Pharmaceutical Regulations in CMC

Episode 5

Ed Narke

Welcome to CMC live! On this episode, we will be speaking to Dr. Catherine Bernard. Catherine directs our Regulatory efforts as a key strategist working closely with our client's mission teams. Catherine is an industry expert for Regulatory Submission Lifecycle Management, including both large and small molecules and all dosage forms.

Her expertise includes successfully negotiating CMC pathways with global health agencies, authoring and submitting briefing books, attending in-person meetings, and more recently, virtual meetings. Catherine has over two decades of experience in authoring and reviewing the CMC sections of Investigational (IND and IMPDs) and Marketing Applications (NDAs, BLAs, and CTAs). She holds a Ph.D. in Biochemistry and Cell Biology from the University of Paul Sabatier Toulouse, in France. Catherine's also an active skier on the slopes of the Rocky Mountains near her home in Denver, Colorado.

Catherine welcome! One thing I wanted to say, and this is true, I have been one of your biggest fans for a long time. I am looking forward to talking with you here briefly, getting to hear some of your favorite experiences, and also going back and reminiscing about some of the stories from when we first met.

> "You need to be very careful what you're going to put in a dossier during the product development."

I was thinking about the components for discussion today if we can go through them. First, we might want to talk about preparing the CMC Dossier - which can be a daunting task. It is detail-oriented, and as the saying goes 'the devil is in the details.' We can also talk about some of those experiences.

The next point I wanted to talk to you about and will have you discuss, are some of the challenges in preparing CMC dossiers. Maybe you can share some tips for success. A third point we want to cover here is some thorny experiences. Specifically, recently we have done a little bit on expedited drug development, and you have been active on some breakthrough designation programs.

Fourthly, we'll move on and examine some manufacturing readiness advice, especially in the breakthrough and expedited timelines when sponsors talk to the FDA, when they have no time to talk to the FDA, and how you might deal with that. Finally, from there, we wanted to look into the future of pharmaceutical regulations. Where guidance and regulations are going to go, in your opinion, in the area CMC, we can foresee and maybe follow over the next couple of years.

With that said, the first question, how did you get into regulatory affairs or CMC?

Catherine Bernard
It started with a Ph.D. I did a lot of research in a cold - freezing room. I was always pretty cold. I thought to myself I need to move out of science, I cannot do benchwork anymore. I looked at other options that could help the pharmaceutical industry with my scientific background, and that is how I ended up in Regulatory Affairs.

And I started in Regulatory Affairs in England, because in France, most of the Regulatory Affairs assignments were filled by pharmacists, because when you enter Regulatory Affairs or Pharmacy in France, you have training so that helps you get there faster. To sum it up. It was fun! I did it about 20 years ago and I do not regret leaving the benchwork to build a career in Regulatory Affairs.

Ed Narke
Okay, so besides not being cold anymore, what do you enjoy most about it though?

Catherine Bernard
Skiing unless I'm cold? No. I do like contact with people and that's what I enjoy, consulting because you have a variety of products, a variety of people, and a variety of challenges.

Ed Narke
Okay. Is there one moment, in particular, like a memory, that you have doing this, that you can share with us?

Catherine Bernard
Yes, definitely.

Ed Narke
Good memory, not a bad one.

Catherine Bernard
It is a very good memory, Brian and I, we still laugh. It was Christmas time, and I was going skiing on the slopes when one of the clients called me and said, 'I need to get a document to the FDA, we need to discuss now.' So, I went to lunch on the slopes, and we had a conference call for an hour. We were able to successfully put the dossier together. So, that's one good fun memory. Maybe not fun at the time, but it is to this day, still pretty fun.

Ed Narke
I think I remember that one. Brian, you have anything to add to that one?

Brian Lihou
Oh, well, I'm very glad that you labeled it as fun because I remember at the time, it was a bit tense. The fact that we didn't see it coming. But I have to tell you, it was just a handful of people and when they needed us, we were there. I think that's what makes it fun is that all of us were kind of in it together, so to speak. You know, I think we can all kind of laugh about it now, not then so much. But now. Yes, I agree.

Ed Narke
Well, I thought it was the other story when we took that trip, Catherine, to Switzerland, with that company that licensed that one product that no one could characterize, and we went up into the -- Do you remember that company? I can't name the name, of course, but this is where I met Catherine. I think she was consulting, and I was working for this small biotech company that rhymes with Aleta, let's just say.

We traveled over to Switzerland, and there was the partner company that had licensed the product out, but they wouldn't give any information to the US company that licensed a piece of it. So, it was very difficult because the FDA wanted us to characterize the product. That's a novel idea, right? You couldn't tell if each batch was the same because there might have been 100 actives in it.

So, one of my memories -- we were outside Geneva, there was some nice farm -- but do you guys remember the location and what it was sitting on top of? The Hadron Collider. It was that particle accelerator that they have? I think it's on the border of France. So, it's about 100 miles underground and I think that they [Catherine and Chet] were there the first time they planned to push protons or ions to near the speed of light. We were all sitting around this nice picnic table in the countryside, and the accelerator was going to be tested for the first time that afternoon. If you guys know anything about it, I think it creates mini black holes and could suck the whole galaxy into this thing.

I probably shouldn't have been so worried, but I thought the whole countryside was just going to vacuum in. It didn't work out, the testing that day that it. I think something happened, some of the magnets weren't working. So, it took another three years and they finally tested it. Anyway, we had a great trip.

We had another consultant, his name was Chet Myers, he used to work with us. I think between him and me, you know, this is where we start to realize small biotech companies might need a little help and may not know how to make the right decisions in some circumstances.

So, anyway, moving right along here, preparing these CMC sections, in general, over the years has changed a bit - really hasn't - the amount of information maybe you provide is different based on your purpose there. You may want to hold some back, or you may not have enough information, so you must give a little bit more in another area.

Catherine, can you talk to us about some of the challenges in preparing CMC dossiers. Some of the situational stuff, without going down too deep, and maybe again, share some tips. Things that you've seen mistakes on, and things that you've seen that you can offer us [insight on].

Catherine Bernard

From an authoring standpoint, you need to be very careful of what you're going to put in a dossier during the product development. So basically, when you start preparing for an IND under a Phase One study, the level of detail will be different than for the BLA, or an NDA.

So, what happens during the product development, sometimes the sponsor will move along to be acquired by a different sponsor, and so on. By the time you are ready to file your NDA, you kind of have lost some of the documentation that may have been generated in the early development.

Then, as you know, you still must recreate the story for the FDA when it's time to put the product on the market. We have had a bit of challenge in certain instances, you know, retrieving the documentation and explaining what was done at the time.

> "And that's where the interaction with the FDA is critical. So, the sooner, the better. You need to be upfront when you go to those meetings with the FDA. However, you don't ask a question for which you don't want to hear the answer."

So, you may want to talk to the FDA and make sure that they will be on board. This is where the interaction with the FDA is so critical. The sooner the better. You need to be upfront when you go to those meetings with the FDA.

However, you do not ask questions for which you don't want to hear the answer. It's a balance of 'Yes, we would like to have an answer, but what could we propose that would satisfy the FDA and will make the dossier successful?'

Ed Narke
Okay, so that's a common theme then, from what we do as well. So, the first question, do you have all the information required to assemble a high-quality dossier? Maybe right? More often than not, the answer is yes. But I have information that is missing, or I have all the information, but I can't find it, are typical answers that we hear. So how about if there is missing information? How would you deal with that? Is there a chance that you might want to bring that up? Or do you want to hold back and talk about that after you get questions?

Catherine Bernard
Usually, if we do not have the information, we try to put the justification together based on science, the FDA is reasonable there. And if your justification is based on science, not just, you know, 'I lost the information,' you will have a good chance to have a successful application and ultimate marketing approval.

Ed Narke
So that is a good one! I found out early on when I was doing it by myself. A lot of folks wanted help with submission authoring. They said they had all the source information, but then you get there and it's sporadic or they don't know where it's located, or if the product was licensed, where the story started. Then somehow, it's missing, and you have to find it too. So, project management is also important in submission authoring?

Catherine Bernard
It is a critical piece because it takes a long time to put a submission together even though it could be an IND for Phase One. You still need some information to be gathered or to be collected, and then to be written into a dossier so that the FDA will accept your IND. The timing is critical, definitely more so these days even with the pandemic, because if you don't have the best submission that you could put together, the FDA may just put you on clinical hold as they are under a lot of pressure to get moving on the COVID-19 programs.

Ed Narke
Okay, and a follow-up to that, target dates. Many people, to meet objectives for the boards and their bosses or their shareholders, set a target date. Can you tell us a little bit about how that works, especially with CMC, and how sometimes that is the last piece, even without a breakthrough designation or a rolling submission? As you can say, maybe folks push some of the decisions and also some of the work off on for CMC until they are convinced by the clinical data. So, you've worked on this for a long time. Can you talk about target dates, realistic timelines, for our listeners out there?

Catherine Bernard
Right. Again, usually, the CMC is the last piece, for example in an NDA or BLA submission. If you read the guidelines, you'll need a certain amount of Stability Data, three Validation lots, etc. Two or three consistent Process Performance Qualification (PPQ) registration lots, and that takes time. And so, you could negotiate with the FDA, say, for example, submit with the first PPQ lot, do your second PPQ lot during the review of your BLA or NDA. Before launch, you follow with a third PPQ lot.

Having said that, if you, for example, are in an orphan designation situation where you are not going to use your three lots because there are not that many patients, it is negotiable to submit your NDA/BLA with one PPQ lot and do a post commitment that you're going to submit the two other PPQ lot validations when they will be available, meaning when the first PPQ lot will run out.

Ed Narke
Going back to the breakthrough designation and expedited drug development, can you talk about some experiences? In particular, the CMC considerations when a drug development project is assigned a breakthrough designation status.

Catherine Bernard
The breakthrough status is granted somewhere during the product development. When you get the breakthrough designation, it doesn't mean that you could cut corners, it means that you're going to get more regulatory interaction with the FDA. It also means that you have a lot less time to generate data before you file.

Ed Narke
Speaking of assignment of breakthrough therapy designation, and how it leads to accelerating a clinical program - which could cut off two years of conventional development, right? The timelines are affected by that, versus the traditional timelines. It might reduce real-time stability for your commercial material. So, you might have to leverage stability information from developmental studies, you likely may have limited manufacturing experience. If you get a breakthrough designation right before you even put an IND in, you don't have a lot of time to make materials or generate data.

You may need to consider launches with initial commercial supplies in a lot of instances and during the formulation development process. Transfers, tech transfers, and finding an actual commercial facility that can supply you or your patient population might not be happening or unavailable or not ready and could delay you.

With all those things said, Catherine, can you tell us about some of those experiences that you had? Maybe in some ways what you learned, would change, or advise people on in the future knowing what you know? Or are there things that that you can talk about?

Catherine Bernard
So, with a breakthrough, my experience was not so much on the stability data, but definitely on the process. The lack of experience on the process methods, not completely optimized or characterized, generally posted commitment to ensure that the method forced liquidation - to make sure that the method or stability-indicating, and things like that.

So, for me, those were the two big issues that we encountered with a breakthrough designation. The Fast Track is also another expedite program where you could also encounter the same challenges. Recently, the FDA for biological products has made the regenerative medicine advance therapy guideline, Again, with all of those expedited programs during drug development, there is an unmet medical need. So, we truly need to get the product available to the patient population as fast as possible, I would say for certain however without compromising safety and efficacy.

Ed Narke
Okay, so when you're examining manufacturing readiness, whether pre-IND and you know that they're going to give you the designation for breakthrough or, if like you said fast track, right? You mentioned methods, analytical methodology, and that that's traditional development, too. You have bad methods; you can't equate materials across the phases of development.

> "So, it's not because you're going to get a breakthrough or a fast track that you're going to cut the corner and not have all the appropriate information that is required or expected by the FDA. However, what you could do is do a science-based or some justification that you could propose to the FDA to mitigate the risk and ensure that your product meets always the same quality and strength."

This is probably one thing you can talk about at any kind of pre-meeting, but at the end of the day, you have to have appropriate methods. Qualified and ultimately validated. Is there anything else that you might discuss if you have a Breakthrough or a Fast Track, besides methodologies with the FDA during these meetings?

Catherine Bernard
Right. So, you're going to discuss your process, your critical process parameters, and how many lots or what would be considered sufficient experience from a manufacturing development to be able to get a successful application.

The critical process parameter(s) is one of them, what's your control strategy during your process? If you do not have a lot of manufacturing experience, you may consider replacing the experience with more description in process control. So, to ensure that the manufacturing process is under control which is one of the main worries about the FDA.

Ed Narke
Okay, that's more like a science-based approach to where you're at and heading. Right?

Catherine Bernard
That would be correct. Yes, definitely.

Ed Narke
Brian, any thoughts? We've done many breakthrough programs and Fast Track programs. Typically, the sponsor has limited time to develop the drug without delaying the filing. There is not as much development work as is usually done in this situation, on top of an already limited budget(s) most sponsors face. So, regardless of the indication and the need to generate data fast as they have to have a very sharp runway before takeoff, would you have any questions, or do you have any thoughts yourself?

Brian Lihou
Yeah sure, we have done a few now. Catherine, what are some of the challenges in managing the sponsors' expectations? A lot of the time when you see a breakthrough or fast track, certain assumptions are made on what the agency will and will not tolerate or accept. How do you manage the expectations? Or do they always seem to agree with what the FDA is expecting? Or do you have to educate them in a sense and how do you do it?

Catherine Bernard
Yes. So basically, from a sponsor's standpoint, it is kind of a magic door. But in reality, it is not, because as I said, there is an expectation from the FDA and any health agency. So, it's not because you're going to get a breakthrough or a fast track that you're going to cut the corner and not have all of the appropriate information that is required or expected by the FDA. However, what you could do is do a science-based, or some justification practice, that you could propose to the FDA to mitigate the risk and ensure that your product always meets the same strength, quantity, and safety profile.

Brian Lihou
Another thing, we have situations where each agency reviewer is different, as well, and their expectations on the review of the CMC package are sometimes different than as expected. So, have you come across situations where you're dealing with a reviewer that has thrown you a question, or a response, that's something you hadn't seen before? And how do you manage that? Because I do think it runs the gambit depending on who you get. I mean, they are people as well and as they review. If you write something in a way to tell the story and then a question comes, what is the strangest, off the chart, type of questions you got and how do you manage those?

Catherine Bernard
If you truly believe that the response or the question you got from the FDA, might be unreasonable, it could be just because the story you write was not clear enough. So, in the first place, I would at least, at a minimum, try to get either the reviewer on the phone or via email explaining what we thought, or explain, what our position is. I had come across, maybe not on the CMC, but on the clinical, where it was a different product, not so much for the clinical division. They did not understand the disease. We truly had a key opinion leader teach the FDA what the disease was and how to treat it because it was a rare disease.

So, you could educate the FDA. As you said, the FDA are people too, they do not know everything, so you also have that option. Now, you also have to bear in mind that if the FDA asks or recommends something, it's because they have seen another dossier from another competitor. They may have seen a method, process, or step that was better. They may advise you to do it that way. That's also what you have to take into consideration, did they not understand your process? Did you not write a proper story? Or because they have reviewed something else that is not available to you as a sponsor. That's what and how the questions or responses come from.

Ed Narke
So, it sounds like the adoption of a customized risk-based plan from a CMC perspective is recommended by you here. Also, in consideration of the benefit of the patient-focused on control strategies, etc. to ensure compliance is met, consistent qualities met, that should all be acceptable to the health authorities around the globe. I guess the question part of that is, is it good advice to listen to the agency and their advice?

Catherine Bernard
Always, I'm sorry to say it. Yes, if you don't want to follow them, justify your position as to why you don't want to follow them. Make sure that they are on board with your justification. Because if those recommendations are made at the IND stage, and when the time comes for your NDA or your BLA and you have not taken this into consideration, those recommendations, may be a showstopper. So, either during, or along the line, you put the justification and you make sure that the FDA is on board with that, or you do the experiment or whatever is recommended by the agency.

Brian Lihou
I think we oftentimes ask to do at least a cursory gap assessment of the program, and if there's a prior dialogue with the agency, or if there's a particular area focus that we find in the gap assessment, we spend more time to develop that argument in that position, because we know it could be a potential question coming back.

Catherine Bernard
Correct.

Ed Narke
I did like your answer, you know, these FDA reviewers, this is what they do for a living, they may not have worked in the industry on the other side, but they are a gatekeeper for safety and compliance, which is important. Like you mentioned, or somebody mentioned, listening is a skill that not many folks have. Communication is a skill not many folks have. If you can use those two, you can also learn things. Like you, I, and Brian know -- going through this with different sponsors, dealing with situations, kind of seeing how to handle things, how not to handle things. Did you listen to your parents when you were younger Catherine?

Catherine Bernard
Obviously not. But maybe I should, I don't know.

Ed Narke
You know what they say you should always listen; I tell my kids this. 'You should always listen to your parents not because they're always right, but because they've made more mistakes. They have more experience with being wrong.

I have an example of this. So, when I was younger, my parents said, you know, never -- first of all they didn't like when I went to concerts, and they didn't like some of the folks I hung out with and stuff. So, they also said, Never talk to strangers. So, I think we were going to a Metallica concert and I was like, 17, and I was a good Catholic boy and stuff hanging out with good friends.

So, we had a van, and we are driving down the road. This is back in the day when you went to concerts. You couldn't buy tickets online, you had to buy from scalpers, right? Find the cheapest ones, we would sit wherever. So, we're driving down the road and we see another van and it looked a little suspicious. It was broken down, no one was helping, and there was a guy outside. I told my friend, why don't we stop and help him right. And then that thing in the background, you know, listen to my parents.

You remember back in the 70s and 80s, Brian, like people on the side of the road hitchhikers, right? So, we stopped and of course, you know, they asked us where we were going? To the concert, it was a Metallica concert. And I said, what are you guys doing? We are going to a concert as well. So, I said, Do you guys have tickets? No. And of course, they gave us some acid, you know, we just put it in our pocket because as we were good Catholic kids, we can't do that stuff. Right?

So, we were scared, though, how were these guys going to get tickets? They didn't have any money. Right? So, I think the one guy says we're going to get a screwdriver and kill somebody for their tickets or something like that. So, we got to the point where we got out of there and, you know, kind of fear for our lives for a little bit. We look back and go, Wow, we should've listened to our parents. Then, you know, I would have had no chance of whatever was going to happen there. Right? I can tell you about the concert later.

The moral of the story is there are a lot of folks that believe they know better than some of the agencies. You know, as conservative sometimes as the advice is these folks, reviewers and, etc. see a lot of information. They see a lot of holes; they see a lot of programs. So, listening to them could help certainly, and I think you guys both agree. I don't know if you have your own stories to share.

Brian Lihou
What I was thinking about, Catherine, perhaps an example of when you started into the journey of authoring a submission and as the story became clearer, you had to adjust the strategy accordingly. At what point do you realize that perhaps, the client or the sponsors' argument maybe will not pass muster, and you need to try to convince them of a different direction and still brace them for the fact that they still may get questions?

Before we come on board, oftentimes, the client and their people, their experiences at their company, are ingrained in their head and they say the FDA will do X, Y, and Z because it's in the guidance, and that's what they know. But again, as we said, They're people. So, at what point when you look at a strategy that a client presents to you and you realize that's not going to work? How do you manage that? And have you had that in a situation where you've had to come up with a different strategy?

Catherine Bernard
Yeah, and as you said, usually, most of the time we kind of do a gap analysis. So, the client will come with their strategy. Then we looked at what you did to convert, based on that strategy? Then we will review, internally at DSI, and figure out that maybe it's not the best strategy and we'll provide a slightly different or alternative strategy. Or we'll say to the sponsor, that if they want to carry on with that strategy, there is a risk at the end that the FDA would not agree.

So, you know, it's always a company risk to determine. Yes, I understand your position, but I'm going to submit it. It could be also tied up with investors and for some biotech companies, the submission of an IND is a big milestone. Maybe the outcome is not as big as just the submission. There is a time where a consultant could provide the best of their knowledge, but then the sponsor will decide ultimately what to do and when to do it.

Brian Lihou
I was just thinking, Catherine, I think the importance of a project timeline that's agreed to by the client. Do you understand? That not everything can be done that day and that things have to be done in order, you know, how important it is to map out that plan for the authoring for the client.

"There are times where, as a consultant, you could provide the best of your knowledge, but then the sponsor will decide, ultimately, what to do and when to do it."

Catherine Bernard
Right. So, there are sections that are easier and more readily available, for example, all the specifications. Most of the time the sponsor knows the product and knows what they are going to do, and then there is a section that is a bit more difficult, like all the process development or the analytical method development. Those sections potentially can come last.

So, when you write your dossier if it's an IND or later in development, a BLA or an NDA, you have to consider that. Which section could we write now versus the sections that we could write later? The sponsors must understand that it's not in order. Usually, you don't write it in order.

However, having said that, in the end, all of these sections are interrelated to each other. Your process development will impact how you're going to present your commercial manufacturing process, for example. The justification of your specification will impact your batch analysis.

All of those sections, even though they are written independently at the end, you must do a global review to ensure that they all make sense and they're all tied up together.

Ed Narke
Right, completely agree, I do. Can you tell us a little about your thoughts on the trends and take a look into the future of pharmaceutical regulations in the areas of CMC? What do you foresee?

Catherine Bernard
To be honest, I would say not too much change, you are still going to demonstrate that your product has met the quality, and you're still required to manufacture vendor GMP.

Ed Narke
Maybe a different take on it. We went from small molecules to large molecules and characterization, there are new techniques, and there are things like that. Now you're seeing different types of Biotherapeutics, those types of new modalities that are not necessarily the same. There is not a lot of guidance or gene therapies, for example.

Some guidance came out a few years ago. They're similar, they took the same concepts, as you know, from the more well-characterized programs. Do you see any changes there? You talked about methodology, good methodologies, and processes. Maybe some of these you only have one batch or a continuous batch, anything you know, with some of the futuristic stuff the new products we know about coming down the road. Do you see any of those influencing the regulation?

Catherine Bernard
My only experience would be with autologous cell therapy products, which obviously, the challenge is on the manufacturing process. As I said, it's autologous cell therapy, it's designed per patient. And so instead of having a big manufacturing suite, you'll have a small entity, and you're going to share maybe the same incubator with two patients or three patients.

So, the cross-examination, and how would you trace the product from beginning to the end, is the most critical piece. Your process validation will be a bit different. You're not going to do three batches, but you may be doing a matrix to ensure that you have to take into account all the different parameters during your process. So, that's my experience with the cell therapy product.

Ed Narke
Okay, last question. I learned a bit about how you got into regulatory, I've known you for several years and have been on some and many projects together and we had some similar experiences as well. Can you tell us something that we don't know about you, Catherine? So, we can talk about that next time?

Catherine Bernard
No, just as I said at the beginning, I would like to retire soon. Not right now though. Being able to choose an exciting product, most projects are fun, and I love the challenges. I tend to never say no to any project. I end up with a lot of projects.

Ed Narke
Okay, the very last question then because I know your time is important here. So, if you can have dinner with two people, dead or alive, who would they are and why?

Catherine Bernard
That being said, I do not know. I have no answer on the top of my head. The only answer I would say would be Metallica because I have a husband that is very fond of Metallica and he does play in a group. So, I would say Metallica, but that's...

Ed Narke
... and the other one, obviously, is Ed Narke as we know.

Catherine Bernard
We already had dinner together.

Ed Narke
I said in the future if you can have dinner. I mean, alive hopefully. We'll do that sometime soon, hopefully. All right, I'll wrap it up here but again, Catherine Bernard, exceptional. I met you when I was a bit younger, I had some fairly good experiences already then. But I also learned a great deal from you, not just in the beginning, but

I hear a great amount of information about how you handle some of these sponsors every day.
You made a difference in our industry to get some of these approved products out there on the market based on your help with some of the sponsors. So, I appreciate it. And I do look forward to meeting you in person again, at some point soon. The final thing I want to say thank you, and I'll talk to you soon.

Catherine Bernard
Thank you very much.

Ed Narke
On our next episode, we'll be talking with Coleman Byrne live from King of Prussia, Pa. This is going to be a rare treat people. I have known Coleman for many years now and we've worked together, actually in the industry even before DSI. We'll be talking about how to know when to toss your prescription drug or refrigerate it, stability studies provide that answer. Check the label, any prescription you fill in, chances are it'll have a label with an expiration date as well as for instructions on where to keep the drug out of the sunlight, refrigerator, and other instructions.

Coleman is our most senior analytical services expert here at DSI and is very technically proficient in all aspects of analytical as well as stability. Having spent many years managing both contract labs and RND groups, farm, and emerging biotech companies. His background includes biologic large material and synthetic small molecules, raw materials, release testing, HPLC, and you name it, API manufacturing process, lipid-based product testing, and various forms of drug product testing and supportive combination products.

Coleman provides oversight to our internal analytical team as well. He directs and supports these clients in any stage of drug development. So, using his technical ability in conjunction with his knowledge of submission requirements, he can not only support initial filings but also as a technical guru in the defense of submissions, including information requests in-person regulatory agency meetings, and annual reports and updates. This is a podcast that you don't want to miss!

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.