

The White Coat Effect is Real – The Role of Person in Plant Discussion

Episode 10



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Daniel Torok
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A DS Inpharmatics Production

Ed Narke

Welcome to CMC live. Today we have a very special guest that will be talking about some important things. Trust is important in a relationship, particularly one between a sponsor company and a contract manufacturing organization, or CMO. As outsourcing becomes ever more important in the industry today, the effective management of these CMOs is a topic of high interest. By assigning a person-in-plant, sponsors have the ability to develop a more trusting relationship with their CMO partner. There is no widely agreed definition for person-in-plant, which is partly the reason for the confusion around the term. From the wording, the term refers to having a project sponsor, employee, designated employee, or a consultant present at a contract manufacturing site to observe observations.

“The white coat effect is real. Trust me, even in a good facility, it's absolutely real. When operators find out the client is coming, they behave very differently, and the level of detail is much more.”

So today, we'll be talking about a few things: the dilemmas around person-in-plant and the value of a person-in-plant. A person-in-plant could be beneficial for a sponsor to better understand the actual manufacturing process at the CMO. So, it's just one of the tools in the CMO toolbox, but it's an important one. Also, when is the person-in-plant needed? I'm sure this depends upon the specific project's risk assessment, CMO, and the process. The person-in-plant is often required to be there during initial batches, first three batches, maybe validation batches, or mainly when critical steps or safety-related stages are involved during upstream/downstream processing, unit operations, etc. Afterward, the person-in-plant approach might be used if the process changes during a technology transfer or when unexpected issues arise.

Another thought we will go over will be who can be designated as a person-in-plant. This is a question that I have myself. For the development project, this individual should probably select it from somebody on the product development team or one from the technical team. So today, we have Dr. Dan Torok on the show. Dan is a process chemist by training and has worked with the group here at DSI for close to 10 years. I've also known Dan for 20 years, worked with him at a facility, and learned a lot from him. So, Dan, let's get this episode started by going into some of your background, how you got started, and getting your thoughts on the role of a person-in-plant.

Daniel Torok

My background is a Ph.D. in synthetic organic chemistry, a postdoc with the National Institute of Health in medicinal chemistry. I wouldn't say I liked medicinal chemistry, but I like to scale up because I did some during my postdoc. I got the opportunity to learn process development and manufacturing chemistry in the agricultural industry. Since most of the people listening to us now are pharma, it's a whole other world. Think bulk chemicals,

think when you go into a production plant, it was the kind of production plant that scared some people. It was more like going into an oil refinery-type facility than it was a modern pharmaceutical manufacturing facility. So, the learning was different. I made the jump into CMOs. I worked for companies like Hovione and Lonza doing process development, running pilot plants, making batches hands-on in the pilot plants, running an entire facility, and being responsible for the production floor. So, at the end of the day, a lot of my career, 15 plus years of it, was spent with half the time or more on a production floor solving the problems, walking down the equipment, things like that. I'm a little unusual compared to your typical process development chemist because of the amount of time I've spent in production facilities. When it comes time to go into a plant for a client, either a client who just wants somebody to watch over an important campaign or registration campaign, validation campaign, or that time when the client calls on a Friday afternoon with a crisis because the batch is going up in smoke and they need someone there to look at it. My perspective is very different, probably from your average chemist when I walk in.

Brian Lihou

Well, Dan, let me ask you this. We know a lot of smaller companies that completely push all chips in with their CMO. They entrust the process. They entrust the future of their company in the CMO. Again, there are many reputable CMOs, not to lean your answer any one way here. What's the benefit of incurring the cost to send someone with your background to a site to run their process? It seems a little belt and suspenders, but what are the advantages to doing it?

Daniel Torok

Working at CMOs for a lot of my career, I had the man-in-plant, the person-in-plant, the woman-in-plant coming into the production floor that I was in charge of. I'd have to watch him, and there are many times where it turns into a babysitting exercise, and you don't want it to be that. So, if you are going to get a person-in-plant, first off, you want to have the right one there. Second off, the reason I think you want them there is twofold. One is often referred to- you've probably heard it as a manufacturing guy- the white coat effect. There is a white coat effect when the client comes on site. The behavior is different, the level of attention is different. That's really what we're talking about here. When you walk into a very reputable, very solid CMO, you want that attention to detail to go up on a further notch; it may not always be there. When you're talking about, perhaps, the CMO that you're having issues with, you have to go beyond the white coat effect. You have to bring a piece of knowledge into the plant to help them out because they may be the type of place that's having issues. The white coat effect is real. Trust me, even in a good facility; it's absolutely real. When operators find out the client who's coming and will be watching, they behave very differently; that level of detail is much more. The reason you need that is that I have never worked for a CMO, or I've never been at a CMO, where a plant manager would tell you, "I got five extra people. I'll put them on your campaign this month because we care about you. We've got these people in the backroom, and we've got more than we need." CMOs are profitable because they run with the number of people they need when the plant is at full occupancy. Certainly, today in the last year or two, everyone who's good is at full occupancy; you can't find extra room. There's a lot of good CMOs out there who'd love to toss a couple of extra engineers on your validation campaign and just have them on the floor watching at all critical points. They don't have the bodies. So having a person-in-plant go and represent you covers that lack of additional attention that a CMO can give to you during a time of need.

Brian Lihou

So, with that in mind, it's one thing to have a person-in-plant to check the box and have that condition met. It's another thing to have a person-in-plant that adds value to the day, value to the process. You and I have been doing this a long time, and you can see when it's an effective relationship coming in from the outside, and you can see when it's not. So, what stands out to you as the keys to being an effective person-in-plant and working with the site, as opposed to telling on them?

Daniel Torok

Yeah, that's good. You walk in, and a lot of the attitude is that 'Oh man, it's just another person who's going to be looking over my shoulder.' If you're walking in for the first time, it's going to be that for anyone, I think, because there's a level of trust that builds between people over time, no matter where you are, not just solely in the person-in-plant scenario. It builds over time. What people who worked in a manufacturing facility can bring to that man-in-plant is that you do know what's going on, you know what to look for. We're talking about going into some older API facilities. The operations happen over maybe four different plant levels, and the batch may move through all these plant levels in the course of an afternoon. So having someone who can come in and say, "The first thing we want to do is walk through the process real fast and see how everything looks so that you can teach me." It's taking the person in charge of the facility and convincing them that you are there to help; you're there to learn from them. You don't cop an attitude with them. It's their plant. The biggest thing you can do is cop attitude with the person who's running the plant or try to tell their people what to do. The first thing I ever do when I walk into a plant is explain to whoever is in charge of the process that 'I'm here to help. You guys should know more about this than I ever will. I'm here to give advice. If at any point you hear me tell your operator to do something, you are allowed to hit me and throw me off site because I'll eat the cost of this at that point, because it's not my facility, I can't tell you what to do.' You start to build that level of trust. Then they'll begin to go to you with problems. I've had a couple. Probably the most touching was when I spent a lot of time on an API facility on the east coast. On the last day, when I was finally walking out, their process chemists said, "You know, I want to thank you. You're the first person-in-plant who's ever actually helped me. You gave me useful advice. You caught problems that would have bitten me in the behind, and people would have been yelling at me about them, but you kept them from happening." Now, that's trust that comes over time; in the short term, you have to work it in faster.

Brian Lihou

I think you raise a good point. I think, having done this myself, people notice when you don a shoe cover the right way, when you've done this before. When you walk in, and your eyes start spinning, you can tell when you're just coming out of the cubicle and into the plant. But if you've been in that plant, and you say, "I liked the way you guys handle X, Y, and Z," and it's that collaborative effort. You can even work your way into shift exchange meetings where they're talking about the day. If you consider this, most of our clients run small-volume batches and often large CMOs, so they're running these one or two times a year. But they've got to get it right. So, you're asking a lot of a facility that runs every day, often around the clock, and they're supposed to remember the nuances of your process because it's your process amidst everything else they do. Every BD person will tell you that's the way they do it. That's the way they've always done it. But then there's reality. I think you raise a really good point- it's integrating yourself into their operating in a guest capacity and helping to move them forward. When you start talking about the process, it must come across in conversation that you know what you're talking about. You know the equipment they're using and how they're using it, and you can explain the nuance of the process you're overseeing.

"Probably the most touching was when I spent a lot of time on an API facility on the East Coast. On the last day, their process chemist said, 'I want to thank you. You're the first person-in-plant who's ever actually helped me.'"

Daniel Torok

It's also when people like you or I walk into a plant; it's that we've had years of experience with the equipment. It may not be the same piece of equipment, but it's all pretty similar. A cam lock hose is a cam lock hose, be it in Switzerland or be it Iowa. It's the same. For example, I was walking a train one evening, and I noticed the operator didn't have the cam lock properly fashioned onto the bottom valve, and they were about to try to transfer a batch. I know what happens when it happens because I've lost batches. I've been in facilities where it's happened.

The operator's face was so happy, and I walked upstairs and just said, "Go check your cam lock on the bottom of reactor 3359, and do me a favor, lock it down." He came back up. He thanked me. It was funny because I worked with him the night before. He said, "So you're going to tell my supervisor I didn't have that locked down?" I said, "No, not at all. We got it. We're here. We're working as a team, and this is what we're going to do because this is expensive and important to my client." In these batches, even if the batch is cheap from a raw material perspective, rescheduling it or having a delay in a clinical trial is incredibly expensive. So, getting it right and only having maybe one shot to get it right means having an extra set of eyes is cheap insurance at the end of the day.

Brian Lihou

I think that's well put. It was once explained to me by someone with many more years of experience than I have, is to think about it like this, when you get in the car and you turn the key, so many things have to happen in unison or in sequence to have that car fire. When you're in a teleconference and listening to the CMO talk about all the things they're going to do on the batch, you're only getting about 40% of the actual things that have to happen correctly for that batch to be made. So being on-site and being a part of the team that's manufacturing your batch, I think, is essential. It's one thing to sit there with a clipboard and make notes, and then at the end, send a direct, fully detailed email on everything you observed. That's a surefire way that the next time you roll into that plant, you may not be welcomed with open arms as you were the first time there. So, I think the things that you say, you talk about experience, having blown that cam lock and a hose fly off, you've seen it. You know what it looks like. I think you touched on a really important point. You don't ring the alarm bell. You don't make everything come to a halt, saying, "Hey, check that. In my case, you've just steamed a system. Check the clamp and expand; make sure it's tight before we start product transfer." All of these things have to happen. Then the more you become integrated into the team, and you said earlier on, which I think was a really important point for people considering this, is that information then becomes shared with you proactively rather than reactively.

Daniel Torok

Yes, when people will start to call you first. I've been in that situation as well. I left the site in the afternoon, went to have dinner. The phone rang over dinner, and they said, "We don't know what's happened all the way yet, but this is what we know." It develops the trust level. The next words out of their mouth were, "Please do not tell anyone yet. I'd like your advice and help as we look at this. Not bringing in anyone yet, we still need a little time to know what happened." When you can start to integrate into sites and people like that, you'll bring a whole lot more value to what you're doing.

Brian Lihou

That's a great point. Also, as you listen to this podcast, you consider whether you feel it's something that you can handle. Consider this, when you are on-site, you are working with a process. You're not working on a punch clock. So, if you roll in at 3:30, 4:00, a critical part of a process, get comfortable. You could very well be there...Two Christmases ago, I spent 18 hours in Germany, watching a machine that moved very little, but I had to be there because it spits out data. So, get comfortable.

Daniel Torok

Yeah, absolutely. Clients and CMOs will try to say, “Book into this hotel, this one’s nice,” and “How many miles is it from the plant?” I’ll tell them, “No, I know this one that’s only four miles from the plant.” I warn them, “I’m going to be there when you don’t want me there.” You’ve got to keep in mind, and this is something that, again, my background comes from being 15 plus years in CMOs. When one of us will be on-site, there will probably be a special person from the CMO also on site. It takes a lot of trust before they’ll just let a shift supervisor let you into the building. It’s happened to me, but it’s a rare occasion. Now you’re putting the employee who’s going to have to be there the next day, from nine to five, they are going to have to come in with you from three in the morning till eight in the morning and then keep staying. You have to keep that in mind too. These people have lives, and you feel bad for them at times because you are, as you said, there for weird numbers of hours, weird amounts of time. You’re on a production floor, and you’re dealing with operators. Not all operators have college degrees; some haven’t finished high school, I’m convinced of it, in some places I’ve been. Not that it’s bad, that comes off bad, but it’s a working-class environment. You’re now under a different scenario. You have to keep in mind the different people you’re working with when you’re on-site so that you bring over the best of everything it can.

Brian Lihou

Yeah, I think it’s a good point. As you consider this for, say, your company, I think the expectations for that person traveling to the plant are exactly as Dan laid out. They’re long days. You are available proactively for critical parts of the process. Updates are sent back to the sponsor or back to the company from the site. They’re frequent because a lack of information is often more condemning than bad information. You keep that moving forward. I think they’re really important factors to consider. Then you sleep for two days when you get home because you’re just catching up on all that sleep you lost. When you consider person-in-plant, and whether it’s value-added or not, it’s, “is that person traveling to the plant prepared to stay there as long as it takes? Or are they asking for two or three people to go?” You get a flavor for how this is going to work often before you step on the plant.

“I warn them, ‘I’m going to be there when you don’t really want me there.’”

Meranda Parascandola

Brian, with the companies that are small emerging biotechs, how would you or Dan approach bringing a person-in-plant on a limited budget? What would you say to those types of companies?

Daniel Torok

I think you need to plan. You need to look at the process and decide whether...Every process doesn’t need a person-in-plant. If you have an unlimited budget, sure. I like to travel; I like to go to production plants. You should have someone if you’ve got an unlimited budget. Now, since that company doesn’t exist, you should look at what they’re going to be doing in this portion of a campaign or the next step and look at the risks involved with the type of production going on and decide whether there’s a benefit. If it’s from a drug substance perspective, if you’re throwing two powders into a vessel, stirring them around, and draining them into another tank, you probably don’t need me there just for that. If it involves some filtration, some crystallization, and three days of heavy manipulation of the product, it’s probably going to pay off in the long run to have someone there.

Brian Lihou

Suppose you consider what they’re going to see, for example, validation batches. In that case, there is an enormous amount of adherence to the protocol, samples generated, how those samples were labeled, and how they’re handled. All of that needs to have oversight. The project manager for the CMO will be there on-site overseeing, but quite frankly, you want to avoid those inevitable deviations that happen because a sample wasn’t taken, or the sample quantity wasn’t sufficient. Because it’s important to you and the firm you represent, having

that information in front of you, and constantly checking that everything is done, because when it comes to things like launch stock material, process validation, or critical clinical batch manufacture, it is hard to justify why you're not going to have an interest in the plant on your behalf, with the CMO. It should just be considered into your budget.

Daniel Torok

Yeah. In some of it, there can be savings. As we said, you should look at the process beforehand, think about where the risks are. You should also come up with the CMO with a plan of when you want to be on-site and what you want to see, and it ought to be timed out. So often, when we're on man-in-plant, person-in-plant projects, a lot of the time is spent sitting in a conference room doing something for something else and not even billing the client you're on-site for. It's the reality of it. There are times when you'll spend one or two days sitting in a hotel room doing other work because you've got a space between two very important parts of a process. You'll be working for someone else, but it just doesn't make sense to jump on a plane and fly back and forth. This kind of planning can save the client some money along the way. At the end of the day, people looking for us to do this kind of thing need to grasp the cost of their batches that we're watching. They have to understand the impact that it could have on the asset down the road because, at the end of the day, it's not that much money in comparison.

Brian Lihou

One of the things that we do is talk about when you wrap up a site visit, what sort of information is value-added back to the client and not only the client, but perhaps the CMO. So maybe we talk about what does that information exchanged following the production run look like. We talked about how to select that person to be effective. We talked about the value that that person has on-site, and we talked about things needed while you're on-site. Now the run is done. The milestone is met. The batch is in the can. What information or insight is shared, either with the client or with the CMO you just visited, that puts it to bed and makes that whole visit 'Value Added' for the time you go back into production again?

Daniel Torok

We've been talking about preparing to go into the plant, a lot about being in the plant, and what can be brought to the table by an experienced manufacturing person. The other thing to consider is what happens when those batches are done, or the batch is done, or the materials in the filter, it's been dried, the vials have been lyophilized, and they're being packed out. Just because you walk out the door of the plant and go to the airport and get on the plane, it shouldn't be done. It shouldn't be finished for us because there's certainly not a true wrap-up report, but there are things we've seen that are in our minds that wouldn't be in other people's minds because of our background. There are things to be documented about what we saw, both good and bad. There are things to be documented about the process we saw and how it behaves from a physical chemistry point of view. If I'm getting on a long plane ride on the way home, these are the things I start to document then - while they're still fresh in my mind, while I've seen them, concerns I may have from the batch or batches that I've watched that maybe weren't a problem, but are going to become one in the future. The filtration was slower than we expected. The stuff in the filter looked a little more like mud than a crystalline product. We got through it, but where do we go, and what do we do with it in the future? Those are the kinds of things we start to put together, get written down so we don't lose at the end of the day.

Brian Lihou

I think that's a great point. You're collecting your thoughts. It's a ledger of what had happened in the time you were at the plant. I think you said something very important because this relationship between our client and the CMO is not a one-hit-wonder. You're there for the long haul. So, you expect that relationship to grow their knowledge of your process to increase, and they become a valuable partner in that company's growth. So, when you make these reports, or these bullet lists, observation sheets, it's really important to highlight not only issues and possible change control or remediation steps, but also what worked well.

You said that, both the good and the bad. If you highlight that good, and the CMO is going to get a copy of what you see, even if it's in a bullet point email, which could very well be, it's something you decide before you leave on the trip, what type of assessment, but highlight what worked well. I have been in runs that I would not have described as a success. But there are things you can glean from it that are positive. Suppose you have an event, a plan deviation, where you had to do something on the batch because of a problem. There are good things that come from that. Some people rise to the challenge. There could be a facilities mechanic that comes in and goes above and beyond to keep our process moving forward. These are all things that have to be in a well-rounded site wrap-up report. Dan, I just wanted to expand on that point because that helps that relationship in the long term.

Ed Narke

Yeah, that's a great point. We're getting closer to the end of the podcast. It's that time of the show where we play a little fun and games. It's called facts and myths today, Dan. Can you give us a couple of facts about CMOs, and then maybe also add a couple of myths and kind of explain them? Good stories, of course.

Daniel Torok

Oh, good stories. Okay. One of the myths that people have is that a CMO knows their equipment all the time, and the process will be run the same every time. I can think of an example. I was watching a validation campaign one time. On a Monday night, we transferred the first batch from vessel one to vessel two. We went back the next night to watch batch two do the same transfer through the same equipment. Standing there about 11 at night and I watched the operator do the transfer completely differently, not through the same set of hoses or pipes. My jaw dropped. My assumption, my myth in my mind had been, everybody always transfers every batch the same way. It's like when you go to work in the morning, get on the road, and you always drive that same road to work every morning. Well, they didn't. So, we had to have some talks with the plant afterward. We talked about the pros, cons, benefits, but not everything is always the same every time you go into production.

The batch record may say 'transfer the batch,' and we all assume the method is done the same way. The fact is, it's not always, and you have to be cognizant of that. That's where having somebody there to watch, you can realize when that reality becomes the myth. No matter how upset you get at your CMO; and people get upset at their CMO. I do believe every CMO I've ever worked with really does want to do the right thing. The folks on the floor who are running the process, the person who's writing your batch record, and the analyst analyzing your IPCs do want to do a good job. There becomes this myth of everybody there is a screwup. They're not. They want to do the right job. So, when you go there, don't treat them badly. If you want to treat anyone badly, treat the plant manager badly. At the end of the day, they're there to be the person responsible. So, when things go wrong, do your best not to take it out on the person who's there turning the wrench for you at 3 am. First, take it out on the person in the corner office who can take it and should take it for you.

“Just because you walk out the door of the plant and you go to the airport and get on the plane, it [the process] shouldn't be done or finished for us.”

Ed Narke

That's a really good one. Yeah, that's empathy. I didn't know you had that.

Daniel Torok

I don't. That's why I'm not that good. Why? I take it out on everybody.

Brian Lihou

I know this was directed to Dan, but I have one I want to add, and Dan, you can expand on it. One myth is that a process start time is a suggestion. So plus, or minus eight hours, you're starting on time. Just come prepared.

"I think one of the myths people have is that a CMO absolutely knows their equipment all the time and the process is going to be run the same every single time."

Daniel Torok

Yeah, you have to. In the drug substance thing, I was taught by a very good old friend, who now builds furniture for a living, that if the process is going to start Friday at 6:00 pm, no matter what you do the week before to make it start Monday at 9:00, it's going to end up starting Friday at 6:00. There's very little you can do about it. It's hard to be a manufacturing person first off, which is where my empathy comes from. It's hard to stick to a schedule. It just really is because things can slip. Where my empathy comes from for the folks who are working there, you got to remember, a lot of times these people now are giving up their weekend to start on Friday, so that your product can make it out closer to time. So, you've got to have that bit of empathy.

The other thing that I love is the change in the airline industry in the last few years because Meranda had asked about saving clients' money. One-way tickets are the same price now as a round trip. Remember back when you bought a round trip because they were cheaper than the one-way. Do

you know how many one-way returns I've eaten over the years because of this? A lot of you know this, when I go on these trips, my clients all ask, "When's your flight home?" A lot of them will meet me in the plant for the first day or two of production because they want to be there. They'll ask me when my return ticket is. I have to shrug my shoulders and say, "I don't have one." They'll look at me and go, "What?" I said, "I don't know when we're going to be done. I don't have a return trip".

As part of that plan, we talked about scheduling things. I'll typically have a milestone of once we're here, I'll book my ticket home. That's become a Godsent to saving clients' money in this day and age. Now there is a downside as a funny story. If you buy too many tickets in 24 to 48 hours, I can guarantee you they're going to be trying to pull the battery out of your laptop when you check into a major international airport. It does raise red flags. There are downsides to it, but you'll get through security and on your plane and go home eventually.

Brian Lihou

Yeah, be sure to befriend your travel agent because if plans change, you want to have that number because you're going to want to know. By the time it is time to leave, you want to go home.

Daniel Torok

Yeah, it changes. It will be fluid in this industry and this particular part of it just because things happen, things go wrong. You're on an airplane, and you find out you've landed, and a ruptured disc has blown on one of the vessels during a pressure vacuum check. You're now 12 to 24 hours out of it, if you're lucky. The flexibility is there. I like to think it's something that we can bring to the clients because our jobs are flexible. We're used to working virtually. So, to work in the Marriott instead of working here in my house isn't any different at the end of the day. I might even have better internet at the Marriott than I do in my house. It's one of the things we can bring to the client. Their people have to be someplace else. You and I both had this happen. We flew in someplace with a client, and they've had to leave, and they leave it in our hands to watch because they have to be somewhere else. We bring this to them; we are that person they depend on to be there when they cannot... The thing to keep in mind for people is we're bringing experience in a manufacturing facility that's rarer and rarer today. There are very few 'kids.' I'm old and gray. Now, that means anyone under 40. Meranda is a kid. There are

very few kids who have been in manufacturing plants. Ed is much younger than I am, and he's been there. It was a while ago, but he's been there.

The jobs have left the United States for a large part. So, there are fewer people with the experience. A lot of manufacturing is now in Europe and Asia. It's harder and harder to find people with those backgrounds. It's a key, I think, for what people should look for when they're trying to find a person-in-plant. You and I both agree, I think Brian, body-in-plant, there's the white coat effect we talked about initially. It hardly brings what you can get if you've got somebody who's been on the production for four to eight hours a day for 15/20 years of their life.

Ed Narke

Yep, absolutely. Well, here's the fact. Dan, you're an amazing person. You've been a mentor of mine, a very good close friend, especially recently. So, you're a person-in-plant extraordinaire.

Daniel Torok

And it comes with brewing beer.

Ed Narke

And into the brewing beer episode that will be down the road or the trips that we used to take. We could talk about femme fatale and Gary and some of those times too. At this point, I think it's time to wrap up. I also want to say once again, I appreciate your time. I wanted to make sure some of this was recorded because there are many young kids out there that will learn tremendously just from listening to this and hopefully inspire them to become the next person-in-plant so our industry could benefit from that. So, with that, thanks, Brian and Meranda, of course, as always. Dan, we will talk to you soon, and thank you once again.

“It changes, it's going to be fluid in this industry. Things happen. Things go wrong.”

Daniel Torok

All right. Cheers.

Meranda Parascandola

Thank you, guys.

Daniel Torok

Have a great day.

Ed Narke

In short, the person-in-plant approach is part of joint product and process understanding. It is only one of the tools available to build an effective partner relationship, establishing and maintaining a long-lasting partner relationship, which also relies on mutual understanding here. Understanding is the first step to trust, of course. There is an old Chinese proverb, “Work with who you trust and trust who you work with.” Designating a person-in-plant is one way to build that trust. On our next episode, we'll be talking with Kyriakos Michailaros, also known as Q, here at DSI.

FDA CMC regulations and guidance simplified through examination, real life experiences and risk-based advice. This podcast hopes to educate sponsors and individuals on agency related regulatory CMC matters. We will focus on the critical CMC issues and build programs that enhance drug development. CMC topics will include Regulatory Starting Materials, API and Drug Product Process, Formulation Development, Supply Chains, Analytical Controls. Advocating and interpreting CMC Strategy, directing CMC Operations and Quality Assurance oversight in conjunction with developing CMC submission content that represents the best interests of emerging biotech. NOT INTENDED TO BE PRESCRIPTIVE ADVICE BUT RATHER INTERPRETATION THAT IS RIGHT FOR YOU. Since 2007 we have provided our partners with innovative strategies and exceptional advice intended to enhance program development, product approval, and marketing presence.