

Selecting a Contract Manufacturing Organization (CMO)

Episode 7



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Les Mintzmyer

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A DS Inpharmatics Production

Ed Narke

Welcome everyone to the Tuesday, August 18th edition of CMC Live. I wanted to start by telling you guys something I learned yesterday on a long weekend vacation. I took the day off yesterday, even though I checked my emails all day. The word talkoot. First of all, it's Finnish, if you're wondering, It's to a T.A.L.K.O.O.T. It means if something has to get done, let's do it together. Again, I was thinking about the eighth edition here and how we've done these. I listened to quite a number of them. Whoever's joining us new today, maybe go back and listen to them. They're pretty exciting, and I'm pretty impressed. So, let's do it all together.

So, Brian, I want you to introduce our special guests today because you work closely with him. I would like to sit back and listen and ask some very good questions. So Brian?

“If you put effort into getting a very detailed and exact Request for Proposal written, then the CMO or CDMO reviewing the request can determine if they have the resources to accomplish the task you're looking for. That allows them to propose accordingly.”

Brian Lihou

Today we have with us Les Mintzmyer. Les comes to us from a large molecule background with many years of experience. Les, I won't give that away. I'll let you do it. Les has been instrumental in assisting clients through the pitfalls of CMC. Part of that becomes finding and vetting CMOs. We thought it would be a great opportunity to have somebody with Les's background come in and speak to his approach, and what may provide all of you out there some insight as you go through that process yourself. Les, welcome!

Les Mintzmyer

Thank you very much, Brian. I guess the way to kick this thing off might be to fall back on the uniformity of the issue, and that is it doesn't matter if the company is large, medium, small, or virtual; the path towards getting a CMO on board is pretty much the same. For those fortunate enough to have prior experience, it's a little bit easier because they'll have a few names in mind and know a few things that went wrong in the preceding time of doing this to avoid those. Anyhow, the path is pretty much the same. I want to mention a couple of key things right away for success. That is whether the company has a lot of experience or zero experience, especially if it's zero experience. There's an absolute requirement to get some SMEs on board that knows how to “walk the walk and talk the talk, etc.” Those typically are in two camps; the CMC camp; the reason you go to a CMO or CDMO is that you're trying to get a process moving forward. The other is that there also should be a view towards, “How did this process get licensed and approved at some point.” So, regulatory consulting is a key factor right from the beginning. Those

two consultants, if they're hired onboard, that's great too. They need to be intimately involved in every aspect of this to ensure that the three big things: quality, cost, and time can be hit as best as you can on every point.

Brian Lihou

When you're talking about putting these SMEs, subject matter experts, onto a team, why? I understand CMOs are supposed to be able to handle everything for you, right? I mean, that's the beauty of pushing back and letting the contract group do it. Why do we need those experts when you already have the Meta-CMO, and we're in the selection process, but really what's the benefit of that?

Les Mintzmyer

Right, it's usually a language problem to oversimplify it. The terminology that is going to be used from CMO to CMO it's going to overlap, but some of it's going to be very distinct. Also, there's the regulatory language that needs to be in there. So, if you're trying to write a proposal or a request for proposal rather, and you have language in there, for example, 'verify a method instead of qualify or validate,' those have different meanings that a regulatory person can easily suss out. A CMC expert probably can too. When it comes down to getting the CMO on board and actually getting what you think you're going to get out of it, you need to have that quality check as the process moves forward to avoid the surprises. The surprises are always costly, it is costly in dollars, and it is costly in time. Hopefully, it is not costly in quality. That's the reason that those people need to be on board.

Ed Narke

Maybe for some of the audience, the CMO CDMO debate, which one is it? Can you define what CMOs and CDMOs are? However, most folks might know what they mean for folks from larger companies that don't work directly with them. Can you tell us about the differences or what the acronyms actually mean?

Les Mintzmyer

Sure, the CMO is Contract Manufacturing Organization. The D part brings development into it. If the organization also provides developmental services, then they'll usually refer to themselves as CDMO. Does it sort of depend on what the company is looking for? What is the client looking for? Do they have a well-defined process? If you just need somebody to manufacture stuff, then the development portion probably is not very important.

Like many people just getting their company going, there's a fair amount of development work to go along with it. So, they'll be looking for a CDMO or somebody that can do development also. That's the development of a process, the development of methods, and the qualifications that go along with that. Again, it targets back to what I said initially, 'you need to have SMEs in both of those camps to ensure that the work done in your development arena can apply and then be used to support various submission work.'

Brian Lihou

So, the first step in the process is writing, as you had mentioned, an RFP, Request for Proposal. So how much effort is put in? What needs to go into that to make sure you get a bid that makes sense, and you can base decisions on?

Les Mintzmyer

This is really one of the cases of garbage in - garbage out. So, if you put effort into getting a very detailed and exact Request for Proposal written, then the CMO or CDMO reviewing the request can determine if they have the resources to accomplish the task you're looking for. That allows them to propose accordingly. In some cases, they'll say, 'Oh, you know, what? We don't do that type of product.' This is great, but if they can tell you that it's, you know, things the crowd of having CMOS you have to look through.

On the other hand, they might come back and say, 'we do this and this and this, but we don't do this. We outsource it, and we can handle that for you.' That's fine too, but there is a need to know what those capabilities are. The more detailed you can make the Request for Proposals, the better the resulting proposal will be when it comes back.

Brian Lihou

It is a collaborative effort with the client to get that information together.

Les Mintzmyer

Absolutely.

Brian Lihou

Okay. So now you've got a comprehensive RFP. You understand the product to the degree of the information you've been provided to generate the RFP. What are your initial search criteria? How do you know from the hundreds of possible vendors out there how you want to narrow this down? I'm sure if you hand a list of 50 to a client, it's not much worth the paper it's printed on. You said something earlier, and you based it on experience. I'm curious why people want to remember the bad experiences and don't highlight the good ones very often. What criteria do you have when you select that initial group? It gets pared down, but how do you match that up for that initial search?

Les Mintzmyer

A lot of the selection does come down to networking and word of mouth from other people working in the area. The nice thing about having a good network is that you can certainly weed out those you don't want to be involved with. That's part of the criteria. Usually, if you need to cast a broader net, maybe you only come up with a couple of recommendations from others. The internet is an excellent source to at least get some information on the various companies.

“The nice thing about having a good network is that you can certainly weed out those you don't want to be involved with.”

Beyond that, looking at some of the regulatory histories of the company's is also pretty important. If you look somebody up and you find that they've had lots of audit problems, then that's probably not someplace you want to go. I don't know if that's a complete answer to your question, but most of us see a dozen companies that we've had some interaction with, and when you get into a group, like DSI, we've got a lot of other consultants that know another six or a dozen. That's a great way to bring some additional names in for consideration.

Ed Narke

That was my next question. I think people should ask friends, colleagues, ex-colleagues, others in the industry what their experiences have been. Right? We haven't worked with everyone individually. Some show amazingly. I used to work at a manufacturing facility, and they had the sales team walk everyone around. Everything looked great, but when it comes time to go, they can't do it. What do you think about asking friends and asking colleagues, especially if you identify one in particular? I have a follow-up question as well.

Les Mintzmyer

Okay, to the first part of that question, getting information from friends, colleagues, and networking through that way, I think that's a great way to rule out the ones you don't want. The other part of what you were saying is that it is frequently the same salesperson or BD person walking around the facility. That's not necessarily going to be a great source of information. They're going to be very careful about showing you the stuff that works. You're not

going to know how things work on a day-to-day basis; that comes later when you've narrowed the search. We can maybe touch on that right now and maybe talk more later.

Once you've narrowed it down to, 'we want at least two or three that look like they can do the job,' then you need to get into the facility and see what's there. Talk to some of the people that perform the work. That's important for a couple of reasons. If you have audited at a few of these places like I have, you can pick out the good from the bad relatively quickly and chat with some of the folks performing the work. Also, they have to pass the BS test, and that's also very helpful. The other thing that's useful in doing that ultimately, when you sign a contract, you got to work collaboratively with the CMO and with the people in the CMO. Meeting people face to face, understanding who they are, and starting to develop that rapport will pay back many benefits for the initial search and ultimately when you begin to work with them.

Brian Lihou

To take a step back, we've gone through the RFP. When we provide that RFP, do we have a CDA in place?

Les Mintzmyer

Of course, yeah. Because in the request, there has to be a certain amount of confidential information for the CMO to evaluate if they can do the work properly. A CDA is the first thing you got to get in place with these guys.

Brian Lihou

The CDA is then in place with candidates you have, and then the RFP is distributed. How important is the timing of everything that happens beyond that? Let's say, for example, how important is the timeliness of the correspondence to weigh into your decision on going with that CMO? Now you've got the RFP distributed, the clock starts. How do you typically manage that?

Les Mintzmyer

If you get a timely response that tells you some great things about the company and will be responsive, they're looking for work. That's a good sign, they're hungry, and they want to want to work with you. Generally, as far as managing it goes, let them know that we have an X deadline, and all proposals that are received by that deadline will get consideration, and if you miss it, you won't. That allows them to get something in place and get it in front of you. Every company wanted everything yesterday, and so that is also part of the quagmire. You have to go through it to get to a point. Without a lot of experience, younger companies are going to say, 'we'll send this on Monday, and we'll get responses on Friday.' Well, that's not very realistic.

For an RFP to be properly evaluated, it can't just come back from the BD folks because they will not necessarily know all of the ins and outs of the capabilities. Maybe that's not fair to say, but it happens. So, they need to get input from the folks that will be performing parts of the proposal. To do that, it had to make its rounds to the quality organization, the manufacturing organization, and anybody else that the RFP touches. They've got to have some input on it. That takes time; every company is busy, that is just the way this business is. To have the time to have an RFP distributed, make its rounds, and get comments back, it's a time-consuming endeavor. The deadline to receive stuff back, you need to be a little bit patient. It's not a week, but it's probably not more than a month, preferably less. If you give them a month and come back in 10 days, that's a pretty good sign that they're taking your request seriously. If it comes back at the end of the game, then maybe they're too busy to perform for you. So that gives you a little bit of insight as well.

One other thing that that happens, I'll bring it up now, is for proposals. If you get enough proposals, let's say you get a half a dozen coming in, and that's kind of like a minimum you'd want to have at least a half a dozen to look at. I've seen many times that proposals one through five will be X, and proposal six will be 2X. It tells you a lot. It means that they don't want to do this. Still, they're going to put a bid in, for whatever reason, probably some

internal political reason. Still, those can essentially be discounted because nobody will consider when it's time and cost. Nobody's going to consider a 2X proposal against a one X. I've seen those, I don't know exactly the reasons for them, but I have seen it because they don't want to work.

Ed Narke

That's an interesting thing. You just said about half a dozen at minimum. I was never shopping for CMOs. I worked at them, and then as a regulatory person, I took data from them and judged it and used it or whatever. But Brian, actually I have a question for you. So, I was taught by somebody that says a minimum of 3 in the high, middle, and low, and maybe it was just because of the time involved and stuff like that, right? Do you have any thoughts on that number? Minimum number? Have you ever dealt with more than six? Less than six? Sometimes only one vendor, of course, right? If there are only two people that can make it in the world, it limits you. I'd like to hear.

Brian Lihou

Yeah, that's a good question. In my experience, it depends on the product. If it's cytotoxic, it narrows the field. Suppose there are certain nuances with your product that make it unique. I realize everyone knows their product is special, but it may be special to manufacture, and it narrows that field. Typically, we try to strive for that half dozen number. It does a couple of things: one, it shows that the Request for Proposal that went out was understood the same way consistently, the numbers that come back match, and the cost is similar. To do any more than that because you're not going to actively pursue all six to the very end of the negotiation.

Another thing is understanding your client's priority. If cost is their main driver, you're now looking at only a portion of that list. You will have a high, low, and midpoint. Also, it's how you look at those bids. Sometimes costs are not exactly very clearly put in these proposals, and you have to look at them. I know a few CMOs off the top of my head that are very big on a change of scope. That is a price increase, and they will quote you the minimum, assuming everything is right in the world, and then just continue to hit you with a change of scope. Knowing as much detail as you can put in the RFP without slowing down the bidding process, the better. Air your laundry, if it is a difficult product to manufacture, if there are very complicated methods, have that in there, so there are no surprises. To answer your question, I would say anywhere from four to six is a good number. Then you pair it down to two.

“Every company
wanted everything
yesterday.”

Ed Narke

Yeah, you guys are great. Do you know how much I learned from these things every time we do them? A lot! Les, let's that's a great point. It kind of just goes to show, as far as garbage in garbage out. I guess my question is, it seems like you have to pay attention to what you're asking for, almost a frame of what you want to get back because you can get a generic something like Brian mentioned, that cost overrides will come in. You're never even thinking about them until you get burned once or twice. In

your experiences, is that something you have to have? Someone that's kind of used to getting bids? I know we work with many folks that maybe do it once in their career in the role that they're in, and they move on. Can you talk to maybe some of that, as far as you know, some of the things that you've learned over the years? Perhaps some of the 'reading the tarot cards,' I would say, look at a proposal, and some things that you see that are alarming or may cause problems later.

Les Mintzmyer

Right. The proposals that are returned from the companies are never one template. Companies will respond with their proposal in a variety of means. They'll have a word document that has a lot of words. I have an Excel spreadsheet that has things very abbreviated with a cost associated with it. This is another point where it's

important to have your CMC, and your Regulatory person involved because the first thing you need to do in comparing these is to get them on the same template. This requires a lot of effort. As an engineer, I love an Excel spreadsheet, so I try to take that word document and get it into Excel to make a one-on-one comparison. I can look at all the deliverables that were asked for in the request, and I can compare that against 'what did the companies say they could do for that deliverable? What was the cost they had associated with that? So, that's one of the things.

The lingo that companies will use from one to the next isn't always the same. If you're looking at CMOs that are XUS, you have an additional problem with English not necessarily being the first language. Now you've got to sort through what they mean when they said, 'full development.' A lot has to be deciphered in that, and the back and forth has to begin right there. Having a contact person at each of the CMOs and having an SME that understands what they're asking and what they're going to receive is very important. So, this has a lot of communication going back and forth with each of these CMOs in that process to make sure that everything is adequately understood. I mentioned earlier the verification, qualification, and validation. It is pretty crucial to make sure that that's well understood. You don't want to be midway through your process and think that you were getting a validation activity when in fact, they're just verifying a few compendial methods. So, that needs to be sorted out.

Brian Lihou

I think the term development is a rather broad term. I guess when a CMO says, 'I support development,' immediately your attention turns to, how? Have you done it before? Do you have a pilot-scale? Show me the capabilities of your development lab. I think that's where, to your point earlier, Les, having a qualified subject matter expert looking at the bids, there may be follow-up questions based on what they propose to you. That is the benefit to the point you raised earlier about putting that team together with the endpoint in mind to make sure the CMO you then sign with, and trust for further down the road has been fully vetted.

Les Mintzmyer

Right, yes. To put another point on that, companies are, especially the startup companies that are very dollar conscious (it's good that they are who doesn't want a good deal), may be a little reluctant to spend consultant money on that early stage. I'll tell you what, the money they'll spend on consultants early on is a drop in the bucket compared to change orders and change of scope and misunderstandings that occurred later on. There needs to be built into the proposal a contingency too. As long as the proposal appears well done and well proposed, it passes muster with the CMC and the regulatory. I'm comfortable usually telling the client that they should add 25% for the stuff that you didn't think about, don't know about, and it's going to pop up. That number is pretty good, but it can be a heck of many more than that if the proposal isn't well vetted. It's easy for that one X to become 50% 75% more with change orders and repeats of things that went awry.

Ed Narke

Yeah. This is kind of uncanny because I wrote some questions down, and somehow you must have received them, Les, because you answered all of them so far. There's one I'm waiting for you to answer, and if you do it, you're going to be four for four. I want to go back, and you talked about the language barrier and how that should be considered. Most European CMOs have PMs who probably speak great English. Actually, from everyone I met, most of the legit ones have that. Asia, maybe not so much. That could be an issue that comes up as far as the language. I know you mentioned it, but is that something that we want to consider when you're selecting a CMO?

Les Mintzmyer

Well, not language so much. We can talk about that in a second. The thing that jumped out at me when you're asking this question is, how difficult will it be to communicate and collaborate with the CMO you choose? If you're in the US and looking at Europe, you got at least six hours' time difference. That's not insurmountable, but

it does pose some additional potential delays. By the time you receive information, get it through the network locally, and then try to get back. Usually, a day is lost before you can get things to happen. If you're looking at a CMO, that's 10, 11, 12 hours' time difference that becomes very problematic. Somebody's got to get up very early or stay up very late to keep that communication going. Collaboration with these companies is paramount in getting the result you want at the cost and time you are hoping for.

Let's talk about the language a little bit. That's what you asked. Although the BD and the PMs and these companies speak pretty good English, there are a couple of things I've found. One, you may be their only English-speaking client. If that's the case, then their English kind of comes and goes.

As you know, in Europe, they have a hiatus for vacation in the summer. When we get back on the communication, I've noticed that their English kind of needs to be sharpened up again. So, that's not a big deal, but you have to be listening carefully not to mistake what's being said. The other thing I wanted to talk about is culture. We've had some experiences where things were promised because it's sort of saving face to promise, but then they don't get delivered. You also have to be aware that if you're asking for something to be delivered, make sure that it's not a request that will take the person out of their ability to provide it. I don't know how to describe that any closer, I don't think.

Ed Narke

Yeah. It's interesting because the other question was, 'ask Les about time zones and if they become a hassle.' East Coast here is pretty straightforward. California gets a little more challenging. Asia, you have to be on call. You just mentioned it, of course, right? Time zones. It's a bland question, so I wanted to expand it for where we're at in modern times here, COVID-19 and travel. Those things seemed to have changed. One thing I'll ask, how far are you willing to travel to visit your CMOs. The second part of that, Are you okay never visiting it?

Les Mintzmyer

Well, that's a heck of a question. In normal times, I would insist that a visit happen because, as I said earlier, you have to get in there to see what the facility is capable of delivering and what the people can deliver and form that relationship. With COVID, that has become next to impossible. The best we can do is rely on our network and hope that we get good advice from our colleagues. One thing that we've tried is virtual auditing. I need to see more of that to see how effective that can be. You can tell a lot about an organization if they'll let you take a look at their regulatory history, for instance, and look at their maintenance history. Those are two key things.

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Also, suppose you find that there are lots of deviations associated with environmental problems. In that case, you probably don't want to put your biologic into a facility that's having mold and bacterial hits, right and left. If you are looking at deviations that have maintenance issues, that's a heck of a smoking gun too. That suggests maybe the company is scrimping on keeping equipment properly maintained. That's going to bite you big time. If you've got a few hundred thousand dollars worth of run going and their equipment breaks down, there better be a provision in the contract about who's going to be responsible for that. Those are things that can happen. You can sort out some of those problem areas if you can access some of the documentation in those facilities. I mentioned regulatory audits and stuff too, that's always a good place to look, just to know whether you're weeding them out at the beginning or if you're now having to decide based on not being able to go to the facility. With a webcast, you've got some opportunity to interface. It's not there, but at least it's something.

Brian Lihou

Do you encourage the team involved in the CMO selection process to be involved in the product transfer process? Or are these two completely separate functions, and you can just turn the key to somebody else and transfer the product?

Les Mintzmyer

Well, some handoffs can happen. It's not impossible to move from person A to B as long as they have a similar skill set. For continuity, though, if you can maintain the same relationship with the same SMEs from start to finish, you're going to have a lot fewer surprises. They will have vetted the proposal in the first place. They'll be there for the tech transfer, the kickoff and probably be there for at least some of the work that gets done. My recommendation would be to keep those people in place so that you don't have different opinions.

Yeah, I have some sores from people that might have the same skill set, but they have a different approach to how they're interpreting what they're seeing. That can be a real problem if a company's running down the path thinking they've got everything covered, and then you have somebody come in that came from a different place. It potentially costs time and money. You have to build a new relationship with people you're interacting with too.

Brian Lihou

That's a friendly way to look at it. I'd like to back up a bit if I may. Can you give a little bit of an overview of your experience in the industry? We just spent all this time talking about CMOs and CDMO selection. Based on your experience, could you perhaps talk briefly about where you've been and what you've done?

Les Mintzmyer

Sure. I mentioned everything from large, medium, small, and startup companies. I've worked for all of those. I've also been involved with auditing as well as CMO selection. I was the VP of Manufacturing at two CMOs. At those places, I was on the proposal side of the equation, so I can tell you it has to make the rounds a good proposal. The BD people always promise more than you can fall off your chair and deliver. It's sometimes a very creative process to figure out how you're going to get the job done for the client. Anyway, it's fun. I've been involved with proposal writing, proposal reviewing, requests for proposals. I've been the person in the plant and a couple of CMOs for different clients, and I've kind of seen it, and I have done it.

Ed Narke

I hear you as well. Working in a manufacturing facility, when you go over and become part of small biotech or maybe a larger company that is using CMOs, you have a different view versus if you're just at that biotech right out of school or right out of another piece, not working in manufacturing, you see it from both ways. I think it's very helpful, and it sounds like you had great experiences and those things. I wanted to recap; I think there were a couple of things that I forgot about. We talked about observations by regulatory agencies, the history; that's a large portion of selecting them. We didn't get into some of the quality systems, and that's more of a QA topic. Personal interaction, we kind of hit on a few things here, especially during these new times. Getting in there and being there in person, examining the facilities, that's kind of part and parcel of the same thing. The technology capacity depends on your product. There are two types of CMOs in my mind, the ones that make the act of the API manufacturers. That's where I came from, very low margins. In most cases, biologics, not so much but the drug product is very different, I think, just because they do other things there.

One thing that we didn't talk about is capacity. There are different vendors, different CMOs for various purposes, and one may be suited well for one type of company and a different one for a certain stage. It may be the wrong fit for another one; it doesn't mean they're bad. Can you talk about capacity and in the framework of the very large CROs out there that market all over the place, and people go by the name? There are also small ones that

might be more accommodating for smaller emerging biotech. However, make the good with the bad. You have to look at everything. Les, maybe you can talk about capacity in the sense of selecting a CMO and how that might work or things to look for?

“You can tell a lot about an organization if they'll let you take a look at their regulatory history, for instance, and look at their maintenance history. Those are two really key things.”

Les Mintzmyer

Sure. The capacity part of it generally will sort itself out when you're in the request for proposal stage. If you have a product, it's always going to be a thousand-liter product. That is the proposed commercial batch size based on some initial marketing study. An outfit that does 20,000 liters, and that's kind of what they do, isn't going to propose. They're going to sort themselves out of the equation. Capacity means a couple of different things to me. One is the equipment sizing, which I think is where you're coming from right now, but the other is the facility's capacity to get the work done. Most CMOs want to be around 70 to 80% at capacity, and many of them struggle to be there.

Ed Narke

As far as capacity, I was thinking in case of an upset in manufacturing, for example. That happens frequently, right? Your manufacturing date could get postponed, and that could mean a couple of different things. It's bad if you're making it for a specific time period to dose a study or run a trial.

Really, it's more so if it's a milestone. You're planning a validation, you're planning for a launch, or when you get approval like seasonal distribution, or if you're running short on material. If you miss the date, in that instance the latter part, you lose market share, you lose money, right? These things happen during development, too, as we all know, for different reasons. So, that's the question about the capacity.

I've worked at one large CMO, the name shall go unnamed, but you can find it on my LinkedIn page. They were always at 100%. When things happen, people got pushed aside. Small companies that were delayed and stuff like that are detected. That is what I was talking about. When you're looking into a facility, should you be scared at half capacity, does that send a message that they do a lousy job? Or is it just that they actually know how to plan better, and they're probably more appropriate?

Les Mintzmyer

Okay, I think I understand your question better now. So, I guess I'll address it in a couple of ways. A CMO may have excess capacity because they're newcomers to the field. Some companies think it's a good idea to create that capability at some point in the company. If that's the case, then it does take a while to build up a client base. Also, as products move in and out, sometimes capacity arrives because some larger volume product, maybe it's gone off of patent, will not be produced in the same kind of quantity. So, that could cause extra capacity to be available. As far as the 100% capacity, I can tell you when you have a problem. Sometimes they'll have a client that's that has a pretty large inventory. So, they can approach that client and say, 'Hey, we had you scheduled for November, but how about if we move you to January? Does that cause a problem?' It kind of comes down to what I was saying before about relationships with the CMO. If you have a good relationship and things happen, things will happen, they will be more likely to work with you to resolve those. If you don't have a good relationship, they would be less inclined to go to one of their established clients and ask them to move. So, it can be a problem. Most of the CMOs are not working at 100% capacity. Like I said, if they can get 70 or 80, they're pretty happy. I've only seen that in one instance where we had to go and be on our knees asking if we can get into this time slot somehow.

Ed Narke

Right. Okay, so it is just another thing to consider, I would say. Meranda, any questions from your angle? You asked me these questions about FEMA selections. I can't tell you; I make stuff up sometimes, but any inquiries you've heard or any questions you might have from listening to Les today?

Meranda Parascandola

Most of them have been answered, but many of the things that come to us from prospective clients are they'll say, 'Is this CMO good?' There can be times where we'll be on a call and be like, 'Oh, I might need a little bit more information.' I guess it depends on what the CMO is looking for. I've had prospective clients come to me and tell me what CMO they will be using under a CDA. We've asked those prospective clients if they've had multiple bids and requests for proposals, and they said, 'No, this is a very good CMO; we don't need one.' What would be your advice to somebody in that predicament where they have a consultant or somebody onboarded into the company that is very comfortable with a particular CMO? What do they lose for not looking elsewhere?

“Most of the CMOs are not working at 100% capacity. Like I said, if they can get 70 or 80 [percent], they're pretty happy.

Ed Narke

Les, before you answer, can I add on to that because that's a good question. This is part of it, but I think I see people who just don't know about the CMOs, and they put too much emphasis on a name, right? There's a couple of very large API and/or product folks out there that say they can do everything, and they'll tell you this. The second part of the question is the name. Should you put a lot of emphasis on a name, or is, does that lead you down the wrong road?

Les Mintzmyer

Yes. Indeed, there are many good CMOs out there, and they've got their name brand relatively well known. There's not necessarily anything wrong with going in that direction, but what I kind of began this with is that the startup companies, especially if they're looking for time and cost primarily qualities in there too but going with the name brand company is not necessarily going to get them either time or cost. It's important to have those other CMOs vetted through the RFP process to see where the value lies. Being able to work with the CMO is paramount to success. It's not that you can't work with a large CMO, you certainly can, but you're a bigger part of the CMOs business. You're going to get a little bit more attention than you may if you're going with a larger CMO. The short answer is you got to go through the RFP process to be sure that you're getting the best value. Money is always going to be a problem, and so to shortcut that process is setting yourself up for some heartache down the road.

Ed Narke

While I presumed, we could talk for a couple more hours. I realize how naive I am about CMO selections. It's been a while since I worked on it, but I think this was a great start, Les. Any other questions right now, Meranda?

Meranda Parascandola

No, but I look forward to having you back on a future podcast about biologics.

Ed Narke

Les, that's a good point. For the folks that can't see the screen here, we have a name for Les. He calls himself the adventurous engineer, and there's a space. It's not all one word. That's a great title. It's kind of reminds me now of Les, but we have a new name for you at DSI. I'm going to start calling this, so prepare yourself. Your name is

now “Super Les.” It flows perfectly. Once again, thanks a lot Les Mintzmyer. Perfect, great story here. I think this will benefit folks, and we look forward to talking to you again. Thank you.

Les Mintzmyer

You’re very welcome.

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