Eric Sandy:

Hello, everyone. This is Eric Sandy. I'm the digital editor at Cannabis Business Times. We're going to let everyone open up the Zoom room here and get settled, and I'll be chiming in again in about 15-20 seconds and we will get this event underway. Thank you.

Eric Sandy:

(silence)

Eric Sandy:

All right. We're seeing a lot of people coming to the webinar here, and we're going to get things started here. I'd like to formally welcome everyone to today's webinar, three simple steps toward good manufacturing practices certification. Once again, my name is Eric Sandy and I'm the digital editor of Cannabis Business Times.

Eric Sandy:

Today you're going to be learning about GMP, and that's good manufacturing practices by the way, and the benefits of implementing this approach to your business. We've got a great presentation in store for you. As with all of our products on the market such as medicinal products, cosmetics, and supplements, cannabis products must be safe and effective. And they must meet quality requirements in order to ensure its safety, identity, potency, and purity characteristics.

Eric Sandy:

However, in this market and with limited published standards for cannabis, what's the best approach for getting started? Here in this webinar we're going to be getting into the detailed written procedures that are essential for the cannabis industry.

Eric Sandy:

Real quick before we really get going, a few housekeeping items. You're going to see at the bottom of your screen a Q&A box. Please feel free to open that up as the presentation goes on and type your questions in. We will be getting around to a Q&A session at the end of this presentation, and we'll try to get to as many questions as possible.

Eric Sandy:

Also just know that we are recording this session and we're going to be sending an archived video that will include the slides, of course, to all registrants. That'll be coming out via email shortly after today's presentation. And now with that, I'm very pleased to welcome Neil Coole, the director of the Food & Retail Sector at BSI.

Neil Coole:

Thanks, Eric. Appreciate the introduction. Welcome, everyone. Yes, my name is Neil Coole, regional director for BSI, America's Food & Retail Sector. For those who may not be familiar with BSI, BSI is the world's first national standards body. We were founded in 1901 and we're incorporated on the Royal Charter, which means that we're completely independent from outside influence. We have no shareholders to answer to and our purpose is to ensure that products and services are safe for their intended purpose.

Neil Coole:

For those of you that may be familiar with the International Organization for Standardization, also known as ISO, BSI is proud to be a founding member of ISO. And you may be familiar with such of the business risk management standards like ISO 9001. Again, another one of the standards adopted around the world across all industries that originates from BSI.

Neil Coole:

We're pleased to have such a large audience join us today for this highly important topic of good manufacturing practices, or GMPs, which is a system for ensuring that products are consistently produced and controlled according to quality standards.

Neil Coole:

GMP has been designed to minimized the risks involved in any production that cannot be eliminated through the testing of the final product. As with all products on the market such as medicinal products, cosmetics, and supplements, cannabis products must be safe, effective, and meet quality requirements in order to assure its safety, identity, potency, and meet all quality and purity characteristics.

Neil Coole:

However, in a global market with limited published GMP standards for cannabis, what is the best approach in getting started? I'd now like to take an opportunity to introduce you to today's speakers. First we have David Vaillancourt. David is the founder and CEO of the GMP Collective. David holds a master's of science and brings over 10 years of experience in education, project management, government contracting, and quality control work in the cannabis industry.

Neil Coole:

David has served as an expert witness for hemp lawsuits, developed international consensus standards, and built out several quality units for multi-state and multinational cannabis operations. Committed to advancing the industry through sound science and education, David serves as an officer for the ASTM International D37 Standards Committee on Cannabis, where he was recently awarded for his contributions in developing the first laboratory standard for cannabis test method validation.

Neil Coole:

He also serves on the National Cannabis Industry Association's facility design committee. And when not enjoying the three Ls of life, leadership, learning, and listening. That's four, David. You can also find him in the mountains with his dog Humphry. Thank you very much, David, and we're glad to have you with us today.

Neil Coole:

And with David we have Andrew Cole. Andrew is our customized compliance manager at BSI Group with over 27 years of experience in quality, regulatory, and solutions based compliance strategies. Andrew has extensive experience in GMP, manufacturing, and regulatory requirements.

Neil Coole:

As a skilled QMS auditor, Andrew also leverages his ability to work with organizations in trending, forecasting, and eventual predictive analytics. While working for multiple international companies,

Andrew has successfully completed major projects to remediate and eliminate deficiencies and gaps. And management system based evidence and gleaned from internal audits and externally assessed findings. For example, 483s, warning letters, et cetera.

Neil Coole:

Andrew has been involved in the cannabis industry since legalization in Canada, and has been integral in the development... Sorry, developing and implementing GMP compliance schemes for the industry. Please welcome our speakers David Vaillancourt and Andrew Cole.

Neil Coole:

Today we'll be talking about the challenges that the cannabis industry faces, what GMP is, and the benefits of implementing it. We will go through a three simple phased approach to your GMP certification. We will also discuss the importance of a mark of trust, which we'll cover later on.

Neil Coole:

Our webinar will run for approximately 45 minutes with time for Q&A at the end. However, as Eric's already stated, questions are always welcome from you throughout the course of the webinar, so please feel free to use the chat function whenever you feel that you need to raise a question. We will do our best to answer the questions throughout the course of the webinar, and any that we can't we will circle back to afterwards.

Neil Coole:

All participants today will receive a link to the webinar recording. A short survey will pop up as soon as the webinar is finished. If you're able to complete this post-event survey, on top of the recording you will also receive the slides from the presentation and a copy of the HACCP and GMP certification criteria for the cannabis industry.

Neil Coole:

With that we're going to kick things off with our first poll of the day. The question is where would you say your organization is in relation to GMP compliance? If you're looking to start the process, you've already begun it, part way down the route, or it's something that's completely new. No right or wrong answers here. We simply want to understand where is your organization today, and where would you see your organization moving forward.

Neil Coole:

We're going to close the poll out in five, four, three, two, one. That's good to see. We've got nearly half of the attendees today that have not started but know that they need to begin. David, Andrew, based on the question set what are your thoughts?

Andrew Cole:

It's going to be a great conversation. Hopefully we can clear up some confusion, point a lot of people in the right direction, and provide a foundation to begin.

David Vaillancourt:

Exactly. There's multiple components to it, but following give Andrew credit for this with the phased approached. Starting somewhere, putting a line in the sand. Hopefully we'll be able to articulate that so you know where to begin and how to get there.

Neil Coole:

Brilliant. Thank you. Appreciate that, guys. And obviously one of the things we really want to understand when we're talking about the important topic of GMP, is also how you would describe your organization today in the cannabis industry. If you can complete the next poll to give us a better indication of how you would describe your activities within the cannabis industry, please.

Neil Coole:

I hope that's given you all enough time to... You can use multiple choice as it says on the screen. If you are an organization involved in producing edibles and personal care items, or medicinals, nutritional supplements, whatever it may be. No wrong answers, again. Please make sure that you give us as much information as you can about how you would describe your organization's activities. If we can close the poll in five, four, three, two, one.

Neil Coole:

Wonderful. That's great information. Thank you all very much for participating in that. Again, Andrew, David, how would you see the blend in descriptions from the audience today?

Andrew Cole:

A great cross section.

David Vaillancourt:

Yeah. No, agreed. Looking forward to diving into it, because there's commonalities throughout the whole thing. And as I think somebody mentioned in the chat, a lot of folks are going to transcend multiple components of this, and having GMPs help with cross contamination and other considerations based on the intended use of the product. Potentially being multi faceted for one business.

Neil Coole:

Excellent point. Thank you, David. With that we'll move forward into the next phase of the presentation, so covering challenges in the cannabis industry. And with that I'll hand over to David. Thank you.

David Vaillancourt:

Awesome. Thanks, Neil. Yeah. If you want to go to the next slide there, we kind of distilled it down to there's lots of challenges that keep business owners, that keep cannabis businesses up at night. Some of the main ones that are especially prevalent and painful for the industry. I'm going to touch on a few of those and Andrew Cole will jump in and complement as well.

David Vaillancourt:

Federal versus state regulations. We all know that in the United States at least, it is federally illegal. Every state has crafted its own regulations. In the state of California even more specifically, there is a paper that I was just recently reviewing where they talked about back to the county and city level.

David Vaillancourt:

There can be 115 different regulations. So if you're working between different county or city jurisdictions, it's a complicated process and none of them are harmonized and standardized. There's lots of issues there.

David Vaillancourt:

Looking at the potency, testing, dosage, and symbology. The lack of clear standards around the testing world. Again, we can't test interstate, so if you're in Colorado and you're dealing with a THC based product, you have to test it in the state of Colorado. Being able to level set between different testing agencies to know that 17% is actually 17%, is actually 17%, is a challenge when we're not able to do interstate shipping.

David Vaillancourt:

The symbology. I've seen that a lot. You mentioned ASTM International. One of the groups that I'm working with, we've got [inaudible 00:11:24] for a universal symbol. Because the idea of a universal symbol is that it should be truly universal, and right now there's almost a couple of dozen different formations of symbols from different state markets.

David Vaillancourt:

Which confuses the consumer, and from a packaging, and if you're a multi-state operation having labels that have to be different to each state. And then dealing with a multitude of changes as emergency regulations are updated. There's a lot here to unpack, and it all ties back into red flags and what do standards even mean. What are the standards in compliance versus certification, which I'll kind of hand it over to Andrew there to fill in those gaps.

Andrew Cole:

Yeah. Hey, brilliant segue on that one because compliant versus certified, I think we all hear that one. I know I hear it quite a bit from cannabis companies or customers. I've heard it for years having been in the industry for so long.

Andrew Cole:

What's the difference? Right off the bat, whenever I see compliance to or operation under GMP or ISO, immediately in my mind I kind of thing that's a play on words, or possibly even a little bit dubious. Because compliance is your management or quality system that fully adheres to the requires of X, whatever it is you're compliant to, because you say so.

Andrew Cole:

It's a self claim, where certification means essentially it's kind of the same thing. It does mean that you comply, with the exception of you proved it to an accredited third party certification body or auditor, so it really carries additional value. Again, when I see or I hear, "We're compliant to," immediately I think, "Well, says who?"

Neil Coole:

To that point, are you saying that is to provide the independent validation and verification from a trusted third party, who can actually say to the companies in a position to say, "This is who we are and

what we do. Here's evidence to support it against their recognized third party standard." Is that really the value that you see under the certified angle as it were?

Andrew Cole:

Yeah. It comes down to two words, prove it. And we were able to proven rather than because I said so. You've met the prerequisites, you've met the requirements, you've put the controls in place, and you've had somebody come in from a third party. Non biased, non objective viewpoint, take a look at it and they probably asked or they probably said a lot, "Show me."

Andrew Cole:

And you showed them, so in my opinion it carries a significant amount of weight. And I don't mean to digress, but I pulled into a 7-11 one time and I saw a huge sign outdoors that said CBD sold here, GMP compliant. And I thought, "By who? Against what?" What exactly does that mean? Again, I kind of think it's a bit of a play on words.

David Vaillancourt:

And Andrew, if I could jump in quickly to tie that all together, too. When there's a case, whether it's a lawsuit or whether you have some sort of issues with a consumer, or product complaint, or a recall, or a business to business relationship is a major supplier to distributor or dispensary.

David Vaillancourt:

If you have an independent recognition, certification let's call it, that's going to hold a lot more weight. And when we go into, I served as an expert witness. Having that carries a lot more weight that, "Well, my quality person said we're compliant. My team, we're good people."

David Vaillancourt:

We're all good people but we're humans and we're infallible. We make mistakes and having that outside group come in to be able to show that gives you a level of distinction, and shows trust in the marketplace and ultimately reduces your risk.

Andrew Cole:

Yeah. Hey, do you mind if I talk a little about confusion around standards or that trust gap? Because it-

David Vaillancourt:

I think that's important. Yeah.

Andrew Cole:

... segues perfectly, especially when you talk about trust gap. When you see these signs that say GMP compliant or whatever, what does that mean? I think there is a bit of a trust gap. And while this whole topic of confusion of standards and guidelines, I was thinking to myself, "This can be an entire standalone webinar."

Andrew Cole:

But I also thought, "I think we've done that webinar. I think it was called lifting the fog of confusion," which is probably still available as a recording, and I thought it was pretty informative. But when there is no harmonization or standardized approach to cannabis compliance, everybody is asking, "Which direction do I go? What do I do? What do I apply? I don't have the 30 years of experience."

Andrew Cole:

At the moment, I tend to ask two questions, or ask yourself two questions. And it's most likely going to lead you to the right conclusion. First question is what does your state license requirements call for? Number one, no license, no go to market. Have a very, very thorough understanding of what the requirements are.

Andrew Cole:

And number two, what are your product claims? Or what are your intended use of the product? Are you claiming that your product treats or lessens a symptom or effects? It's probably going to fall under a pharmaceutical. If you claimed it's a food or a vape, it's probably going to fall under a food based standard, CFR 117 or ISO 22000. Tinctures, capsules, could be a dietary supplement and follow CFR 111.

Andrew Cole:

Those two questions, what do your state requirements call for and what are your product claims? What do you intend the use to be? Those are probably two critical aspects.

Neil Coole:

Excellent point, Andrew. Not that I'm trying to pile any pressure on you, but that's really what we're hoping both of you will cover on today's webinar, and to help the audience understand the value behind embedding an effective GMP system. Really help them to tackle all of these points that you can see in front of you. That's been really, really helpful, guys.

Neil Coole:

Moving on, just circling back to you, David. If you could just give us your impression of where the industry is today, as Andrew's already described a variety of different scenarios from a product and intended use perspective. Where do you see the advantages for organizations who may be in one of those boxes, or have products in multiple boxes? How would a GMP system or approach in GMP support them moving forward?

David Vaillancourt:

Indeed, yeah. We've kind of put up here four different boxes. And when you look at your products that you're selling, whether you're a consumer or producer making these products. Does it have medicinal properties? Is it intended use for medicinal? Is it a food or beverage? Or another way to say that, is it orally ingested? Are you consuming it?

David Vaillancourt:

Cosmetics, is it being topically applied or a pharmaceutical? There's a distinction as we've seen now becoming especially clear, thanks to the herbal product movement and the cannabis industry I would give a lot of credit to. Between medicinal but natural products and pharmaceutical grade, which truly means clinical trials, data, objectives, stricter criteria.

David Vaillancourt:

And based one which one of those come you're working, and it may be a combination of all of them, there are different risks involved. There's a different risk involved if you inhale or ingest something, or if you apply it topically from a cosmetic standpoint.

David Vaillancourt:

Not to say that one risk doesn't transfer over, but you need to assess that into your entire operation, and apply the GMPs that are the most applicable. And where you have multiple product lines, from a risk perspective you need to apply the most stringent GMPs or standards, so that you can ensure that things don't slip through the cracks and cross contaminate into those product lines where the risk and the stakes are higher.

David Vaillancourt:

Whether you're dealing with immuno compromised patients or clientele or otherwise, you need to take those considerations into play. And so this is I think one way to really bring it down to think about the four main buckets that you may apply to.

Neil Coole:

Brilliant. Thank, David. Andrew?

Andrew Cole:

Yeah. I agree with David. These four boxes. Now, granted two of the boxes, medicinal and pharmaceutical, I can kind of argue that maybe that's the same or similar. But this is what's going to guide you to what GMP is appropriate. And this kind of gets a little bit confusing at first, because some people call me and say, "Hey, Andrew. I need GMP certification."

Andrew Cole:

What exactly does that mean? Because in the ISO world for instance, ISO 9000 is just general. It plays to virtually anything and everything. What if you were talking about TS? Well, it plays specifically, it's ISO for automotive. AS 9100, it's ISO for aerospace. ISO 220000, it's ISO for food.

Andrew Cole:

The core elements are still the same just like in GMP, but it becomes kind of product specific. This is what's really going to guide you, and one thing we did talk about is cosmetics or personal care items. If you're manufacturing or cultivating, extracting an ingredient that is going to become a cosmetic or personal care item, your path is probably going to be CFR 700 for cosmetic personal care items. Or ISO 22716 or EFFCI cosmetic ingredients.

Andrew Cole:

Again, the moral of the story is this is what you determine, where you fall in these boxes, what your label claims are is going to guide you to the appropriate GMP.

Neil Coole:

Brilliant. Thank you. Sorry, David. Did you [inaudible 00:21:25]?

David Vaillancourt:

Just quickly round out about adding too much alphabet soup for folks. But remember one, this is how you can apply these use cases to the world. And how food is distributed and sold for safe consumption within our global society we live in with seven billion people on the planet. Pharmaceuticals, cosmetics, agricultural, et cetera.

David Vaillancourt:

We're applying these same concepts. We're not reinventing the wheel here, to allow our industry as the cannabis industry to be able to work in this framework, and be able to have safe, repeatable products. There's obviously the nuances that we'll touch on a bit. But it's a lot to cover, so let's keep moving.

Neil Coole:

Excellent point. Thank you, David. But before moving onto the next phase of the webinar, we just want to find out a bit more about your objectives as the audience today. If you could just take a moment to complete the next poll. Do your GMP objectives include, and it's a multiple choice answer.

David Vaillancourt:

While the poll folks are filling, maybe I'll address quickly, a question came up. Where do flower cultivators or producers fall? Again, if you're just selling raw flow that's maybe an herbal product for inhalation, are you in the medical? Are you in the rec market, adult use market? That will kind of lead you to that answer. And then are you selling it to other folks that are doing followup formulations, extraction, et cetera, and what are they using it for?

David Vaillancourt:

A lot of it will depend on a relationship with your supplier or your contract relationships you have, to determine where and what risks you need to apply for and consider in your facility. [crosstalk 00:23:04].

Andrew Cole:

Yeah. And where do you need to or want to apply the controls as well? Cultivation. If you're just growing [inaudible 00:23:15], maybe it's a different version of GAP called GACP, good agricultural collection practices. There's a variety of them out there, and maybe the conclusion you have to pull the salient aspects out of a variety of things that already exist. But I'll talk about that in the next slide or two.

Neil Coole:

Thanks, Andrew. I think we'll close the poll out now in five, four, three, two, one. And let's see what we've got as our results. Wonderful. Okay. There's I think all of the above [inaudible 00:23:47] there, but it's just great to see that kind of response from the participants on today's webinar.

Neil Coole:

And to circle back to a point Andrew's already made, what is the intended use and who's going to be using it will help work with industry professionals like David, to ensure you're doing the right thing at the start. Thank you all very much for that. I think now what we're going to do is move ahead with the next phase of the webinar, where we'll talk more about GMP. With that I'll hand back to you, David and Andrew. Thank you.

Andrew Cole:

Yeah. We've already kind of touched upon this. What do you do? Which GMP when there's nothing that specifically exists from seed to sale? And GMP in the absence of a standardized approach, GMP applies to standardized products. That's kind of what you're trying to do. That's the intent is standardize an approach, document an approach.

Andrew Cole:

I always resort back to which GMP currently exists? Again, what are your license requirements, that's first and foremost. No license, no go to market. But then beyond that it's again, what do you claim that your product does? Because you need to select the appropriate GMP that's specific to what you're doing. That whole dietary supplement, pharmaceutical, personal care, whatever the case may be.

Andrew Cole:

And then where do you want to apply the controls? That's something that I think everybody should be asking, and where do you want to apply the controls should be a result of... And I always go back to this. What does your risk assessment say? When I'm auditing, realistically what I want to know is have you given this thought? In each area of your business, have you given this thought? What was your conclusion and what are the controls?

Andrew Cole:

That's kind of the basis around everything. Again, standards. What do you do? If you're cultivating, maybe it's GOCP that we talked about. If you have a laboratory within your facility, maybe you can pull out the salient aspects of GOP, good laboratory practices.

Andrew Cole:

Warehousing and distribution to control the movement of product so it does not become adulterated. Maybe it's GDP, good distribution practices. Maybe we can pull out if you're... Broad spectrum. Well, then maybe you can pull out the salient aspects of a lot of different things and create your own GMP that maybe we'll call GXP.

Neil Coole:

David, what are your thoughts?

David Vaillancourt:

Yeah. No, exactly. I think looking at it, and somebody will kind of try to interweave this with a question that we saw, but can ISO 9001 apply to an industry that has medical, cosmetics, food and beverage products? And the way I answer this is yes. It's not very simple, but it provides a really basic framework and there's two things within that, that I'd like to touch one.

David Vaillancourt:

One is management commitment. Without management buy in and understanding and providing the resources, tools, and kind of culture for that, doesn't matter who wants to do what. You need that support, you need the resources. And that's a fundamental component of ISO 9001.

David Vaillancourt:

Two is a risk assessment and understanding where your products come into play. And if you do a really good risk assessment, actually think through this, I make the argument with clients all the time and I walk them through this. "Well, you're producing something that goes into tinctures. You're producing gummies. Well, what's your risk?" "Oh, there's allergen control because we're dealing with foods." There's et cetera, et cetera.

David Vaillancourt:

"Okay. What's the preventative control?" "A GMP program like ISO 22000 or some sort of GFSI scheme." Starting with ISO 9001 and following that process and framework can allow you to become aware of and choose to implement certain GMPs based on the products.

David Vaillancourt:

And again, it's a best practice. You don't have to reinvent the wheel, we can follow from 100 years of everything from the Federal Food, Drug, and Cosmetic Act of 1938 that kind of set this framework up from a regulatory standpoint. And then folks like the GFSI scheme and the ISO 9000 series that was created in the '80s and 2000s respectively. I think I've got the order there backwards, but just follow that framework. Ask the questions and I think that's where we'll get into kind of what our phased approach that we're talking about here today.

Andrew Cole:

And to kind of add onto that. Sorry, Neil. To where David said in the question about can ISO 9000 apply to a variety of different industries? [inaudible 00:28:33] cosmetics, food, beverage, whatever the case is.

Andrew Cole:

ISO 9000 is the foundation. It's the foundation. Once you have the core it's just like building your home. It's the foundation for doing everything in the future. You build off of that. It was kind of interesting, I almost hate to say this. Back in the late '80s, early '90s when I was trying to explain to people what ISO 9000 was.

Andrew Cole:

What I would say is... And remember, this is time sensitive so I'm time stamping this. ISO 9000 is a daily planner. We used to use daily planners. You plan your day and you work your plan. You write down what you need to do, how you need to do it, when you need to do it, so at the end of the day you can roll something forward. So at the end of that day, you can then determine, "Hey, where do I need to tweak my day so that I can get it all in?" Or again, you keep rolling it forward.

Andrew Cole:

The moral of the story is documentation provides traceability, and traceability allows you to pinpoint exactly where you need to tweak in order to become more efficient and effective. Without documentation and traceability, it's guess work. You're literally taking a stab at the dark. You think you know but do you know? And whatever tweaks and changes you make could be causing more harm than good.

Andrew Cole:

That's really kind of the foundation of documentation and traceability. I see one more question on here about is EU GMP a separate entity? We'll have to go into an entire new webinar for that.

Neil Coole:

I was going to say. I just want to go back to your point that you just made, Andrew, because I think this fits perfectly with what we're trying to talk about as the core elements of GMP. Can you come back to that point around say what you do, do what you say, look for improvement? Just touching on the points that you see in front of you here with regards to some of the prerequisites that are embedded into an effective GMP.

Andrew Cole:

Yeah. Probably another good segue. And I know that David's involved in trying to create a standardized [inaudible 00:30:30] ASPM. I'm involved with the International Working Group 37 for ISO to try to create something specific for cannabis. The industry is definitely moving there and we're going to go there.

Andrew Cole:

That being said, regardless of at the end of the day you're manufacturer a food, cosmetic, blah, blah, blah. There are core elements of GMP. Maybe you can kind of say that those core elements are similar for, say ISO 9000 which applies to virtually anything and everything.

Andrew Cole:

There are core elements. Personal hygiene, cleaning, approved supplier [inaudible 00:31:05], specifications and labeling. We talked about this earlier offline. Allergens probably going to apply more or less to foods. But regardless, non performing product recall, terms of services, [inaudible 00:31:18] pest control, calibration, and training.

Andrew Cole:

Those are the core elements of GMP whether you're saying it's CFR 111 for dietary supplements. That's GMP for dietary supplements. 117 for food, 700 for cosmetics, and it goes on, and on, and on. These core elements exist throughout any GMP system.

Andrew Cole:

If I were going to start somewhere, this is exactly where I would start, in pulling out these things and creating a foundation. Because with a foundation I can then make lateral moves and start building onto my existing system, tweaking my existing system to add additional controls.

Neil Coole:

Understood. And David, in your opinion would you say that having a GMP does support an organization in ensuring that their products and services are safe for their intended use?

David Vaillancourt:

Most definitely. And to Andrew's point, you look at all these elements, there's quite a bit here. But don't overthink it and that's where higher folks with this experience call us. Between us and BSI we've got training and educational opportunities to provide you with the capacity and the framework to implement these, and it's a phased approach.

David Vaillancourt:

You're not going to have a whole robust corporate training program tomorrow. But are you asking the questions of do your employees know what they're doing? Have they done this before, and what kind of guidance are you giving them so that they know how to produce these products safely and consistently?

David Vaillancourt:

Do they know what pest control means? Have you set up a pest control program? What pests are you looking for? Have you just asked the questions? Have you done maintenance so that your equipment continues to work as intended, so that you don't get the call at 3:00 in the morning on a Friday morning when you've got a huge order to go out? And hear that your line or your extractor blew up because we didn't check the gaskets, we didn't check the seals and, "Oh, crap."

David Vaillancourt:

Those are major bummers that from business continuity or product safety standpoint, and just again business continuity and business 101, will sink your ship. And these programs provide the framework. They're not bulletproof but they reduce your risk and they ensure safety, consistency, and quality of products.

Neil Coole:

David, would it be fair to say in your opinion and BSI's obviously there to support clients in the certification side, but would the GMP Collective be able to work with organizations in the cannabis industry? Not just on the what which you can see in front of you, as Andrew's already touched on. The what is very important, but also the why.

David Vaillancourt:

Yes. I always like to start out with the why. I know that's what we're trying to work towards here today, is this is not just something that is a cost. It's more than a label and I like to see that a lot of folks that entered one of the earlier poll questions did it. To reduce variation in their business, and that reduces their risk, that reduces uncertainty. That increases your understanding and predictability of your process as a business.

David Vaillancourt:

How do you predict month to month if you don't know what's coming at you and you're flying blind? We start with the why and then we apply it to your business and show you the how, so that then you can get credit where credit is due, if that makes sense.

Neil Coole:

Brilliant. It makes perfect sense. Thank you, David. I'll hand back to you now, Andrew, if you don't mind to go through the overview for the three steps towards GMP.

Andrew Cole:

Yeah. Thanks, Neil. Before we do that there was a couple of questions. Maybe David and I can talk to a couple of these. One of them was CBD, can this be a nutraceutical? Where do nutraceuticals fall? It's not quite a pharma, it's not quite a food. It's doing something. It's supposed to do something. It's intended to have an effect.

Andrew Cole:

I would say a nutraceutical is probably going to fall somewhere in between that dietary supplement require of 21 CFR Part 111, and maybe 21 CFR 210, 211 which is pharmaceutical. But a caveat or differentiation is light. It's pharma light. You're not going through virtually every single two step validation process that involves everything in pharma. Not to that extent, but it probably falls somewhere in between. It's a good question.

Andrew Cole:

And then second, how does ISO relate to 21 CFR rule and kind of what's the difference? The easiest way to explain that for me, what I tell people is ISO says you shall. It's in there a lot, "You shall do this, you shall do that." And CFR says, "You should." It's a guideline.

Andrew Cole:

ISO is a standard, CFR is a guideline. Now, I don't know if the FDA really differentiates between should and shall. I'm pretty sure they interpret most you should as you shall. But nonetheless, that's the primary difference is one is a guideline that says you should, and the other is a standard that says you shall. David, do you want to add anything?

David Vaillancourt:

No, I think you kind of hit that on the head. I guess I will add just briefly, this is not a perfect system. There's no perfect system. This is a good system, this is a framework, this provides risk reduction. And when it says you shall do it, it's for a reason.

David Vaillancourt:

And when it says should in the eyes of the FDA, you got to have a compelling reason to explain why you don't feel like you should do it. That's how the rules get set up and these words having meaning, so they're there as a framework. But at the end of the day, having your systems in place, implementing these, understanding the why, showing how it applies to your business allows you to defend yourself and show good intentions to an auditor, to an inspector, or whoever it is.

Andrew Cole:

Yeah. Also I kind of wanted to go back because that one question about EU GMP. EU GMP is the European Union version of 21 CFR 210, 210 for the production of pharmaceutical goods. Medicinals. It really is an entirely separate conversation. I get the question all the time, "Hey, we want to do this. Can we go down this route?"

Andrew Cole:

And I'm not saying I'm trying to dissuade anybody. It is an arduous path. Looks easy, sounds easy, it's not that easy. That's exactly where EU GMP fits in. Both David and I can talk anybody through this, it's just probably a totally separate conversation.

Neil Coole:

Andrew, one of the things that we'll do post webinar is invite everyone on today's webinar to reach out and have that one to one kind of conversation with either Andrew and/or David. If you do have those kind of discussions you want to take up, please make use of that option in your post webinar survey.

Neil Coole:

Circling back to the phased approach now, Andrew. Would you mind giving us the overview from your and David's viewpoint of where an organization... Because there's quite a few from the survey, so I'm going to be starting this for the first time. Would you mind giving us your expertise and opinion on where things would start and how they would go about this?

Andrew Cole:

Yeah. There's definitely things that I tell people, pitfalls to avoid. And I think that's probably, knowing what you shouldn't do sometimes is more important than knowing what you should do. And what you shouldn't do is over complicate this, and what you shouldn't do is your company is working for the requirements rather than the requirements working for you.

Andrew Cole:

Then you become kind of a slave to a bad policy or bad process. It's something you're not doing, you wouldn't do, you shouldn't do, but the requirements said you have to have something in place. Then you can argue, "Well, I've lost my autonomy. I can't be flexible."

Andrew Cole:

But at the end of the day, keep in mind that it's you who's writing this and there is no one way to do anything. The first one to three months I advise be basic, be general in your documentation. Because if you live by the theory of documentation provides traceability, traceability allows you to pinpoint where to make the tweaks and the changes.

Andrew Cole:

Being general to begin with is drawing your line in the sand saying, "From this point on, we will be operating under these conditions. We will be manufacturing under these conditions." Keep it simple. Everything else will allow you to pinpoint and adjust and fine tune.

Andrew Cole:

I remind people that unlike, say a restaurant, you walk into a restaurant and you look to your left or right or behind you, and there's an inspection score sitting on the door. Well, at least in the certification body industry we don't do that. There is no score. Matter of fact, it's not even pass or fail.

Andrew Cole:

At the end of your certification on it, which I really think is kind of a leap of faith. What you get is if you don't receive your certificate or recommendation for your certification at the conclusion of this process, you just end up with a laundry list of more or less items that you need to fix, tweak, or correct.

Andrew Cole:

And then once you submit your corrective actions that you've addressed these items, the auditor then reviews these things. Then they look at it and say, "Hey, good to go." And we can pick up the actual implementation on a future surveillance visit or something. Keep it simple, don't over complicate, stop reading into it. What you don't want is policies and procedures on how to run a copy machine.

Neil Coole:

Understood. David, in your opinion all the work that you're doing with organizations across the cannabis industry, what does the first one to three months look like when they engage you and your organization?

David Vaillancourt:

Yeah. Step one kind of to where I think Andrew was going towards and you'd say, "Start with a gap assessment. Start with understanding, collecting data." Where are you today relative to where you want to be tomorrow? Get that baseline. That data will inform you, to Andrew's point when the gap assessment, when the GMP, when the certification body comes in.

David Vaillancourt:

What are your [inaudible 00:41:47]? Where are the things that you are weak and nonconforming in, and what's the risk? Is it a minor, is it a major, is it simply an observation? Prioritize this and start implementing them one on one. They don't have to be perfect but you've got to have the intent there and you've got to be able to show that you're doing what you're saying. You have to have records of it.

David Vaillancourt:

Start there. If your records are absent then there's not much to audit and assess. You can't work on hearsay. A lot of these need to be written, so start there. Assess where you're at, we can support you with that, and then from there you make an action plan, an implementation plan, a phased approach. And that's where I think Andrew will get into kind of phase two.

David Vaillancourt:

Start putting in these programs and then continually check. The one other thing I'll quickly add is, to kind of bring it back to something most folks can relate to. You buy a used car, you buy a house, you get an inspection. Almost no inspection report comes back perfect. Even new house builds have issues.

David Vaillancourt:

What are the risks? What are the weaknesses? Do you need to hire a plumber to look a bit further because there's low water pressure, or do you take the risk like I did with one of our houses when I moved into Minneapolis a few years ago and, "Oh, crap. There's low water pressure." That was a $6,000 bill to change the 1912 water main pipe from the main city that got grandfathered to us.

David Vaillancourt:

Those are the things you want to avoid if you can, so do your due diligence. Figure out where your weaknesses and blind spots are and then take a risk based approach to start implementing them.

Andrew Cole:

I also want to add quickly. I understand, we all understand that when you're first looking into this, GMPs and trying to do your research and figure out what it is and isn't, it looks daunting. I get it. Totally get it. And human nature says the easiest thing to do is to do nothing, but also how do you eat an elephant? Small bites at a time.

Andrew Cole:

If you just kind of take these core elements that we already went through and start addressing these, or even thinking about them. Rough outlining each one of these little requirements and those common GMP requirements, and how they apply to your business and what you're doing. That's small bites at a time, and what you end up with is it continues to build out. And that's the intent of step two or phase to.

Neil Coole:

And I just want to reiterate a point you've already made and you always make on the calls that I join you and Andrew, is that the system is there to serve the client, not the other way around. Very, very important point I want the audience to make sure that we understand. For step two, Andrew, what does that typically look like for the clients that you're supporting?

Andrew Cole:

Step two is kind of where you take your foundation and you start building on that foundation. What does that mean? It means increasing the controls or maybe applying a different set of controls. Maybe the first controls that you implemented, they didn't work so well. Maybe they had unintended consequences. Maybe there was residual problems.

Andrew Cole:

It's taking a look at this, leveraging all the documentation and the traceability, and just fine tuning your system. You should also at this point in time if you haven't done it initially, really start that process of risk based thinking.

Andrew Cole:

Again, depending upon who's talking and what subject matter, it can get very complex or it can be very simple, or simplified. And risk based thinking is asking yourself, retrace your business, what could possibly go wrong? What's the likelihood? What's the likelihood of this going wrong and what's the impact of it going wrong?

Andrew Cole:

Now, I used to say before the pandemic you probably don't want to consider a meteor hitting the earth. But like I said, the pandemic kind of threw everything out of sorts. Again, but you start thinking to yourself likelihood of occurrence. You start figuring out the root cause of problems that exist. Those are all results of risk based thinking. David.

David Vaillancourt:

Yeah. No, exactly. And to kind of hit on a question that came in through the chat about training programs, and BSI I think I actually send most of my team through a BSI program, if they haven't gone through some sort of ISO or GMP training before, or HACCP if you're in food.

David Vaillancourt:

There's lots of options out there. Take a look at them. Get training, and that's one of the biggest components during step two as well, is making sure that you have the right team with the appropriate tools and knowledge. Because to the points we've been talking about here, this is not our program. This is not GMP Collective, this is not BSI's program to own at the end of the day.

David Vaillancourt:

This is your program, it's for your business, so make sure that the program is being implemented. And that after if it's a consulting firm like guys that comes in and helps you, that it works after you leave. I like to say work yourself out of a job will really empower the company to be able to own this.

David Vaillancourt:

This is your program, so getting the training, going through these risk assessments. It really is as simple as just dumb it down, right Andrew? As you said, dumb it down to just a brainstorming session. Sit in the room, get your engineer, get your cultivator, get the financial person. Get the team in place and say, "What are the things that could go wrong?"

David Vaillancourt:

Map your process. Look at your SOPs, and what risks and what's the likelihood of them? How big of a deal would it be from a consumer, from a financial, from a business risk? What can we do to mitigate it? And let's document that and then let's test it.

David Vaillancourt:

And it's a continual iteration process of building in one step at a time, different controls and reevaluating them. And getting to a place where now all of a sudden you have a full quality system. You have a full GMP system. Everybody's been trained. That's the goal of kind of phase two.

Andrew Cole:

Yeah. And again, simplify it. When I talk about risk, risk based thinking, risk assessments, that unto itself sounds very complicated. But we use risk based thinking every single day. And again, the pandemic, there is no better example by using risk based thinking on a daily basis.

Andrew Cole:

We consider the risk every single day when we wake up, the pandemic. You go outside. The control measures of going outside are going into crowded places, you wear a mask, you social distance. Those are controls to control or mitigate the risk itself, so we're thinking about this on a daily basis.

Neil Coole:

I want to highlight something you actually said on a client call recently, Andrew, which I thought was a brilliant way to articulate it when they were getting into the individual components of a GMP. The points we covered earlier about training or housekeeping and hygiene and so on, were say what you do now, do what you say now, and provide evidence to support it.

Neil Coole:

And then to your point, David. What is their likelihood of risk going wrong? What is the severity if it does go wrong, and what improvements need to be made? That's something that we really want the audience to take away from today's webinar, is there is a pragmatic approach to this by engaging the right people. What's step three, Andrew and David? What are we looking at for an organization that's now nine to 12 months down the route. What does that last phase of it look like?

Andrew Cole:

The last phase is ongoing effort. With your documentation, traceability throughout the departments that you're looking to control or even increase or at metrics to, you have measurable data. I always use Sam Gregory's saying, if you can't measure it you can't manage it.

Andrew Cole:

That's the point of the data itself. These answers or the measurable data again leads you or isolates best practices, and the intent is to reduce or eliminate deficiencies. I can add from a business standpoint what you want to do is reduce variation. You just don't want steep rises in catastrophes, constant alarm bells going off.

Andrew Cole:

Obviously from a consumer perspective the goal or the intent is ensuring safety and efficacy. But really phase three is about best practices. From best practices you can get into world class manufacturing. These are capturing different techniques or philosophies that work very well, and they've been around for a long time.

Andrew Cole:

There's nothing new about this, it's just how it's used or manipulated for your industry. Made to order, streamline flow, smaller lot sizes, doing it right the first time, zero defects. These are all methodologies or techniques.

Neil Coole:

Yeah. And David, what does it look like in your world when you're working with an organization, they're nine to 12 months down the route? [crosstalk 00:50:38].

David Vaillancourt:

Yeah. Ideally, folks come because they want to be ready for GMP certification. They want to get that seal, that trusted market, that attestation, that credit. Give credit where credit is due. At that poin you should have enough data, enough historics, enough training, enough of the culture imparted to be ready for that certification.

David Vaillancourt:

And then again to the point, this is an ongoing living, breathing system just like any business, just like life. If you're not growing you're dying. These are not SOPs that sit on the shelf that just sit there and collect dust, that are trophy papers. These are revised, these are reviewed regularly, you're conducting your regular internal self assessment audits, you're having third party audits come in.

David Vaillancourt:

You're tearing down your operation looking for weaknesses and improving it, and rebuilding better and stronger every time. By that point you should have a certification. You should have a good feeling under your belt, you should have data that shows, "Wow. Here's where we were at month two and three." And objective data from employee satisfaction, turnover, variability, product loss, number of product failures, or number of suppliers that you're having to send product back to. Those numbers should be significantly reduced and you'll have the data to show it with a GMP system.

Neil Coole:

No, that's fantastic. Thank you both very much for that. Before we come to the end of the webinar we have another poll we'd like to get your inputs on. Do you think that GMP can reduce failure rates and provide a return on investment? We're hoping that the answer is a positive one, but obviously the webinar is designed to support everyone here on the journey or the pathway as it were towards GMP.

Neil Coole:

I really want to get your inputs on that one, so if you could just take a moment to give us your thoughts on whether you think a GMP will help you reduce failure rates and provide a return on the investment. We'll close that poll out in five, four, three, two, one. And let's see what the audience has said. Wonderful.

Neil Coole:

Only two aren't showing. Those two I hope will be reaching out to David and Andrew after the webinar to have a more detailed discussion, and that's great feedback. It's goo to see that people see the value in doing this. And like David and Andrew have said, it's not about meeting the standard for the standard's sake, it's about using it to make your business more successful and more profitable moving forward.

Neil Coole:

One thing we want to touch on before we wrap up the webinar and hand it back to Eric, is one of the topics that we've discussed with David and some of our other industry colleagues on previous calls and webinars. Is how can we support the industry in bridging that trust gap, by providing a consumer facing mark of trust that distills your customer promise.

Neil Coole:

And it's something we just want to share with you now, that we do have a mark of trust program that covers all of these component elements, is industry agnostic, like 9001. We do it in other industries at the moment for people that want to show trust and credibility to their particular product.

Neil Coole:

For example, recently as Andrew already alluded to, the pandemic has highlighted certain issues in the industry. One of them is fraudulent products, and fraudulent products unfortunately does include things like hand sanitizers, so we've got companies out there that have met a consensus based standard.

Neil Coole:

Very much what David's doing with STM and all that great work to support the industry, or to distill that into a client facing mark of trust that captures your customer promise. Is something that we could pick up on a later webinar or discuss at a later date.

Neil Coole:

It's really just to get the wheels turning in your head and think about how that would serve your organization based on your products. Whether it's a consumer good, a nutritional supplement, whatever it may be, there's a consensus based framework out there that can be used to measure that customer promise. And then capture that in a client facing mark of trust.

Neil Coole:

Just to provide an example of that, you can see here there's a company based in Scotland that produces heather based honey. And the food industry has real issues with honey being heavily adulterated and mixed with other products.

Neil Coole:

This organization has taken the positive steps in tackling that issue, that stigma, and providing a client facing mark of trust that shows what that product is, how they've made it. That's been independently and scientifically verified. Just something to bear in mind for future reference and obviously circle back to Andrew, myself, David if you need more in on anything we've covered on today's webinar.

Neil Coole:

What we want to do is really identify where are you today and how can the GMP collective and BSI support you on your pathway towards GMP and beyond. Whether that's ISO 9001, HACCP and GMP, really anything and everything is available to you. It's about using the post webinar survey to let us know how we can support you with your current and future requirements.

Neil Coole:

What's listed on here is just a few of the items that Andrew and David are supporting clients with today. It could be anything else regarding other areas of risk or focus. No wrong answers, it's simply about letting us know how we can better serve you moving forward.

Neil Coole:

I just wanted to kind of touch on those points for you, and also just to remind everybody that the post webinar survey will be made available to you all after today's webinar, which will be sent to you. And we ask you to take just a moment to complete it. There's five questions within there and we really want to know more about how we can better serve you moving forward.

Neil Coole:

There's also the option to reach out and have one to one conversations with David and Andrew. You can do it as a tag team or individually, it's entirely your choice. And obviously their websites are available to you whether you're in the US or in Canada, with further information on what BSI is doing to support organizations throughout the cannabis industry. Before we wrap up and hand back to Eric, are there any final questions, David, Andrew, that you wanted to touch on before we close out today's webinar?

Andrew Cole:

There was a couple of questions on there. One of the questions was is there a significant difference in ISO or the CFRs as it pertains to process? And the answer is yeah, kind of. ISO 9000 tends to be really, really documentation heavy. Policies, procedures, work instructions where GMP, two things.

Andrew Cole:

Number one, GMP tends to be facility or infrastructure specific, equipment specific. And you'll see a lot in there as it pertains to GMPs. Trying to circle back to how do you know. I'm not going to say validation because that's a, "Oh, my goodness."

Andrew Cole:

But how do you know the machine is working? How do you know the process is working? That's probably a main difference there. And also are there templates for starting points of GACP or GDP? Who asked that question? 100%. Everything starts with a gap assessment.

Andrew Cole:

We have, David has checklists that go through every question you need to ask yourself internally. Does it exist? Does it not exist? It's a perfect starting point to figure out where you stand.

David Vaillancourt:

Exactly. The one thing I'd quickly add to that, too, you bring a really good point and we get this all the time. Do you have templates? Can we just implement these templates? Well, yes and no. Yes, there's a standard framework for how to develop a procedure. The main things that it needs to have from a document control ID, to a name, to an authorization signature, tO certain sections.

David Vaillancourt:

Obviously if you follow the ISO or different GMPs that you're looking at, if you need a documented procedure of this and that. And there are great templates out there that you can start with. If you're looking to start somewhere, Google it. You can find lots of places.

David Vaillancourt:

The real key though comes into the implementation and really starting... We like to tell folks don't even start with those, start with just mapping your process. Start with bullet points. Make it stupid simple. Visualizations. From there build out the procedures as you need to. You don't have to get too far into the weeds, but start there.

David Vaillancourt:

Make it process based and then make sure, use the gap assessment, the auditing process to verify where and how you tie those back to the regulations, to make sure you're meeting the framework and the programs that we showed there. That comprise fundamental GMP programs from maintenance, sanitation, training, et cetera.

Neil Coole:

Brilliant. That's very helpful. Thank you. And as always, David, every time we have you on one of these webinars I've always got a list of things that I've just learned. Again, thank you very, very much for your support. Andrew, thank you again for all of your expertise. With that I'd like to thank everyone for joining us for today's webinar. I'll be handing back to Eric now to conclude. Thank you.

Eric Sandy:

Excellent. Thank you, Neil. I'll just echo that, and I want to thank everyone for attending today. And I'll remind everyone of course that we'll be sending out the archived video of today's presentation via email, and I'll again remind everyone that there was a post even survey. Please keep an eye out for that momentarily and check that out.

Eric Sandy:

To Neil, David, Andrew, and the whole BSI team, I want to thank you so much for the time today and the presentation. This was really great. You got every question in there pretty much and provided some really clear information on where to go from here, so thank you so much.

Neil Coole:

Pleasure.

Andrew Cole:

Thank you.

David Vaillancourt:

Awesome. Thanks, guys.

Neil Coole:

Thank you.

Eric Sandy:

Have a great day.

Andrew Cole:

[inaudible 01:00:06].

Neil Coole:

Thanks, everyone.