



Why lab certification/accreditation matters; Are you a THV native or a foreigner in a strange land, and the value of using raw data - all in this issue of ViVitro Labs' VNews



Your Source for Cardiovascular Device Testing News

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ViVitro News

Upcoming Conferences

MD&M West - February 13-16 2012; Anaheim, California
(Visit us at Booth #933)

A New Online Community for Cardiovascular Device

Welcome to the Winter 2012 Edition of the VNews

We're making news. Since this newsletter is being published directly after our recent accreditation to ISO/IEC 17025:2005 by the American Association for Laboratory Accreditation (A2LA) to perform Laboratory Testing in accordance with ISO 5840 Cardiovascular Implants - Cardiac Valve Prostheses Annex L and M, we think of this as the "certification edition". We admit that it took a lot of preparation and painstaking attention to detail to achieve the accreditation, but it was worth it. We believe in providing laboratory services that meet the highest quality of standards and regulatory requirements for heart valve testing so that our clients are assured that their cardiovascular devices are being tested by the best. This accreditation from A2LA confirms our commitment to our laboratory services, our clients, and to the industry.

The news of our accreditation was featured in several online industry publications, but if you missed it and

Professionals

Ask questions, offer answers, and discuss the latest trends in testing heart valves, LVADs, TAHs, stents, and other cardiovascular devices. Guess less, do more at:

**Cardiovascular
Device Testing Forum**



Cardiovascular Device Testing Tips and Tricks

Tip: Data acquisition software should always provide raw data files for accurate validation. Check your ViVITro manual or contact us for the raw data file designation for all our software products.

Trick: Use patient specific models to simulate the most challenging diseased conditions. CT scans can be used to build accurate models to demonstrate and assess performance.

would like to read the press release, please [click here](#).

Still getting around. We're fortunate to have clients and community members in 39 countries around the globe but it's not always easy to spend as much time with each group as we would like. That's one of the reasons that we look forward to conferences and tradeshows. If you're attending **MD&M West February 13-16, 2012 in Anaheim, California**, why not contact us to set up a time to meet or simply drop by our tradeshow booth to have a chat and give our equipment a test run?

We're on Google+. How about you? We've added another network to our online social sphere and look forward to connecting with you there. If you're on Google Plus, add us to your industry circles and we'll do the same!

In the News

[Biotronik Opens New Asia Pacific Headquarters in Singapore, BERLIN](#)

[Medtronic Expansion Boosts Santa Ana's Status, Orange County Business Journal, CA 1/14/2012](#)

[SynCardia Nearly Doubles Sales for Second Straight Year in 2011](#)

[FDA: Computational Modeling Could Lead to Big Gains in Device Safety](#)

[FDA Issues Draft Guidance Documents To Facilitate Investigational Medical Device Studies](#)

[St. Jude Medical's Portico Transcatheter Valve Shows Promising Results in Feasibility Study](#)

[FDA approves first artificial aortic heart valve placed without open-heart surgery](#)

[Edwards Receives FDA Approval to Expand U.S. Clinical](#)



ISO/FDA FAQs

ISO5840

Note that ISO 25539 references "simulated use" as a bench/analytical method to determine a device/procedure's ability to access, deploy, and be withdrawn. These considerations recommended for stents would be applicable to a transcatheter heart valve.

FDA

Recommends AWT should continue for 600 million cycles for rigid valves and 200 million cycles for flexible valves. Since there is mention of synthetic, it would be best to justify 400 million or comply with 600 million.



Publications of Interest

[Experimental and numerical flow visualization in patient specific pre operative human](#)

Trial of Transcatheter Valve

Satya's Corner



ViVitro's Director of Laboratory Services, Satyaprakesh Karri, offers his opinion on cardiovascular device testing issues

Experimentalists Always Question Their Results, But Those Who Use an Accredited Lab Never Need Question the Facility

It is a common saying that "experimentalists always question their results, while everyone else might trust them". The reliability of the experimental results is dependent on several factors such as the qualifications of the personnel, training, experimental planning, specifications of the equipment used and application of proper procedures. Apart from these factors, the validation of the equipment used, control tests, and validation of software used becomes critical in obtaining reliable and repeatable results. All of these considerations are well captured with an appropriate accreditation/certification of the laboratory.

If you've ever considered getting third party verification of lab services, or have wanted to use an external lab for services, then you would have asked the question, "Does laboratory certification matter?" ViVitro Labs is well known by regulatory agencies all over the world for providing credible laboratory services, but as the client, you are responsible for demonstrating that the company meets all regulatory requirements. Choosing an external lab that has made the effort to attain certification provides you with the certainty that all regulatory requirements have been met and certified by an accreditation body, ensuring that test methods are appropriate and the test results reliable.

Certification is expected for materials laboratories so why shouldn't it be expected for a fluids laboratory?

airway geometry; Mathias Vermeulen, Cedric Van Holsbeke, Tom Claessens, Jan De Backer, Peter Van Ransbeeck, and Pascal Verdonck (University of Ghent); American Society of Mechanical Engineers (ASME); Proceedings of the ASME 2011 Summer Bioengineering Conference 2011.

Potential Role of Reynolds Number in Resolving Doppler- and Catheter-Based Transvalvular Gradient Discrepancies in Aortic Stenosis; Jonathon C.

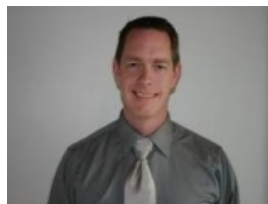
Adams¹, Panupong Jiamsripong¹, Marek Belohlavek¹, Eileen M. McMahon¹, Vidyasagargoud Marupakula¹, Jeff Heys², Hari P. Chaliki¹, ¹Division of Cardiovascular Diseases, Mayo Clinic, Scottsdale, Arizona, ²Montana State University, Bozeman, Montana, USA; The Journal of Heart Valve Disease 2011;20:159-164.



As the first laboratory in the world to be accredited for performing ISO 5840 hydrodynamic, durability and flow visualization assessments for heart valves per the ISO 17025 standard, we agree with those who question why it's only the materials labs that require certification. We do understand the rigors associated with achieving such accreditation. Creating a traceable calibration for each piece of test equipment, creating appropriate procedures, and validating software, all amounted to a challenging and arduous undertaking. We were committed to doing it, however, because it provides additional confidence, as well as repeatability, in the test results. It was not simple to demonstrate a standard test method that can be verified and validated for methods such as flow visualization or durability testing, but it can be done.

So now the question is: Should you not expect all laboratories to meet these standards?

ViVitro Labs is renowned for fluidics testing, so shouldn't our expertise be able to demonstrate our capability for certification? If it's too difficult to demonstrate certainty, repeatability, reproducibility, and reference testing as essential elements of a good validation program, then should you be trusted to conduct these tests? In fact, they are all required elements of the ISO 5840 standard, so they should already be available by audit. Certification does matter. It's how you identify a professional laboratory that is willing to put its validation processes, testing environment and equipment to the test to ensure that when your device is put to the test, there is no question about the validity of the results.



Hot Topic

ViVitro's General Manager, David Mester, discusses current topics in the cardiovascular device arena

Are You a Native or a Foreigner to the Transcatheter Revolution?

Working with clients from all over the world provides unique



Your source for information and emerging trends related to heart valve, stent, LVADs, TAHs, and other cardiovascular device development and testing. We welcome your comments and invite you to contribute items for inclusion in future issues of VNews. Please submit your ideas and news to: info@vivitrolabs.com

insight into the way people view transcatheter heart valve (THV) technology. At ViVITro Labs, we work with regulatory agencies, start-ups, multi-billion dollar corporations, and educational institutions in more than 40 countries around the world. During the course of that work we encounter hundreds of engineers, professors, and researchers, some who are new to the field and others who are seasoned veterans of the industry. I have spent over 20 years testing heart valves and I've noticed there are two different ways that these people view THV technology.

THV native or foreigner, which one are you?

Here's my take on it. People that worked with heart valves prior to transcatheter technology are THV foreigners. Those that have only known heart valves since transcatheter technology are THV natives. It's important to understand which camp you fall into and why it matters to the scope of your work.

The Foreigner

Consider how a THV foreigner would view a surgical valve product development lifecycle or submission. There would be a predictable list of attainable and understood design verification goals that could be vetted out and determined acceptable. This could be done in a relatively short period of time followed by a high expectation for approval followed by clinical results that substantiate the claims. Seems simple, doesn't it? Now consider how this person would view a THV design development and its accompanying submission process. The list for design verification testing would seem unending, some might say even impossible. Uncertainty and doubt would remain as to whether every concern and risk had been investigated. Faced with all that, we can be fairly certain that any cardiovascular device professional who is a THV foreigner would experience many sleepless nights as the clinical trial begins.

The Native

Now let's look at the THV native's point of view. They view the THV product development lifecycle or submission as a predictable list of attainable and understood design

verification goals that can be vetted out and be determined acceptable. Do you see where I'm going with this? Without "history of use" getting in the way, everything seems very achievable, with the acknowledgement that some tests need to be altered for the special features of the THV. They are more accepting of the fact that you can't resolve everything before a clinical trial and have the utmost confidence that their valve will work.

What we have in front of us is a technology leap that has caused an inevitable paradox between experience and confidence. Often, more experience will cause us to be less confident in new technology while high confidence in new technology may be a reflection of less experience.

Natives and foreigners in practice

Our MD community is a prime example of this situation. Surgeons are skeptical that THVs will soon replace surgical solutions, while interventional cardiologists are very optimistic. This is a broad generalization, of course, but you get the idea. There is more to the opposing points of view than meets the eye. Think about what might be informing the attitudes of those who profess that the possibilities of successful THV outcomes are nothing more than irrational exuberance while others are pursuing sutureless surgical valve solutions as an incremental step toward the future.

Why does any of this matter?

Understanding that different approaches and attitudes to THVs are formed by history, experience, ease with new technology, and levels of confidence can only help you to form the best team possible. The best teams are those that understand it takes both confidence to stay motivated and experience to keep perspective to realize the best possible TCV outcomes, both in the lab and in the field.

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