

Complexity of Project Management in Drug Development

Episode 19



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Ed Narke

Good morning, folks, it's Ed Narke here again. Welcome to a new edition of CMC.Live, 2021 version.

Today we have Paul Long on the podcast. I can share a few stories about how Paul and I got to know each other a little bit, but I'll save that for later.

“We’re fairly comfortable with the virtual environment that allows us to be flexible in who we staff. That’s a plus. It allows us to be flexible in our time when there is a global project. That flexibility has always been there at DSI.”

Paul has supervised governmental regulatory pharmaceutical industries. He has pretty good business sense as a project manager for over 20 years, managed a lot of interdependencies: manufacturing regulatory teams, driving drug development process, directing some cross-functional teams by matching the desired technical expertise to some of the projects, knowing how to prioritize. He knows the importance of meeting budgets, the scope of work things, endpoints and targets, and delivering things.

So, Paul, let's get started with this podcast going into some of your background. Can you tell us how you got started, where you're at, and get some of your thoughts?

Paul Long

Thank you, Ed, thank you for the introduction. Good morning to everybody. My background comes from operational and a lot of life science experience. Along the way, I developed a pretty well rounded resume. I've done a lot of IT work; I've done a lot of clinical work. I began in the emergency department of a hospital and worked my way up through management, directorships, and spent a lot of time consulting on

the operational side. During that journey, I obtained my project management professional certification, and I also have an Agile Certification. I became involved in the pharmaceutical industry a few years back, working with a major consulting firm, and I spent time at a very large global pharmaceutical in their regulatory department. That exposed me to that side of the work, I gained a lot of knowledge, and I have to thank the people who helped me along the way. I began working with PCI about a year and a half ago, and began working with DSI. I was lucky enough to run into Brian and Ed through a common contact, and immediately was placed on some of the regulatory filing work. I've done a number of INDs, IND amendments. I had a successful BLA submission recently, and have been lucky enough to work with a lot of smart people at DSI. And I've really enjoyed it. Thank you, both of you.

Brian Lihou

Paul, if you look at your career, and you match it up against what you're doing now, one of the things that really jumps out in a typical project management environment, you have some aspects of it that are virtual: there are conference calls, especially in today's climate; it's become very normal. But with DSI, you're working completely virtual. So, when you look at the types of clients that we have, they're both small and medium sized companies. Given all of your background, all of your qualifications as a project manager, what are some of the benefits of

being completely virtual, as a project manager?

Paul Long

I'm lucky enough to have been a virtual project manager for a while now before I joined DSI. And what I'm finding about that is, of course, it saves travel time, things like that. But there are challenges there. It's not much different from the challenges that you have when you're in place in real time. It's communication, it's visibility, it's transparency. What I found at DSI is most of the people that we work with here are virtual and are used to that environment. There are some tasks that we've always performed on site - CMO audits, site visits, things like that - but we're fairly comfortable with the virtual environment that allows us to be flexible and who we staff. That's a plus. It allows us to be flexible in our time when there is a global project. We are in the same environment, in our home offices, or wherever we are, and able to join those things. That flexibility has always been there with DSI. I think what we're seeing now, in the changing environment, is more of our clients joining that virtual team, where they've been consolidated at a single site with their organization. Now we're able to bring them into more of the virtual environment, and they're becoming comfortable, something that DSI is good at - and we're bringing our clients along.

Brian Lihou

I appreciate that. I think you're right; the one thing to not lose sight of is the fact that you can be flexible in your project teams, bring people on, and that's often appealing to various companies in their budgets. I think having that flexibility virtually is important. Now, what are some of the challenges to traditional project management, and of completely virtual? Let's start first with just internal challenges you have in project management.

Paul Long

Well first, I always start with communication. Communication is key. And establishing communication. In a virtual environment, there's a little bit of a challenge there. When you're in person, there's a quick read, an easier read to the person, the people around you and your teammates. And that involves knowing how people are comfortable with communication, what level of communication they need, whether you're communicating to a peer, to a client, to a C suite level, to an SME level - you have to establish how you're going to communicate, and everybody has to be comfortable and understand how that communication will occur. It's easier when you're face to face; visiting a client, I used to find a lot of value in that. I don't get to do that now. But as we've moved towards these virtual communications, people are becoming more comfortable with virtual communication. There are enough platforms now whether it's a webcast, Teams, Zoom, whatever you're using; people are becoming more comfortable at turning the video on, we're seeing each other. That's not exactly virtual in the sense that I see your face. Now I know what your expression is, you see me, we get to know each other a little bit better in these meetings. And I see people becoming more comfortable with that.

“Again it comes down to communication, transparency and open discussion. And that’s one of the things I try to drive as a project manager.”

Brian Lihou

So that's much different from the traditional conference call; there's something to be said for that. And it was at the beginning of COVID, and the beginning of all this isolation that we're all becoming sort of accustomed to, that no one used their cameras. They didn't use their cameras until you started asking, and people started feeling comfortable. I think you're absolutely right, it opens up much more in terms of interpersonal relationships, because you can see them, and it's somewhat disarming if you can see the person on the other side.

“It’s similar to managing the communication prior to the COVID environment. You have to establish how the person wishes to communicate, what level they wish to communicate on. So, when I meet a client, I ask them these questions directly. ‘Are you comfortable with this kind of communication? Do you want a weekly update? What’s the cadence for meetings?’”

Paul Long

It makes me more comfortable with whom I’m speaking to. I also find more and more people are quicker to call. Maybe it’s they’re getting to know us and some of our SMEs are getting to know me, but I have people picking up the phone and calling me more often. They know they can do that. And maybe it’s because we’ve met in video chat, we’ve talked to each other, they see the kind of person I am.

Brian Lihou

Yes, it’s a great point. And I think it’s an evolution, right? I feel as though now we’re kind of hitting our stride virtually, where this just becomes the norm. The other part of this, though, is clients, and clients come in all shapes and sizes. When you’re working with them virtually, some are more adept at working virtually, some are not. So how do you manage that?

Paul Long

It’s similar to managing the communication prior to the COVID environment. You have to establish how the person wishes to communicate, what level they wish to communicate on. So, when I meet a client, I ask them those questions directly. “Are you comfortable with this kind of communication? Do you want a weekly update? What’s the cadence for meetings? How do you want meetings to be held? What kind of an agenda do you want?” And now, it’s those same questions. This time, instead of setting up a meeting, which is just a phone call or a meeting in person, it’s setting up a meeting that involves possibility of video, too. I find that our clients are pretty quick to use video, and I think they appreciate seeing our faces and seeing our expressions. When it involves a third party such as a CMO, I find that they come on board with the video a little bit later, but I think that helps everybody join as a team. And I encourage that.

Ed Narke

I think that’s a really good point. And now you’ve set the parameters, you move forward with projects, you have the relationships internally already built in. And if all is right with the world, then we move forward. Now, in that vein, for folks listening to the podcast: one of the things that I’ve learned over time is that people often question the value of project management. We’re challenged with it every day, where someone will say, really, why do I need a project manager? because I’m doing this aspect of this project on the side, and it’s going just fine. I used to struggle with that response, kind of just wait and see - and it’ll become clear to you very soon why you need a project manager. But let’s say you’re in a situation where you’ve got these relationships established, all the introductions are done. What tools can you use in a project, that you use often, to really set the tempo and the expectations for how the project’s going to be run?

Paul Long

Personal tools or physical tools, online tools? They’re all part of it. I like to keep things moving. And very often, there’s a funnel. Funnels occur because the SMEs are working different projects, and because our clients have multiple tests to perform. I’m not their only interest. And I am able to keep that focus going. What I try to do is keep track of what the dates are, and what we are shooting for. I have to integrate our team and the client’s needs into common goal, and make sure we’re meeting that. Plenty of things can happen.

We've had clients that because of COVID, internally, we had learning curves on systems and platforms. All of those things can create delays or roadblocks to getting things done. It's not just bringing the people into the meetings at the correct time; there are reviews going on on both sides. Sometimes those reviews can be delayed; people have other priorities, unexpected things happen. Knowing how to keep that schedule going is crucial. For instance, on a current Briefing Book, it's going back between a global organization; we have people reviewing the document on our side here in the United States, we have people on their side, in the United States, and also in on different continents, and they all have their own schedules. Knowing and communicating when those things will happen, and making sure that the handoffs happen, keeps us moving - to the point that we're going to make a pre-determined goal that was kind of shot out from the air, I am very happy about that. I think the client and the people, too, appreciate that we've been able to keep everybody coordinated, and meet that time goal.

Ed Narke

Certainly things have evolved, technology has evolved. Talking to folks one year ago, we would have never predicted that we would be doing podcasts, we were talking about meeting people on screen. Once upon a time, there was a way of doing this, right? Most projects happened in house. When I got started, I went to an office, there was a PM, there were folks around the table in a conference room, at least locally, or dial in - but not so much the case any more. We have jumped ahead of the telephone call, there're some benefits to having video screens.

As Brian mentioned, there is a value and importance of having a project manager on any project. So simply stated, what is project management? I kind of bandied this around for my whole career here, managing people activities, time, money, budgets, and scope of work, to complete the goal. So it "sounds" easy. I think we all do this in our daily lives, right? We get out of bed, and literally we're all project managers, some better than others.

So, Paul, you have some good history with us now, working with small emerging biotechs - very innovative, very forward thinking, moving very fast. Can you give us some loose examples of how project management fits into this drug development continuum, many times with a limited budget? You know, maybe some things that you see from that side that folks out there listening to the podcast can appreciate, or that may trigger a thought that might help them. As Brian mentioned, a lot of folks look at it as overhead. They're hiring folks, subject matter experts that are going to do something in a chair, but for any kind of a team, without a coach, without a manager, for example, there's no cohesiveness there. There's not a plan, it's not communicated. So, can you talk to us about your role, and maybe some of the projects that you've worked on without details? You know, how does that that role fit into the development process?

Paul Long

Well, we're seeing that the challenges haven't changed with COVID, but our work environment has. So, a lot of it is still coordination between the different working parts in the client, and we help out with that. On our side, we're very communicative. And one of the things that we do try to do is have some an internal cadence, and discussion between the different areas: regulatory, drug substance, drug product, quality assurance, we have multiple SMEs working for a client. We find that it's helpful for us to sit and talk about what's going on, and do a lot of cross-sharing of information; I find that mirrors what's going on in the client sometimes. I find that we can often help clients to improve their internal communications when we talk about what we're seeing in different areas in our own discussions - for instance, linking up the clinical supply chain, along with the some of the drug substance, drug product supply chain. Very often recently, we've found that we've been able to help on the dependencies there, documentation dependencies that are affecting the clinical supply, and the depots and what's going on as they tried to move things into clinical trials in different areas of the world. Again, it comes down to communication, transparency, open discussion. And that's one of the things that I try as a project manager to drive - make sure that the right people are talking.

Meranda Parascandola

We asked the question briefly about what tools you use. I know that there's always flexibility with our clients and preferred tools to use, but have you found anything to be a very effective project management tool particularly? Just for my own knowledge...

Paul Long

With everybody going virtual, there are some tools that we've all used when we're sitting in the same room, desktop tools, etc. Now most of it is moving to web-based, cloud based. There are questions about that, that I won't discuss here: the security, the logins and all. All that affects our work, though. I'm probably using and you're probably using maybe four or five different platforms for video conferencing right now, depending on who's on the call and who's scheduled it. But what I'm finding with the project management side now, is that people are exploring different tools to support the collaborative effort. And that's not just the workplan, which in the old days was always MS Project - everybody knew MS Project - or JIRA, and a few others. But now people are looking at the web-based versions of those - for instance, Office 365 and Teams.

“I have to integrate our team and the client’s needs into a common goal and make sure we’re meeting that.”

There are other products on the market now that we're using, that have some advantages and make it easy to collaborate and share these tools, inside and even outside the organization. For instance, at DSI, we've begun experimenting on something called Smartsheet, and some of our clients are already using this with us. I've used some other products as well; those tools change the game, when you're able to share things that way, and look at the same project plan. These new project planning tools also allow us to create dependencies across organizations, if we use them right. There are what I would call “social networking” aspects to them. And tracking aspects outside of the project plan, where people can collaborate and have discussion groups, online project teams, much like social networking.

Ed Narke

Okay, so I just got a note from one of the listeners, and there's a question for you, Paul: what is the utility of a Gantt chart, good question, right? I associate myself the Gantt chart with Project Management. Can you tell us, has the Gantt chart changed in the virtual world? Is that something that's still kind of common use? Are there other things out there that can take the place of Gantt chart?

Paul Long

No, I don't think the Gantt chart goes away. I think it becomes easier to use. I didn't like the Gantt chart, and certainly on the older platforms. I can produce one more easily on some of the new tools. I think more importantly, are you producing the right Gantt chart for the right audience? Do you have the correct milestones on there? Is there a discussion for what level you're tracking? The roadmap for the C suite looks different from the roadmap for the drug product people. So, I think the use of the Gantt chart only expands as the tools make it easier to produce them and use them to update them.

Brian Lihou

Yeah, I think we've seen where Gantt charts still have a purpose to serve. We've seen also where they've taken on a life of their own, and they're now consuming resources just on the status of the Gantt chart, and you have to step back and consider if the tool is really serving the purpose. I think that's what gains the respect of the client and of the internal team members, if you've got a tool that people really can base decisions off of. I think to your point, Paul, that if it's easier to use, it makes it a little more efficient, a little more effective. And that's really what it becomes. But I think to caution, you really have to look at how the tools are used to make sure they don't

consume resources just on that alone.

Paul Long

Same thing, Brian, we might not just say Gantt chart, but what we're also looking at now are some of the dashboards. In my past jobs, I would produce monthly dashboards that might take me all week to produce. I don't like spending my time that way. And some of these new collaborative tools can be set up to produce dashboards on demand. If you're not doing that, you should question, is there a better tool? Why do I have people spending their time, I don't want to spend my time, client time creating a dashboard, I want to run a dashboard. I want to set that dashboard up once, I want to set that Gantt chart up to where it pulls milestones, and all I have to do is hit a button once a month and say, here's the dashboard. Here's what we expected. Here's where we are.

“Keeping the communication up avoids risk. We don't want surprises, unless they're good.”

Brian Lihou

Yes, becomes meaningful, good point. Okay, so we've talked a lot about some of the aspects of working virtually, pros and cons, some of the tools that we use; if you were to sum it up, why is project management important? Thinking about the audience, because like I said at the beginning of the call, you've got folks that may question the need for it. Is it cost effective to have project management? Is it just another layer? People are always very averse to layers. What would you say in terms of the benefit of effective project management?

Paul Long

Risk management. That things don't go awry, that someone is stepping back and taking that look at the pieces, the dependencies. Keeping the communication up avoids risk. We don't want surprises unless they're good.

Brian Lihou

That's right. Boring is okay. Exactly.

Paul Long

Boring is great. Went exactly as expected, we recognized something going wrong in the middle of the project, and we were able to mitigate that, we were able to inform the affected parties. That doesn't occur without someone taking a step back from time to time, you know, on a weekly basis, talking to the client saying things are going well - if it keeps that boring look up, great.

Brian Lihou

Yes, I think it's very well put, you're right. I think it comes down to risk mitigation, efficiencies that are built into the processes. It's all those things that we mentioned at the top of the podcast, because I think people do it as a side job, so to speak, to what their other projects are - whether it's the lead chemist on a project, it's someone who's been given the project in regulatory, there are so many other aspects to run and, and CMC is a very broad term, right? It covers a lot of different areas. I think one of the advantages to effective project management that you touched on, is really letting them know there's a central point of contact, because if the need changes, and there's an expanded need or reduced scope, they have one person to talk to. I think that really resonates with clients that, when I'm in trouble, or if I have a question, or if my board's is asking a question, I have one phone number to call. And if that person doesn't know the answer, they can certainly find it. I think that really kind of sums up effective project management. Absolutely.

Ed Narke

I agree, Brian, and as you mentioned earlier, what is often, the classic view of a PM? You start a project: how many technical experts do we need to complete project? We need $n + 1$. That's great. We know what we need to do here. And then next question, how many project managers? Do we need a project manager to complete? How many? Zero, since they don't do anything meaningful, anyway, right? That's normally the train of thought. But there is a meaningful function: sometimes I call it crisis management. The folks that I worked with over the years that were good PMs, really good ones, took crisis and defused that, and then made the goal happen.

“The challenges haven't changed with COVID, but our work environment has.”

So, with that, I guess we can go in a little bit into how I got to know Paul, and in this story I always find analogies to his work here as a project manager. Over the summer we went deep sea fishing, and we started off getting up early in the morning. I brought my two sons with me. And you know, Paul was very organized. We only went on a certain day, with a certain water situation, and it had to be the right circumstances. So, he navigated us out to a wreck off the Atlantic City area. By the way - Paul's from Somers Point, New Jersey, very nice town down there. But anyway, what was the name of the wreck, do you remember, Paul?

Paul Long

It'll come back to me. We were about 30 miles offshore.

Ed Narke

Yes, 30 miles. It was a pleasant day. But of course, my family and I have genes for seasickness, apparently. The long and short of it all is that we were successful in getting some fish and got back safely. It's kind of akin to what Paul does here, as far as projects go; he does make sure that the goal is set and made and delivered. So that said, if the name didn't come back to you, you'll have to look it up, and we'll put it on the podcast notes.

At this point, any other questions? Just general one off funny jokes? Anybody want to add anything?

Paul Long

Yes, I'd like to make one point, too: that sometimes there's the question, and you mentioned it, What do I need a project manager for? And I want to differentiate between a project coordinator and a project manager. It's not simply coordination skills, it's not keeping the dates, making the meeting. That is one of the things I take care of, and I think I'm okay with that. But it's also the soft skills. Sometimes that means dealing with a personality. Sometimes that means recognizing a personal issue on your team, and helping that person out. And that only comes with time, and experiencing some of those things, and being able to support your team as well as the client in that mode.

Ed Narke

That's a great point. Okay, with that said, I'd like to thank Paul again for joining us on this podcast, and I look forward to talking with you again in the future. Catch us next week for another podcast.

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