Quality Management Systems Explained!

Episode 24

Ed Narke
Hello, everyone, it's Ed Narke once again. Welcome to CMC live, here again to play another round of "What are your thoughts with regulatory drug development". CMC operations at hand again, with my co-hosts, Meranda and Brian, as always. So, Meranda and Brian, hello. So, just one note, the beginning of the start of the PDA conference, Proneural Drug Association 2021, style virtual starting today live from New Orleans. I really wish I was in New Orleans for the conference for many reasons, obviously. But we'll give it a go. I'm going to touch the end of the podcast here some instructions for next week's podcast, and also some more information on PDA and what we've learned over the last year. So, to get started, in short, we're going to be talking with Mike Carroll and Shelley today, myself, as always, as well as Meranda, Brian, essentially touching on the beginner's guide to quality management systems, which your company like to realize better productivity and less waste, you know, how many, how much information, how much knowledge goes into this?

> "Quality System Management provides an infrastructure for a company to ensure the quality of your drug product with patient safety in mind as its primary function."

Who does this? So, stepping back, just you know, for those that aren't familiar, quality management system, your QMS might be a solution you're looking for. So unfortunately, these management systems are highly complex. And many companies struggle with implementing them. So, we're going to kind of go through maybe a beginner's guide here to QMS, how it's designed to provide you with knowledge, tools, resources, when to do it, what quality management systems are, and how they can improve your business functions and day to day operations. Since podcasts also could provide some tools and resources that can help you learn how to successfully implement this into your business. A couple of the areas and I won't get too deep into this, again, as we talked about what's what is the quality management system? And why does it matter, maybe a little bit of a history on the quality management system, why it started and most important discoveries, especially from our eyes, what we've seen how companies are using QMS today improve things, some different methods to managing quality, some of the biggest obstacles in QMS, and how to avoid them, and some of the automation that's involved. So, without further ado, I will maybe turn it over to Brian here to introduce our delightful team here a lot of experiences from our quality unit, Bettina, and Robbi, and Susan and etc. So with that, Brian, why don't you maybe give us some background.

Brian Lihou
So welcome to this edition of CMC live. We're here with our quality services team at DSI. And we're fortunate to have the whole team here. And what we'd like to cover is the quality management system. So, before we get too

far, I want to let folks introduce themselves and we'll start with the head of quality assurance services here at DSI, Bettina Kaplan.

Bettina Kaplan
Thank you, Brian. A little about myself, I'm in the industry 30+ years. I've worked in all aspects of quality, from QC through QA, and all levels up to senior vice president in the industry at various companies and all different product types and dosage forms. And I've been a consultant for DSI for roughly five years. And I enjoy it. Quality is my passion.

Brian Lihou
Right? Thank you. Awesome.

Susan Fasso
I am Susan Fasso. I've also been in the pharmaceutical industry over 30+ years and was involved in multiple dosage forms working for a small pharma as well as Big Pharma. I have a degree in chemistry and also a master's degree in Quality and Regulatory Affairs. And I've been in the GXP arena meaning drug development as well as commercial products.

Brian Lihou
Thank you. And then the next person Robbie Freisem has been with DSI from its inception. So Robbi.

Robbi Freisem
Hi, I'm Robbi Freisem, and I have also been in the industry for over 30 years. I started out in biological vaccine product development. And I've worked in large pharma startup companies hand performed many quality functions over the years.

Brian Lihou
Thank you very much. And then lastly, we've got Maria. Maria, do you want to introduce yourself?

Maria Arakil
Hi, I'm Maria Araki. I have not been in the industry 30 years, I have been in the industry a little over 11 years now. I have worked with also various dosage forms. My specialty is QA and vendor oversight.

Brian Lihou
Yeah, it's funny when you go down 30, 30, 30. It's like, really? 11 years is a long time. An important thing to note here is that the areas that we cover, and again, we're going to talk about quality management systems. There's a breadth of experience here. It's rare that you get them all in one call talking about these topics. So, we're really looking forward to the content on this one, I really hope that this provides some insight for the folks listening to the podcast. So why don't we start with quality management? And first of all, Would anyone like to take what exactly is a quality management system? Because some of our smaller clients will look at a QMS and say, well, I really need it, I can't see where I actually need it. So perhaps someone can talk a little bit about what a quality management system is, before we get to whether it's important or not.

Susan Fasso
Well, it provides an infrastructure for a company to so that to ensure the quality of your drug product, with the patient's safety in mind as primary function.

Brian Lihou
Okay, so but when you look at the brass tacks of it, what exactly is a QMS? Are we talking about policies? Are we what exactly makes up a QMS?

Robbi Freisem
It's the organizational structure of responsibilities, procedures, processes, and resources for implementing the quality management, which is necessary to have to build into the product, the quality of the product for the safety of the human beings that it gets put into?

Brian Lihou
Well, it's interesting, we had a podcast earlier with Jim Mencel, and it is one of the episodes that you'll get to hear on CMC live. And we talked about registration, engineering, the validation loss. And the one thing he said, I don't think can be overlooked is the fact that quality consideration has to be made early. So when you talk about our range of sets, how something is determined that actually winds up in a masterbatch record, you need to have the information to support that. So as you get into investigations, things like that, you need to have a good sound scientific rationale to support your assertion. So really inviting quality into the process sooner, rather than later, is certainly more cost effective. And it certainly does save time, in the long run, inviting that quality perspective into how ideally protocols are written, batch records are drafted is really important. And having an infrastructure I think, is essential. So then let me ask Bettina, what is the timing for QMS? We have a lot of our clients DSI, are early stage. And when they talk about "I don't need all of these SLPs. I'm just making a phase two clinical batch." And yes, they've actually said that. So, when is really the right time for a QMS? And is it all encompassing? Is it all or nothing.

Susan Fasso
So QMS should begin as early as possible, GMPs are supposed to begin at phase one. But most companies don't do that. They think they can wait. I've worked for some companies where they waited till phase three, meaning they brought me in at phase three. And that is not beneficial, obviously, to the organization.

> "It helps determine and define management's commitment to quality. Because if you don't have senior management commitment, all could be lost."

Brian Lihou
Okay, where you're playing catch up.

Bettina Kaplan
Yeah, there's guidances. they tell you at phase one, this is what's expected to be in place, phase two and phase three, where you start to use your product in humans, you need to have your GMP set, you need to have basic procedures in place at phase two. And then continue by phase three to start getting them closer to commercial like. And I say commercial like until you get to commercial at the end. So, you can break it up into key policies, maybe only do some policies and a couple SOPs to more SOPs at the next phase, till you're full SOPs, policies, and everything else, but you want to have a quality manual upfront. You want to be able to say this is what our vision is, this is what our quality statement is and how we're going to go about it. They can even have a plan of how they want to implement quality at their site over time at the various stages.

Brian Lihou
Why so many questions about that. So quality manual. That's what you know, like I said, I've been doing this for a while and early in my career midway through my career, quality manuals didn't really come up with me, they weren't really discussed. I mean, we had a table of contents, SOPs. But I've worked in a few companies where we

didn't have a quality manual. So, can someone tell me why this quality manuals and what is it? By the way, other than a table of contents? What exactly does it do?

Susan Fasso
It's really just a high level description of the infrastructure of your quality management system, basically. And as Bettina said, it includes your quality policy, your mission statement, the hierarchy of your documentation, do you have policies, procedures, work instructions, for example, it'll show that, It'll tell you the high-level requirements that you have to have adequate resources and personnel. And they have to be trained properly, they have to have the proper experience. And then it'll go into maybe some of the manufacturing portion or other aspects that are needed for your drug substance and drug product.

Brian Lihou
Okay.

Bettina Kaplan
Brian, a lot of this has been reinforced by the introduction of ICH, Q8, Q9, and Q10, that we've seen this infusion of the quality manual, a lot of other parts of the quality management system that you never saw years ago. I don't know, Robbi, if you want to add more to that, or Maria,

Robbi Freisem
No, I agree, it is started somewhere around 2008 with the implementation of the QMS in devices, and that's not right, that was 98. And it has merged into the biologics and pharmaceutical side, because it is a structure as a virtual company, early phase, you can start by putting in place your quality manual, and from that, you can drop out the procedures that will follow to support that. It defines upfront with the quality policy, what your plans are for the future, how you're going to act as you move into later phases of development.

Brian Lihou
Basically, your responsibility that the company is going to take, in terms of quality going forward, that there is a point,

Robbi Freisem
Right,

Susan Fasso
Yeah, the other advantage of that, Brian, excuse me is it helps determine and define the management's commitment to quality. Because if you don't have senior management level commitment, all could be lost.

Robbi Freisem
Yeah, yeah.

Bettina Kaplan
And that's what came out through Q8, Q9 and Q10, you never saw them say, a manager is responsible for making sure you have adequate personnel, adequate training. They're now responsible for these things, which you never saw. GMP s don't find that the ICH guidelines define it.

Brian Lihou
So I have a question. So, one of the things and Maria, this is for you, one of the things our industry is not lacking is the amount of acronyms. I mean, every time I see an acronym, and I have to quickly look it up, and there's about seven definitions of the same acronym. So, one of the things, it's true, and it's just what we do. But Maria,

one of the things that I've heard, I guess, in the last year or so, come up time and time again, I remember the little booklet system called CFR and can you perhaps tell us what exactly what the CFRs are? And what is their intended purpose? Because some people take them literally, and I'm not sure that's how we were intended.

Maria Arakil
So the Code of Federal Regulations, essentially, they're very high level, they don't really describe in detail how you're supposed to do things. So they tell you, you're supposed to, for example, make sure all your employees have the proper education and training to do their jobs, but they don't tell you how to do it. So, it's a very high level, and then the ICHs go into it a little bit more in depth. So, you do have to take the CFRs for what they're worth, they, they tell you what you're supposed to do, what you're supposed to have, and that's what you get audited on. But nobody actually says how to do it. So your procedures that you create are supposed to define exactly how you do it. And there are some industry standards on how to do certain things. Because the CFRs are so high level and very general.

> "To begin at the beginning, when you set up your QMS, you need to start with the procedures and processes that will reduce risk and help you prepare for your submission in the long run. That would come through managing your documents."

Robbi Freisem
Well, you need to remember that the CFR actually is the rule of law, the law. So no matter how you accomplish what's in the CFR, you need to be doing it. It's the law.

Susan Fasso
I mean, they are the minimum requirements, they are minimum requirements, and they're, they're broad because of the fact that the pharmaceutical industry has so many different variations of things. So, we have to remember.

Bettina Kaplan
CFR is a very broad term. CFR covers almost every industry in the country.

Robbi Freisem
And it's chapter 21.

Bettina Kaplan
Right, chapter 21, CFR blah, blah, blah, covers pharmaceutical, medical devices, food, a lot of different things.

Robbi Freisem
Animal medicines,

Brian Lihou
Yeah.

Robbi Freisem
Blood products.

Bettina Kaplan
Right. And that there are updates, and they're published by the FDA on a almost daily basis

Susan Fasso
And the Federal Register

Bettina Kaplan
Exactly. But what we refer to as GMP s and is in CFR 210, 211 for drug products. A20, for medical devices, there's a couple others for medical devices. Even clinical, which is in a different part of the CFR is covered in the CFR. And they are just the basics. Then, just to give you an example of GMP s, we have this little thing in front of it, and it's with all GXP. So, what is GXPs? GMP, GLP, GDPs, GCPS. It stands for everything, right? The C goes in front of it, because it means that's the current practices. FDA will cite you on something from the CFR but they actually can cite you, if you're not following what is expected by the agency. So, the current practices, there's a lot of courses and a lot of venues where you can learn from other companies, what is being done, what FDA is inspecting, because the CFRs don't have detail. So, you always have to be up on what's being expected by you at the current time,

Brian Lihou
I remember when I was first given that little book, when I first got started, I just interpreted it, well, I'm going to have to remember this whole thing. And then I realized early on that I was reading things that absolutely did not pertain to my job. And it was really having someone pointing my direction, well just pay attention to these two sections, and don't do what it says not to do. Well, that was lovely guidance. I mean that you can drive a truck through the holes and in that. So, it's important to note that these are good guidance documents. And like any regulatory guidance documents, they are guidance, they don't tell you specifically how to do it, because they rely on your education and training and systems in place to develop procedures that are governed in those. So those are things that I know from conversations I've had with various sponsors and their understanding of quality, especially small companies with defined budgets are having to impress upon them the need for quality, the need for quality oversight, it's really a challenge. You know, certainly Robbi has worked on a few projects in the past where we've been asked to put in phase appropriate quality systems. And that's a great term. Again, it's large enough you can drive a truck through the holes in it, but it really is something to know where it depends on the state of a program. How do you define any one? And we can back this around? How do you define phase appropriate?

Robbi Freisem
Well, to begin at the beginning, when you set up your QMS, you need to start with the procedures and processes that will reduce risk and help you prepare for your submission in the long run. And that would come through managing your documents and having change control. And having documented that the people doing the work are appropriately trained. Since a virtual company is likely to be working with contract manufacturing organization, you need to put a quality agreement in place to ensure that they're following GMP s, and that will support you in the long run in your submission process.

Meranda Parascandola
So Robbi, that's actually a good point. I think that some of our clients that come to us rely on the CMO to rely on their systems. So, as a sponsor themselves, as a biotech company themselves, they need some SRP is and quality systems in place as well, right?

Robbi Freisem
Yes, that's very true. There are warning letters that I know of back to 2008. About companies that use contract manufacturers and think that they don't need to have their own quality systems in place and get cited by the FDA for not taking on the quality responsibility involved with the manufacturing of the product,

Brian Lihou
Even so far as to say, even how the vendors themselves were selected, there's a procedure for that. So, you know, really,

Susan Fasso
The sponsor is ultimately responsible for the product, regardless of who's doing what to it, they also have to be responsible for releasing it. And it's written in black and white in several of their guidance documents, that you cannot, you can contract it out, however, you are still ultimately responsible.

Brian Lihou
And they forget, people interpret things appropriate as meaning "Well, I can do less". Because phase one, phase two, phase three, you know, it's still clinical. Early phase means I can do less. And I'm not quite sure that's accurate. I know, I've worked with several of you here, where we have worked with very small virtual companies and try to impress upon them that whether, you know, what is the intended use of the material you're making? I think that's the distinction that has to be raised.

Susan Fasso
I think the only, well, not to get into too much detail with phase one. But there is the phase one guidance document. And really, you still have to follow GMP s, they actually say it there, they just cut back maybe on some of the testing that you can use a CFA for the raw materials and excipients. Or you don't have dedicated equipment, so they're worried about cross contamination. But basically, you still have to have your quality system in place to have the documentation of what you're doing as far as batch records. So it really just cuts down on some of the detail. But you still have to apply the same principles in phase,

Bettina Kaplan
Right. And once you go to phase two, you're going into human beings. So you now have responsibilities to make sure that this product is manufactured according to GMP s, you need to be sure that you have the right procedures in place. The other thing I try to remind everybody is, even early on, the equipment you use, the instrumentation you use, you may not do full blown out in qualifications or validations. But you at least need to calibrate and do some interim method qualifications and validations to make sure that the value of the data you're gaining out of these experiments and trials are scientifically sound, if the data going in is like I always say, going in is garbage, you're gonna get garbage out, you have no idea if that data is beneficial. So that's where you have your appropriateness? Is it full blown? Or can you do an interim, the guidelines allow you at certain phases to have certain requirements for validation? It must be a full phase two, but by phase three, you need to start getting your full validation done.

> "Guidance documents are just an opinion. And they actually say that in the documents. So, you kinda try to do a combination of everything."

Susan Fasso
Yeah, I mean, you could do more of a verification and validation in phase one. But you better be ready by phase two, if you can

Brian Lihou
One of the things that's difficult to navigate for some of our clients and smaller companies out there, and Maria, you and I saw this on that same project I referred to where they'll pick up one guidance document and say, Well, I'm meeting those requirements, but there's many other guidance documents out there, right and how do you pick and choose which one to follow? Is it ICH? Is it CFR? Is it SUPAC? Is it ISO? How do we determine what you have to adhere to at what phase so if someone says, you know, I'm following CFRs, which again as we already stated earlier, is very, very broad. How do you educate them that well, you may be doing that, but you have to also do these things.

Susan Fasso
Well, first of all, Brian CFR 210 and 211 are really for commercial product, believe it or not, but we do use this but the regs, the guidance documents say to follow CFR for clinical material, number one. Number two, when you were talking about CFRs and guidance documents, CFR, as Robbie said is the law so we have to make sure we follow the CFR regulations. Guidance documents are just an opinion, and they actually say that in the documents, so you kind of try to do a combination of everything. ICH according is a product is for us is a for rest of the world because ICH is for, you know, the harmonization of Japan, EU and US. So, you know, every situation is different, actually. But we must have The CFR.

Robbi Freisem
The 210 and 211 actually define the parts of GMP that your CMO needs will be if they're actually a licensed establishment following and have in place and what a virtual company needs to do it well and GMP s need to be in place in phase one. I mean, that's why you use contract manufacturer, I mean, it is necessary for the safety of even the healthy people, right, that your new product is going into, just to test its safety. And the GMP s that the virtual company has in place, because they're contracting, is the reason why they can start simple. But as they get further along in their process, there needs to be more fleshing out of how they're going to accomplish, the commitments that they make in their quality management system.

Bettina Kaplan
I think I just want to add to that a little bit, that now that we're doing a harmonized set of guidance documents, so ICH documents, we are expected to follow those, as well as, again, the guidance documents and you have to look at like I said, the c for current, what is currently expected. Now the other thing that comes into this is where is the product going to be used? Where is where's the product going to be filed as being filed in the US or is being filed outside? Is it being filed in both the US and outside of the US, because there are other guidance documents and GMP s, from other countries that we also might have to take into account. When we're setting up a QMS system. If it goes to Europe, there are certain things that are stricter in Europe than they are in the US. And other things more lacks. So you might need to pick from both the most stringent because that's what your expectations are. So there's a lot to consider.

Brian Lihou
That brings me to my question. And Maria, I'll direct this to you. So from what I'm hearing is there's a lot of sources for information. So I could probably just look all this stuff up. And I'll be just fine. I can look all this stuff up. When it comes to quality, and I mean, look, it's really clear on this call, we have a lot of experience in quality assurance, how important is the experience? So, Maria, you know, it seems to me like everything is written for me, I just have to go look it up. But what's the value in having an experienced, quality person, this counterpart you're working with a sponsor or CMO?

Maria Arakil
I think the biggest thing with it is when you have somebody that's experienced and they've been through various things like, let's say, FDA audits, or have worked with a very small company versus a very large company, they can differentiate what you really need right now. You can look things up, there's a plethora of information, and there's a bunch of it that you may not need at your phase, your current phase. So you could potentially be overdoing it. Or maybe even under doing it, having somebody experienced there can guide you in the right direction, what you actually need at what phase and who's supposed to be doing it. Sometimes these companies don't have the right personnel to do it. And specifically, the CFR says you have to have the training experience to be able to do certain tasks. So, in other words, somebody that's let's say, a scientist shouldn't be acting as quality, because that's not what their experience is in, overtraining. So it is important to have somebody that actually knows what they're doing phase appropriate.

Brian Lihou
But I think that's a really important point to make. I think it was about, what, five or six years ago, I was on a project with a virtual company with Robbi. And we learned that the person responsible for distributing product is doing the final sign off on all GMP batch records. And didn't seem to have a problem with it, because they didn't really have to read it. They just signed it. And we realized what they were doing. And it was a real education process, trying to explain to them that this is a terrible idea. And they were actually signing things that perhaps they shouldn't or had no working knowledge of what they were signing, they just knew they needed a signature on that line before they could distribute the product. And I remember, I can spare you all the colorful descriptors, but I remember our response to that once we found out what was going on. And it was a real education because you had people that really didn't understand or appreciate what quality represented. And you remember that project Robbi?

Robbi Freisem
Oh yeah, seems to me that we were not early phase at that point.

Brian Lihou
We were not. No, we were actually moving to commercial. That's correct.

Bettina Kaplan
One thing that virtual companies, I think need to realize is that they can be inspected as well as the CMOS. And they can get observations from supplier management, appropriate personnel having the training and experience for work, a lot of things that we're talking about now. So it's not only your CMOS that get inspected by FDA but you actually can get inspected as a virtual company by FDA, or other agencies.

Susan Fasso
I can attest to that, Bettina. Because I was head of quality at one firm, and I had a fast track and accelerated approval product. And we had the clinical portion in, we had the CMC portion in, PII was already done, we were just waiting for clinical data. And they came and sat with me for two weeks at a virtual company, because of the fact that, you know, we wanted to get it approved. You know, they were, they recognize that, but they can come in. I mean, we were surprised. And like I said they stayed for two weeks.

Brian Lihou
There's another distinction there. And I remember this from the project I just mentioned working with Robbi, I learned a lot actually on that project. Because there were SOPs that simply didn't exist, document retention, product recall, these are all the responsibility of the sponsor. And then what's happened is over time, these small companies get a comfort established with their consultants, but the consultants are not the sponsor. And I think that was a real distinction. And we've had to do this throughout just the time I've worked with DSI, as we bring in quality support for these sponsors. It's that constant reminder that you're still responsive. Can someone tell me why a quality agreement is really even needed?

Susan Fasso
It delineates the responsibilities of who's doing what or how they're transferring the obligation to the CMO.

Bettina Kaplan
Yes, the FDA requires it.

Susan Fasso
Yeah.

Brian Lihou
Yeah. Yeah. The FDA, you need it. Okay. So next time it comes up in conversation, I'm going to say please make sure you have it. I just did.

Susan Fasso
It wasn't required before until I think it went into ICH. But basically, believe it or not. It wasn't required in US at first. It was more a European thing. And then when it went to ICH, that's when everybody started doing it.

Brian Lihou
That's a good idea. It's funny. And for those of you listening to the podcast, you'll see that particular question, eliciting quite a few responses. And for many, many reasons, it has to be done. I will say that Meranda, and I've been in conversations with potential clients. And we've talked about the need, where the first thing you do is establish that quality agreement. So we call that the responsibility matrix, which is in the back of the document clearly states out for people like me that needs it really clearly defined, who does what, and who's responsible for what, but doesn't mean you stop looking at it. But ultimately, you're responsible for this aspect of the quality system. So it's something that's important. It's something that it's surprising how often we have to explain that. But as someone had mentioned, it's, it's really just come on with the harmonization of EU expectations. It's not a bad document to have

Maria Arakil
Legally binding as well. So somebody doesn't do something, then you can go back.

> "The biggest thing is that when you have somebody who's experienced and they've been through various things like FDA audits or have worked with a very small company versus a very large company, they can differentiate what you really need right now."

Brian Lihou
That'll make you sit up in your chair. Yeah, you're right.

Robbi Freisem
Yeah. It runs kind of parallel to the clinical practice of delegation of responsibilities.

Susan Fasso
Yeah, the transfer of obligations document, right.

Brian Lihou
So, Meranda, maybe you can ask the question, but we talked about the QMS at the top of the call. And it's things like a quality agreement mentioned in the QMS. So that it's an overarching governing document of your quality system, or things like that that level of granularity detail mentioned in the QMS,

Bettina Kaplan
It depends on how detailed you have your quality manual, but in the QMS quality agreements fall under supplier management,

Susan Fasso
Yeah, Vendor qualification and oversight of the vendors.

Bettina Kaplan
And that's where it falls under. And it that's where you would see it being addressed. So yes, I would say that it, you can state that it is covered under QMS. And it should also be delineated in your quality manual. Especially because you're a virtual company, right?

Susan Fasso
And there should be an SOP for one also meaning at that level.

Brian Lihou
I think one thing to note for those folks that are listening to podcasts is that we haven't had a lot of differing opinions on the call today. So it seems to me there's a lot of continuity in what's being said and what's expected out there in industry. So I think this is really helpful to people that are learning more about what a quality system is, when it's needed, the fact that it is needed. And I really think that your differing opinions and level of experience all seem to point in the same direction, that QMS is absolutely important in establishing quality as a priority in a company.

Meranda Parascandola
So thank you all for joining us today on CMC live, I know it's very hard to get everybody on the same call. So does anybody have anything else they'd like to say about quality systems?

Bettina Kaplan
Just that they're the key to your organization and putting it in at the right time will help you in the long run, you will have a more successful PAI and that your product will hopefully have been produced with quality first and in the product versus having to slap on a bandaid later, which is something you want to stay away from.

Meranda Parascandola
Great. Thank you so much Bettina, Susan, Maria, and Robbi, we really appreciate you joining us today. And thank you, Brian, for leading this call.

Bettina Kaplan
Thank you, everyone.

Meranda Parascandola
Welcome.

Robbi Freisem
Thank you. Thanks, Meranda bye.

Ed Narke
So, to everyone in the call today here in the podcast, I appreciate it. I learned a lot. There's an old Chinese proverb: if you want to find out about the road ahead, then ask about it from those coming back. Very appropriate here. So, on next week's podcast, we will be talking a bit about the purpose of pharmaceutical microbiology. And maybe touch on some of the information in the manual that the FDA manages collectively clarifying and standardizing communicating information on how you're dealing with those type of things like that. We'll have Mike Carroll and Shelley on the podcast. And again to talk maybe another Chinese proverb the best time to plant a tree was 20 years ago. The second best time is today. That's kind of a lead into the end of our season here. CMC live 24 episodes, do encourage you all to go back. we have covered many of the topics in drug development, from API's to regulatory starting materials to ICH guidance. To drug product issues, just to some background, how we all got here and in our experiences and what drove us here in fact, so let us know what you

guys think of the topics we always, as always love your feedback, email, comments on anywhere where you receive the podcast, we'd love your comments. Sometimes they make us laugh and sometimes they give us ideas for more things. Sometimes we learn a few things as well. So we'd love to chat with you guys. We look forward to our next season. We'll be on a brief hiatus here. One exciting thing I wanted to announce here is in between we will have a sort of pseudo podcast blog called 10 minutes in the gold mine, where yours truly, Ed Narke will be going through some of his previous blogs and reading them and kind of just giving a little bit more insight on literally five minutes of your time. You can listen to this gym, driving in the car, anywhere you get your podcasts Of course. So once again, thanks look forward to engaging 2021 a new year, more successful year than last year and, of course, success for everyone. Thanks everyone. Talk to you soon.

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.