

Lessons Gleaned from Twenty Five Years of a Regulatory CMC Life with Ed Narke

Episode 20



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A DS Inpharmatics Production

Meranda Parascandola

Welcome to a new episode of CMC live. My name is Meranda Parascandola and I am a co-host of CMC live, along with Brian Lihou, and host Ed Narke. Today is going to be a little bit different than the other podcasts that you've heard as of late. Typically, our podcasts are myself, Meranda, Brian, and Ed talking with subject matter experts about their experiences and what they bring to the table at DSI, which gives you a little bit more insight into the industry and our knowledge of the industry. Today, I wanted to flip the tables and put Ed Narke in the hot seat. Ed Narke is co-founder, principal managing regulatory director, you name it, at DSI. He and I have been working closely together for three and a half years. I am head of business development and marketing, and I have been talking about doing podcasts for a couple of years. And now that the dream is a reality, I have Ed Narke here to share his experiences and how DSI was shaped. Ed, welcome.

“Comparing INDs, NDAs, BLAs, I’ve always had this fascination with putting stuff together into a story.”

Ed Narke

So, I was once upon a time, like, an industry newbie like most everyone was working in the process Development Lab. I still remember my first day, and the fellow who was like my first mentor, how he approached me and my first lesson of like life was, “can you show me how to use some instrumentation,” right. But this was back in the day, when, like, I worked in the lab, at a process chemistry lab, but I would still wear like a shirt and tie. And I had like a lab coat and stuff like that, over the years, this is a side story, but like, you know, that was like jeans on Friday, you were allowed to do that, and then blah, blah, blah. So that was like a long time ago.

Now, you know, fast forward, I discovered and found this interesting group called DSI here, you know, by sticking to my values and doing the right things, you know, that all the mentors over the years from manufacturing to Big Pharma, to small biotechs, that kind of ingrained in me. And now it's my turn to pay them back. It's my turn to like, translate and pass a lot of this on to new people, including our consultants here yourself, anybody, you know, that I could share with, including the bad stuff. So, if anyone doesn't like it, they do the opposite. And they're successful. I've done my job.

I look back on my career, right. And I kind of made a few big mistakes. I didn't realize at that time, but then I did. But it gave me a chance to move forward. Like, for example, I think I went into my effective vice president of this company's office to resign based on that I was just a kid, and I was just like, upset about certain stupid little things, right? So, when I walked in there, instead of like, leaving the job, I made a connection with him as another lifelong mentor. We had a discussion and turned out was like, the inspiration that I need to get me to the next spot, right. So, building like relationships based on trust, you know, living that thing, it translated into

maybe some of the ease of you know, we're working with people to try to find partnerships out there, you know, that relationship, that trust, but what's it called? It's called just being honest, and you know, that maybe that helps a lot. Sometimes when you're talking to people to have them allow them to be able to work with you if you come across this too salesy or sterile, you know, there's no, they don't have a relation. There's no relation point, right?

Everyone grew up in the same way they had the first day at the job with a tie on, this was back in the day. And they had the first boss who they didn't know who he was, or she was. And you know that that person influenced them and gave them you know, a start and basically kind of brought them up to the, you know, where they're at, to a point where they were not able to grow and learn anymore. So, they left right, like I left, not ever for money, but it was for more responsibilities and more opportunities. There are things like that, right.

I have like 25 years exactly. No, it's 24 years of industry experience, extensive experience, right? All phases of development. I started off in post-approval and regulatory, globally working with distributor markets, really not the flashiest place you want to be in Big Pharma. That's where they put like new people. Suddenly, you know, I got an opportunity to work in development side in the US and then you know, I got a great start to go to the FDA meetings face to face with a large number of a Big Pharma team for a number of projects that I was involved with. And while I sat there as a young guy, young person, it never was case. I mean, I look back, I was always the person that was discussing things and had all the energy. And I looked over, and I saw some of my colleagues. And they may remind me of myself now, where there's other people, not really, I mean, there was definitely some bright people and you know, guides, but it's the fact that they gave me some opportunity to shine. That gave me the confidence to talk in front of people to people talk up to people, and then also not talk down to them like that, but to get on different levels that folks don't understand technical people about regulatory things. My main experience before that was manufacturing.

You know, I met guys like Dan Torok, and Dave Adams and a few other folks that work with us now, but you know, I learned a lot from them. And then I went in a different trajectory, and they stayed in the same trajectory. And, you know, we kind of mesh well together now. So, comparing IND, NDAs, BLAs, I always had this fascination with putting stuff together into a story. And there was all this data stuff, you know, working in Big Pharma, you have access to all these great development ports that you can cut and paste out or, you know, utilize it, where you're not writing everything from scratch, but then you get a chance to write the interim, the stuff to tie together, like the glue. So, I worked on this product, a fusion protein through it was made through expression, recombinant DNA. It was ironic, because I guess before I joined Big Pharma, I worked in manufacturing, I moved from bonds of small molecules to biologics for a bit. And I learned the process side of it kind of in the QA area, and then going into the regulatory just to see everything laid out and data, you know, cell bank information, those type of historical things to through the process, upstream process and down, I was like really able to visualize things having seen all this in manufacturing, you know, actually, when you're, what do they say, like, you can't, you know, no one can teach you something, you have to learn it, right. And sometimes you learn it by doing it and experiencing it. And

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a lot of times you learn it by making mistakes doing it, and then suddenly, you know, you don't know you're an expert, some people don't think that they're experts.

But we are here, you know, we definitely have some opinions on things. And I personally probably have more opinions about regulatory submissions based on, you know, doing 10-12 years, while I don't do it, necessarily, and sit in a chair and write this stuff anymore. You know, I still, anytime I hear something about submission, you would be surprised it pops in my brain pictures of PDF files, with these files that I wrote or reviewed, or whatever. So, it's almost like, you know, second nature. And then I was like, I was actually involved as like a co-instructor for a lot of these courses on CT module three. Now that I look back, it seemed like so long ago, at least 10 years ago, but for like seven years, I would be part of wraps and APS at their conferences and workshops with like, 100 people. And it would be myself and three or four other people and showing examples and really getting, you know, very passionate about certain things and have an active discussion. A lot of times with folks that aren't totally in agreement, these workshops were a lot of big pharma. So, they had different ways of dealing with things. They didn't have to put everything in there. And I wouldn't recommend that anyway. But because they had all this information that they can tie together, they can summarize things. And they had information in their pocket, that if there were questions, and they knew exactly where the questions would come, they would be prepared to give a robust answer without spilling the beans, like when you have no information, and you put so much into a filing and it's not cohesive, then you just beg for questions, right? But if you don't put any information in there, you're gonna get questions. So, it's that little art that I used to love. And then you know, I would have to agree to disagree type of discussions with them. When I started doing the submission filings and writings for small biotechs that didn't have data. At some point, I thought I became like an advocate for small biotech and emerging biotech. When I was volunteering for these, these workshops and etc. It was all big pharma folks alongside of me FDA, you know, not a lot of folks were small biotechs. Most of them didn't have time, because they were so busy with their biotechs. Luckily, I was at a few jobs that had failures, products that failed, and I had some downtime here and there, or I just, you know, put a lot of effort into it on my own personal time. So, that was a very career shaping for me.

I was also the regulatory sciences section content advisory committee chair for APS magazine. Back in the day, I remember my editor, Linda Brown, who was so gracious and special and helpful. And I chaired this APS regulatory sciences section, which used to be just the best section of APS. It was comparable to the biotech section or PK PD or other sections, other drug development areas, but I just remember some of the folks that I worked with. I didn't just get the position, I had to start as like the scribe and then it became like a treasure and then the Vice President and then the chair waiting or whatever. So, it was over five years and I remember I did so much work up front and you know, as like the low person on the totem pole, and maybe I just got better at it or it was just that, you know, that was the role of the person low on the totem pole. But when I got to the regulatory chair position, a lot of great people, I think I helped to recruit a lot of them but so did others, you know, we really had a pretty decent team. And a lot of the stuff that we discussed there went on to go into building programming for APS, over the years.

Now, unfortunately, there's a movie called like, "The Man That Was Alive When the World Ended" or something like that. My last year there was when they had a reboot of APS, because the attendance was down, there was a lot of problems with the organization, and how people traveled to these things and what they, so unfortunately, everything sort of fell apart. They took this section, and they turned it into one of these communities, they call them and they're still active on the APS website. But now that was kind of like the first foray into digital and those things like that. Unfortunately, it takes time. I mean, I think maybe in 15 years, that'll be the norm. But, you know, there's this transition that is occurring now, it doesn't necessarily reflect on the whole membership. So, you know, back to DSI, I don't know what my title is anymore here Managing Director of, I like, somebody I know, his title is self-proclaimed optimist. So, I'm going to stick with that right now. I think I accelerate DSI's push beyond like the traditional strategy consulting to like a highly tactical, actionable advice consulting. I

mentioned a little bit about the consultants that we used to hire very disappointed or expensive, and they just didn't leave you with something, knowledge or anything, you know, it was always it depends, there was no real answer. So, I think that kind of shaped the way I operate and talking with Tony and starting off the business with him, it was very easy, because you know, we both had the same mindset and valued the same thing.

So, it's always been the focus, but the new again, re-emphasize focus 2021 here is helping the expanding emerging biotech community, you know, where we're DSI, obviously gets much of its revenue. And also, medium sized pharma clients become regulatory compliant. So over 14 years here since founding VSI, it seemed like it was like yesterday, I do remember the day I was introduced full time to the role. Unfortunately, I left my last job in a hurry. And then it was like, really here. So, like, I have a story. I came home and told my wife that and she was like, what? My mother-in-law was here as well. And she's like, What? Do you have a job? And I was like, yes, we build an unprecedented record of achievement, I think, in my opinion, assisting clients all over the globe, to address like drug development, product development, compliance, and regulatory program and project management. It's all blending together. We'll have this episode for you someday soon, probably. I'm sorry, Meranda.

“I hope I look back in fourteen years and say, ‘These are the best days of my life.’”

Ed Narke

Oh, yeah. But it's funny, because like, yeah, maybe we should keep this recording, because like, well, probably 12 years now, you'll be like, I remember those early days, like I even woke up today, Meranda, and I said, What does the world smell like to you right now. Because I remember when I was, like, in my early 30s, you know, warmer days in January, there was a certain smell in the air. It's like spring was about to come, you know, it's not going to get here for a while. But you could smell it right? So, after 14 years, the smell is dead, gone. And that doesn't smell the same. Maybe because I have teenagers now in the house. But and

maybe the house is 14 years older, and we have a lot of pets. But I think you're not going to understand like right now for yourself until 14 years from now. And you're going to look back and you're like best times in my life, right? And I hope that my future is the same. I mean, I hope I look back in 14 years say these are the best days. Sometimes I could look back and say this is the darkest days. Right? But that's part of life, right? So, 14 years in the past, you know, worked with over 200 biotech companies at least plus, right? US International, I think we kind of worked on at least and contributed to like 60 probably more than that, because it's 200 clients but 60 original AND's, you know, ones that are not me too type of products, original programs, products that potentially could become unique and different game changers and a lot of them have. And I think I counted a couple months ago 25 NDA or BLA fully support it. And that might be an underscore under shoot here. I know we got involved with a lot that kind of didn't go anywhere. It was never started. But it's pretty impressive. I would say it's like two a year, two plus three a year. And I know I remember when I was starting, I think I was really actively involved with the consulting parts, I probably could say worked on half of them and wrote a lot of the sections. And then I think we actually got better when we got some further staff in here that can do that.

So, you know, I think the cornerstone of this success again, to move forward as found in our team of consultants and project management staff. One of the things I see all the time that's taking action the good ones here and we know we maintain, we take the subject matter expertness of their selves, decades of practical experiences and are able to project manage things as well. So, it's kind of unique. And then you know, the experience that we have here allows everyone to borrow that and have that, you know, without too much effort, that's real-world perspectives on how to navigate things and how to decide on things and how to deal with things.

So, I don't know about you, but sometimes I get, people don't like me for this maybe. And sometimes maybe I don't practice it, sometimes I should be better at it. But I believe open communications and transparency are the

foundation for successful outcomes for your product. And that, when I'm talking about that, not about my personal views on politics or anything, it's really with the agency, right? You don't want to hide certain things. In fact, you know, it's really something you want to be honest with them upfront, and try to figure out what they're looking for, you know, what they're most interested in, and then addressing that, that's been my success back in the day, and maybe, you know, still, you know, talking to someone like they're human, like, they're a partner, it's not a, you know, you give me some questions, and I'll give you some answers that I want to give you. It's, I want to answer your question, and I want to make sure you're comfortable with the answer.

I think most, if not all of us here, I think all of us hold ourselves to the highest standards of professionalism and scientific practice, and ethics, and etc. So, I'm very impressed with that. I learned a lot from everyone. But hopefully, I, you know, inspired some folks to do the same over the years. I did learn a lot from a lot of people too, though. So, you know, we know, regulatory and operations management and oversight. You know, we're trying to be big believers of change here in the future, we are embracing technology and those things like that, at some point, we talked about perhaps having archiving all the brains of everybody here at DSI, and creating some sort of like good looking holograms, where, you know, these folks could maybe live in perpetuity, and maybe have collect, like the TV shows, maybe collect some sort of like whatever that call that's called that the residual, every time someone sees their hologram, they get 10 cents or something like that. So, but we do live in a, you know, a very small niche area. So, if I had to do it all over again, I'd probably find you know, something big that everybody needs. But you know, I'm proud that we have our small group here. And you know, it while it only serves two to 3000 people in the whole world, I think it does make an impact. I've heard it from numerous partners and stuff. And that's kind of like what I get up for every day.

Speaking of, I grew up in an average middle-class family in the 1980s. If you don't know, Meranda, much like today, the ongoing economic and social unrest at the time now was the same then it was just different. I understood it differently. I was nervous in a different way. I had parents and I had a future. You know, now, things are very scary for certain people, and they're really relying on other people now, so but it didn't, it taught me the importance of like adapting to an uncertain world, some of the things I have to remind myself every day, is that, you know, life really hasn't changed, I have. So, you know, I have to remember that. So, I live my whole life as a kid watching my parents sort of looking to survive, and not get swept up under the, you know, the tide of the latest crisis. And now I do it myself with my children, maybe actually overstep some of the conversations about certain topics out there with them. I'm sure they, I can tell by their actions, sometimes they're not interested, or they want me to shut up. But, you know, that's part of what it is. I remember my dad, he like saved half his pay, stocking away money and stuff just for survival, I kind of do the same thing. I'm sort of frugal, always will be, I guess. So. It's always about building something for the future.

You know, I think some of this stuff, some of the work I do. Offline is really, like, I see payback now, you know, into relationships and free advice from other people that I earned over the years by helping them and there's things like that. So, you know, it's not all about money. It's about you know that whole, whatever that pay thing is right. And I think I mentioned this to you before, Meranda, having a plan is important. But also, being willing to change course, is kind of really more important. that stuck with me, I think someone told me that a few times, and there's a couple books I read about it, you're going to have to adapt pretty drastically to circumstances, right. And in the regulatory space, if you apply to life, it's very similar. Things are gonna come up batch is going to fail. questions that are don't have answers, black and white are going to come up and you're going to have to kind of make decisions. So, when COVID-19 crisis hit earlier this year, for example, most sponsors went to like the 90% telework plan almost overnight, right on our travel actually essentially stopped. So, while it sounds bad, and you know, on the surface, like I've been talking with folks about this year, and I feel very grateful and lucky that it was a really great year, it was easy for us to step into situations to assist you know, as we already transformed into these instances process years before a cost containment and efficiencies right. While I always like to prefer to hang across the table from somebody and share a brew or coffee or whatever. With technology, it kind of saved

us you know, for this crisis, if it was just back in the day email and phone calls, then the industry would have been way more disconnected but introspectively I think this probably was required.

I think on our group, you know, intellectual horsepower, and the ability to think strategically kind of ramped up, I know, that's a lot of the reasons why we got more ingrained, which kind of shined when COVID hit I would think, and no one predicted it. Now, we're not only coming up with not just fixes, but you know, real solutions. And we're plotting these courses together and haven't seen a lot of hiccups in the last or haven't heard of a lot of hiccups, besides the obvious ones, right? The ones that you can't control, but of course, our jobs, Meranda, is not just for business development, and, you know, breaking contracts and it but it's to influence folks, becoming influencers, like, you know, giving them an option to leverage something that they don't necessarily have. And on the other side, you know, operationally, Brian and Bob and a few other folks, you know, kind of collecting the right people in the field of or the department, you know, whatever you want to call it. So, I think working together has been important, and it will kind of continue to be important, you know, we have to be on the same page. And I think we all have the same goals, though. So, I shifted my focus on the last couple of years to learning again, I did the first you know, my first part of my career was learning. And then it was kind of teaching or training. And I think that's the natural progression, you know, when you get older, you're expected to teach and train and be that person. But I found just personally, when I learn stuff at work, when I, you know, discover new things, it's more fun, it's more fulfilling. So, success comes even faster. So just FYI, anyone listening to this, here at DSI, if I can learn anything, I'm probably easier to work with and I think you'll get more out of me. But I think it's for a lot of people learning is definitely fulfilling. And even today, I'm constantly scanning, you know, naturally curious as you know, Meranda.

So, I have to credit some people. Paul Deutsch, my first boss at lonza. I met him many, many years later, over actually many years he used to have black hair. I think Dan Torok took his desk when he left graduate school at University of Iowa. The guy was a baby nine months, a year and a half of my life. Well, there's a guy before that David Brennan, I worked at DuPont experimental station, sort of a temporary kind of a college or what's it called internship, right. And I cannot even get into it, David taught me about life more so about how to deal with this system, the management and the administrators that accompany right so he actually did give me some, I don't know if you remember, there was a software called leisure suite, Larry, all these guys in the lab. They're all like lab guys. Pretty much. That's what they were. They all played leisure suite, but that's the procedure.

So, Paul Deutsch was like the first real, where I was responsible. And then, you know, I worked there for a couple of years. And then I moved up the ranks pretty quickly and moved into a different space, got a great foundation. And then I went to this company and there was a fellow named Jeff who is very, very influential. I don't know if I ever heard him say anything to me, now that I'm looking back at it, but he would put me in a position to go to hit all of his meetings. He was like a higher up person. And everybody in his group, he did that actually, the funny thing was now I could probably say this safely. I was one of two men in his group, there were 10 people and eight of them were female. And they actually called them Jeff's angels. Charlie's angels for who didn't get that reference. But the question that this fellow Mike got before I did, he was my male counterpart. He was there about six months earlier. We both got was like, how did you get a job in his group? He only hires females, young females, by the way. And I said, you know, we must be just, we're the only ones who qualified out of all the men. There's not a lot of good guys out there, obviously. Right. And then through him, I got expanded over to actually, the CMC operations for the US and Europe.

“One of the things I have to remind myself every day is that life really hasn't changed, I have.”

This guy, Mike Fenster, who's in the UK right now, I'm not sure if he's still working in industry, Mike gave me some great opportunities to travel to Europe and UK mainly, and work with him on a number of compliance issues. And he also introduced me to 10 people, a lot of them I don't remember their names right now. Brian Corrigan is a fellow that was kind of like another understudy of Mike. And I have to connect back again with him, but just phenomenal experiences. And then of course, there was, and I may be leaving people out in the middle here, but these are some of the highlights, right. Lisa DeLuca. She was my boss at three different companies, you know, with breaks in between. So clearly, she liked something about me that I did and how I operate it. And obviously I valued and treasured working for her. And who knows, maybe the future you know, maybe we work together again, some of the people I did leave out like the glue, or you know, guys like Dan Torok, who worked with me at Lonzo and more training and experience in the lab. You know, I kind of watched him and some of the older fellows and just watch how they operate and how they dealt with management in production and emulated that so obviously I can say this. Everything I learned that is valuable. I learned from Dan, everything that I learned that is dicey and on the edge, I learned from Dan. So obviously I have a lot of respect for him. You know, we've very similar personalities, but I'm sure I'm sure I emulate, you know, I mimic some of how he operates just because it's, it makes me feel like that's a good thing, right.

I won't go through all the podcasts, inspirational people that did but you know, a couple take a bow, right. You know, most of the folks, especially in the technical, functional and new technologies area, you know, talking about stuff that half the time is over my head, I don't really understand sometimes when they're talking about, but you know, as I grow more, and I talk to other people, it starts to fit in, and it's become part of the makeup. So, one of the things I'd like to kind of talk about and share is like, just some ways to live, you know, industry, if you're a regulatory person, the goal should be building knowledge and effectiveness. And what does that mean? Right, the more you know, the more effective you can be. Right? So just like I was mentioning about AI, you know, understanding that and also new therapies is part of the part of the job emerging. biotech companies, as we know, have mountains of data to process, you know, some of them don't know what it is, I think that's where we at DSI, know someone like Colman Byrne with analytical origin, that's with process chemistry to the natural, right, they come, and they can figure stuff out based on some data. It's impressive, right, you know, years and

“Everything I learned that is valuable and dicey and on the edge, I learned from Dan [Torok].”

years of experiences, right? That's kind of like the inherent value of a consultant, you know, someone that it's like a switch just turn on and it works like a, I don't know, blender or something like that, right? You just expect it to work, a refrigerator. Right? Not saying that Jim's a refrigerator, he's very non refrigerator. He has, you know, and Dan Torok. And I you know, just from the dealings with I'll just name a few more folks, Catherine Bernard, certain folks that have that appetite for building knowledge and becoming an effective person. So again, I am very happy to have access to these folks and work with these folks daily. So, listening to podcasts wasn't always a waste of time, Meranda.

In June, we rolled out our latest innovative offering for emerging companies here, CMC live, which, obviously, is this podcast, right? My goal, hopefully, is to kind of grow it make it more interactive, you know, maybe have a live audience with questions, maybe bring individuals in that could do a better job or, you know, maybe answer better questions, bigger questions, but I think we're getting there are SMEs, and our project managers all have kind of a lot of them have core have contributed to it. Now next round this, maybe we you know, kind of enhance that. always going to be discussing regulatory industry trends and discussing hot topics. So, you know, I guess whoever does hear this and happens to listen to this actual one part, drop us a note, you know, drop Meranda a note, drop myself a note about some questions, join our podcast, let's become friends, let's, if any of this inspiration is interesting for you, you know, hopefully, that's why I'm doing it, right. Think of us as or whatever this is, here's another resource to build up trust to build up the knowledge and, you know, become effective. So, I think one of the other things I can share going into 2021.

And remember, 2020 was a not a great year for a lot of things, right? But personally, I maybe looking back on it, I think I learned a lot about myself, whether I liked it or not, whether I'm going to change and become better or not. I know what the game plan is, right? So, one of the things I think I would have to say in a bullet point, you know, remember, there's no more to life than work, which sounds kind of weird, right? So, I'm the boss here in theory, right? Maybe, but that's not the case when I return home, or maybe when I'm at work, which is the other side of my house here you know, like the family right? Then three kids 13, 16 and 17. I can't believe my eldest son's going to be 18 in like a month so after a long day at work I'm the last person on the totem pole at home obviously, right? The reason why I am who I am is because DSI right? All that good stuff that I did, also brought all this other excitement and pressure and except right so now Of course, everyone else is trying to be the boss around me, including the dogs and pets and of course, right. So, I got to deal with that. Sometimes family talk gets intense, right, you learn a lot from how family views world events, like I've mentioned. But that helps me crystallize my thinking, you know, some of the stuff I'm pulling back and forth between family and work stuff now is helpful. And also, family time, helps me see my problems and helps me see myself with much more perspective, something that I wouldn't count on from work. But then again, you think about it. The relationship with you is, you know, a very open, your very good friend of mine, Meranda.

So, I think that's, you know, again, it's the, it's the trust factor and the communications factor. And then you have to be professional too. So, mix that in, but so connect with others by being yourself. That's my secret formula. Did you know that just be yourself? Right? That's all right, when employees view me as just the boss, barriers to communications go up, right. So, to truly build trust, this is why I like the coffee time and the watercooler was just in my nature. So, to truly build trust, you know, I learned it's better to let colleagues get to know me as a person, I always been real before COVID, I was real. And after COVID I'm real, and for me, to get them to know me and to get to know them, I try to understand them as who they are not what they do. So, while I have conversations with everyone here, for our clients, and customers, I really do try to understand who they are, I figured out more than 13 years ago, probably when my daughter was born, I was coming to work. And my body language was all off, people start to get worried about me, something really bad was happening. This was a surprise in my life. Let's say Meranda, there wasn't supposed to be a third child. And I was acting strange because I was acting strange. I just remember sleeping a couple hours a night. And just I was younger, too. And I was just burnt out. I was like, how, how did this happen? How am I just telling people, I simply did not get enough sleep, put everything in context, I got a lot of, you know, personal experiences through them and build some great friendships over time, including a lot of, you know, industry people that we know, which I think, you know, generating a different level of trust, because people again, got to know me. And I think that helped, you know, getting the ball rolling with DSI here. So again, back since the COVID-19 crisis struck and you know, obviously, during the Black Lives Matter protest, right, we, we watched the news, try not to, I opened it up to whatever people want to talk about, except politics, of course, what worries them or concerns them and what needs to change. So, you know, I don't get a lot of phone calls from our group. But when I do, you know, I always get a really great conversation. I talked to a good many of them. Not everyone, but you know, really, kind of some of the value some of my, my pay here is just that right? So next thing you know, opening doors with trust and integrity, it goes against, you know, how I do my job which is why I'm good at it, you know, being a successful business owner isn't just about strong earnings or closing another deal to partner. It's about, you know, being fair, honest, ethical, as how I hopefully I am right, hopefully, Tony and we all are, I think we are, it's easier to do business with people who trust you. And that goes off to our clients. We have countless feedback from them about some of these things.

I read some stories in the newspaper, I just got something I saw something today about a phenomenal basketball player that went to Pitt, you know, he's freshmen this year, and top recruit basically had the world going for him. And he got indefinitely suspended from the team this morning. Because he did something he shouldn't have. And it was just such a disappointment by me. And I'm like, you know, how does someone not know what they have?

Right? So, one of the things I think in life, you know, trust and integrity, you have to be able to say you make decisions, sometimes they're not forgivable. So how do you amp up self-improvement? This is something I read a lot of books on self-improvement, leadership, we're going to look up there, the essentials, let's see, emotional intelligence change management strategy. I also have the Art of War up there. Many, many finance books and a lot of stuff about chemistry and regulatory that I have really bad, boring titles. One of them is actually communications, that's a book I interestingly enough, every time I open it, I get distracted. So, it's a sign, but seeking feedback. You know, obviously, I learned a lot from you so far, Meranda, there's things that I don't know that I want to find out because you're curious, or I'm not familiar with, right? So, finding the right colleagues and mentors, or mentor who was willing to provide you with constructive feedback is essential in your career. You can read all the books up on my shelf up there. But again, I think I mentioned it earlier, you know, someone can't teach you a book can't necessarily teach you; I think you have to learn it. And I think sometimes that's the interaction.

So, you know, it's natural to have blind spots. But we rarely noticed them until they're pointed out to us and that's, that's some of the things I treasure in our conversations every day, you know, that's what makes them blind spots, right? So, the ideal person for feedback has the ability to zero in your blind spots, and provide an actionable path to improvement. So, I didn't think of this until now. But we should think about doing a future podcast about like, you know, the ins and outs of regulatory CMC or the ins and outs of consulting, you know, just what makes a successful consultant, you know, just how you deal with things differently. Some folks could say it's the same as my regular day job, but it's not, you know, so you serve many masters, I think sometimes. And it's not for everybody, you know, it's a really intense, and also rewarding job, you know, at least I found it that way, you know, you put a little more effort, and you see more progress, and you feel a little bit better. So, self-improvement areas, you know, those are things that I think that we, as a society struggle with, sometimes not a hot topic that we want to talk about, as consultants, you know, we get a lot of feedback. So, I think that kind of helps build us, if you're a director in a group at a company, surrounding yourself with people who push you is pretty important. We talked about the monkeys, if anybody has the time, Google how to get the monkey off your back or something like that, you know, it's a different topic we hear I think, I think one of our main things I talked to Bob about this, you know, we seek employees and consultants that are curious, enthusiastic, lifelong learners, right. Like I mentioned that like, lifelong learning thing, guys like Jim Mencil, and Catherine Barnard, again, like just every time I speak to them, they've had a different new experience. And I think that's phenomenon. I think that's, you know, continuing where I want to go as help myself just saying, you know, they may know more about a topic or skill than 99.99999999% of the population, but they also maintain the humility to understand that they don't know everything, and they never will.

“My goal, hopefully, is to grow CMC Live, make it more interactive and maybe have a live audience with questions.”

Every year, you know, New Year's resolutions, I just thought about, like, I guess for five or seven straight years now, I didn't actually have new year's resolutions, like I gave that back up when I was like, late 30s. Even if it was like, you know, I just wanted to healthier or bla bla bla, but I did think about finding inspiring goals. And I think about that, not just on January 1, but I think about that every day. You know, success is best thought of not as a point in time, but as a way of life. And we all know the saying, you know how you think is everything, always be positive, think success, not failure be aware of a negative environment. So those who view success as a way of life, we're constantly looking forward, definitely very important, especially for folks who get stuck in setbacks, you know, lose a job, they may have made a tough, bad decision, or if just you know, generally things aren't working for them. There's always a new opportunity and a new challenge, I can

pretty much assure you that sometimes they're not all fun, but they definitely are, you know, they're out there. So a key for individuals who sustained success over decades, is they don't rest on their past successes, right?

I never looked back and said, this is what I did. And I'm done. You know, I'm always trying to figure out how to sustain success and find more success. And I think everyone, you know, always be open to updating your thinking as times and circumstances change, actually, as we had to share, you know, certainly we could all went in a foxhole in our basements and just said, Hey, we're gonna wait until everything you know, viruses clear, and you know, everything is normal, but it will never be normal. Normal is now and that's what we have to live with. Right and deal with. And tomorrow, it'll change again, and next year, it'll change again. And if you don't accept that, then certainly you wouldn't be happy, creating a personal case for change. That's what I sort of did talk to some of our folks, individuals, even our clients, again, maintaining a high level of motivation requires knowing while you're pushing, you know, to get better. I think we had a conversation this morning about this again, I think we had a conversation last week, one month ago, six months ago, blah, blah, right? I also used to get a little frustrated, because I didn't have the answers for you. And I felt like I wasn't doing my job. And I went out and searched and try to fix or find a fix. But I couldn't do that, you know, I mean, I can only do what I can do. Sometimes other people are involved, right, and then they have to get involved. So, I think the best thing I could do is just maintain my composure. And you know, again, going back to how you think is everything always be positive, kind of inspiring other folks that you need to join the team, whether that's the FDA, like I said, trying to tie this back to CMC and what I used to do, it's about teamwork, and getting there you know, as long as you have efficacy, what's the word I can't even remember, as long as you have that word, you know, and you are moving things forward for the betterment of society, then I think, you know, you can pretty much pull most people in to be on your team, even if they are the FDA, right?

These days, I actually not so much, you know, I my goal of wanting to write a blog and getting a podcast as an example is to kind of spread the message. So, if I wrote a blog or recorded a podcast, then I would feel tremendous sense of accomplishment, which I did. You know, maybe they weren't the best, maybe these aren't the best, but I certainly enjoy doing them, you know, and it also builds our brand awareness. And it's a tool for us to market our services. And I would love in 10-15 years come back. This is why I need you to talk more on these things and ask questions we can measure how much more successful, and you know, skilled you've become, because I could see it in the last two years before a podcast I wish I could show you. It's kind of crazy amazing.

Meranda Parascandola

Yeah, that's a little bit difficult when the show started recording all of our conversations to start,

Ed Narke

Right. So now if I don't try to write some weekly thing or you know, records I have a new conversation. You know, I feel a deep sense of guilt. I feel like I'm limiting our brand awareness and I continue to struggle and struggle with the marketing of our services. And I would love to be the person that has to be all end all answer solution for everyone on how to market services, you know, that could help you. Hopefully, maybe that's my goal in life. I'm going to be on some platform going this is going to fit in, invented it like whatever that is. I just don't know what that is yet. And I think we talked about this.

Meranda Parascandola

So, add, are you ready for hot question? I just got into our email.

Ed Narke

Yes. Give me a question. We'll take a break here. Go for it.

Meranda Parascandola

What are our experiences with Microbiome based products? Okay. They want to know, before they get on a call with us.

“To truly build trust, I learned it’s better for my colleagues to get to know me as a person.”

Ed Narke

Well, you know, I think it's a great question. So

Meranda Parascandola

what do you think?

Ed Narke

To be truthful, and our experience is probably pretty good, for the process. microbiome. probably to me means you know, live bacteria in the gut, some gut chemistry, fascinating topic, obviously, two things control the way we operate and who we are our brains. There's a very complicated

computer there, and our guts, you know, so there's certainly little creatures and animals all over our body that whether we believe it or not, or know it or not, obviously, make us who we are, and make us act who we are like we are. But I think you know, just to be a serious answer that question, I am not a microbiome expert. I don't think a lot of people are here, either. I think what they are, though, are they're scientists. And they're process oriented and their project management oriented or analytical. And they're able to take a lot of what the drug development process is, and apply it to a new medium, like a new continuum. And while they'll have to get some information, and they'll have to have some inherent someone person that might have to bring some of the glue, I think it's one of the great just common problems, I think, 15 years ago, 20 years ago, maybe not everyone was an expert in the biologics space, monoclonal antibodies, but it's like brewing beer, kind of, you know, there's a reactor and there's another reactor, there's a filter, and blah, blah, blah, very different than synthetic chemistry. But, you know, the rules kind of were written over time, nothing was written and put out there. And that's the operations, anything that we can contribute, I think is a valuable contribution, starting with an FDA discussion, you know, where would the issues lie? You know, controlling this? What is it? What type of product? How's it made? You know, where does it come from? Can it come consistently? Where do we make adequate scale, make a lot of it?

Those are basic things I only scratched the surface on, our technical colleagues can ask, especially the biologics, folks can ask a lot of just questions, and probably reach over and borrow some guidance, you know, and really have a conversation with the agency to learn what they're looking for, but also to educate them that, you know, maybe some things are a little bit more under control. Now, this is my one chance, I'm going to just put it out there, right. There are people out there that just assume the only people that know everything are the people who have done everything. And the truth is no one's done everything. You know, like I said before, 99.9%, expert, Jim Mencil, for example, right? I wouldn't say there's point one, if more in the world, but he doesn't know everything. There are still things that he's learning, right. He's human. So, the answer your question, I think we could give it really the old college try. I know, folks don't want to spend tons of money, hundreds and hundreds of hours just to learn on the job and churn. But any small group I think, you know, that's again, why I like working here. Someone comes to us and challenges us to a little thing. If we want the work, we'll do the legwork. I think everyone would and only because they want to learn a little bit more about something else to make them more valuable. So, I'm going to switch over to developing powerful positive routineers, which you've certainly bring to the table, Meranda, powerful positive routineers. PPR's right. You're responsible for fast tracking self-improvement, you know, to start a routine. I got up today, early, right. I enjoy the quiet time of the early morning and find it conducive to

“Two things control the way we operate and who we are: our brains and our gut.”

writing blogs thinking about things other people start their day by meditating. Right maybe I tried that actually. Still others exercise I think I see Tony's calendar and I think he's exercising every day. But I think you brought me into a different routine. I think it said it's that discussion first thing in the morning, even if we have nothing to talk about just to get the things running right now.

I'll leave it at that just as important as establish an end of day routine to prepare for success the following day. And that's really what I like I'm an end of day person, you know, let's sleep let's figure out what my last thing and let's prepare for tomorrow. Right. And also, an important is an evening routine, you know, includes reviewing personal objectives and goals. Sometimes you don't sit down with papers sometimes through your head somehow, like subliminally scheduling priorities for the next day, you know, and then also I would have learned finally after 43 years, maybe like hearing to lights out time, I stay up till the wee hours and I used to get up pretty early still, but now I need my sleep. So, these powerful positive routineers any recommendation for anybody in regulatory equality, you know, certainly you have to have some sort of consistency because it does affect your decisions and how you feel about things. There's things like that be if you have data or not. So as a start of the day routine, no one pattern is best for everyone. Everyone benefits from consistent patterns, though. So, I'll just say, you know, what takes discipline is to repeat a behavior regularly. And often enough, so it becomes a habit, right? I tell my kids; my son is starting to lift weights. If he could do it for five days, it becomes a habit. Right? Straight or anything you do.

Meranda Parascandola

Is it five days? I'm pretty sure it takes a lot longer in my head.

Ed Narke

I think it's three to be honest with you. I, for me, at least Yeah.

Meranda Parascandola

Then why is it so difficult to break the bad habits longer? Yes, you can create some good habits three to five days. What about breaking those bad habits? Why does it take so long?

Ed Narke

That's not, my curriculum today? Well, I'll make sure I'll make sure it's on the next podcast. I only have the positive topics here, which the next one is understanding the urgency of self-improvement. Right? So, the year 2020 took the next five to 10 years of inevitable change. Right? Now we're on Zoom talking, I see a picture of you there 2020, packaged it up, and forced the world to figure it out, like 10 months, right? And we talked about this this morning as well. How do we network? myself, you know, my, what brings energy to me is like being an extrovert and having dialogue with folks learning from them about what they're doing, what their needs are, what they like about me Even I'm a words of affirmation, guy who like to be affirmed, sometimes this is kind of like what would happen suddenly, and I guess it's we're not going back, you know, we're gonna eventually meet people in person some places, but just say, you know, I think a lot of the meetings and stuff and conferences kind of like were dead. We just talked about this this morning. You know, like some of the stuff it's just now it's finally recognizing it like, well, some of them weren't that productive. I talked to you about, you know, networking 3.0 where we're not just a bunch of people heading to a conference, just exchanging business cards, trying to sell something, listen to elevator pitches, and not really caring, you know, that that doesn't really work. It hasn't for a long time.

Meranda Parascandola

I guess the good thing about that is it has more meaningful meetings, rather than just meet and greet and take a meeting to fill the gaps. That's great.

Ed Narke

Yeah. So, you know, navigating a new, virtual new normal, where it's called a remote world, it's not that easy. Maintaining this peak performance, these you know, metrics we have when you talk to certain number of people, that certain number of things and stuff not easy for those of us who embrace change will experience an accelerated leap for sure. Right ahead of the pack in the coming months and years, and I'm pretty happy. I'm pretty excited.

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