

EP.92 - Jeff Boyle

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis, your host for *BioTalk*. And as you know, we introduce and interview regional leaders that are making significant contributions to the BioHealth Capital Region, which is Maryland, DC, and Virginia. And we have one of the newest entrants to the BioHealth Capital Region. They're coming in in a big way, and it's an international company landing in Frederick, Maryland. And we're going to talk with Jeff Boyle, who's the President of Ellume USA. It's a really exciting story for the listeners, and most of you have not heard about this yet, even though you may have read about it in the press. Jeff's going to give you the straight scoop on everything related to what's going on with Ellume, the United States, and the relationship with Australia.

0:01:02 So, Jeff, welcome to BioTalk.

Jeff Boyle: Thanks for having me.

Rich Bendis: We're all excited to hear more, but before we get into the story about Ellume, I think the listeners are going to be more interested to learn about you personally and how you've evolved in your career to get to where you are today.

Jeff Boyle: It wasn't something as planned as most people's careers. You sort of look back and say, "How did I get here?" So I started in Canada, then migrated to Australia, where I finished my studies and got into biotech. Originally, in vaccines, development with a biopharmaceutical company in Australia, and then I joined a spinoff from that company, entered into the diagnostics fray, and really started to build a business with them. And we were acquired by a local company, QIAGEN, and convinced to come across the pond and transfer that tech.

0:02:00 And slowly, over the next decade, built that business up in the US and ended up running a franchise for QIAGEN. And that's where I met Ellume, when we were looking for a partner to help solve a problem in TB diagnostics and came across Sean, and Ellume, and their technology. And now, I've joined Ellume as President.

Rich Bendis:

That's very interesting, Jeff, because what started out as looking for a strategic partnership with a company to meet one of QIAGEN's needs, and for background purposes, QIAGEN was also one of the founding board members of BioHealth Innovation. So we've had a long term relationship with QIAGEN, and it's going to continue with them, but also with you now as an extension of that. But I guess at the end of the day, it was fortuitous for you to identify Ellume in Australia as one of the solutions for QIAGEN technology. And a lot of people don't know about Ellume and their history.

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So if you don't mind, let's talk a little bit about Ellume and their background history, and then also we'll get into what led to the entry into the United States later. But let's talk about the origination of Ellume.

Jeff Boyle:

That was really where I started with them, probably four years ago now, and really started to get the story. And I was hooked, as were many of us at QIAGEN, to see what had started out as Sean Parsons's vision as a clinician in dealing with the last pandemic and realizing a lot of the shortfalls of the approaches that were being taken. And he decided to leave medicine and put on a hat as a designer, developer, entrepreneur and start Ellume to really come up with the tech and solve the underlying problems associated with pandemics. And I think that's really what we have to do. A lot of times, there's tech out there searching for solutions, whereas he's really started with, "What's the problem?"

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And how do we find the technology to solve that?" And as we've just lived through this now, these problems are still evident, unfortunately. So certainly, our tech is there and is going to be a key player as we come out of this one and, with the US government, start to prepare for the next one. And I think when you talk about, "What were the problems and what are the problems that the solutions we have at Ellume solve?" There are a few, and they're pretty key. One is that you're blind without a good diagnostic. You don't know what to do, you don't know where to go. And relying on a public health infrastructure, or even a private infrastructure, to respond to that, as we saw, is just not doable. You need something that's truly scalable that can get out to ordinary people, a technology that has the performance that you would get from a professional use test, but able to be done by an ordinary person.

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So it has to be simple, and it has to be high-performance. That's probably number one that was solved with the at-home testing solution. And problem number two was that information is key. And if you don't know what that test result, and it doesn't get to the right people, it might as well not have been done. So that was the second and really key part to the tech was building that cloud infrastructure that says, "We're going to capture that data, we're going to take it out of the hands of ordinary people to interpret tests, have the test reliable, be able to get that result, and then get it to the right people who can say, 'What are the results? Where are they?' and then enable them to respond in an appropriate manner."

Rich Bendis:

With the development of this technology and test in Australia, how did the US government come to learn about it, and then ultimately end up in some partnership with an Australian company?

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Jeff Boyle:

That really started early on with Sean, again, and his vision around how to get this engagement with governments to be ready. And so, those discussions started a decade ago and continued. And it was really centered around the flu as they developed a flu-based product with the eye that the flu would likely be a pandemic player. They engaged with the FDA to get that approved and to build the right test to get all the right controls, etc., into the test technology, and at the same time, engaging with players like the CDC as well to talk about how best to engage with the US government to get ahead of the next one. And then, the pandemic hit right in the middle of all of that. And so, that was when RADx came and recognized Ellume as a good technology and quite a unique player that really had been at the forefront of this in terms of developing these over-the-counter tests for this purpose.

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But as we had this collaboration with QIAGEN for a high throughput test, and also Ellume have the at-home test, but also a professional use version of the test. So it's one test across three platforms. So RADx really saw this as a good investment in terms of accelerating that development and recognizing that Ellume's vision was really to be a development company focused on innovation, creating great products, and then partnering those out. And with the pandemic, Ellume was thrust upon the world stage in terms of having to take out the burden of becoming a

manufacturer as well. So RADx also provided support there for the manufacturing startup.

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And as those programs went forward, there were some serious commitments made by the Department of Defense to really get this technology transferred over onto the US soil, set up a facility that's able to respond in the future, transfer the tech, get the skills there, and be able to respond.

Rich Bendis:

And so, when you mentioned RADx, a lot of people probably don't know what RADx is. But I guess that's the HHS program for the development of rapid diagnostics. Is that correct?

Jeff Boyle:

Yeah, they had a number of different programs, of which there was point of care, at-home testing as part of that was really to fast-track a lot of this development and the investment needed in manufacturing scale-up for diagnostic players.

Rich Bendis:

And the size of the agreement was pretty sizable with the US government as a first agreement. In the press releases I've read, it was \$231 million, which really gives a company a great amount of money to do it right, I would imagine.

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Jeff Boyle:

It is huge, and it's important because it gives you some certainty around putting your own money in and your own investment to meet that. So absolutely critical in terms of giving us that certainty around coming and establishing a facility.

Rich Bendis:

And then, also, you mentioned the FDA, with what you were doing around the flu test. But I think that Ellume got some emergency use authorization, EUA, as a result of how important it could be related to the COVID-19 pandemic. Could you talk a little bit about your interaction and relationship with the FDA during this process?

Jeff Boyle:

A lot of that was very interactive, positive. At-home testing was seen as a top priority for the FDA. And so, the engagement was very timely, and we were able to get an approval and be the first true over-the-counter test that was approved that really met all of the criteria.

0:10:12 Again, as we've been dealing with them with the flu, there was a good understanding of what the requirements would be to develop such a test, and they had a good understanding of it, so that really helped in terms of the FDA having confidence in the technology.

Rich Bendis: A lot of people, and the listeners, basically understand that the FDA sometimes becomes very bureaucratic, but has been very nimble during the COVID-19 pandemic. So can you explain, from the time that it was identified that you might have an OTC home COVID test and it was introduced to the FDA to look from a regulatory process, how long did it take from the beginning to the end before you got your EUA with the FDA?

Jeff Boyle: I'm not 100% sure on these dates. But it's in the magnitude of months.

0:11:06 So certainly, much faster than what was normal.

Rich Bendis: I think normally, people are accustomed to years. And it was very impressive with the accelerated regulatory approvals that the FDA went through because of the crisis that was happening with the pandemic. It shows that you actually can create a little entrepreneurial spirit within a bureaucratic federal agency sometimes, huh?

Jeff Boyle: That, I think, has been really quite remarkable. I'll say I wouldn't want to have been in the FDA's shoes. From what we understand, they were fairly overwhelmed by the amount of work and were really good at prioritizing and engaging to stay focused and get things done in a timely manner. And also, with HHS and the Department of Defense. I'd say they have also been incredibly nimble. It's been a tough time for everyone.

0:12:03 If a plan survives a day, you probably missed something, or it was a bad plan. But you have to be nimble. So we've been like that, and so have the Department of Defense in terms of being able to adapt to what is a continuously changing environment with incredible challenges that have put everyone, really, into a tough situation.

Rich Bendis: And then, also, I guess, it was probably that \$231 million agreement to set up this operation in the United States somewhere that stimulated the dialog between you and Ellume regarding a position. Maybe talk a little bit about how that evolved with your discussions with Ellume and what decisions led to your taking the President of Ellume USA.

Jeff Boyle: Given the timing that was required, it really helped to have somebody come in who had a history with Ellume and would not take that six-month learning curve to come up to speed with a lot of those things and establish the relationships.

0:13:10 So on that side, I think it was a good fit. And in terms of, then, starting from scratch, it helps to have a background in the area and in IVD to go out and recruit a whole team to start this whole process.

Rich Bendis: So basically, it was a relatively seamless transition because you'd already had a relationship, understood the company, and QIAGEN had a long relationship with Ellume, and the parties knew one another.

Jeff Boyle: For sure. And it also, I think, is something that doesn't compromise our ongoing partnership because it's something that's going to be critical for us in the long term as well, to continue on the work that we had started.

Rich Bendis: And then, also, you brought on another person who's very familiar with our region to assist from a business development standpoint, Dan Mallon. So had you established a relationship with him over the past years as well?

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Jeff Boyle: No. So Dan was really boots on the ground first in terms of a hire. So he came onto Ellume officially before I did, as I had to complete things up and hand over. So Dan was on the ground and really has continued to be a great leader, and as with all startups, he's been able to wear many hats and answer the call as we have to build these things and as we're building out our team now. He's just continued to be a strength. And as you say, he's got a tremendous level of experience in the area dealing with government-based contracts and understanding how to navigate through those.

Rich Bendis: And I think another interesting thing for our listeners--and we're talking with Jeff Boyle, who's the President of Ellume, USA--is that it wasn't immediately determined that Ellume was going to locate in the state of Maryland. I guess that there was a site selection process the company had to go to to decide where the best place to be was to execute and fulfill the agreement that you have with DOD and HHS.

0:15:15 So if you don't mind, could you talk a little bit about the site selection process you went through and how it ultimately ended in Maryland?

Jeff Boyle: It was a US-wide selection process looking at multiple different potential areas. And Maryland really came to the forefront for a number of different reasons. I'd say, when you're looking at where to go, number one is people. That's what makes your business sink or swim. And that's what this area has to offer. It's got a very strong industry and a very strong sector for training and engagement.

0:16:00 It's also very close to government and the key players there in NIH, FDA, Fort Detrick, ideal there, and then in terms of just its general location, close to airports, ports, and the like. So it comes out very favorably there. And then, on the other aspect, it's really around state and local governments and their willingness to engage and support. And we've been very, very happy with how welcoming and supportive both Frederick County and the Maryland state government have been in terms of providing incentives as well as helping wherever they can at the county level, in terms of getting these permits and the like that you need in order to get buildings up from ground zero to operations in a timely manner.

0:17:00 So it's been a great thing. And Maryland state, really great engagement. Also very supportive of seeing some of their work in terms of working with our allies in Australia and getting tech transfer into the state, which was obviously an objective that they've had for quite some time, and then creating jobs for the state and providing incentives that scale with the jobs as we build that within the state.

Rich Bendis: Yeah, I think that the specifications for this site location were pretty dynamic. They were large and had some very specific uses of the facility as well as the amount of people that you were going to involve. So can you talk a little bit about what the site is going to do and how many people are going to be required to fulfill all the obligations of the agreement?

Jeff Boyle: So I'd say we have a couple main targets. One is that we have to build something that makes sense as a business, as an ongoing entity that is sustainable, and that's been very much at the forefront with the

government around this, as they don't want to just build a big white elephant that never gets used.

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So it has to fit within our business, and our ongoing test development, and our ongoing core business is there to sustain it. And so, in terms of how we're looking at staffing this, we're going to have one aspect of the facility, there'll be two buildings, one building in which we have a capacity that is there to meet the demands of an ongoing business for the foreseeable future, probably three to five years, as we build the core business, and that will suffice. And the challenge for us, then, is to have the second building, which is really going to house even more automation, that can go and ultimately deliver half a million tests per day to meet the demands, really, of the next pandemic as it comes.

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And so, our challenge in terms of staffing is, we'll have a core staff, and then we're going to need to staff it more than normal, but enough that you can scale rapidly, so you have the skills there that are able to keep that facility validated and in a state that's ready at any point in time to be switched into full operation, and we have the skills that can then go from normal operations of one shift per day, five days a week to 24/7 pandemic response, get those machines running constantly. So you need that core capability to expand rapidly on the skill side as well as the equipment side.

Rich Bendis:

From what my understanding is, Jeff, it's almost 200,000 square feet for the two buildings, but it's going to be what I'd classify a totally integrated operation that would have manufacturing, R&D, sales, distribution, and all functions you would need to have a totally independent business in one location in the United States.

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Is that true?

Jeff Boyle:

I'd say initially, we're going to focus on manufacturing, so its core function will be as a manufacturing site. And then, obviously, all of the support functions that go with that in terms of your HR, IT, finance. Sales and marketing, I think the market has shown that those don't necessarily have to be colocated. They'll go where they need to be. But at its core, we will be a manufacturing facility, and as you said, fully integrated. The idea is that we are not just reliant on a facility for the final assembly, it's a fully integrated supply chain. That's the end goal, that we go right

through the entire process and are able to supply the US with its capacity without reliance on an international supply chain. And other functions as we build down the track, things like R&D, we can look at those types of activities and where to position those.

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Rich Bendis: So I guess the key will be, and listeners will be interested, is, as you ramp up, when do you believe the site will be, first, operational, and when does the recruitment process begin to hire the people for that first operation, and how many people will be in the first tranche?

Jeff Boyle: We've been recruiting already, and there are certain roles that are tougher. And particularly, with the pandemic, we have challenges around skill sharing and training. You can't just hop on a plane and go anywhere these days. So particularly, as Australia is really managing its borders quite strictly, it's quite difficult. And so, some things, we're having to recruit much earlier to provide that timing to get the training across.

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The start of our site validation's in October. We're considerably delayed, as are many groups we've seen. As everyone comes out of the pandemic, there has been an absolute building boom, which has actually forced us to redesign completely mid-project, really taking into consideration what we can get our hands on in terms of material. And so, we've had to be very nimble on all of these approaches.

Rich Bendis: I guess it's a challenge because you've got a solution to the pandemic, but at the same time, you're encountering some of the problems that the pandemic is creating for people around the world. So it's a double management challenge for you, I would imagine.

Jeff Boyle: Yes, absolutely. And it's going to continue at least through the next winter, and we really have to continue to be nimble and understand that the disrupted supply chains and global disruption are just going to be normal for the foreseeable future.

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Rich Bendis: Well, the big topic right now is the delta variant. And when the test was developed, the delta variant didn't exist. But how does the test perform against the new variant?

Jeff Boyle: So variant testing is something that obviously is front and center with the FDA and the RADx program. So we've been engaged with them and following along to make sure that we understand the performance as we go. So the delta variant testing is set to be undertaken shortly, and then we can report that out in due course. But so far, in terms of what we're seeing in the market and our ability to monitor results coming in, we're not seeing anything that's alarming us.

Rich Bendis: Great, that's good news.

0:24:01 One of the things that I'm very interested in, since we've been trying to increase the profile of this BioHealth Capital Region--as you know, we're ranking fourth right now within the top biopharma clusters, want to get to number 23 by 2023--and at the end of the day, your selection of this as the site, I think, is a very important indicator of the visibility and the growth within this region. Also, I think your knowledge of what's going on in this region and Dan's knowledge of this region hopefully played a role in the site selection process because you understand what assets and resources there were to work with. So if you could sort of talk in the closing here a little bit about why this region is right for this decision right now and for the growth of the company, and how you plan to get more engaged within this BioHealth Capital Region for Ellume USA.

Jeff Boyle: I think it's, as we were sort of going through before, all the benefits of this area.

0:25:01 It really has quite a lot of firepower is what you would say in this region, across all of the aspects that are needed in order to form a comprehensive response to pandemics. And I think it's really great to see all of the organizations that have been so proactive in building it, like BioHealth Innovations really getting engaged here to bring all the parties together. And we want Ellume to have a seat at that table as we engage with the other partners in the area and government to help navigate through the planning process to really get in front of the next one and make sure that we have, from Ellume's side, a good diagnostics program in place that is there and able to respond in a way that makes the next pandemic nothing like this one has been.

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Rich Bendis: I sort of gave you a softball there because we are very proud to have you join the BioHealth Innovation board, which is nice, and our next board meeting will be in September, so you have a little time to get oriented a little bit more before we get you engaged in BHI board activities. But we think that you'll bring a different perspective to our board than what we've had in the past, even though we've had global companies sit on the board. But none of them that have really had to go through this major decision process, the crisis management, and the pandemic and everything as Ellume USA is going through right now. So we're excited to have you join the board, Jeff, and we also think it's going to be a very good interaction with some of the other peers, some of which you may know, and some you may not know, at the board level.

Jeff Boyle: Very much looking forward to it. And I think one of the things I've really found quite heartening has been the industry response during this pandemic, and how I think everybody sort of understood we're all in it and all in the same boat, trying to do our best to respond.

0:27:05 We're all human beings at the end, as well, and understanding how important it is what we all do. And so, I think it's a great collaborative environment that we have. And I'm really looking forward to working with the partners to not just respond to the future pandemics, but also ongoing improving healthcare.

Rich Bendis: In closing, Jeff, I'm going to give you a little open mic if you have any last words you'd like to share with the listeners, and if anybody wants to get more information about Ellume USA, or if you need any additional exposure in your recruitment efforts, we'd be glad to help you make some of those needs aware to the people in the community. But do you have any closing comments you'd like to share with the listeners at this time?

Jeff Boyle: No, just really looking forward to it. It's been a great pleasure so far dealing with everyone. Looking forward to becoming a long term player in the region and hitting our goals.

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Rich Bendis: Great. Well, thank you very much. This has been a very interesting and educational BioTalk podcast with Jeff Boyle, President of Ellume USA. I think what we'll do, Jeff, is, if you don't mind, we'll try to come back in six

months, after you're fully operational, and then you can give everybody an update on how everything's progressed here. And I'm not going to say three months in October. Let's get beyond October. Let's get the first quarter of operation once you're operating, and then come back and talk about the successes.

Jeff Boyle: I look forward to that day myself.

Rich Bendis: Well, good luck to you, and if there's anything we can do to help you, please let us know.

Jeff Boyle: Terrific. All right. Thank you.

Narrator: Thanks for listening to *BioTalk* with Rich Bendis.

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