PharmaVOICE Podcast Series

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In this episode, Taren Grom, Editor-In-Chief of PharmaVOICE Magazine meets with Clareece West, VP General Manager at Cardinal Health Regulatory Sciences.

Taren: Clareece, welcome to the PharmaVOICE WoW Podcast Program and congratulations again on being a PharmaVOICE 100 honoree.

Clareece: Thank you Taren. I'm thrilled back in 2016 to have been an honoree, and I'm thrilled to be a part of the PharmaVOICE WoW Podcast Program as well.

Taren: We're thrilled to have you as part of the community. Let's get started. You have had such a varied and successful career over the past 25 years or so. You've had leadership in executive positions at two Fortune 500 companies, two large CROs and during this time you have successfully restructured and built large business development teams, been part of six acquisitions – which I couldn't believe – and gained global expertise through all of this. I'd love to know out of all of this, what has been your most rewarding experience and what are some of the biggest learnings you gained along the way?

Clareece: I would probably think and say that my biggest reward, Taren, is really watching the staff get excited and be able to independently drive initiative. Truly, when I think about what it has in common, whether it was business development or operational teams, to truly see the potential that a talented company has and how we take that talent and convert a few changes into really sustainable growth, that's extremely rewarding. I love giving back all the knowledge that I've been so fortunate to gain along my journey, and so that would be to me the biggest reward.

As I think about learning experiences and what I had gained across rebuilding operational and business development teams, biggest learning opportunity for me is really there's no rubber stamp or cookie cutter when you learn about any industry or any particular business. You must bring – you've got to have an appreciation, extreme passion because each industry and each type of business whether it's a lab, a technology organization, a small or large CRO or even a regulatory services business, consulting business, they're all unique. So that would be probably what I would say.

Taren: That's excellent. I also know that you have a passion for marrying science and technology to improve and advance devices and therapies for all patients. Talk to us about why this kind of collaboration is so important today.

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Clareece: Where the industry is heading, the two are virtually inseparable. We won't be able to improve patient therapies, nor will we improve the impact of medical devices without this powerful combination. It's just virtually impossible this day and age.

I firmly believe that the technology really can help us expand science when carefully used. It forces all of us to think differently, be a bit more innovative and to push our market ahead especially for regulatory pathways and clinical trials as I've done over the years.

I always think back, technology has always been near the industry and actually in certain areas like we think of it in data management and monitoring, but now it's being used to help us predict and inform more and more of what we do. I can actually think of several professional examples and when I look at all my professional examples I mean when we graduated from paper, if you think about the adoption from paper CRF to the data fax, and then we graduated from data fax to EDC, now we're looking at obviously EDC into comprehensive technology platforms that allow us to get access to real time data and produce key indicator reports whether it be in a dashboard or individual reports, that is a great pathway professionally that I have watched the two marry and progress.

I can also speak to that on a personal side. If you think about I look at where my cardiologist and friend of several years diagnosed me with a-fib a few years back, and she knew. I mean she absolutely knew I was not going to slow down, but she was able to provide me with an app that was used to send her directly information about my heart and what it was doing. And so you know there are so many examples that you could walk through, but professionally and personally I've been influenced over my span over my career. I think the key is balance, balance the scientific findings with the technology to make better decisions for patients.

Taren: I think those are great examples, and I was kind of chuckling when you were talking about the EDC days and I remember back when EDC was all these things, but yet everybody was still holding on to all the paper. Moving just past that part of the bottleneck to me is a huge leap forward. When we think about technology and the future, where do you think technology will have the biggest impact?

Clareece: Oh, goodness. The impact it can have on improving therapies for patients – it's immeasurable, Taren. I have seen the impact technologies had over the years and obviously in pockets what we just discussed. And now we have the opportunity to demonstrate and utilize copious amounts of data that may be able to help speed up drug and device development which can increase the amount of approvals so that it will help patients have access to better therapies and even go as far as say to live longer.

A recent example really of that is the head of the FDA just recently laid out several... I think there were four activities around technology that the FDA is taking into connection



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and into consideration with real world evidence and real world data this year and one of the things – I'm going to pick on two of them – one of the things that FDA stated that they will support the integration of digital technologies in clinical trials and how digital systems can be used to enhance the oversight within the clinical trials.

Again, that excites me because we're looking at the greater efficiencies. Just looking at what risk-based monitoring has provided in the development process already not only does this provide really better regulatory oversight, it actually has the possibility and real possibility of reducing development cost over time. FDA will also embrace and utilize digital technologies to bring clinical trials to the patient rather than always requiring the patient to travel to the investigator. That's so new. I mean they feel that technology can help us with and around the centralized trials.

That can be game changers when you look at the caregiver side of it and what that can do for the patient and as I've always said, the more engaged the patient and the caregiver are, the better off we're going to be in what we get approved into the market.

Taren: I couldn't agree with you more and I agree, I think it is a game changer in terms of the clinical trials space and it'll be interesting to see how this plays out over the next couple of years when we start to hear some of these new initiatives popping up at conferences like DIA. When it starts to become part of the normal conversation we'll know we may have arrived and to have the regulatory agency get on board with this it's good news.

Clareece: It's fantastic news.

Taren: So let's talk about the regulatory sciences business and your role at Cardinal. What does that entail today?

Clareece: Really, I don't know that it's very different than any business or any industry. My goal for Cardinal Health Regulatory Sciences is to lead a group of truly some of the most remarkable people and talent in this industry and just take in a sort of trusted business model that really can help biopharma and device companies solve complex regulatory and clinical problems to where we can expedite the approval pathway. This is just an area of expertise for me because of really the passion and the listening that you do. We've got a really talented team. So my goal is to insert the right business model that just can flourish and grow.

Taren: Awesome. Looking in the regulatory space, it's not always glamorous, it's not always straight fast forward. How do you keep your team inspired and motivated and focused?

Clareece: I think about this a lot because this is always in the front of my mind, but simply put I think the ability and especially in today's world you've got to have the



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ability to balance work and home and you have to have a trusting process and trusting the individuals through their actions and encouraging them to be, to move the business needle. There has to be. So I pick on a couple of things is balance, trust and encouragement. When you challenge employees to think and not be scared to push the envelope, to me it helps accelerate the focus and their motivation.

Most people love, absolutely love to collaborate and bring new ideas to the table that can improve whether it's departments or processes or working conditions, whatever that is, but empowering them to have the autonomy and be part of the change it really does and it can build trust and great working relationships and those working relationships last so long in your career and I have those relationships around the globe today. Pushing employees to evolve and really continually think of innovative ways to run our business ultimately – I mean it has a positive impact on patients, but it also has a positive impact on the employees driving that because any one of us and our loved ones can be the patient.

So, I would say ultimately I just want the employees to have the freedom to think and create at work and balance that with family time at home because happy people are really more innovative and helpful at work.

Taren: That's great. Thank you so much for those great insights. Let's switch gears now a little bit to your philanthropic and volunteer side. I know you are a founding member of the Women's Capital Connection which is a regional angel investment group and you're an active member of the Mid-America Angel Investors Network. Talk to me about these organizations and why they're important to you and important to the industry.

Clareece: Yeah. It's a good question. I believe that investment firms all started their — investment firms provide seed money to help great ideas flourish, get started, so that seed money has been a passion of mine and also working with the Ewing Kauffman Foundation as a reviewer of some of their awards in businesses that come forward out of that. So, I think that again getting that start, everybody needs a start, so they are vital. The investment community is vital to brilliant ideas to help propel them to become a business and also it also has to balance them to know what their exit strategy really is and can they exit.

I feel extremely privileged and grateful for a very long career in leadership and executive positions, which really compels me to want to share and give back. I can't tell you how much I enjoyed that piece of it. I would love to volunteer even more as I feel that volunteering really is part of community stewardship and in my personal passion as — and I have mentioned this to you probably before is the Alzheimer's Foundation as well as Kansas City Hospice House that when diseases and opportunities hit close to home it helps put in perspective how important volunteering is, how important donating is and whether that's time or money, both very much matter and just as I said I've been very blessed in my leadership roles over several years.

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Taren: If you don't mind, let's talk about that Alzheimer's volunteer, but I know you just did a panel with the Healthcare Business Women's Association and it's a topic that we don't talk about often enough, but it's about that caregiver and dealing with that horrific disease.

Clareece: Yeah, it is. We see it so much through the scientific lens. When it hits you personally, in talking about it at HBA, we did a panel for a large pharma, the caregiver as well as an advocacy group and every disease humbles you in a way, but when it hits close to home it changes your life. It changes your perspective and I've been doing this a long time and I'm so passionate about it because of that reason and those pieces will continue to propel my passion in this industry because as a caregiver for whatever disease it changes your life and what impact it has and that should align with the community service that you do.

Taren: Well, thank you so much for all that you do and for giving back at such important causes. It's hard to believe that I have to say this in 2019, but here we are and it's still an issue within the industry in terms of gender parity in having women reaching the executive levels as you have, but you are one of the champions out there. You're one of the role models for up and coming women. I'd love to know, what are some of the lessons you learned along the way that might benefit other women who aspire to reach the executive level?

Clareece: I've learned so many lessons along my journey, Taren, and I'll start with kind of the basics. I believe you have to be morally grounded and really come to the table with a can do collaborative, team-driven mindset. That sounds kind of corny, but sometimes we come with one, sometimes we come with half a one. You have to know that you're morally grounded and that you come to the table with a team mindset. If it's all about you, I believe and I firmly believe that you'll limit yourself and it may not limit yourself in the first year or the fifth year, but over time.

This is a small industry. Reputation is everything and I also believe that how you treat people is paramount in this small industry we all work in. I would also remind everyone to stop and assess their goals annually. I've done this for the past 20 years and I always ask myself are you where you want to be, why are you or why are you not and what are your goals for the upcoming year. If you're not planning to be successful, you're not going to be successful. And do your goals actually align with your spouse? Sometimes those conflict and it's good to talk about.

My time of the year to talk about it is usually about the first or second week in December. Those are the times where things start kind of winding down and you can actually breathe and start really identifying what your goals are. Again, I've done this each and every year because I believe it's important to plan for success as I said. Our lives are really just a series of chapters that make up a book and I'm under the impression we get to write most of them that they're not written for us.

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Taren: That's great advice. Thank you so much. And I know this next question is a bit of a way up, but I'm going to ask you anyway. You are obviously a driven and an innovative leader and you're a planner and I love your approach to business and to leadership. What drives you everyday? What's that one thing that gets you jazzed up?

Clareece: Probably the same thing that drives anyone else in this industry and that is that we've had friends and family with diseases like cancer, Alzheimer's, diabetes, heart condition. What wakes me up, what keeps me up is the impact that our industry is making either a patient like better or longer. Early in my career, my mentor, he coached me on the importance of putting the patient first. And if there's one thing that drives me beyond anything else, I will be passionate until I don't have a heartbeat about putting the patient first.

I've always said, every click you make, every decision you do in this industry has an impact on a patient. So stay the extra minute, put the extra time in and do the right thing because that patient can be any person, whether it's you, me or someone we love. I'm passionate about that. The power and impact that we can have as an industry and the contribution that we can make in science and technology and healthcare I know it has an impact on the loved ones that I've known and other people's loved ones.

So what drives me everyday to get up is the passion and the care that I have. I may not be a nurse, I may not be a doctor, but everything that we do in this industry has an incredible impact for the outcome of a patient.

Taren: That's one of those drop the mike moment. It's obvious the passion is evident in your voice and it's in your words and it is in your actions, so thank you for all you do for patients. It is a calling and I do agree that you don't get into this industry without thinking about the patients. I often say the talent of people who work in this industry could be involved in almost any other industry, but they serve for the benefit of patients, so thank you. Finally, what's the one piece of advice you would give to your younger self?

Clareece: Well, just be very frank. First, I would probably be a little more patient with colleagues and maybe members of my team. Patience is not my strong suit. I'd be the first to admit it, but with that said that doesn't mean I would ever take my foot off the gas nor would I take my eyes off the road. Anybody who knows me in this industry I do happen to like full throttle and what I mean by that is because it takes passion. There's a multitude of things that we do in the industry that have to all align.

So, I'd tell myself to fully understand, appreciate that all people operate differently and let's bring various talents together to the table because we're not all alike. We should appreciate them all and finally, I would tell probably my younger self to fail fast, recover



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faster and never quit, ever quit. That's the final advice that I would say is you don't ever give up.

Taren: I think those are three great key takeaways, so thank you so much. And thank you so much for being part of our WoW Podcast Program. I really enjoyed our conversation.

Clareece: Thank you and I really enjoyed the questions. Thank you very much.

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