EP.127 - Gaurav Walia

Narrator: You're listening to *BioTalk* with Rich Bendis, the only podcast focused on the BioHealth Capital Region. Each episode, we'll talk to leaders in the industry to break down the biggest topics happening today in BioHealth.

Rich Bendis: Hi, this is Rich Bendis. I'm your host for *BioTalk*. We have a new topic that has never been on *BioTalk* in our over 120 episodes we've done, and it's really one of the most important that's emerging today. It really relates to data, and how you protect it, and data integrity. With everything that's going on post-pandemic and during the pandemic with remote workers and our workforce changing, our data has to be managed in a different way. We have an expert in this field to be on *BioTalk* today. His name is Gaurav Walia, and he has the longest title of anybody that has ever been on *BioTalk*, so I'm going to read it for you.

0:00:59 He is the Senior Director of Business Development and Principal Computer Systems Validation and Data Integrity Consultant and Senior Associate Partner with the PQE Group. Gaurav, welcome to *BioTalk*.

Gaurav Walia: Thank you, Rich. Appreciate that. Thanks for the kind introduction.

Rich Bendis: You're welcome, and you're going to tell us about everything that's included in your title, and we're going to discuss all of those different areas today. What we'd like to do, first of all, Gaurav, is rather than me introduce you, there's nobody better to introduce yourself than you. So, why don't you give our listeners an introduction to your background, please?

Gaurav Walia: As Rich said, my name is Gaurav Walia. I have been in the pharmaceutical, medical device industry for 26+ years. I started my career pretty much from the ground up. After my master's degree in biology and chemistry, I started as an analytical chemist, basically working in research and development. In the beginning of my career, I quickly moved up the food chain, if you will, up to Associate Director of Research and Development, basically inventing new innovative drugs, including, at that time, the first modern- to late-stage Alzheimer's medication.

0:02:10 After that, I pivoted into the quality space, since I was involved in a lot of FDA inspections, even as a Research Director. I moved into become a Director of Quality for several firms, where over the course of my career I have over 100+ FDA inspections under my experience, as well as several other international regulatory inspections. Then on top of that, more attributable to this topic today is three major consent decree projects for large firms, focusing on computer systems validation and data integrity. After which basically spent 10, 11 years purely on the road, doing consulting, working at various small to large companies, for different projects from computer systems validation or implementing new technologies, to doing gap assessments, to find where the risks, where the gaps, lie, and helping major organizations fix or mediate these issues, whether it's a laboratory or manufacturing space, or anything in between.

0:03:10 My first dealing with PQE Group was about three and a half years ago, when I joined them on a large remediation project. After three months, ironically my client stole me away from PQE Group and made me their Regional Director, and then I became the client at that time, for two years, for PQE Group. After a merger of that company, they decided to shut down some facilities, and hence, PQE had approached me to come back, and here we are today, where I manage some major clients, and sole focus—computer system validation and data integrity space.

Rich Bendis: Thank you, Gaurav. Great introduction. I got introduced to PQE through Debbie Kaufmann, who is located in Bethesda, and regional representative for the PQE Group, which I had not heard of before. I would imagine there's a lot of our listeners, even though you have a great number of clients around the world, that have not heard of PQE.

0:04:02 Can you give us an introduction to what PQE is, and what you do, primarily?

Gaurav Walia: PQE Group was founded in Italy in the late 1990s, and basically since then has grown tremendously, globally. PQE Group is a global consulting firm, one-stop shopping for items like compliance, quality assurance, commissioning and qualifications, CSV, data integrity projects, you name it. Today we stand at 2,000+ employees. We've grown significantly even just during COVID. Just a few years ago, we were only 500 employees.

We've also expanded from originally in our infancy when we started in our first year from one office, to today where we stand at 22 legal entities and over 40+ offices spanning from Latin America to as far as Australia today. For somebody that has worked at seven or eight different consulting firms as well as spent more than half of my career in industry, what I can tell you is that one of the nice benefits I think with this organization, even just from a company standpoint, is it kind of follows that old-school U.S. mentality, where there's a significant amount of permanent employees, whereas in traditional consulting firms in the United States, it's just what we call "body rental"; they're just getting people to satisfy a project and then the relationship ends, more or less.

0:05:24 Whereas, in our organization, we have people that have been in the organization since day one. So it just talks about a level of quality of the individuals that you get. If you have repeat projects, or even just the relationship between clients, I think is a different animal in that you can build upon that relationship, whereas in other organizations, it's almost one-and-done. By chance, you may cross paths, but from a different company or a different person, in a different fashion, I guess you could say.

Rich Bendis: So you have a little differential advantage versus some of your competitors, you're saying.

Gaurav Walia: Yes, and I think the trend today is that large companies, or even down to startups—I think today, companies are starting to find that there's a lot of choices in the market, but at the end of the day, what people really want is that where they don't have to have a surprise, where after a one-hour interview or resume, that the person is not what it appears, or that sometimes the hiring manager of clients has to spend too much time with the consultant.

0:06:28 At the end of the day, let's not forget, this is consulting, so you shouldn't have to handhold the consultant too much, especially when you're hiring them to do a specific task. I think this is what the industry is leaning towards these days, and really having that relationship with the firms, with the individuals, and also the success and the efficiency of the work that is being done, more or less.

Rich Bendis: Sure, I understand. It's all about the people relationships. Can you talk a little bit about the industry focus, and, since we're focused in BioHealth and life sciences, where that rates based on all of the other industries you might service?

0:07:07

Gaurav Walia: Primarily, it's pharmaceutical, medical device, as well as emerging industries in BioTech, for example, or Biologics. So, it's basically in the healthcare region of manufacturers of either pharmaceutical products or medical device, as a high-level summary.

Rich Bendis: I would say, then, you're a pure play, where your primary interest and focus lies in, and expertise, in the whole life science and BioHealth industry, rather than being a general consulting firm that services many industries.

Gaurav Walia: That's correct. I think the focus is in that space. We do dabble in some other areas as well, but that's the primary focus.

Rich Bendis: Let's get into some of the areas that relate to the industry today that are becoming increasingly important. Let's talk about the importance of computer systems validation, and it's referred to as CSV, and some of the new regulatory trends that have emerged since COVID-19.

0:08:02

Gaurav Walia: As you mentioned, CSV, or computer systems validation, very simply put, high level, is ensuring that the software or computerized systems that are being utilized today—maybe 40 years ago when everything was paper-based—that's the difference today. Many companies have automated their technologies or gone to moving away from paper, let's just say. And so, this is really ensuring that the testing or validation of these systems, whether it's a laboratory system—an HPLC, which is utilized high-level for testing of the drug's purity or impurities, which in many cases, some of the impurities could cause side effects to a human. Or, it could be a manufacturing technology that's making the tablet that you take. Or an injectable, for example if you take insulin for diabetes. And also general systems—building monitoring systems, or an environmental monitoring

systems. At the end of the day, the main focus today is really ensuring about the data integrity, the product quality, and ultimately the patient's safety in this regard.

0:09:08 I think during COVID is a unique time, even still today, as some trends do go up and down regarding COVID or different regions of the world. In the last 20 to 30 years, we have truly become a multinational, global entity when it comes to not only our firm, but just the business alone of pharmaceutical and medical device manufacturing. So, what is one of the biggest gaps that has occurred during COVID? Well, I think that the biggest gap is obviously the travel, including the agency as well, had huge travel huge travel restrictions. In one space alone, for example, if you are buying a lot of different technology or computerized systems or software, one of the requirements is to audit those vendors and do a vendor risk management program that basically shows that their quality systems are good.

0:10:00 That is a gap that could not occur very often, including during COVID, because of travel restrictions. So somebody might have 200 vendors they deal with, and they might go inspect them every couple years, for example. So, how do you go to India or China during COVID to do that? And how do you replace that function if you cannot? And so, this tends to be, even before COVID, a big gap, in where industry is not really checking those vendors so much, and the quality systems. So, overall, the major gap during COVID regarding CSV and/or data integrity is that we're not able to go and check the companies that we're doing business with. Even within our own company, sometimes for example, a large client that may have 100 sites in the globe, or they might have two main ways to check if they're doing well, from a computer systems validation or data integrity standpoint. One might be internal audit and the other might be a regulatory inspection. In the last few years—let me give you an example—I've spoken at at least 10 to 15 conferences in the last couple years.

0:11:06 I've been speaking at conferences for the last 25 years, and I will tell you that I would poll the audience in the last couple years, and ask them, "Well, how many people have returned to work normally?" A lot of people, even today, would say it's still limited, or that maybe they're on a

hybrid methodology. The next question will be, “How many people are pursuing business as normal now that COVID is either a couple years back, or now decreasing?” The answer is, most companies are still either not performing internal audits or corporate quality checks, or at a reduced level. There wasn’t many hands being raised no matter which question I asked, and it became less and less, until I got to the last question. The last question was, “How many people have had a regulatory inspection?” And I can tell you that over the course of 10 conferences with maybe a couple thousand people, maybe less than two handfuls had raised their hand.

0:12:00 Which means that we're not checking our own data, we're not checking our own systems, and it’s also not being checked at the normal frequency prior to COVID, from a regulatory standpoint. Again, these are limitations that we have during COVID. Not to promote too much about PQE, but it’s one of the technologies we have, is that we do have some technologies, using augmented reality or virtual reality glasses, as well as some connectivity tools, where it allows us to not only do a vendor inspection remotely—basically any part of the pharmaceutical business, whether it’s inspection, it’s validating a computerized system, checking for gaps in data integrity, we're able to do these projects, as we've done many of them, remotely, utilizing these technologies. We're seeing some uptick in a lot of companies as well, even within the organizations, where they're trying to utilize technology to come up with a hybridized approach or even a completely remote approach. This obviously also is helpful as well as curing the backlog internally of not being able to check this data or doing an audit.

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Rich Bendis: So, times are changing, but you mentioned the term “regulatory inspection.” For those novices who are not in this field, in the data field, talk about who performs a regulatory inspection, when is it required. You've mentioned very few people are raising their hands that have gone through regulatory inspections. So, talk a little bit about regulatory inspections in general, which I haven't heard much about.

Gaurav Walia: In the United States, this would be basically your FDA inspection. Outside

of the United States, wherever you're selling that product, it could be different governmental agencies similar to the FDA globally that would be inspecting these firms. Traditionally, in the pharmaceutical and medical device industry, we're regulated by the Food and Drug Administration here in the United States, as well as several counterparts around the globe, similar to the agency itself, referred to either as the FDA, or the agency that performed these regulatory inspections.

0:14:15 These inspections typically can vary for different reasons. Let's just say in a normal practice, typically every two years there's a GMP inspection that is performed, just to see the quality and health of the organizations producing products. When somebody has done a filing for a drug or a device, they can have a pre-approval inspection, basically allowing them basically a future approval of the product. Then, if there is a recall or an issue that has been notified to the government regarding a particular product or a company, then they also could come quickly on the spot, due to a product quality issue that can affect the patient safety. There's obviously other instances but these are the major instances of a regulatory inspection, if you will, or FDA inspection.

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Rich Bendis: Based on where we are today with some of the challenges and changes that have occurred, would you say that the regulatory inspections are now basically reactive, rather than proactive, and basically they're only occurring when something has happened that stimulates the need for an inspection to occur?

Gaurav Walia: No, the regulatory inspections still occur as needed. It's just starting back up, as you can imagine, with the previous restrictions or heavy restrictions with travel and COVID over the last several years. Some are reactive, in the sense that if there's product quality issues—for example, globally in the last year, there has been cough syrup contamination where 500+ children under five years old have died in several countries. Just in the last couple months, there has been eyedrop contamination where people have died or gone permanently blind. Then there's instances where companies have a track record of not performing, or not doing things right, so the reinspection or rechecking of those companies that

could pose a risk, even in just the examples I gave, come under a little bit of further scrutiny, rightfully so.

0:16:09 I think that's the current operation. There is a significant backlog. I think things have picked up again nicely, starting at the beginning of this year, globally, in terms of regulatory inspections. Because everybody has had a break, if you will, both from internal checks or quality inspections within the organization, as well as some of the third-party checks—as I mentioned earlier, checking your vendors or your partners, and then the regulatory inspections as well. I think those have all started coming back, and it is showing us where some of the issues are lying, either because people are rusty, they're not following the laws or the rules, or just because maybe they're not mature enough in their organizational technical skills or quality or compliance organization.

Rich Bendis: For the listeners, we're talking with Gaurav Walia who is Senior Director of Business Development and Principal Computer Systems Validation and Data Integrity Consultant, and Senior Associate Partner for the PQE Group, who is really focused on all of these topics that we've been talking to today.

0:17:11 I guess the role of PQE would be to get a company internally, and their quality controls, to be in compliance, so that if a regulatory inspection occurred, they would be able to pass that with flying colors, then, Gaurav?

Gaurav Walia: That's well said. I think a lot of organizations attack those in two fashions, or three. One will be if they already have some known issues from an inspection or from a quality audit where they might need help from an outside party that has expertise in various areas that you mentioned. The other would be, in many cases companies that are being preventative will employ our services to do a gap assessment in different areas, from quality to compliance, even specifically in some of the bread-and-butter core categories of strengths of our business, coming from computer systems validation and data integrity.

0:18:07 From there, basically several organizations will get a report and they will see where the risks lie. From that, in many cases, they will employ

ourselves, or a combination of doing the—basically to perform the remediation, correct the problems, prior to an inspection. Lastly would be what we call audit or inspection readiness. It's really targeting different areas, not just CSV and data integrity, but other areas as well that could pose a risk. Basically looking at these systems or areas, and processes of business, and basically helping those clients and organizations optimize their potential for success during an inspection. Or even sometimes the corporate quality audits that they have internally are equally important, and so they want to perform well, as well. Companies will do this often to ensure that they are not only audit-ready or inspection-ready but also to ensure that, for example, during COVID—years that you're not falling off or going away from what you said you were going to do or improve.

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Rich Bendis: You've just talked about what some of the best practices would be, but let's assume you're the CIO of a multinational company. What would *you* do to ensure that you would have CSV in compliance and data integrity for your form?

Gaurav Walia: I think it starts with understanding, where do you fall on the performance chart? Do you have gaps in certain areas? Is the technology being tested and ensuring that it is working properly on a frequent basis? As well as even today a CIO would be concerned with cybersecurity. Today—I won't name the firms, but there have been instances over the last decade where entire laboratories, their technologies were seized, and they couldn't operate for six months, losing hundreds of millions of dollars.

0:20:05 On the counterpart in the medical device space, there's known cases were people hacked into somebody's device. Now, I bring this example enough, and it's not funny, but this is known cases where people have accessed, for example, an infusion pump, or something delivering medication in the hospital, and can potentially alter the medication levels, turn off the device. Imagine if somebody did that with a pacemaker or something heart-related; they could turn it on or turn it off. These are some of the key areas that I think that a CIO or industry has been focused on. Then, ultimately today, both from industry and any kind of quality audit or regulatory inspection, the following three things are

often stated: “We want to make sure that data integrity is in place and is being checked, to make sure that the data itself is being secured, is not being manipulated, is not being deleted or changed, for the interest of selling a product.”

0:21:07 I wouldn't say that many people falsify, but there are instances where people are throwing out data where somebody doesn't pass, or taking two different batches and trying to combine them, just so they can sell it to market, obviously which is against the law. Basically, overall, I think these are the critical aspects. People want to ensure the last two, which is, the product is safe, that you're making it safe, that the systems are safe that help make that product. Because it’s just like if you were cooking in a kitchen. I’m famous for my weird, quirky analogies, but it’s just like if you're cooking in a kitchen, and you don’t wash your hands, or you don’t follow the instructions on how to make that pizza properly; there’s a good chance that you could contaminate that pizza, somebody could get sick, or just a complaint in general. And, same thing when it comes to manufacturing. There’s much more of a risk when it comes to a pharmaceutical product or a medical device in that it’s helping a patient’s life, or it could be helping them live, and if it’s not done correctly from a product quality standpoint, then the result can be indirect or direct outcome of an adverse event or patient safety, basically, more or less.

0:22:14 In the past, we did more documentation-focused, and I think today, it’s more looking at the end game and then working your way backwards to make sure that the process and your state of quality and compliance helps you to achieve a good product and have safeness within the people taking your medication or medical device.

Rich Bendis: You're talking about numerous challenges the industry had, and guess what? The challenges increased during COVID, because basically it was probably easier to inspect and ensure quality when everybody was in one location. But now that you have the remote workforce, I would imagine it creates different challenges. What do you see as some of these challenges and some of the best practices that people have implemented related to the hybrid and remote workforce that we have today?

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Gaurav Walia: I remember being at the beginning of COVID and stuck in a hotel. I was doing just that; I was doing a gap assessment where I wanted to see—and very similarly speaking, either people are not in the same building, or they're not in the same conference room, or they're not in front of a system. If I'm looking at a tablet press that makes tablets—if I want to see what kind of gaps are there—it makes it much more difficult pre-COVID, and then even at the beginning of COVID, unless you advance your technology. So, how do I stand in front of a computerized system and see, are the right people accessing the system? Do they have user IDs and passwords? And are we following our procedures and global policies when it comes to security configuration of the system? That becomes difficult. Literally, I remember sitting in the hotel room in a lobby, and having people use either a cell phone or a laptop camera, and the picture quality wasn't as good. It was hard. Sometimes they had to communicate what they were trying to show you.

0:24:00 And so, imagine you're sharing data with somebody else, or now you're inspecting your own other site or doing a quality check, say, in manufacturing, or in a laboratory space. You're in the United States. As part of a corporate quality group, you're inspecting another site of yours all the way out in, let's say, Australia or India; not so easy. So I think utilizing—one, having the bandwidth, having proper Wi-Fi connections within the facilities has been one thing that has been a gap in the past, where companies were not ready for that. Having the infrastructure to be able to support more data being shared back and forth, more remote workers, or basically being virtual, if you will, was another gap that companies had to increase their bandwidths, and where do they share data, how they share data, how they protect that data. Overall, I think those have been some of the—even today within many companies—the challenges. How do you satisfy what you should be doing normally and making sure you have a good quality system, and compliance, and do what you normally did?

0:25:04 How do you go back to normal life, as best as possible, even when you're working from home? I think utilization of different social tools, using Microsoft Teams, for example, or virtual marketplaces where you can utilize tools to be able to communicate—how do you store, share, and

protect that data? Whether you're sharing it internally, or if you're checking a vendor, if you're sharing it with an agency or regulatory body—these become important. From speaking at conferences with some major industry partners, I think those companies that started that endeavor to dry-run it and see how it works and where the gaps lie—maybe the picture quality is not great, the lighting is not great. I have a dead spot in the facility where I can't show you, "Hey, this is how I'm storing my medications properly," for example. These are what companies have piloted and pivoted away from the normal in-person, onsite, flying from one location to another where I can see it face to face, or in front of a computerized system, for example. That has improved, although I think a lot of companies are still not back to normal when it comes to it.

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Rich Bendis: Well, they're not back to normal; they're trying to adjust to the new normal—

Gaurav Walia: Correct.

Rich Bendis: —which hasn't really been totally defined yet. I guess the key is, based on all of this that you have observed and the challenges of what the new normal is at this point, what do you predict to be some of the computer systems validation trends that will be emerging in the future based on where we are today and where technology is also emerging?

Gaurav Walia: I think one of the new trends is alluding to something we talked about earlier, but basically, there's a new draft guidance called CSA, or Computer Software Assurance. I think the trend is going in that fashion, where even some companies are already starting to implement it, even though it has not become a law or a regulation yet.

0:27:02 More or less, I'll give you an analogy or comparison between CSV and CSA. Traditionally over the last 50+ years, computer systems validation has been a documentation activity or what some people might call a checklist. It has been based on what do I create from a documentation standpoint to prove that my process is working, my system is working, my computerized system is working properly to make that a safe drug or product. What it wasn't doing is focusing on what's the risk that I have at

hand. For example—and what we call critical thinking. Today, those that are starting to implement CSA—and I'll mention why that helps from an efficiency and technology standpoint—CSA basically says, utilize the opposite methodology and take critical thinking, and really decide, what are my risks from a quality perspective? What is my risk to the patient? What is my risk from a validation standpoint or data integrity that could affect my product?

0:28:08 Or, maybe historically I know I have some issues here, and I should put better focus on that, more or less, versus doing the same testing over and over again that people have done for many years. Let me give you an example. If you have a software system that has been well-deployed in the marketplace, it maybe has 10,000 deployments, has been around 40 years, companies have been routinely just testing it out of the box, or COTS, they call it—commercial off-the-shelf functionality—today companies or even industry and the agency might say that this is basically a wasted effort. Especially if you have a good vendor risk management program and you've audited your vendors, they have a good quality system—if you've documented that, then you can leverage that, *and* the deployments in the industry, and focus on things that have been configured or customized. CSA basically flips the way that business has been done for several decades and says, focus on where the risk lies that could affect the data, or the product, or the patient, and also based on your track record or historical knowledge of those systems, where there may be risk.

0:29:15 So, applying the critical thinking, to apply how you perform those quality activities, or testing, and then from that, the last step would be, how do I document? Funny example—I remember in my first job, more than 25 years ago, when there was an inspection, we used to pull in carts worth of paperwork, and the bigger the cart, or the heavier the paperwork, or the bigger the pile, the mountain of paperwork basically, literally where you barely could see the inspector's face. It was, one, to keep them busy, and number two, we thought quantity means quality. And of course, it doesn't. Today the shift that is starting to occur is, it's not about the amount of paperwork, but the focus to ensure, again, that the product is safe.

030:00 What we call the intended use—how do I plan on using that system, that software, that manufacturing tool, that laboratory equipment, to ensure the product is safe before I sell it to the public, and to make sure the patient is safe. That's not a technology but it's basically a draft regulation that's out there. I think technologically speaking, the difference is that people are starting to think better, even before they purchase the technology, what do I really need? What am I trying to achieve? *That's* the best way. Too many times—somebody buying a car, not knowing what it's for. Sorry again for my quirky analogies, but would you buy a Lamborghini to drive up a snowy mountain that has five feet of snow and it routinely snows? Versus, would I take a Lamborghini as my main car to drive only to go to the grocery store? So it's really understanding what your needs are, and buying the technology and the tools that you need in accordance to that, to be able to satisfy your end goals.

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Rich Bendis: The challenge becomes, I think, for a lot of early-stage and small companies. What advice do you have for companies to ensure that they have CSV compliance regardless of size, and when should they begin it?

Gaurav Walia: Again, as I had said at the beginning of the conversation, when I was a research chemist, there's different phases of research, and some are early stage in the product life cycle development from phase 1 to phase 4. In early stages, I used to have a lot of colleagues that would say, "Oh, well, it's early. It's still research. We don't need to be total strictness of GMP or good manufacturing practice." Or GXP, which can cover good laboratory practices, good manufacturing practices, good documentation practices, et cetera. Really what I always found was to have a good foundation, even early in development, in an organization, is important. Because you're building a culture. It's not just checking off a box on a piece of paper to say I'm doing it, or I'm not.

0:32:00 It's really implementing a culture within the organization, improving upon that culture. Many companies have continuous improvement projects which include, "How do I train people? How do I show them?" For example, many companies will do an annual GMP training, and it's the same training over and over and over again. The gap is that people are

doing the training to satisfy a requirement, to check off a box, versus, maybe I'd change the format. If it's your first time, your first day, your first year, your first job in industry, that makes sense to have that kind of training. As you move forward in your career, either you have different types of training that are more advanced, that also combine, in my opinion, what are some of the gaps you experienced in the last year? What are some of the problems that you had? What are some of the mistakes that people made? I think learning from your mistakes is what's important, to ensure that the gaps are corrective and improving. Back to your original question—when should it be implemented?—it should be done on day one. It should be done on day one.

0:33:05 It also should have some harmony or harmonization between the organization, because you have different disciplines, from research, to IT, to quality, to compliance, to regulatory groups, just to name a few. It's important that everybody speaks the same language coming into the room. And it's important that there's at least some common thread of discussion and sharing of information that everybody can understand. Because at the end of the day, it's the total package that gets looked at, potentially, as well as specific areas that can be looked at, during an audit or an inspection. So, my advice to companies is, understand where your risks lie. Earlier I said I've been involved in consent decrees. Consent decrees are legal injunctions where you can be stopped from manufacturing a drug for four or five years—or your product—until you fix your problems. It's a serious legal designation that comes from usually quality manufacturing issues.

0:34:00 So, it's important for people to learn from their mistakes and really understand where their gaps lie. Because what you don't know is what you don't know. And, as we talked about, even during COVID more especially, people have not been performing tasks. They're off their game, more or less, if you will. They've gotten rusty, because they've not been doing it, or they've not been inspected. There's a lot of turnover in the industry, too, so you get new bodies, or you're getting people that are not going into the office. People are working in a different mindset. Of course, if you're making a drug, you still have to go onsite to produce a product. So, that interaction becomes important. Being able to develop that

culture, whether it's internally or getting outside help, and is at the same time spot-checking different areas throughout the year, or over the course of a few years, highlighting different areas where you might have risk and improving those gaps and fixing them is really what I would recommend.

Rich Bendis: So you're a gap specialist, Gaurav.

Gaurav Walia: My executive director of Research and Development, when I was probably in my second job, called me a chameleon.

0:35:03 More or less, it was before we were calling it gaps; it was really being a problem-solver. Even if it wasn't an area that you may work in every day, it takes a certain personality and skill set to be able to walk into any room, in front of any system, talk to any individual, or look at something, and be able to quickly identify where there's gaps or significant issues. Again, that's where you assign the risk level—what's defective, or it doesn't meet, or it's failing.

Rich Bendis: As we come to a close of this special podcast on this new topic we've had on computer systems validation and data integrity, I want to thank Gaurav Walia who is the Senior Director of Business Development and Principal of Computer System Validation and Data Integrity Consultant, and Senior Associate Partner for the PQE Group. I'm sure the listeners may have an interest in learning more from you, so how would they get in touch with you, Gaurav, or the PQE Group?

0:36:05

Gaurav Walia: Thank you for having me here today. It has been a wonderful discussion. For those that are interested in learning more about PQE Group, or have some needs, you can look us up on www.PQEGroup.com. You can also find PQE Group on LinkedIn. You can find myself, Gaurav Walia, on LinkedIn, as well as my email address is g.walia@pqegroup.com.

Rich Bendis: Super. It will be easier to find you with that email address than your title, Gaurav.

Gaurav Walia: [laughs]

Rich Bendis: I want to thank you for being on *BioTalk* today and look forward to seeing you in the future, Gaurav.

Gaurav Walia: Thank you, Rich. Appreciate it.

Narrator: Thanks for listening to *BioTalk* with Rich Bendis.

End of recording.