EP.103 - Ron Piervincenzi Returns

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: Welcome to another edition of *BioTalk*. I'm Rich Bendis, CEO of BioHealth Innovation and your host. We haven't done this much, but we have a repeat performer today. The reason for that is, there's a lot going on in the BioHealth Capital Region, and one of our leading organizations in this region is also engaged in a lot of new activities, which we're going to talk about. Also, more importantly, US Pharmacopeia and Dr. Ron Piervincenzi, as CEO, has become a new board member of BioHealth Innovation in the past year in 2021 with Tony Lakavage, one of its senior VPs, serving on the BHI board. We have a much closer relationship and understanding of each other today than we did a year ago, so we have a lot to talk about. Ron, welcome to *BioTalk* again.

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Ron Piervincenzi: Thank you, Rich. It's a pleasure. And you're right, we've really made quite a journey since that discussion we had a year ago, and I daresay the discussion played a part in that.

Rich Bendis: Yeah, I think it did because I thought we said, at the end of that discussion, that we needed to talk a little bit more deeply about the ways we could work together. And guess what? We are. At the end of this, one of the topics we're going to talk about is a way we can partner on some events together, and we'll be talking to the audience. Not telling the audience about that now, we'll keep them engaged for the next 30 minutes, so they'll stay until the end to know what those events are going to be.

Ron Piervincenzi: I think it's great, Rich. And something about BioHealth Innovation, we all hear this same thing all the time. "Oh, we'll catch up, we'll figure out these ways to work together," and most of the time, nothing happens. Not the case here. I think that actually bodes really well for not just BioHealth, but the region itself.

Rich Bendis: Well, thank you very much. It really takes active participants, it takes two to tango, as they say, and I think we found a way that we can dance together.

0:02:03 Let's start. There are probably numerous listeners who were not involved in listening to our first *BioTalk* a year ago. Ron, if you don't mind, do a brief introduction of yourself and your background so everybody understands how you got to become the CEO of USP.

Ron Piervincenzi: Yeah, happy to. I daresay I hope that most listeners have been busy enough the last year that they haven't been trying to remember my backstory. [Laugh] My training is in biomedical engineering. I got my PhD at Duke in protein engineering, so I'd always been fascinating with the crossover between science and production engineering. But upon completion of my PhD, I made a bit of a turn and decided to work in the healthcare space, but through management consulting at McKinsey and Company, based in New Jersey. I was based in New Jersey. I ended up there a long time through election to partner, working in R&D across biotech and pharma globally. Probably half my work was outside the US and about half was inside.

0:03:01 Through that work, not only did I learn quite a bit, but I also learned to appreciate the nuances of the pharmaceutical industry, but also some of its shortcomings. I craved something different. After McKinsey, I worked at Biogen for a while up in Boston, but then soon found my dream opportunity at USP, working at a nonprofit organization dedicated right within science and health, right at that same cusp, but looking at the entirety of the industry from a different perspective. That brought me back down to the DC area. I had started my science career working in the Naval Research Lab in DC. That was even before graduate school. Then, even back here, where USP sits in between government, industry, and practitioners, in our region, that's not actually that unusual. But in most of the world, it's a pretty unusual spot to sit in.

Rich Bendis: Yeah, I think we're fortunate in the BioHealth Capital Region that we basically have all of those players, including academia, which is very rich as well, right in our backyard.

0:04:00 Rather than having to get on planes or trains, we basically get in a car and drive to go see somebody rather than having to make that journey across

the country, which people in Boston or San Francisco would have to do to interact. We do have a distinct advantage in our region. And it's nice to have you with your global headquarters headquartered here right off of Rockville Pike an Twinbrook.

Ron Piervincenzi: I can tell you the very short version of our story. USP turned 202 three weeks ago, as of our recording. Our story began in 1820, 11 physicians got together to try to solve the problem of poor-quality medicine in the US at the time. A lot of it was being dumped on our shores from Europe, especially the UK. The problem here in the US was, we had no system at all, and everybody was making medicine differently, buying it from abroad with no way to set an expectation of what it should look like. Long story short, these physicians came together, decided we should create our own standard in the US. It was a new country, and the notion of a national pharmacopeia was actually the first in the world.

0:05:00 They created essentially a recipe book, if we're honest about what we were in 1820. But it has evolved quite a bit in the 200 years since then. As an organization, USP was based in New York. It was volunteer-based. But the headquarters was an actual physical location on Park Avenue in New York. I only wish we'd kept the real estate. [Laugh] But in any case, made the right decision in the 1950s to move down to Bethesda for a short time, and then Rockville, located right down the street from what was the FDA headquarters. It was an obvious move, the right decision to make, and we've been thriving ever since, about 65 years or so, in Montgomery County for USP.

Rich Bendis: Let's talk a little more background there. How many employees, how many different countries you serve, the nature of this volunteer organization, how far it reaches.

Ron Piervincenzi: When USP moved down to the region, we had two employees. We had a CEO and, I think, an assistant. We have grown, that's for sure. We have about 1,300 staff today, most of whom, literally more than half, about 800 or so, are based in the US between Frederick, Maryland and then mostly in Rockville, right near Twinbrook Metro Station.

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Rich Bendis: That's fantastic growth. I don't know of many organizations within our region that have had two to 1,300 in their growth path. I know some of

these people are located outside the US as well because you have several global operations centers, don't you?

Ron Piervincenzi: Yeah, that's right. And I think another reason it's helpful to be based in such a global hub, take a step back from health for a moment, DC is a global hub, and that really helps us because we do have offices in about 14 or 15 countries now. The ability to have a headquarters for such a complex operation in a top world metro center is all the difference and has been really helpful.

Rich Bendis: And then, when you talk about standards, I go into my CVS and get supplements or something, and I'll see a USP logo on there. I never knew what it meant until I had a chance to meet you or get organized. But talk a little bit about the wide range of standards that USP is involved in and the different types of products you engage with.

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Ron Piervincenzi: I'll share with you the scope, and then I'll give you one example, a very specific but ordinary one, to make it feel more real. The scope for USP is quite broad. It's all medicines. We also play roles in dietary supplements and foods. It's very, very broad. And by medicine, I mean that in the broadest sense. Everything from small-molecule pills to complex biologics, vaccines. The role is formal in multiple ways. First, it's formal in that it's written into US law. When the FDA was created 100 years ago, that same statute, and a few others that have followed up since, wrote in that the FDA is to enforce on multiple things, but medicine quality, they are to use the USP as the basis. That's sort of at the heart of it. That was already about halfway through our timeline, about 100 years in. Since that time, of course, that means we're very closely partnered with the FDA across all these areas. To make it feel a little less mysterious, in the early days, I mentioned, USP was a recipe book.

0:08:03 It was how to create tincture of opium, three parts of this, couple parts of that, put it in water, mix it up. A little more sophisticated than that, but more or less. Today, it's not that. It's not a recipe book at all, it's actually a set of analytical tools to measure what you have to ensure that it is what it's supposed to be, that it doesn't contain impurities, it will dissolve, which we call perform, in the way it should when ingested, or that it has sterility, let's say, if it's an injectable. It's an analytical set of

procedures that just says it's what you think. As a consumer, if you were buying a sweater, you would test these things yourself. Does it feel solid? Do the colors look bright? All the things you could do that you cannot do with a generic medicine. You pick it up, and you don't know. All you know is what the label says, and you have no way to test it. But that's what our standards do. They do all that work so that you can, by the enforcement of those standards through, in the US, US FDA, and regulators in other countries, use them.

0:09:00 Ultimately, with the exception of dietary supplements that you can see on the shelf in the drug store, the patient doesn't really have to worry about that. That's the only way our system can really operate.

Rich Bendis: You're using a term now, as you've migrated, of analytical tools. I would imagine when you look at analytical tools, the profile of a typical worker or employee of USP might have been changed and migrated, based on all of the different forms of analysis available today, machine learning, quantum computing, and all the other things you have in the information technology world to help you do this analysis.

Ron Piervincenzi: Yeah, that's insightful. And actually, it has a secondary effect. The same is true for the industry. And by the industry, we mean drug manufacturers. In the earliest days, we were really talking about pharmacists and physicians. In the earliest days, it was really physicians. But even then, bridging to today, the level of specialization is incredible. Our laboratories both here and in our site in Hyderabad, India are stocked with every kind of analytical equipment you could imagine and very specific tests.

0:10:12 But I will mention that it's easy to just take the most expensive, new equipment and try to do all your work, but it would be very ineffective for a standards-setting organization to create such expensive barriers to medicine production. What we actually do is, we try to figure out what the most effective standards are to create, which involve the tools that you need. Sometimes, like work in Heparin, for example, where there's a high risk of serious adulteration that is only detectable through very expensive NMR instrumentation, then you have to do it. You have no choice. But the vast majority of the time, you can use much less expensive and less technically complex tools so that manufacturers can use it all around the world at a much more reasonable cost and make

medicine more available. It's a balance of usefulness as well as practicality. I guess as everything is, to some degree, in the world.

0:11:00 But therefore, our labs literally have everything because we have to have everything from the simplest to the most complex in order to create the standards for others to use.

Rich Bendis: Another element, since you're a global organization, you probably have a chance to monitor what's going on in the pandemic based on all the different countries where your workers are. How has the COVID-19 pandemic impacted the effectiveness of USP and your workforce?

Ron Piervincenzi: Even about a month before COVID was declared a pandemic, because we have a substantial operation in China, our staff were already living it. As a set of executives in the US, it was a real benefit for us. We were helping our staff, we were actually sending masks and other equipment from the US to our team in China, and we were learning about COVID. We were much less surprised, not because we're brilliant and genius, but we were living it with our colleagues in Shanghai and China. That gave us a little bit of an advantage, literally weeks.

0:12:02 But we said, "OK, this is what's probably going to come our way. Here are some of the things we should be thinking about, how to have our staff be remote, thinking about their safety, keeping our labs operational, ensuring we can ship our standards around the world." We ship 800,000 individual reference standards a year around the world to literally thousands of manufacturers to help them in their analytical tools. We cannot stop. In a pandemic, you don't want to stop the supply of medicine. But finally, the third one is, once we could ensure the safety and continuing operations, then it was, "What do we do to help fight this pandemic? How do we join the fight?" That really defined the first part of 2020, creating that work. The last thing I can share is, our staff and volunteers, which are our non-paid scientific experts who work on all our expert committees to set our standards, felt much more empowered by that. I actually felt for people who were suffering from this and had no active role to fight it because I would imagine it's even more disorienting.

0:13:02 Because all the BioHealth companies in the region had some role to play, and I think that helped with morale and everything else, which was not a small factor in being successful in our work the last couple years.

Rich Bendis: Probably, there are a few people in DC who could've listened to you early in the pandemic and learned something that could've been applied much sooner if people were in a listening mode.

Ron Piervincenzi: I don't think we knew all the answers, but we definitely were not kidding ourselves that we were going to escape it for any particular reason.

Rich Bendis: I'm sure. One of the things that happens in the pharmaceutical and biomedical area is that innovation is key for all of the major pharmaceutical firms, biotechnology firms, all of the firms producing products, to really look at applying the most current innovation they can in all of their processes. How does USP and your standards engage in this innovation world? How do you keep track and up to date on everything that's occurring from an innovative standpoint?

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Ron Piervincenzi: There are two completely different kinds of innovation here, and I'll describe both. On one hand, it's literally changes in how things are done. Think about new ways to make vaccines through mRNA technology, an example we all know now. That's one kind of innovation. Another kind of innovation is, let's say, how you produce the medicine, for example. We talked about new analytical methods, maybe things that are less transparent to a patient. How the medicine's being produced, how its quality's being monitored, how the supply chain is being run, that sort of innovation. We, at USP, until recently, have, I think, underestimated the role of our standards in the first kind of innovation, the one that most patients think of, a new way to treat disease. I'll just share a very brief anecdote that was about two years ago. I was presenting at Harvard for a health forum. After the meeting, these two young men in their mid-20s–they weren't particularly young until I found out what they were doing, then they seemed young to me–approached me and said how they were essentially creating a startup company, and they wanted to talk to me because USP was the only thing they had of certainty in their entire world.

0:15:14 They described their work, and they had this very ambitious idea to fight ALS, which, having worked at Biogen, I know how desperately important but difficult that space is. But innovation can happen, so I rooted for them. They shared how everything was uncertain. How they'd get their

drug manufactured, how they'd get their clinical trials running, who would fund them. Everything was unknown except one thing. They said, "We have our USP book, we open it up, we know exactly how we'll test it, we know exactly how to control sterility." Two years later, they had a positive feedback from the FDA. They're starting their phase 3 trial, and it looks pretty exciting. They're coming to speak to our staff. We learned a lot from that moment because we didn't think typically of this kind of cutting-edge innovation in the role we play because we think of ourselves more in the mass production of medicines, at-scale, thousands of generic molecules, hundreds of millions of doses.

0:16:05 But my point is that standards reduce uncertainty, which can be really helpful in an uncertain world where there's disruption, when you have high risks in areas like innovation. That realization, to us, has shifted our focus as to who we should be talking to and sharing what we have because unfortunately, some of the leading innovators are less likely to be aware of USP because mostly, we're being used by the larger companies. That was the first kind of innovation. The second one is more obvious. If there are new analytical tools, there's exciting new work going on, advanced manufacturing techniques that we hear about maybe to create some supply chain resilience in our country, there are regulatory barriers. Not because the regulator, say, the FDA, wants to slow it down. But rather, it's uncertain. We don't know how we'll use those new tools, if they'll be the same as the old tools. Many companies don't want to be first. They want to wait.

0:17:02 What can really help is when a standards organization gets out in front of a new technology, creates more certainty, reduces the barrier to entry, and they can come into the new technology sooner, and those new technologies are often a result of higher quality, lower cost, all the good things we want to see. Two kinds of innovation, two different approaches. But the realization that a 202-year-old standards-setting organization can help bring forward innovation faster is kind of a novel-sounding idea, but one that we're really excited about.

Rich Bendis: In your description there, some of the innovation you talked about was supply chain. Based on the challenging times we've had over the last couple years, how resilient has our supply chain been in those areas in which you're focused?

Ron Piervincenzi: I think there are actually two answers to this. On the one hand, it has been quite resilient. The second part of the answer is that there are chronic problems that didn't particularly suffer during the pandemic, but haven't also been resolved. It's neither in good shape, nor did it break down.

0:18:01 I think what I mean is that the majority of the supply chain is pretty resilient and impressive. However, because patients don't take the majority of medicines–there are thousands of them, you don't take a thousand medicines, you take two or three, and maybe one is your life-saving medication. If that's in trouble, it doesn't actually help you that the rest of the medicines are resilient. This is why, unlike used cars, a disruption in the supply chain is unacceptable. A little disruption is still unacceptable. It's what makes it so difficult. With that said, I participated in the National Council of Pharmaceutical Organizations, NCPO, which is a 103-year-old gathering of CEOs of all the leading pharmacy and pharmaceutical organizations. Small group, just 15 or so. And supply chain resilience was on, I think, all but one or two of the members' top-three lists for the year, including USP. It means different things to different people. If you're a distributor, pharmaceutical company, or USP, you're defining a different portion for your relevance, but we all mean the same, that the patient can get the medicine they need when they need it.

0:19:04 What are we doing about it? We decided to take a very multi-pronged approach, including a few things that were brand new. Starting two years ago, when the supply crunch occurred because of demand spikes mostly, but also exacerbated by flight cancellations, we were aware there were problems, and there was a threat of much worse. I was actually really pleased to see mitigations work, not because the danger was exaggerated, but because people took the right action. It was a success in making sure we got through it, but it was a little tight. A little too close for comfort. Starting at that moment, we've invested quite a few million dollars to create what I believe is the first ever global medicine supply map. It's a digital asset, quite complex, actually. Over a dozen data sources, some public, some private, that have all been combined, interlinked, and it's searchable. We call it the medicine supply map.

0:20:00 What it does is let you search down between API and finished dose, right down to the address, all around the world. This is for medicines bound to the US, but of course, it's a global map for medicines that are approved in the US so we can start asking the question, "What would happen if there was a hurricane in the Caribbean? Let's say Puerto Rico were to go offline. What if China and the US got into a trade war? What would happen if there were floods in India? Fires in the Western US?" By the way, all these things have happened, so they aren't theoretical. We actually have tested a few already. On top of that, the secondary piece is that the US government is working to think about how we create resilience from the bottom up, in a sense, how to create more manufacturing capacity, more agile manufacturing. Our focus at the USP is on advanced manufacturing, and this is one of those innovations. A technology innovation that we're working to build standards to help adoption happen more quickly. And this is actually relevant for the region. We partnered up in Richmond, just down the 95, of course, with a flow corporation, a for-the-public corporation. It's basically a not-for-profit.

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Rich Bendis: For-the-public-good.

Ron Piervincenzi: That's right. And they're working under a grant from BARDA to create these essential medicines through continuous and advanced manufacturing. We've partnered to create our own lab, USP lab, USP staff, on-site, it's at the University of Richmond facility and campus, where we're going to work alongside on the analytical methods for these, then use that knowledge to write the standards that will enable that kind of advanced manufacturing to be spread across so many more companies. We're really excited and really serious about this. It's not talk for us, it's real investment. And we're taking some risks from a financial perspective because we believe this is really serious.

Rich Bendis: That's very interesting, as you have to look at all the innovation going on in the industry, which you're monitoring and setting standards for, you're having to go through a reinvention and re-innovation process for USP to stay with industry as well as to try to get ahead of it in certain areas, like supply chain resiliency.

0:22:03 Congratulations to that for being innovative and incorporating other players within the BioHealth Capital Region to be in the forefront of new pioneering innovation, which will benefit everybody.

Ron Piervincenzi: That's what gets me up every day, that change. I don't see it as a threat, I see that as sort of a driving motivation.

Rich Bendis: It's an opportunity, right?

Ron Piervincenzi: It's an opportunity. And this is what's a little bit unique, as a pharmacopeia, we do have to innovate, but we have an obligation to maintain. Like a library, you're always looking to add new books, but you don't throw away the older books every year. We have thousands of standards of old medicines like aspirin. Aspirin's important, the standards have to be available, and they require updates over time. My point being that it accumulates, and it takes quite a lot of work to maintain and keep current all of your information you have. It's a challenge that I really embrace, I'm proud that we're able to do it, but it's one that takes a different approach than I'm used to in the private sector, where you're much more likely to have your new set of products, you phase out your old products to do the new, and that's not an option for us at the USP.

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Rich Bendis: We're speaking with Dr. Ron Piervincenzi, who's the CEO of US Pharmacopeia. You've been talking about change and innovation, but there are a lot of paradigm shifts occurring within qualities and standards. And there have been a number of things that we had a chance to identify getting ready for this *BioTalk*, and I'd like to do something new with you that I haven't done with other people, but I want to do a rapid-fire around these paradigm shifts with you. And I know that might be difficult for you, Ron, because you really like to go into detail to explain everything that we're talking about, but I'm going to test you on how rapid-fire you can be on these six different points

Ron Piervincenzi: It's the elevator test, right?

Rich Bendis: Yeah, it's the elevator test. Let's talk about the shift from US market to global environment to start with.

Ron Piervincenzi: I think we've woken up and will never go back to sleep on this front. People have realized that you can't only think about your country because your components, the pieces and parts of your medicine, are coming from all over.

0:24:08 Why is it an innovation? It's more of an innovation than people are realizing that it happened because it's been true for some time, but there's strength in that diversity, too. There are risks, but there's strength in it. We actually lean into it to say some of that diversity is really helpful and helps us build resilience.

Rich Bendis: Recognizing that in the supply chain and how vulnerable you are is something that's been real over the last two years, for sure. Second, compliance-driven to integrated risk-based approaches.

Ron Piervincenzi: A lot of words there. What it basically means is the world isn't so simple, and most medicines are not either. When you get to your less-simple medicines, you don't have a green light, red light. It's not so simple. Risk-based approaches means, I could test every single product that comes off the line, but no one would get medicine because if it was all tested, you destroy it in testing, nobody can take the medicine. How much do we test, in what ways, at what points in time? Not only do you make those decisions, but in a risk-based approach, you make them, and you automatically change based on what you learn.

0:25:07 The more problems you find, the more testing or changes are required, and the less you find, the more quickly you can keep moving. That's all it means. It sounds obvious and logical, but from a regulatory and compliance standpoint, people have traditionally preferred simple, binary, "I do this, then it's OK." Risk-based approaches take more thinking more tracking, and more analysis. It's better, but it is proving to take longer to make the conversion in the medical industry as opposed to other consumer goods, auto manufacturing, airlines, which have all made this transition faster.

Rich Bendis: The next one is something we've talked about briefly, and that's traditional manufacturing to new manufacturing approaches, like advanced manufacturing and some of the programs you're involved in.

Ron Piervincenzi: The basics is that the new manufacturing techniques have advantages both in cost and quality for many uses. And I'd just be clear, not for all.

Sometimes, the old version of manufacturing, which is batch manufacturing, is wonderfully effective.

0:26:03 But within it, there are new technologies. I wanted to separate because some people just assume it's the entire thing or not, but there's a lot of nuance in between, and there are more advanced, analytical methods within the older method, within the older institutions, which means you could upgrade, even in your existing infrastructure. We look at this quite broadly and believe that there's huge opportunity for cost and speed, which has impact on resilience, but also on access. Not just in the US, but in other countries where a dollar a dose for a medicine might be prohibitive.

Rich Bendis: How about the shift from prescriptive to flexible performance and outcomes?

Ron Piervincenzi: This is very USP-centric, or I should say quality-centric. The way I would say this is that traditional USP tests will tell you, "Run this analysis, and if you have your answer within this range, you're in good shape. If you don't, you're not." In a performance test, again, this is where that is not possible. It's always great if you just have a simple answer. It's not always possible. If you have a gene and cell therapy, it's your cells.

0:27:03 There's no way anyone has ever developed a test for your cells because they've never had your cells before. Instead, you do what we call performance tests. You test the performance of the whole system around it to maximize the chance that your unique, personalized medicine will be effective for you. I think it's more logical when you think of it that way. You think, "Of course, I can't test your cells and say it should look like this because your cells are not mine."

Rich Bendis: It gets back down to personalized medicine, too, then.

Ron Piervincenzi: That's absolutely right.

Rich Bendis: Next would be product testing to quality by design with quality organizations.

Ron Piervincenzi: Quality by design is not a new concept, and for many in our industry, we're quite aware of it. You build the quality into the system, you don't test it at the end, which means if it comes out, and it's OK, it must be OK.

In quality by design, that's not true. It's not good enough to just be OK because if your system is not designed the right way, the second pill that comes out might not be OK. How creating quality by design incentives requires things like performance standards. The manufacturers who move this direction are incentivized to do so.

0:27:02 Currently, some of the activities that would lead in those directions are actually disincentivized unintentionally by costs and other barriers.

Rich Bendis: Really, the last paradigm to talk about, even though it's not the last, and there are many more, is something that's obvious, the reactive versus proactive continuous improvement.

Ron Piervincenzi: Some of this comes down to cost. You run through your R&D, you develop a new drug, you create your manufacturing plant, which has a 15-year life, you get your approval from the regulatory authority to make a drug in a certain way, and you start to produce it. Anything you do from that moment to improve could cost you more money. Everything you do might requires you to change that factory you've already built, to file more paperwork with FDA to show them how your process has changed. Right now, there are natural disincentives to continuous improvement. You might wait 15 years, then improve for your next medicine, but that's not continuous improvement at all. [Laugh] That's the idea of performance, what are the changes that you're able to make that you actually can incentivize and create the standards that give you safe spaces in which to make those improvements?

0:29:10 That's the simplest way to describe it.

Rich Bendis: Thank you for the rapid-fire on paradigm shifts. I know that we could talk about this for the whole *BioTalk*. Maybe we can go deeper next time we talk in the next year. But let's talk about some things more locally about the BioHealth Capital Region. When it moved from New York down to Maryland area, Maryland or the BioHealth Capital Region, Montgomery County wasn't as robust as it is today. And you probably have the ability to operate anywhere in the world you want to because you have 15 different operations. What keeps the headquarters for USP in Rockville, in Montgomery County? And what can we look forward to in the future around that potential growth or evolution?

Ron Piervincenzi: The only reason. It was a big one, but the reason USP came here was to be adjacent to FDA. It actually is still our biggest partner in the world. Over 150 staff members at FDA participate in USP's expert committees, and that's just the day-to-day work.

0:30:07 There are other interactions above that, hundreds of people. It's fantastic. And that, frankly, might be enough reason to stay here anyway, if only for that. However, you're right. Things have changed dramatically in our region. We're excited about the strength of the bio-innovation sector in particular because so much of our focus and our priorities for the next five years is in standards-setting in that space, where we had so many collaborators right up the 270 corridor. But I want to mention another thing in our region, Washington DC. That has proven to be an increasingly important part. And it was relevant. USP's founding, in fact, was in the US Senate Chamber on January 1, 1820. It was not lost on the founders of USP, even then, the importance of advocacy and recognition, and therefore, being heard. That continues to be important, but in much more sophisticated ways now. Every topic we've talked about here, innovation, supply chain resilience, all has political aspects.

0:31:05 They all have funding challenges, other roles where USP is often brought in as an expert to share our views. Being right here in DC has proven to be more important in the last five years than perhaps ever before.

Rich Bendis: And more important in the future, too.

Ron Piervincenzi: Yeah. You have bio-innovation from an industry's perspective, you have FDA, and to a lesser degree for us, but important also, NIH, in particular, NIST, which is even closer to us. Then, third, DC. That's extraordinary. For us, this is an easy call. It's so obviously the right place to be. But I think it's also right for even others for some subset of those same reasons.

Rich Bendis: If we look at the FDA and hear a hint that they might move, then we should be concerned about USP moving. But right now, I don't think that's going to happen.

Ron Piervincenzi: No, I don't think that's going to happen. I think they're happy in White Oak for some time, although they could use some more parking. But that's an issue that's been, I think, somewhat alleviated by more remote working.

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Rich Bendis: Yeah, I think that's probably being addressed. Since we talked last January, there are two events I'd like to talk to you about, or things that have happened or will happen in the region that are pretty impressive. One is, there was a new initiative created in the region, which fortunately, I had a chance to be involved with, working with Connected DMV and Stu Solomon on the creation of a Global Pandemic Prevention and Biodefense Center, which was going to operate a little differently than anybody else in this pandemic prevention space because it was going to engage industry, academia, NGOs, and the government working together, where any of the other entities never had all four of those partners involved. They needed a place to locate. Fortunately, they got a chance to meet you and Tony Lakavage from USP, and you made an offer they couldn't refuse.

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Ron Piervincenzi: That's right. The best kind of offers you can't refuse are lasagna and a room to sleep in, right?

Rich Bendis: And a free room to sleep in. [Laugh] But the Global Pandemic Center is colocated, and their global headquarters is now at USP. Congratulations on that.

Ron Piervincenzi: We're proud to have them. We brought it back and said, "Why not?" We had some space right in our meeting center, and we said, "Look, we can refurbish this in a few weeks' time, then it's yours." I know especially from my days at McKinsey working with startups, you have a lot to worry about, and paying rent is one, so if you don't have to worry about it, it would be lovely. I said, "Great. We don't have the ability like a private industry, as a self-supported nonprofit, to make large donations and such things." But here was something we could do that we could be proud of. I will say that I'm really excited for their mandate. I think there's potential well beyond the initial scope of the work. We're actively supporting looking for additional funding, including from the federal government.

0:34:05 We're serious about this, and we think USP has a direct role to play, in addition to just being a nice neighborhood.

Rich Bendis: I agree. And if you can find another $2.5 billion laying around, they would really appreciate that. The second thing is, because of our relationship between BioHealth Innovation and USP, which has really sprung in 2021, we were looking for some new partners and some homes for our BioHealth Capital Region Forum, which has become sort of the industry-leading confab in our region, and we're looking at our eighth coming up this September. Unfortunately, Astra-Zeneca was our home for that, and they've made a decision in 2022 that they're not going to have any major large outside groups. Tony, a board member on BHI from USP, and I had a discussion, and he said, "You know, we might be able to be an alternative for you." Through those discussions, we're engaged in a dialogue right now to host what we would classify a hybrid, but hopefully more in-person than virtual eighth annual BioHealth Capital Region Forum at USP on September 20 and 21 of 2022.

0:35:14 Ron, we really appreciate your stepping up and willingness to be a partner in this because you have a fantastic facility, and I think, also, you and I have talked, and it may be a way for also creating greater awareness for the USP brand, the organization, and ways for your people to interact with other people within the region.

Ron Piervincenzi: Appreciate your trust in having us host. We're proud of it. We're fortunate we have what we call the Meeting Center. Because of our volunteer model, we have 800 scientific experts who convene across 27 committees around every kind of medicine you could think of to set our standards, so we have this center because they're constantly having meetings, including an auditorium for larger groups and talks. But we renovated our entire lobby and turned it inside out, meaning that now, it's our museum.

0:36:01 It sounds weird to have a museum as a nonprofit, but when you're 202 years old, you actually have some pretty good stuff. We're excited about it, we love to be able to tell our story, not because what happened 200 years ago is important, but because our mission is exactly the same, it actually simplifies it a bit to be able to tell the story and makes you really proud of this region and the role it's played globally in setting our medicine supply today.

Rich Bendis: The other thing is, there are probably a lot of people with your museum and your organization, with the locals or people coming to the region

who are unfamiliar with it. And it will be great to have a different venue with a different look and feel rather than the traditional thing we do, going into an auditorium with not much else there, and people interacting with one another. I think it's going to be a welcome change, and we think it's something we can continue to build on in the future for maybe some other events that might emerge. In closing, why don't you talk a little bit about what you see as the future for your USP goals beyond 2022 and what we have to look forward to.

0:37:03

Ron Piervincenzi: I'll use it as a way to try to bring up brand new things we haven't discussed. A focus on innovation in areas of complex, generics, and biosimilars. It's the medicine that more and more is becoming available to people all around the world, and we're going to be focusing on those to create the standards, even the head of the demand, so manufacturers have what they need to solve the problems they have to produce those medicines. That's one of our priorities. The second is supply chain resilience. The two things I mentioned earlier and others, that we're working on directly all with partners. In fact, none of these we do alone, all with partners. A third dimension for us is advocacy for global access to quality medicines. This involves very different kinds of work in lower-income countries, including to help build the capacity of regulators to improve medicines and make sure they don't become the dumping grounds for poor quality, just like the US was in 1820. As much as things have changed, some of the same trends can occur if we're not careful.

0:38:01 We have teams and offices around the world, over $100-million program with the US government for funding to do this capacity-building work around the world. We're super proud of that work with USAID. That kind of capacity-building, which we call capability-building internally, is sort of our third focus area as we look forward.

Rich Bendis: It's not like you don't have a full plate already, Ron, but I'm sure your associates at USP are excited to hear about all of these new things you'd like to work on when they're already busy doing everything they're doing already, huh?

Ron Piervincenzi: There is that, but fortunately, we're hiring. We have over 100 job openings at the moment. Go to our website. [Laugh]

Rich Bendis: Let us know about those 100 openings because we have a jobs board on our website. Also, if you would like, prepare a little article, and we'll put it in our BHI News, our weekly electronic newsletter, about your 100 job openings that you're looking for, and we could actually do a feature on that. I think that would be great.

Ron Piervincenzi: That would be wonderful. It's an exciting time for us in hiring, as it is for many organizations in the world today. I'll leave it at that. [Laugh]

0:39:04

Rich Bendis: And we're challenged a little bit. We've been talking about workforce in our region. Since there's been so much federal money flowing into our region related to the pandemic, then having to serve the government contracts and meet their milestones, it's challenging for everybody to keep up with the workforce demands they have to meet all of those milestones.

Ron Piervincenzi: Yeah, and it isn't even just pandemic-related. You have growth in staff at FDA, for example, just for ordinary reasons. But it all adds up to quite an extraordinary moment.

Rich Bendis: This has been very educational with me. Every time I interact with you, I learn a lot more. We're just touching the surface, something we should do on a more regular basis, which we will. I want to thank Dr. Ron Piervincenzi, the CEO of the USP, for his second appearance on *BioTalk*, and it won't be the last. Ron, keep up the great work and becoming a stalwart within the BioHealth Capital Region.

0:40:00

Ron Piervincenzi: Thank you, Rich. My pleasure.

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

End of recording