

Transcript: Navigating the Non-Negotiables

Steve 00:09.940: Very good. Hello, and welcome to Informed, a podcast series where you will hear industry experts share their thought-provoking insights and lessons in the field of medical communications. This series is brought to you by ISMPP and is generously sponsored by MedThink SciComm. My name is Steve Palmisano, and I'm joined today by Bob Wright.

The opinions shared here today are those of our own and do not necessarily reflect those of our employers. Today's podcast is titled Navigating the Non-Negotiables. I've spent my entire career in medical communications and this environment where compliance, publication guidelines, and SOPs are king. I lead the publication services here at the Lockwood Group, where we harmonize clinical, medical affairs, HEOR, and real-world evidence publications. We also leverage technology and digital features to ensure appropriate and compliant sharing of this information to the health care community.

I'm very passionate about today's topic, and my guest and I spoke on this topic of navigating the non-negotiables at the inaugural ISMPP Academy meeting in September 2023. We began our session at the ISMPP Academy by describing how far our profession has come over the past 20 years since ISMPP started, and how our industry guidelines, such as ICMJE and GPP 2022, have been developed to ensure transparency, integrity, and trust in all that we do as publication professionals. With me here today is Bob Wright. Bob, would you like to introduce yourself?

Bob 01:44.381: Sure. And Steve, I think you just called us old. So thanks for the quick introduction. I lead publications and external data sharing processes and systems at Sanofi. And I would just say that these are both places where strong documentation and adherence to processes are really needed. The subject of compliance is something that I talk about literally every day. And like you, I've been around the industry for a long time, and I saw, like you did firsthand, a lot of those behaviors 20 years ago that led to the compliance environment that we're in today. And for those of you who weren't, I'll just say, for those of us who were there, it is literally burned into our brains. And it's something that a lot of us like to talk about because we don't want history to repeat itself.

Steve 02:50.127: Absolutely. Absolutely. Thank you, Bob. So let's begin there then. We clearly do not want history to repeat itself. So tell me about your role as a compliance member and your responsibilities and how this applies to us as publication professionals.

Bob 03:06.441: So maybe I can just start and say how we're organized. My group sits in the chief medical officer's office of the company. We are responsible for the process and systems. We handle the SOPs across the company. We handle the systems across the company. And so our focus is primarily on a daily basis about *how* publications are done, but not necessarily the *what*. The day-to-day working on manuscripts and things like that is actually a different part of our organization. So it's a little bit unique. But what it ends up with is because we have a lot of people around the company who are working on publications on a daily basis it's good to have kind of a central command, if you will, someone that people from across the organization can come to with questions about the process. When there are questions about the SOP, things that

are not clear, coming to us and talking to us about various aspects of publications. Now, I don't sit in our compliance organization. compliance officer. And so, I do consult with them on a lot of things.

Steve 04:43.909: So, you interestingly brought up the words command central. It's pretty interesting as a thought process. I look at this also from the agency perspective, which clearly, as we look at compliance, it's our quality management plans that we have, which embody all of what we see and hear and read in ICMJE, GPP 2022, our clients' SOPs, and also in the compliance tracking tools that we use day in and day out. So what might you share a little bit more in terms of the tag team with an agency and a client?

Bob 05:20.244: Well, I mean, to me, that's one of the most important things. And so especially as new people are coming into Publications roles either on the agency or on the pharma side is building a relationship. You know, when I first started in publication in the early two thousands my agency partner literally taught me everything that I know now about publications way back then. And so we spent a lot of time going through the policies, going through the process, her helping me to understand the right way things should be done. And I think that's kind of, you know, at least I'm guessing a lot of the same things that happen on the agency side, right?

Steve 06:12.817: Absolutely. It's that back and forth and having champions within our organization who can make sure that we're in tune day in and day out. I know in our team, we have those individuals as well that are constantly monitoring the various different guidelines that we all are very familiar with, but certainly there's updates. And we'll talk about this a little bit in terms of ICMJE and some of the updates they've recently made, and it's filling the role of GPP 2022 as a kind of a guide for us day in and day out in what we do.

Bob 06:40.257: I would just say certainly, I know each company has their own SOPs, and at least from my conversations that I've had with people, I would say we're all more alike than we are different with the SOPs, but there's certainly some idiosyncrasies and different ways of looking at things. From the agency side, learning the company-specific SOPs are important. But I think for those of us on the company side as well, having a true partnership with your agency can lead you to have conversations. They have the benefit of working with other companies and seeing how other people do things across the company. It really is a great opportunity to work together to be real partners and to share.

Steve 07:31.156: Very interesting thought there. Let me bridge this into a comment you made a little bit earlier that we do have a lot of new members joining ISMPP and joining the publication profession itself. Like all of us as publication professionals, we need to continually stay on top of these criteria, ICMJE criteria, like last month's updates, and then we should all make sure that we're following GPP 2022. Again, it's a great ready-to-go document that provides the basic best practices for planning and developing biomedical publications. So, Bob, any additional thoughts you have on those two elements and how those are incorporated into your team's efforts?

Bob 08:08.184: Well, I mean, GPP has been a guidepost, I would say, for the industry for quite a long time. And, you know, the interest in the updates, I mean, the number one question after

every update's been made is when is the next update coming? People are clearly hungry for this. And, I'll just say, we have used it extensively. I know you've kind of made jokes. It's like everybody should have a copy of this sitting on your desk at all times. And I totally agree with that. We used it extensively in a recent update that we did to our SOP. I would just encourage people who don't have a copy of it to get one. Then also just recognize that it truly is a great source for guidance about various things, but also specific language that you can lift and put into your SOPs. We found that quite useful.

Steve 09:10.300: Excellent. I want to harken back to our ISMPP Academy meeting. You made a very interesting comment, and I'm going to kind of quote you. We're talking about, is there any reason why we should continue to be paranoid? So publication activities aren't being monitored anymore, are they?

Bob 09:25.768: Well, yeah, so it's kind of funny. I made this joke at the ISMPP Academy, and it's something I learned kind of early on in my career. And it was a lawyer that I worked with at another company that always used to say "it's not paranoia when people really are chasing you". And I think this is still the case, although how closely they're following is maybe something we could debate. In the early days, there were a considerable number of corporate integrity agreements that were put in place. Many of them did include publications as part of that corporate integrity agreement. I would say by and large, publications are not the sole reason why people got and are getting, corporate integrity agreements, so maybe it's not a driving factor, but I do see on a regular basis the inclusion of publications into those agreements. If you look at them, they're largely focused on things like contracts and payments to clinicians. But when that triggers the corporate integrity agreement, you see publications included. And when publications are included, it actually is mainly focused on things like author agreements, making sure that there's a firewall in place or some kind of a process in place for corporate involvement.

And so that's kind of the legal side, but I think there's also the PR side that people should think about. And here is where I think there are people really still chasing the industry, especially around this. I think there is a a persistent desire to have a narrative of the pharmaceutical industry as the evil empire. People should be cognizant of what they do and the narrative that they generate. Things that cause problems ultimately support that evil empire narrative and it comes out in the press when bad things happen.

Steve 11:51.498: I think all this reminds me from an agency standpoint that this clearly is a shared responsibility, right? It's the agency and our client individuals that we have to remain diligent day in and day out and not assume anything, but also in the checks and balances. Who is it that's checking against these guidelines, reminding us of those elements that have guided us from the challenging days we had 20 years ago to where we've come, because we have come so far and become so much better at the compliance, but we're still not done yet. We need to continue to remain diligent in this area.

Bob 12:25.042: Yeah, I always feel like I don't know if you're a fan of who framed Roger Rabbit from a long time ago, but I always loved the Jessica Rabbit quote. "I'm not bad. I'm just drawn that way." And I think, you know, it's the same thing for those of us in industry, like so many of us

spend our day trying to do the right thing and trying to help people do the right thing. But out there, there are people that want us to be bad.

Steve 12:54.694: Yes. Well, and we've gotten so much better, so I think we're doing a great job as an industry. One of the next topics that we talked about a little bit at the ISMPP Academy meeting was these unspoken thoughts, these things that people were talking about in the past. You know, what's the impact of this publication on sales, right? Can we truly publish everything, you know, positive and negative data? Can the sponsor be trusted to analyze the data appropriately? Let me go to that point of, you know, the matters of publication and compliance. So can you kind of go through some of the pitfalls in years past? I know you've mentioned things like poor documentation, but tell us more about some of those pitfalls and I'll kind of probe a little bit in those areas with you.

Bob 13:34.351: Well, I mean, just for the history lesson, I think for those of us who were around back in the two thousands, we worked in organizations that were literally called medical marketing. And, you know, that doesn't happen anymore. And thankfully, that doesn't happen anymore. But there was very deep commercial involvement in publication activities. There were a number of companies who were literally suppressing negative studies for various products because it would not be commercially advantageous to them. There were organizations that were paying physicians for ghost authored manuscripts. So it was a fully baked, fully written manuscript that literally somebody would walk to a physician and say, Hey, we'll pay you whatever amount of money if you sign your name on this and publish it. And for the most part, they were kind of marketing oriented, positively toned kind of stuff.

And to me it was like that was really the genesis of good publication practice. I think you know, with many of the things Senator Grassley, we talked about at the ISMPP Academy, exposés on this in the press, etc., really led a lot of people to really put out some guidelines to self-police. And as we talked about at the Academy, I think you can fear all of that stuff, but in reality, this to me is a success story where people took this attitude of compliance to heart and learn something from the mistakes that were made in the past. And really, I don't see this kind of stuff happening to a large extent anymore.

And kind of back to the paranoia, there's another quote that I always love, and it's the Ruth Bader Ginsburg. It's like, don't take your umbrella away while it's raining because you're not getting wet. And so I think a lot of the stuff that's been put in place is in place because of the past, but it doesn't mean we should take them away just because we don't see this stuff every day anymore.

Steve 16:05.520: Sure. As you're talking about these last 20 years, and we'll get back to this core topic a little bit, I recall a presentation from Emily Bruce and Meena Patel and others at, I think, the ISMPP EU meeting in 2022, which they were outlining since 2020, since [clinicaltrials.gov](https://www.clinicaltrials.gov). all the progress that we've made, and all the guidelines that have been put into place, and the updates to those guidelines that have been put into place that we all need to become very intimate with. But recognize that we're not perfect, but we're making tremendous strides. So indeed, this is, as you mentioned, a success story.

And so I would just add to this a little bit when we're talking about poor documentation. I know from our teams on the agency side, working very closely with our clients with the publication planning tools, that we recognize these tools are as much documentation of non-compliance as they are tools to ensure compliance. So making certain we're so diligent with those tools is absolutely critical because they are used as a measure of compliance. Any thoughts on that?

Bob 17:03.759: I would just say for those of us who came from the medical side of the profession, you know, there was something that was always taught to us as students. And it's, if it's not in the chart, it never happened. And I think the same thing is true of publication tools. If it's not in there, it's not accurate, it did not happen. And we have to think about these tools as a way of providing evidence for what was done, explanations. I would say for people as they're thinking about documentation to not just think about what they need to know for tomorrow for their team, but to think about what someone else who didn't work on that project will need to know 10 or 15 years from now when they're standing in front of a lawyer at a deposition.

Steve 18:00.202: Yikes. All right. Well, on that point, let's move to a couple of the other elements where there's maybe been some pitfalls and maybe some things going on today. But tell us about Encores. I know that's a pretty popular sort of thing, but tell us about your perspective there.

Bob 18:13.503: I think many people who know me would know me as a person who is not a fan of encores. And part of that, I'll just say, is because of my academic background and the way I was taught in school. But they do serve a useful purpose. and enabling teams to get data out to people who would not have otherwise seen it, and that's certainly a good thing. I think, to me, the problem comes in with encores and with other things as well, when the mindset shifts from good science to good business. And when we're putting out encores in order to raise awareness, to make noise, to do many things, when you have 10 encores or 20 encores of one thing, are you still talking science are you still being a science person or have you shifted to medical marketing and that to me is the tipping point and I don't know where that tipping point is but it's something at least for people to keep in their mind the *why* I'm doing this not just the *what* I'm doing and what's the motivation.

Steve 19:34.203: I would imagine then as our client teams are developing their publication plans they're mindful of how many encores are they seeing for a specific data set, and probably used in that review process to monitor for that as you go to do.

Bob 19:46.475: Yeah, yeah, exactly. And keep yourself in check. And the best tactic is not always a publication. And sometimes we get siloed into thinking about publications always. But there may be other tactics that you or other parts of your organization might use instead of doing encores.

Steve 20:07.362: Sure. There's another topic that you brought up, which is this idea of doing things for the wrong reasons. Tell us what you mean by that.

Bob 20:15.453: So this is one, I think, as a general rule in this industry and in many other industries, like doing the right things for the right reason will never, will almost never lead to bad outcomes. And so that to me is the mindset that all of us should be in. And when I see trouble it's typically people who are doing the wrong things for the wrong reasons and it's many of the things that we've been talking about. It's the commercial mindset. It's the I'm trying to hide something I'm trying to do whatever. And that to me, it's like it's the path that leads down to problems. If we can sort of bring ourselves back to the spirit behind what we're doing, I think it would help many people to avoid problems.

Steve 21:12.842: Excellent. So I think that's a nice sort of entree into our next topic about publication extenders. Certainly, publication extenders are intended to extend the reach and awareness of the original article and the associated data with the intention of advancing patient care. That seems like a very noble sort of thought process, but journals clearly are rapidly adopting these new digital features that we all recognize with the intended purpose of extending the reach and awareness, again, of that original article. PLS in text, PLSPs, infographics, graphical abstracts are certainly some of those very common called publication extenders or digital features. So tell us how you as a compliance lead looks at these initiatives.

Bob 21:55.015: There's no doubt that these kinds of activities are important. And, many of the things you said, I totally agree with. I think these are exceptional ways of getting information out to people who may not have access, may not be native English speakers, may not be experts on a particular topic, may need information for them to engage in discussions with patients. And all of those are incredibly noble reasons for doing this kind of work.

But there's a slope, a slippery slope as well, and I think it's the same conversation we were just having. What is the motivation behind it? Is the motivation the noble pursuit that we were just talking about, or is the motivation more about making noise, which to me is a marketing purpose behind it? And then I think for companies also, it's not just about the journal, but it's also how you plan to use that information. And so, for many companies, I would say from a compliance point of view, there's quite a difference between the scientific exchange that goes into journals and how subsequent use of those materials is handled. So people need to think about not just about the material itself, not just about the motivations, but about how people downstream will be using it. For example, do companies direct people to those materials in a proactive way.

Steve 23:45.970: Great. So it sounds like there's no issue with these publication extenders or digital tools, but it's the motivation that underpins or that's behind why we're doing what we're doing and whether it's truly a noble effort that we refer to.

Bob 24:00.823: In my opinion, anyway, I was taught very early on, good medicine is good business, but good business is not necessarily good medicine. It's our job to have the wisdom to know the difference between those two.

Steve 24:18.153: I love that thought process. Bob, we've officially gone now 15 minutes and we've not talked about AI. So I'd be curious now, as we just explore just for a moment, what questions are you facing with AI related to compliance matters?

Bob 24:37.045: I'm surprised we made it that long. I'm not sure anyone has ever gone 15 minutes in 2024 without talking AI. But, for me, from a compliance point of view, the concern and I use that word very lightly, but the issue is how fast it's moving. I mean, just the difference from the ISMPP annual meeting last year to the ISMPP Academy and what had developed in that time was incredible, how far companies had gone there. And it's moving so fast and faster than we're used to doing, to dealing with things in the pharma industry and the publications industry. And so that creates gaps. And so, I think from a compliance point of view, we have to think about balance. What's the balance of giving people some reasonable guardrails without stifling innovation? And it's actually kind of funny because I've seen even in the last six months like we talked about the guidance has come out and you know of course people will suggest that we should acknowledge the use of AI in our publications. The algorithms are generated and should not be considered authors. But it's funny, and people started doing that. I've actually seen it come all the way around 360, where now people are disclosing that they did not use AI in the generation of a manuscript.

Steve 26:19.742: Interesting, interesting. Yeah, I think that's full disclosure, right? And a difference.

Bob 26:23.165: Yeah, exactly. I mean, clearly, there's been a lot of discussion about this as well from the agency side. Well, I mean, you've been on both sides. What about your perspective?

Steve 26:34.035: Yeah, there's certainly plenty of discussion around, the quality of the end deliverable, at least the first draft, and then discussion about the efficiency of utilizing these, some of these foundational AI models. I think we clearly have a significant challenge that lies ahead, which is the proper sort of prompt engineering and the efficiency and understanding the best sort of prompts to get us a better end result. But what clearly I've heard from the agency perspective is that, yeah, it may save some time, some time, but then again, it's the quality that we're really focused on. Is the data that we're communicating appropriate for advancing patient care? And I think that's where there's continued to be a challenge in discussion.

Bob 27:15.825: Yeah and you know certainly when it was beginning I think there were tons of people who hoped that this would create a lot of efficiency. I could do more with less people and I think it even came out of the ISMPP Academy. You can't let this loose on its own. There's too many issues with hallucinations, too much to be done with prompt engineering, as you said, and making sure that you're getting the right outputs. And so all of this needs human intervention in order to use it properly. It's a tool to help us, but it's not going to replace us. And in fact, many people are saying they need additional resources. So the people who have technical expertise in machine learning and digital things are coming on board. So there's not the great cost savings that people were hoping for. And if anything else, there may be incremental resources needed.

Steve 28:17.771: And tell us why you think there's incremental, is that additional expertise that's brought on to the team, at least in the interim?

Bob 28:23.112: Yes, definitely.

Steve 28:26.829: Well, I think, Bob, I think we're at a point at which we probably want to summarize. And I think we've probably got three or four core sort of takeaways. And maybe I'll start with the first one, and then you can chime in with the second one. But I think we now understand we really need to know the history. As we've come into this profession, as we keep ourselves in this profession, we need to know the history and know the guidelines.

Bob 28:49.320: Yes. And then I think, that's so important. And then the second one is really what we mentioned early on. This is a partnership. And so making sure that you, your teammates, your agencies are all educated and that you're working in a strong partnership together to better understand and navigate these waters.

Steve 29:17.288: And maybe the third thought is, again, if you ever have a question, you can contact your compliance team. There are a number of individuals that are available to answer those questions and or maybe pose a question in the ISMPP forum. Great way to get expertise from across the industry to help guide your decision making at your respective company.

Bob 29:33.859: Yeah, no doubt that the ISMPP Forum is an amazing place to be able to ask questions in a non-competitive way, find out what your peers are doing.

Steve 29:45.078: And then maybe the final thought here, as we close out, is remember the guidelines are intended to guide, and they will continually be updated. So Bob, thank you very much for today's discussion and the insights that you provided here. Thanks to be able to bounce back and forth between the client and the agency side. So thank you on that.

Bob 30:03.481: Yes, and thank you too.

Steve 30:06.642: So thank you, Bob. This has been a very interesting conversation. And certainly, we're out of time for today. Thanks for listening to Informed for Medical Communications Professionals. Please take a minute to subscribe to the show on your favorite podcast app. Inform your colleagues and rate our show highly if you liked what you heard today, and hopefully you did. Join ISMPP today by becoming a member of our community and to participate in our webinars and to receive instant access to exclusive tools and resources. If you're interested, just go to ismpp.org. That's I-S-M-P-P dot org to learn more. I'm Steve Palmisano.

Bob 30:49.293: And I'm Bob Wright. Thank you.