

The Art of Engineering with Denise McIntosh

Episode 010: Dr. Sarah Miksinski, Senior Director of Global Regulatory Excellence at [AstraZeneca](#)

Sarah's career has gone from working on the regulatory side of pharmaceuticals at the FDA, to the operations side of the creation of pharmaceuticals with AstraZeneca. Sarah received her post-doctoral degree at the National Institute of Health, and spent many years at the Food and Drug Administration. Now at AstraZeneca, she works in research with the coordination of regulations through multiple countries around the world. Sarah and Denise talk about the value of mentors and why it's important to see one out.

Denise McIntosh:

Well, good morning. This is Denise McIntosh coming to you from the art of engineering and custom powder systems. And I'd like to introduce this morning, the senior director in global regulatory excellence at AstraZeneca, Sarah Luzinski and Sarah, did I, did I pronounce that right to begin with

Sarah Miksinski:

You did you did. In fact, the funny story is that I used to be Sarah Pope before I was married and I went from a relatively simple sounding last name to a very complicated last name. So you did well. Thank you.

Denise McIntosh:

Thank you. Well, I'd like to just share a little bit about how you and I got connected, and that was that I tuned into one of the ISPE annual meeting conferences and discovered that you were one of the presenters and discovered our connection with Oklahoma state university, as we both graduated from there, although you'd be with a very high graduate degree in chemistry, and then we also have a love of music, which is where you started. So tell me about your journey,

Sarah Miksinski:

Right? Right. Thank you. Well, first of all, thank you for having me. It's such a pleasure to do these types of interviews and it is so enjoyable to kind of talk about the bigger picture. So my journey is a little unusual as many people are. I started off, as you mentioned, as a musician coming from a family that has a heavy musical presence. My mother's an organist. Both of my parents are actually ordained clergy and I did not come from a family of scientists. In fact, I think the only scientist in my family is my grandfather on my dad's side and my uncle who was an engineer when he was alive. And so I didn't

have much in terms of scientific interest. I played the violin for a very, very long time, played the piano for a long time. Did some singing, not sure how good I was at that.

Sarah Miksinski:

That was maybe third to the violin and piano. And we can talk about this later, but I certainly have maintained my musical interest as a kind of a coping skill for my own current profession and just giving a mental break. So very early on, I wasn't a musician, I started college with an intended music major, and then very quickly discovered that while I enjoyed music, I was not particularly good at the technical pieces. The music theory, composition, things that music therapy, music majors needed to have. And at the same time, I went to a very small school, very small college called Berlin college. And I was required to take a general education requirement in chemistry. And so just due to timing, I took a class called organic chemistry and I will not lie. It was not easy for me, but I liked it enough that the work was fun. And that was why I changed my major. So it all happened at the same time. I was nearly failing my music theory class and I was excelling in chemistry. And I thought, you know, maybe I need to reconsider what I'm really targeting here in college. And so that's how I became a chemistry major. Wow.

Denise McIntosh:

I'm still trying to sort that out in my left brain, right. Brain

Sarah Miksinski:

Are many people in my family who are still trying to sort that out and left right brain,

Denise McIntosh:

Well, still continue on because I'd be in my mind, the story gets even better. Right?

Sarah Miksinski:

Well, thank you for that. That's a very, that's a very kind, I, I always wanted to be a doctor, a clinical doctor physician. And when I was in, I wouldn't even when I was a music major, I was pre-med. So I started as pre-med now again, I had very little awareness of how much science I would take in doing that. And it was actually interesting what I changed to a chemistry major. I was still pre-med. And when I got into my senior year of college, I did a couple of things. The first thing I did was I went to Africa for a few months as an exchange program. I went to Kenya for about four or five months and not had that had very little to do with science, more to do is just international trouble, gaining some exposure using the programs that the college had available.

Sarah Miksinski:

And that definitely expanded my view greatly. And the other thing was I didn't get into medical school. And so I was about 20 years old when I graduated and not getting into medical school was as I look back very, very difficult, very disappointing. I got wait-listed at a few, but I had to very quickly come up in the spring of my senior year. What was I going to do if it wasn't med school? And so that became grad school. And I submitted my name application to several schools that I knew had available openings. Many of them by that point were filled. Many of the programs were filled in Oklahoma state was one of the ones where there was a gentleman working there who was working on something that I was interested in and it just kind of worked out. So I went to grad school was going to do that for a year, reapply to medical school, but I liked grad school enough. I just stayed.

Denise McIntosh:

And from there, Sarah, tell me just a little bit about the journey then from getting all of this science and then finishing grad school and then getting to the east coast.

Sarah Miksinski:

Yes. Yes. Well, the one thing I'll say about me and science and this, I say this whenever I talk about my journey, especially when I'm talking to younger people than me is set and science was never simple for me, it was never easy. I think sometimes there's a perception that people who have a career in science for somehow these people, for these people, it's easier than it is for other people. And I feel I run into that. Sometimes I'll hear people, even just this morning, I was helping my ten-year-old with some online math and he said, oh, mommy, this should be easy for you when you're a scientist. And, and I thought, you know, it's, it's not, I like math. I can do math, but there's nothing about science or my aptitude in the science that is more intuitive than anything else. It is, it is work.

Sarah Miksinski:

And it was always worked for me from, from the time that I started it to even to now, I still have to work very hard to understand some of the things I work with now, what is different for me is that I love it and I love it enough to work at it. And that makes it worthwhile. So moving on from grad school to your question, I did do a post-doc I during graduate school, I had a little bit of a, a U-turn in that my advisor that Oklahoma state decided to switch schools. And so he moved to St. John's university in New York city, and he very kindly offered to help me move to New York city. If I agreed to help him set up a new lab at St. John's. And that's where I did the last year of my postdoc or my graduate degree, I did get my degree from LSU, came back and defended my thesis and then, and then got my PhD from Oklahoma state.

Sarah Miksinski:

So, so it was a little unusual but it gave me a chance of 26 to, to live in New York city for a year and a half, which was again eye opening, a big change from Stillwater. Indeed, indeed. It wasn't to this day, I have to tell you, I can remember the moment of driving my tiny little Ford aspire over the Verizon or narrows bridge into New York city for the very first time packed to the gills, thinking what in the world am I doing? With my hands just glued to the steering wheel thinking, you know what, if, you know, you gotta try these things. Sometimes now now's the time to take a risk. I just felt like it was the right thing to do for myself. And so I'm glad I did it, but there was certainly an element of fear. I still look back on, I'm not sure in my current world, if I would do the same thing. So anyway yeah, I went to St John's and then did a postdoc at NIH, which, which was in Baltimore.

Denise McIntosh:

So I'm just going to explain to our listeners that that's the national Institute of health. It is, it's a prestigious place.

Sarah Miksinski:

I will. Thank you. Thank you. So they have, NIH does have a satellite office in Baltimore that is the national Institute on drug addiction. And that's where I worked, did about two years there and then decided I did not like research. And that's when I moved into what I would call my regulatory career, which is where I've been for about 20 years. So,

Denise McIntosh:

So help me help our listeners understand your transition because the conversation that you and I had about one of your mentors, helping you find that path is very interesting.

Sarah Miksinski:

Yes. I think you're referencing my postdoctoral mentor at at NIH and this, this, I think in maybe the beginning of my second year I just discovered to be honest with you, I just did not like research. And it was, it was a huge challenge because here I am, what they, new doctorate degree pretty much, you know, the whole world will tell you a doctoral degree in chemistry is a research degree. And here I was not sure that I liked research. So it was definitely a bit of an identity crisis. And because again, back to my previous point about science, because I didn't like research, I also, wasn't very good at it. And so my mentor at that point, the over the overseer of my research took me in her office one day and she said, listen, I can't renew you because you're not effective.

Sarah Miksinski:

It's not that you're not effective at, at, at all. You're just not effective at this. So think about it. What do you want to do with this degree? That's not research. And so that

forced me into a space where I really had to be more enterprising and figure out, okay, what was I going to do with this degree? Well, some of the things I like to do, some of the things I'm really good at writing, speaking, presenting all of those things were possible in a career like a regulatory career, but they were not necessarily so accessible with a research career.

Denise McIntosh:

I found that fascinating because my degree is in economics. And I have to tell you that some of those theories and things just scared the heck out of me. And I was never so glad when I believe his name is Steven Levitt started writing those economic books for lay people. And he admitted himself that he didn't really like all those theories. That economics is a lot based in logic. And I had to agree wholeheartedly. That was my interest in economics. What was the simple logic behind supply and demand? Yes.

Sarah Miksinski:

Yes. Agree.

Denise McIntosh:

So tell me about your journey from there and what you've been able to do and, and bloom and that communications.

Sarah Miksinski:

Sure. So when I first, my first, what I would call my real job and when you get out of a post-doc, it's, it's the idea of a real job is just a novelty in and of itself. You've been in school for so long, but I was lucky enough to work at the food and drug administration for quite some time. And I worked there from 2002 till about 2018, had a pretty lengthy career. I had multiple positions. I served initially as what's called a review chemist, which is one of the people who looks at applications for marketing approval, for medications in the U S and evaluates those for adequacy to be approved. Yeah, very, very interesting. It was very heavily based on writing very heavily based on your ability to dive, to digest scientific information, and more importantly, to explain it to people who perhaps are not necessarily in your field.

Denise McIntosh:

And that, that is a real talent,

Sarah Miksinski:

You know, it's funny, I was there for so long and I have to say that that is you're right. It is a challenge. I'm not sure I would have said that going in, but as I got more and more experienced, yes, it is a, it is a skill it's. Some people have to develop it, it, it can be

very, very difficult to develop that skill over time, but it's also a great challenge for people who enjoy digesting large amounts of information and using different types of tools, even storytelling, to try to tell people, explain very complex scientific components or, or issues to people who perhaps don't have the same training. And it's, and I don't necessarily mean to imply that, that there are other people in the approval process who are not scientists, but there's, the science is so broad that as a chemist, I would talk to somebody who would be a clinician or maybe a pharmacologist, and we all have different training.

Sarah Miksinski:

And so the issues we're dealing with and grappling with it really does rest on your ability to draw it back to first principles, explanations, and effective communication to really make sure you're driving home, what you need to. So I did that for a good bit of time. I moved up the management chain, somewhat cautiously. I remember that I at FDA, my, the thing I say now is I, I liked every single job I had. And whenever I have somebody who would come to me and say, Hey, Sarah, we think you should apply for this. And it was kind of like, oh, I don't know. I kind of like what I'm doing. And it's interesting because I did the very end of my FDA career have a fairly high level position as an office director responsible for about two or 300 people doing that function reviewing and was involved in a lot of policy and external communications. But again, I look back on all of those jobs that I had at FDA and just loved them, loved every single one of them.

Denise McIntosh:

So now you are the senior director in global regulatory excellence with one of our favorite customers AstraZeneca. So what does that entail?

Sarah Miksinski:

Well, it's interesting. It's, it's the same thing as what I did at FDA, but on the other side of the table, that's what I say. And I'm always very careful because I don't like the idea of industry being on a side or government being on a different side. And so I see it as a big conference table and ideally it'd be a circular table, you know, so we all have kind of equal say yes, but I, I do think that there is a different perspective and industry. So instead of reviewing applications, now I'm helping to put them together. And I am still focused on what's called chemistry, manufacturing and controls, which is very much how drugs are manufactured, how they're tested all of those different elements that go into making a product for the market. The interesting thing that AstraZeneca, and one of the actual reasons I departed FDA was, or is that I work on a global scale. So I'm not only working in the U S regulatory landscape, but also globally with other countries to get products approved worldwide. And that's a distinct difference between my FDA work and my work now with AstraZeneca. So

Denise McIntosh:

The, so that ISPE conference that I tuned into. So a lot of the people in that were the, the equivalent to FDA people globally.

Sarah Miksinski:

Yes. Yes. In terms of health authorities and regulators, yes. There are, there are different regulatory agencies globally for the, the, the pretty much all the regions in the world that have the drug approval process or rep review and approval process. So, as an example, FDA is US-based con the Canadian regulator has health Canada. Japan is an organization called PMDA and you'll have to forgive me because I don't remember the acronym. Okay. Brazil is, is an organization called N visa. So every different region has their own regulatory authority. And the interesting thing about regulatory in general is that pretty typical for most authorities to have different rules, different legislations on different platforms that they review based on. And so in the regulatory space for a company, any global company, you're constantly trying to figure out how do you, how do you roll products out and submit products globally?

Denise McIntosh:

Interesting. So, I mean, we're, here we are in 2020 in the midst of this pandemic. What are you seeing that might be different in this environment with cooperation among all of those global regulatory people?

Sarah Miksinski:

Well, I think in general collaboration, I would just comment on collaboration is that we've, we've gone to almost entirely virtual. And I find back to your previous point, I find that that's, that's, that's a significant challenge for someone like myself who was very reliant on the face-to-face connections and the ability to connect to people. Face-To-Face it's I think for me, individually as a professional, it definitely has forced me to reinvent some of the ways I work, not only within the company I work with now, but also just in general, when I'm working with nonprofits like ISP how, how do you work virtually? How do you discuss virtually and how do you make that effective so that you're not wasting anybody's time or not wasting your own time. And I think those are really interesting conversations. I it's it's always interesting to me that you can do things virtually, you know, before, before COVID, if somebody said, I have a problem with you, Sarah, I need to talk to you. Let me give you a call. I would say, let me hop in my car and drive to your office, because for me, I always think that in-person is better. It doesn't matter whether it's a, an issue with a business I'm working in, or, you know, something at the church we go to, I'm always more face-to-face. But I think with COVID, that's really taken that option away.

Denise McIntosh:

Well, and those of us who are the communicators. Yes. It's a challenge. Yes. We, we, we cue on, on facial expression and body language. Yes, yes. Joan of voice and yes.

Sarah Miksinski:

Well, and it's, I'm married to a psychologist who always reminds me that 80% of communication is non-verbal or at least 80%. And I think to myself, you know, that's really true when that camera's not on, even when the camera is on, you're not really seeing all of the nonverbal expression,

Denise McIntosh:

Although it does help,

Sarah Miksinski:

It does help. Your correct does help.

Denise McIntosh:

So, Sarah, I want to transition just a little bit because you and I had a very interesting conversation about mentoring others, and the fact that all of these podcasts I've had are, have been with women and our challenges simply being women in what has been in the sciences and in agriculture that I spent many years in, pretty male focused, but you made a comment when we were visiting the first time about being very careful to understand if there has been a perception of discrimination, whether it really is.

Sarah Miksinski:

Yes, I did make that comment. I, so I think that if I look back on my own career as a woman in a scientific field, well, the first thing I would say is I've had the great fortune, the great fortune of working with some extremely dedicated professionals. And I have received some advice. I actually, a lot of advice from different, different people that I admire to really seek mentors as part of my career, to not view it as an auxiliary arm that you do when you have the time. So what that means for me is what, wherever I am, if I'm at a conference, if I'm in a meeting, if I'm working at AstraZeneca, I'm working external to AstraZeneca, I'm always have my eyes open for, you know, who, who do I see that has talents that I admire, who is exhibiting behaviors that I would want to emulate?

Sarah Miksinski:

Who do I respect? And then taking the effort and really making a dedicated effort to connect to those people and letting them know this is something I really respect about. So, you know, not that I'm not going to lie, it's hard. It's, it's hard sometimes to slow

these very busy professionals down and say, Hey, let me, let me ask you a few questions about how you develop that skill. But I will tell you in my experience, most people who are authentic and have that level of compassion will actually slow down and have that conversation. And so over the years I have built what I consider a network of people who are just tremendous mentors to me. And anytime I have a chance to talk to them on the phone now, of course, or have lunch maybe in pre COVID or post COVID, I will always take the opportunity now to your question.

Sarah Miksinski:

I would say that not all of them are women and a lot of people are surprised when I say that I do not seek out mentors based on like a male, female ratio. I seek out mentor mentorship based on behavior. So some of my most valued, valued mentors I can think of at least two or three are men. And I think they are greatly, greatly helpful to me and have been greatly helpful to me over the years. So I think that's one piece of it for me, to be honest, is, is just being open to who you admire and who you respect and responding to that. And it doesn't have to be someone who's just like you, it can be someone who's very different and maybe it has a different demographic, even different training. There have been people that are trained in humanities that I've approached with that kind of question. And I think that's an important thing to, to, for me, at least as a professional, to always keep with me.

Denise McIntosh:

Well, and for me, most of the mentors that I've had over the years have been males simply because those are the people who were available. But I agree with you wholeheartedly finding those people whose skill sets you admire and whose integrity and credibility and just behavior. Yes. So important.

Sarah Miksinski:

Absolutely. Absolutely. In some of those conversations, again, back to your question, what I use that network for would be things like feedback conversations about perhaps career development. But I also use my mentors for support when things don't go the way I want them to go. And yes, that does happen to me now. So I think that that's an important element and some of the conversations I've had especially early in my career things would, I wouldn't perhaps not get a job that I wanted or perhaps I would something would not turn out the way I wanted it to, or even the way I envisioned my brain as an early professional might go into well, that's because I'm a woman and I would be challenged by some of these conversations. Some of my mentors would say, no, no, wait a minute, are you sure about that? Because here are you looking at your CV and you're lacking some skill, you're lacking a gap in your experience. And here's

what I, what I see it as no, again, that can be hard to take, but at the same time, I think it's very honest feedback. In some cases you were spot on.

Denise McIntosh:

So you and I started this conversation, but, and I'm put, I think probably 20 years older than you are. And I, and there was a time in my career that I had gotten a master's degree. I had advanced in this company and I hit the glass ceiling going a hundred miles an hour and was just stunned by not being offered an opportunity that I knew should be mine. And yet in, in the years, since then I look back on that and, and, and thank the good Lord. I didn't get it. God's really determined that I really wasn't a good corporate person. And, and I am the, you know, I'm a risk taker that I didn't know I was so w I wouldn't have helped start two companies had I still been there. And, and then I think back to another conversation with one of my very first mentors, who was one of my customers in Iowa, because I'd been offered an opportunity with another company, and I went to talk to him about it. And he S he said, you need to sit down here.

Denise McIntosh:

He said, you're not a good fit there. And I was stunned. I said, why? He said, because you tell people what you think, and those people won't want to know that I said, oh my, oh, my, there was a revelation. And yet back to the opportunity that I thought I really should have had in the other company, I just was, I know, ahead of my time in, in the people I was working for, being comfortable with me being at the table, because I was successful in what I was doing, but they just didn't have a comfort level to let me in. And, and I now get that it's taken a long time, but I get it. Yeah. And I think we've changed that over the years. And that's why I think it's so exciting and encouraging to see younger women like yourself, advancing to the positions that you are.

Sarah Miksinski:

I thank you for the compliment. I appreciate it. I think to your, to your point, I think the, I mentor people now in, in my leadership capacity. And one of the things that I'm very passionate about, one of the pieces of advice I give the most is who are you when you don't get what you want? And it's almost, I grew up with a dad and a brother who are tremendous baseball fans, and I'm a baseball fan. And it really, in my mind goes back to what happens when you lose the game. For whatever reason, you know, what it could be, that there was an earthquake that was completely beyond your control, but what happens when you don't get what you want, who do you become? And I think that's a really important thing, because there are certain things that an individual can control, and there are certain things that you cannot, and they're not always fair. But again, that question, who are you when you don't get what you want? I think that's an important one. It's one that I always keep in the back of my mind, because again, it's nice to think

that I can control everything fairly, but I can't. So who I am in that situation becomes me as a leader. And who is that going to be?

Sarah Miksinski:

What, what great advice. Thank you.

Denise McIntosh:

So you, how has, how has the pandemic besides being a difficult communication way with your colleagues and, and work impacted your family?

Sarah Miksinski:

Yeah, that's a great question. So I can start out with myself and I'll offer some perceptions just about working at home. I, I actually am one of these people that doesn't like to work at home. I like to get dressed and go into my office. I like the distinction between my home life and my work life. Working at home a hundred percent has been a challenge for me because I work harder and perhaps even harder than I should. And so studying those boundaries between work-life balance has become, I would say more challenging, but far more important even than they were before. That's my experience. I think there are some really great things though about working at home. And one of them for me is that my ten-year-old gets to watch me work. And it's an interesting thing. He will watch me on phone calls.

Sarah Miksinski:

Sometimes he'll watch me type documents. And because he's young, he asks questions. Are you under pressure to get that done, mommy? Yes. I'm under pressure to get this done. Wow. Very authentic questions. And I think that's a great thing for him to see. I, I, I've always been a little uncomfortable that he can't really see that. And so it's nice to have him see that Intuit in its certain element. It's, it's nice to have my husband see it as well to see this, this is what Sarah does. This is the job she has. And I, I really have enjoyed that part of it to be able to share as much as I can. I work in a confidential environment that has to be protected, obviously, but certainly just the mechanics of what I do, the daily, the daily rituals, or even the schedule of how things are scheduled and how many different stakeholders I interact with daily. Those are things that, that people typically just don't see. So

Denise McIntosh:

What excites you most going into 2021 with the position and with AstraZeneca?

Sarah Miksinski:

Well, I think for me as a professional, I think it's, I'm excited by any time, any time that I'm in a field, which I definitely feel like in pharmaceuticals right now, where you impact patients, you asked me actually a great story. I have when I made my transition from working at FDA to AstraZeneca, I was having dinner one night with my family. And it was around the time that I'd made my decision to transition to AstraZeneca. And my ten-year-old asked me was, I think he was eight at the time. He said, well, tell me what, tell me what you'll do at AstraZeneca. And I said, I'll work in pharmaceutical industry and I'll work to help make products available to patients. And I remember he took a minute and he said, well, isn't that what you do now with FDA? I said, well, you know, yeah, it is, it is. So that's still is what excites me the best, the most it's is that is, that is why I do what I do, no matter where I work and what time it is, there will always be public health needs. There are always patients to serve. And just being part of that, I think is just a great inspiration to me. Well, Sarah, thank you.

Denise McIntosh:

The intention for these podcasts has been to make available to young people, male, female, anyone to understand a, how important manufacturing is, whether it's for pharmaceutical or food or chemicals, but to allow people to see those opportunities, whether it's on the regulatory side or on the operation side or on the quality side, any of those that helps us expose young people to opportunities so that we close a wage gap in this country. So thank you for being part of this conversation.

Sarah Miksinski:

My pleasure, my pleasure. I would see that. It's just a great, it's a great honor to be asked to do these types of interviews. And I think if I could say one thing, just one thing to anybody who is an emerging leader is just to make your own story. Don't let somebody write it for you, make it yourself, make it your own. Sarah, you have a great story.

Denise McIntosh:

Thank you for sharing. Absolutely. My pleasure. The art of engineering engineers, talking about their process principles and personal stories presented by custom powder systems. The containment company, custom-powder.com.