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EXPERT INTERVIEW

Perspectives on Business and Bioanalysis: An interview with Dr. Shane Needham

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Dr. Shane Needham received his B.S. degree in chemistry from Washington State University and his Ph.D. in chemistry from the University of Rhode Island. Dr. Needham is Founder, Owner, and Director of Alturas Analytics, Inc. and Needham Scientific, Inc. in Moscow, ID. Alturas Analytics, Inc. is a leader in the bioanalytical industry and known for their high-level science and problem-solving skills. Needham Scientific, Inc. is a consulting company that solves, analytical and business challenges for clients. Shane has more than 200 publications in the area of LC-MS/MS. Shane is often an invited speaker, expert author, and expert witness for bioanalysis. His laboratory leads in the area of dried blood spot (DBS) analysis, microflow HPLC-MS/MS, and large molecule bioanalysis. Shane was also a wrestling coach, champion bodybuilder, state champion powerlifter, and Ted Talk speaker. Shane has four children and considers them his biggest accomplishment.

Could you broadly summarize your experience in Bioanalysis?
I have been working in bioanalysis since 1993 when I started at Pfizer in Groton, CT using serial number one Sciex API-III. At Pfizer, I performed *in-vivo* and *in-vitro* quantitative and qualitative bioanalysis. I have experience using single and triple quadrupole MS, TOF-MS, and Q-TOF MS. In 2000, I took my experience from Pfizer and founded Alturas Analytics, Inc., where we focused on LC-MS/MS quantitative bioanalysis. My team continues to develop LC-MS/MS and GC-MS/MS assays for small molecules, biomarkers, ADCs, oligonucleotides, and mAbs. My team led the industry in micro-LC-MS/MS since 2010 and led the microsampling revolution including coining the term “dried matrix spot (DMS)” analysis in 2010. I was also involved in the development of integrated ESI-MS LC sources and that field continues to develop. I have more than 200 publications and presentations in the area of MS bioanalysis. I am often an invited speaker, Ted Talk speaker, invited expert author, and editor in the area of bioanalysis.

What challenges and hurdles were encountered during the early days of Alturas Analytics?
The main challenge was what any beginning entrepreneur faces, running the business with low overhead with minimal personnel and hustling for revenue. In the

beginning, I did everything from marketing, sales, quote preparation, sample login, SOP preparation, assay development, assay validation, sample analysis, instrument repair, client contact, etc. A contract cycle would look like, “go get business, get the work done, bill for the project” then “go get more business”. All those functions now have their own team members.

What is the size of the global Bioanalytical services market and who are your key competitors?
The size of the bioanalytical services market was estimated at over $3.3 billion in 2020. As the market defines competitors, we have many “large” and “small” competitors. However, our niche of a 100% founder privately funded and operated CRO with a focus of MS/MS bioanalysis that is “perfect-size” is unique and gives us a competitive edge.

Do you collaborate with your competitors?
We of course have and value the synergies we have with other collaborators.

How important is it for contract labs to have regional bioanalytical labs to support customers across the globe?
Regional contract lab support can be advantageous if the culture, quality and speed of service can be maintained in the organization. The climate, the trust, the collaborative spirit, the enthusiasm can be difficult to maintain in many different locations. With nearly immediate contact through email, text, Zoom and overnight services to anywhere in the world; climate, culture, service and quality are still the main drivers in choosing a CRO.

What are the key drivers and market trends that impact the growth of Bioanalytical services?
As the pharmaceutical and biotech industries continue to develop new therapeutics and therapies to treat disease, more bioanalytical tests will be needed. And as instruments such as LC-MS become more sensitive, accurate and easy to use, the growth of bioanalysis will continue. Biology and chemistry have historically driven analytical measurements to push the boundaries of limits of quantitation, speed and accuracy. The future of bioanalysis will be no different as we want to learn more about biology and chemistry to make therapeutics more efficacious, safe and deliverable. It is why I have always been passionate about analytical chemistry – it is needed in all areas of biology, physics and chemistry – an analytical measurement will always be needed to move research forward.

What is the biggest challenge for widespread adoption of microsampling in clinical trials?
I believe the biggest challenge is that clinical scientists, regulators and others in research are still not accustomed to the technologies. Thus, clinical trial planning, set-up, execution and review will all be different with microsampling. The other three barriers to adoption of new technologies is discussed later on in this article and include; skepticism, operational and regulatory barriers. As with any new technology, more data and more trials will facilitate the acceptance of microsampling.

Microsampling has come to the forefront during the COVID-19 crisis, what is your take on adoption of new and emerging techniques like microsampling in Bioanalysis?
As one of the early adopters and leading experts in the field of microsampling, I fully support the future of microsampling and all technologies that move science forward. In the area of bioanalysis, we have seen this past year the importance of accurate, fast and reliable tests during the COVID pandemic. Microsampling brings the patient more convenient methods for collection of samples and allows for smaller sample sizes. Sample collections can often be performed in the comfort of the home of the patient. All this should reduce

the cost of getting new therapies to patients. And it is another reason I enjoy my work in bioanalysis is we can see the direct impact our research has on the patient!

What advice do you have for entrepreneurs who may be looking forward to starting a new company supporting Bioanalytical services?
My first words are “GO FOR IT”!
I fully support entrepreneurs and the dream of owning your own business. I am living the dream of entrepreneurship and enjoy watching others accomplish the same. And I am just getting started! I invite you to find my Ted Talk on YouTube that shows my entrepreneurial journey.

For any entrepreneur looking to start their own company supporting bioanalytical services, I say contact me! I would be glad to help you and put you on the right track. It is a mission for me to help and inspire others including entrepreneurs. I routinely advise entrepreneurs! Surround yourself with good people as you take the next steps. I have always had great mentors, friends, family and colleagues who I go to for advice and support. I still rely on them to this day. As an entrepreneur, be ready for many struggles and challenges on the path. This will only make you a better person, scientist and entrepreneur and create a better business. Our struggle in life is when we find growth, and this makes for a great entrepreneur.

What are the three biggest challenges to adoption of new technologies and platforms in Bioanalysis?
Three biggest challenges of new technology adoption in order of importance: Skepticism, Operational and Regulatory. Let me explain.

- **Skepticism:** Many people say the biggest challenge is the regulatory hurdles given to us by government agencies such as FDA. I disagree. The biggest challenge is our own scientific mindset. As scientists we are trained, “skeptics”. This is often driven by, “show me the data”, again, again and again. This is okay to a limit. yet we need open minds and a vision to move science forward – to do that requires change, at times big change. Skepticism is also “ego” driven. The mindset of, “If I didn’t invent it, it can’t be good”. Again, as scientists and humans, the healthy way of thinking is “I like this idea, I want to see more…”. Just like in life we need a growth mindset not a fixed mindset.

- **Operational:** As a beta test site for many vendors for nearly 30 years, operational hurdles are difficult to overcome in the bioanalytical workflow. If new technology disrupts the workflow even by minutes, the technology has low chance of adoption. Scientists in the lab want to improve productivity, not decrease productivity. All supplies, add-ons, instruments, sample preparation, data analysis, review, etc., should enhance productivity.

- **Regulatory:** Regulatory hurdles of course exist in our industry. However, I believe these hurdles are driven more by operational hurdles as we mention above. Any new method, technique, software, etc. must be “validated”. Do we validate because the regulators tell us too? No - That is a half-truth. We validate because scientifically we want to have confidence that the results generated by our new development are valid. We validate our techniques, methods and applications, because we are scientists. However, new validation decreases productivity on the front end. Time is needed to validate our systems and techniques. The hope is that on the back end, these methods gain us efficiency and productivity.

How do you see these Altura Analytics evolving and adapting to the needs of its clients in next 5 years?

Accurate mass LC-MS instruments will start to be widely accepted into the quantitative analysis field. Alternative molecular dissociation will facilitate quantitative and qualitative workflows. Instruments will become more user friendly with software and hardware that improve productivity. Our lab will continue to expand paperless systems, virtual audits, instrumentation and software to enhance productivity to give better turn-around times to clients with the same high-quality and service. I do believe that clinical diagnostic testing and therapeutic bioanalysis will start to converge as well, and our team will be ready to respond.

What is your vision for the future of bioanalysis?

The future of bioanalysis is a fascinating subject to me. I believe that personalized medicine will drive the future of bioanalysis. Like blood pressure cuffs, oximeters or glucose monitors, handheld instruments will be available for individuals to test their own targeted biomarkers in real-time. Each instrument could be developed specific to each individual and "upgraded" with more tests as needed. It is possible these instruments could be CE-IMS driven? The production of such instruments will also allow medical providers to test patient's health status bedside. Personalized medicine and bedside monitoring should improve patient outcomes. To support personalized medicine, LC-MS technology will be integrated with the ionization source and the separation being in one device or on a chip.

Could you share some of the most exciting market developments that have happened in your Bioanalytical career?

Looking back over nearly 30 years of my career in bioanalysis, the industry has come a long way! LC-MS in the early 1990's was still "novel" in bioanalysis. Now LC-MS is the way, the majority of bioanalysis is performed. What is interesting are the adjunct technology developments I will discuss; accurate mass measurements, microflow HPLC and ion mobility spectrometry have been around for more than 40 years! I was using Q-TOF for bioanalysis in the mid 1990's while I was at Pfizer, yet dynamic range and routine quantitative analysis were problematic compared to a triple quadrupole. I also used Microflow HPLC-MS in the 1990's. Does anyone remember syringe pumps?! These pumps were wonderfully stable, but that early design would have to refill often in the middle of an analytical run! I was exposed to ion mobility spectrometry (IMS) at Washington State University in 1991 yet it didn't see good utility in bioanalysis until the middle of the 2000's. Now, all three of these technologies can be adequately placed into bioanalytical workflows. These "direct" technology developments improve the speed, selectivity and LLOQ of bioanalysis assays. As an incredible example, of where we were in 1993 for LLOQ was approximately ng/mL levels (10^{-9}) now we are monitoring ag/mL levels (10^{-18})

The remainder of the developments for bioanalysis are what I call "indirect" technology developments. These are developments that take place to improve the bioanalysis workflows – efficiency (do more with less resources) and productivity (do more with less people/instruments). Vendors have done a great job at making labs become more efficient and productive. From laboratory information management systems (LIMS) to electronic lab notebooks (ELN) to software for better data processing of bioanalytical data and custom software to monitor efficiency and productivity metrics, I believe the biggest improvements in bioanalysis have been to improved workflows. The bioanalytical LC-MS measurement platform has moved from unique to a mature standard, which continues to be refined.