quality assurance manager, Farzad, had recently joined the team. Farzad worked diligently to quickly get up to speed, becoming familiar with A2LA policy, the customer portal, and the entire assessment process.

> *"The A2LA accreditation officer was very responsive and supportive, which helped a lot throughout this process," said Farzad. "Our assessor was fantastic in terms of being patient, professional and super knowledgeable, which made the assessment process smooth."*

Despite the challenges, the team at ViVitro Laboratories successfully merged the two QMSs and each laboratory had a renewal assessment with A2LA in March of 2023 to maintain their ISO/IEC 17025 accreditation. The laboratories were assessed by the same assessor, just a few weeks apart, so that the entire process was timely and efficient.

Benefits of a Shared QMS

The merger allowed ViVitro Laboratories to streamline their operations, leading to significant cost savings and new opportunities for continual improvement, which gave their customers greater confidence in their test results.

"One of the big benefits was operational efficiency," said Karim. "Our two teams now work off the same QMS with one quality manager."

The team soon realized the merger had perfectly positioned them to conduct high-level interlaboratory studies between the Marseille and Victoria labs. The results of those studies allowed ViVitro Labs to improve the quality of their tests in both locations and to share their newfound knowledge with their customers.

"Interlaboratory studies represent the highest level of test method validation," said Farzad. "They allow us to identify biases and variations that may not be evident in a single-lab method validation or intra-laboratory studies."

ViVitro has conducted two interlaboratory studies thus far on their two primary test methods: particulate matter evaluation and hydrodynamic pulsatile flow testing. Their findings allowed them to find several areas for improvement and reinforce their test method validation process. Next, they will conduct an accelerated wear testing (AWT) study. Through these studies, ViVitro Labs was able to increase their quality and provide more reliable results to their customers.

"Our customers operate in a highly regulated industry. Working with an ISO/IEC 17025 accredited testing partner ensures them that they are working with a company that has the expertise to manage their testing properly and reduce risk," said Karim.

About A2LA

A2LA's ISO/IEC 17025 Mechanical Testing Program relates to tests, measurements, and evaluation of physical properties of materials, components, and assemblies across a wide variety of industries and projects.

As one of the largest accreditation bodies in the world, A2LA is recognized by international, domestic, and industry groups, including the International Laboratory Accreditation Program, the Asia Pacific Accreditation Cooperation, NIST, and more. Our accreditation programs are internationally recognized and based on globally accepted criteria.

A2LA's mission is to embody the highest integrity and expertise to create trust, safety, and quality throughout the world. To learn more about A2LA's accreditation services, visit www.A2LA.org or contact us at info@A2LA.org.