# 020 - Art of Engineering | ISPE Roundtable Discussion

#### Denise:

Let's begin the discussion, getting to know Lindsey Daniel. Lindsey, welcome to the Art of Engineering. I wanna welcome, today, Lindsey Daniel, whom I've known for quite a number of years, who was initially with <u>CRB</u> and has moved to Boston in the last two weeks. And we are here at the annual <u>ISPE</u> meeting in Boston where she is a young mother has a new, great job. And she's gonna tell us about it. So welcome Lindsey.

# Lindsey:

Thanks for having me, Denise.

#### Denise:

So tell me, because when I initially met you, you were with CRB and as an engineer. So tell me how you got there.

## Lindsey:

So I graduated from <u>Virginia Tech</u> in 2012 with a degree in chemical engineering and my husband played lacrosse at Virginia tech and he had graduated a year before me and went to San Diego to work as a mechanical engineer, designing and manufacturing lacrosse sticks, which was his dream job. So I followed him to California.

At the time I was not an ISPE member. I joined ISPE solely because they had a chapter in San Diego. And I sent my resume to the president of the chapter. She sent it out to her board and within two weeks I had an interview at CRB and an interview at <u>Genentech</u>. And two weeks after that, I had two offers, one from Genentech and one from CRB and ultimately ended up choosing CRB. So that really spoke to the power of ISPE and as one of the main reasons I got so involved, because I felt like I really owed my first job to ISPE and the networking opportunities that it provided. So I started out there as a young and overly energetic process engineer working at Genentech worked at that site for about three years.

And then CRB had the big project in Covington, Georgia. And I went down to Covington at the same time that my husband relocated to Minnesota for an opportunity to bring manufacturing in house for a client that he had. And then I just commuted back and forth with CRB to Georgia when he was in Minnesota.

## Denise:

Okay. But then you got to Minnesota. Yes. So tell me about that.

# Lindsey:

Yes ma'am. So then Takeda or, or CRB landed a project with <u>Takeda</u> in Brooklyn Park, Minnesota, and I came back to support the local project. And so I then did the startup of the Takeda Brooklyn Park facility in right outside Minneapolis and ultimately in 2017, I decided to take a position with Takeda as a senior process engineer and transitioned to the owner side after I had had several years of the consulting side and see the boots on the ground, the owner side, and be able to see a project through and be able to own the project after completion.

## Denise:

So I find that fascinating because what is that transition like of going from being that on the engineering side to then transitioning to where you do get to see that project completed?

# Lindsey:

Yeah. So I actually wrote an article about this in ISPE pharmaceutical magazine. Probably now five, six years ago about the differences of consulting versus the owner side and how I really felt like it was important to see both sides of it. I think that when you are on the consulting side, you're getting to see so many different companies and how they're doing things they're different, the different strategies, different approaches, different risks, levels that they're comfortable with getting to see different sides of the industry. I got to do some food stuff with CRB. I got to do some animal vaccine stuff. So I got, see a lot of different industries.

But what I didn't get to see was after the project is done, the mistakes that kind of filter through, right? You don't live with them. And so when you're designing things, you don't really hear about the, the things that didn't work out unless it's catastrophic. And so without working in manufacturing, it was very challenging for me to design something that I had never owned and operated. So when I was designing my first UFDF skid with CRB, I had no idea that there needed to be a sample valve there. How would I, I had never had to take samples before. Right. So in order to be successful, I felt as a design engineer, I needed to have that operational experience. And I also wanted to have the experience of seeing a project through and being able to design something and then living with that design.

And one of the designs that I did for Takeda in the media prep area, involved filter housings that were under a platform. Well, we had to go back and invest about \$80,000 afterwards, because I didn't know that you had to take the filter bell housing off with every changeover to install new filters, because I had never been in operations. So when I designed it, I didn't design it in a flexible way for them to be able to pull that out and think about the, the, the height of the, of

the mezzanine above. So it just taught me, you know, with the design side, the implications of the mistakes that you make and being able to have that operational experience to better understand the design side.

## Denise:

Very good. Yeah. So you were at Takeda in Minneapolis for how long?

# Lindsey:

I was there from 2017 till this summer. So about four years.

## Denise:

Okay. And now you have a new opportunity.

# Linsdey:

Yes, ma'am. I do. And I'm very excited.

## Denise:

So tell us about that.

# Lindsey:

So I've started a global position. So my career so far has really been focused on biologics at the drug substance manufacturing level and more on the technical side in the engineering space. My new job allows me to kind of look at the broader business and above site strategy. So my new position is product operations, program manager, and I am working and managing a global product team that focuses on the more complex assets within Tekata, which does include pipeline products, products that are in clinical trials and have not launched yet. It manages the end-to-end supply chain of the product team that includes regulatory supply chain planning, finance quality and it looks at the product as a whole in managing the strategy and the vision for the product.

Are we manufacturing internal versus external? How much are we keeping on supply? What is our future of the product look like? What does the competitive intelligence and looking at the product as a whole asset and managing that from the life cycle management piece.

#### Denise:

So it's a huge broad look.

# Lindsey:

Yes ma'am. And I came from a very narrow, detailed oriented position to a much broader scope.

## Denise:

What, what a great experience it is be able to do that

# **Lindsey:**

It is, but it's been challenging for me to change my way of thinking. I've struggled to, I want to get into the weeds. I want to get into the details I'm comfortable. I know I can execute the details. Right. But thinking more big picture thinking of how thing is something's going to impact into the future and the strategies associated with the product is a shift in mindset for me that has not been easy. It's been a great learning and I have so much to learn and opportunity ahead of me, but it has been challenging for me to change as well as I came into the position immediately after maternity leave, which was hard to come back to, you know, resetting that mindset, getting back into the grind, but in a new way of thinking.

## Denise:

So tell us just a little bit about Takeda who's Takeda. What are, what are the products and, and what are the life saving things?

# Lindsey:

Yes, ma'am. So Takeda has four therapeutic areas of focus, which are oncology, rare diseases, neuroscience, and gastroenterology. They really are a patient focused company with values called Takedaism: Integrity, fairness, honesty, and perseverance. And we've got four main actions based on putting the patient first, building trust with society, reinforcing our reputation and developing a sustainable business.

And I love this because Takeda really focuses on patient first. And I have seen that in my work where they have made decisions that benefit the patient more than they benefit the business. And it's very refreshing to see a company who really does what they say they are going to do. And it's really a privilege to work for that.

#### Denise:

So, Lindsay, let's just add to that a little bit, because you just mentioned to me, as we were coming up to do this podcast, what Takeda is doing for the employees, for child maternity leave, bonding, leave bonding, it's called bonding leave. It's called bonding leave. I love yes.

# Lindsey:

And they have just, I just got an email about our enrollment and they have just increased bonding leave to 12 weeks, paid bonding, leave for both men and women, which I think is amazing. And that is on top of the short term disability that you would receive as well.

So you can get up to 18 to 20 weeks of paid time off with your child, which is just time that you will never get back and is so critical and so important. And I think that it's amazing that Takeda is focusing on and empowering women to have children and take the time they need to recover physically, mentally, emotionally, as well as have that time with their child

## Denise:

Lindsey:

Great question.

and to get recharged. What, what an opportunity. Well, Lindsay, three quick questions that I've started asking everybody as I do podcasts. Who would you like to be stuck on an elevator with?

# Denise: You can think about it. Lindsey: Oh my gosh. Yeah. I have no idea. Denise:

# Lindsey:

So what brings you joy?

My children for sure. Two beautiful kids. I have an eight month old baby girl and a three year old son. And they are truly the best of me and being around them and seeing them grow and develop every day is the most joyous thing I could have ever asked for.

#### Denise:

And the joy is in your face.

# Lindsey:

Yes

#### Denise:

Well, and, and I just wanna say, because I've seen Lindsay over a period of time, and I know you having moved in the last two weeks and you may be paddling like crazy underneath, but you don't appear to be

# Lindsey:

Thank you.

## Denise:

You appear to be just going along with the flow.

## Lindsey:

I'll be honest. I'm really not that stressed out. Surprisingly. I mean, the move went really well. My job has gone really well. I feel like things are under control. Now I have a lot of balls in the air, so subject to change at any moment, but right now things have gone really great. And a lot of that has been, you know, my company supported me and made this move as easy as it possibly could for me, they've supported a work life balance for me.

And I, I really appreciate that. I admit that is a big impact. And I have gotten into the mindset where I support a work life balance myself. I think a lot of companies support it, but we don't always support it ourselves. We don't always take advantage of it. And we create additional stress for ourselves that we have to do these things and be these places. And I think that I have learned to embrace a a more balanced lifestyle and I recognize that it allows me to be better in all aspects of my life.

#### Denise:

That's a wise thing from a young person. Thank you. Well, I also want to introduce someone else into this conversation who is Jen Clark, another podcast candidate we've been discussing what I got to know, both of you through <u>Women in Pharma</u>, which has just been to me, like Lindsey said such a benefit of, for our jobs for our lives. And so Jen introduce yourself.

#### Jen:

So I work for CAI and I'm our VP of sales and account relationship management. And I have been a part of women in pharma pretty much since its inception. And it is been evolving over the past six years. It has brought many opportunities, I think, to a lot of women and men around the world. And our, our focus is to provide women in the pharmaceutical industry, a forum for connecting and collaborating on technical and advancements topics. And we have created a global network that is encouraging women, helping women and collaborating with women no matter where you are in our new virtual world to be successful, not just in your professional life, but also in your personal life.

## Denise:

Well, thank you. And, and what I do know also about Jen is that she's been promoted in her job recently and is working on an MBA. So tell me how you balance all that.

#### Jen:

Not as gracefully as Lindsey! It's, I it's, it's, it's interesting. I, I wrote an editorial, so this is sneak peak for my editorial in January and the pharmaceutical engineering magazine. My husband is amazing and we have two small kids and I called him small they're 10 and 12 year old, little girls. And my, my husband's my rock. He makes dinner when I can't, when I forget I have an exam and I'm already out of the house doing other things. And then I come home and I'm like, ah, you're in charge of everything until I take this exam. And he just says, okay, what time do you want me to bring you dinner? You know, it's, it's moments like that, that, you know, you made the right decision and it is husbands like that... I know Lindsay has an amazing husband as well, and it's, you can't do it on your own.

And so I, I have a whole network of people that help me survive. And I'm also enjoying my MBA with one of my best friends. That's also in the industry and so misery loves company. And so it's kind of motivating when we're together and you're doing it and we're taking the same classes. And so it's, it's fun. It's, it's good. And I'm using what I'm learning at work, which makes a difference. And it makes it even more motivating. And as Denise said, we're at the annual

meeting, so I have homework due tomorrow morning, but I knew I needed to do it yesterday. And I had Lindsey come up and prove it, cuz I'm so tired, to make sure that it was coherent. So it is, you gotta use the resources you have, whether you're working or in school or your personal life.

#### Denise:

Yes. Yes. Well, I will say both of these women make ISPE and Women in Pharma tick and I'll just share an experience I had last night, we chose to just send me from my company this time and not do an exhibit because we'd, weren't sure with the pandemics still on how many people would be here. And I finally occurred to me that I could walk around and probably find 600 people in two and a half days. And last night when we had the refreshments in the, in the exhibit hall, we found a project for an isolator just introducing ourselves to each other, a, a young woman who has just joined, ISPE and this was her first annual meeting. So the benefits are, are just amazing.

#### Jen:

It's all about connecting and networking and being kind, you weren't looking for a project you were being kind and you probably started talking to someone and that happened.

## Denise:

Yes. Yes. And, and it continues to happen. It's, it's like the experience that Lindsay had with finding the very first connection through ISPE and finding a job.

# Lindsey:

Yeah. And I think that's has literally every annual meeting I have gone to something major has happened for me. And at my first annual meeting, I met Jen and I was part of the now emerging leaders, but it was gen professionals. And I just said, Hey, I wanna get more involved. And she was like, yeah, great. Here's a list of people. You can talk, let's, let's go. Here's all the things you can do. And a year later I was chairing the international committee for young professionals. And it was just one of these things that if you are all in there is opportunity for you. You just have to ask and then follow through.

And in, you know, with, with Takeda and CRB, the CEO of Takeda, Jeff Bisk, I am extremely close with. And he has mentored me because of our involvement with ISP. We've sat on committees together. When I was in 2017 in the San Diego ISPE, I met the head of global engineering for Takeda, and took him on a private tour of Genentech because he wasn't able to make it because

he was flying back early. And since then I've had this wonderful connection with someone high up in Tekada who really has given me so much time and energy when I wasn't even close to his level. And the time that people have given back to people rising in the industry, the mentoring that I have received through ISPE has really blown my mind of how invested people are and how generous people are with their time at ISPE to give back to the future of the industry.

#### Jen:

Something that we just launched at that reception last night that you're talking about is getting involved as a Women in Pharma ambassador. And, you know, Lindsey's a prime example. She just had a baby and she just moved and started a new job. And she probably doesn't have time to give 10 hours a month. And she might have time to give an hour this month and then maybe it'll grow, or maybe she'll find that an hour is okay. And so we've created this ambassador program that you can volunteer at your local level. You can volunteer at the international level. You can help us find ways to get donors to the foundation, to support women in pharma programming. You could just be a social media ambassador, like start where you are, where wherever you are. It doesn't matter. We met women last night that want, wanna help and go all in.

And that are just, they just want permission to not feel guilty for only being able to buy button and represent the Women in Pharmer brand. And it's okay.

# Denise:

It is okay because at various stages in our lives, we can do a little and maybe we can do a lot. And yes, one of, one of the things that we've talked about with doing these podcasts is how can we utilize those to get the word out and what an ideal opportunity for all of us to share the information

# Lindsey:

...and inspire each other. You know, I am doing my Masters of Engineering management at Vanderbilt, and that was inspired by Jen watching her do her MBA with all that she does. I was in the middle of having kids. And I was like, there's no way I can do this. And I found out I was pregnant with my daughter two weeks into the program.

And I remember calling Jen and saying, what do I do? I either accelerate or I quit < laugh> those were my options. One of 'em not really option. One of 'em not really knew me. And, you know, so I accelerated and it's one of those things you see other people, you see what other people

can accomplish and you think I can do this too. And then they're by your side through it to help you and encourage you and remind you that you can do it.

# Denise:

Yes. I, I have an MBA that I got when my son wa was young and I was traveling five states. And I don't know how many people have said to me. You're the only person I know who got hurt, MBA driving up and down Interstate 29. But I literally did. I mean, I, right. I would look at the questions and if it was a strategic thing, you know, I had all this hours of windshield time to think about it ...and I sometimes pulled over and check notes. Sometimes I wrote 'em while driving.

#### Jen:

Yes. It's there's been so many good stories and I, I think one of the, the positives of the pandemic has been able to connect everyone no matter where you are. And I mean, somebody came up to me and introduced himself to me today from a business perspective. And then we started talking and he's an emerging leader for the UK. And then he asked me where Tanya was and it's, it is created this access to each other and access to these connections that we never had before that we took advantage of. We took it for granted that you could just Zoom somebody anytime you wanted, or FaceTime somebody. And this is it's, it's opened up a lot of doors, I think for people. And I've heard some stories, you know, similar to Lindsay's and not about me, but just somebody said like Women in Pharma, like save their job, like from what they heard and the people that they met and they talked to, and like, they made life changing decisions based on what we're doing here at ISPE.

And I think that it's, it's a Testament to, ISPE it's a, it's a great organization it's growing. And it is, it is just that forward thinking place that, that we can all call home.

# Lindsey:

Yes. Yeah. It's evolves for sure. And I think diversity, equity and inclusion is on the forefront of everyone's mind right now. But is ISPR noticed this and recognized this years ago and really got ahead of it. I think with Women in Pharma, yes.

# Denise:

It's changed over the years. It has. Because when you look now at, across the room and see how many women there are, it's so refreshing

## Jen:

And they're smiling at each other. They're saying hello to each, even when they're our best everyone's being kind. And there's, it's not this competition. It's, you know, women wanna help women. Yeah. It is. It's beautiful. Yes, it is. It is beautiful.

# Lindsey:

But I, I think that the biggest thing for me is just watching the inspiration of all the women, like Jen said, misery loves company, but being inspired and seeing what other people can do makes you believe that you can do it too. Yes. And that's powerful.

## Denise:

And know you have a cheering section.

## Jen:

or somebody that's gonna catch you when you fall. Yes, absolutely. Yes. Yes. We've really created a team within ISPE it's a family here. It is a family here.

# Denise:

Ladies. Thank you. This was just what I wanted to do.

#### Jen:

Good. Thanks, Denise.

# Lindsey:

Good. Thank you for having us.