InformED Podcast

Conversation with Compliance

April 16, 2024

Cassie Stox ***00:02.357***: 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 SciCom.

My name is Cassie Stox. I'm the VP of Media Strategy and Audience Insights at MedThink, and I'm joined today by Merry Saba and Megan Weigel. The opinions shared here today are those of our own and do not necessarily reflect those of our employers. Welcome to the podcast. Mary, why don't you introduce yourself first?

Merry Saba ***00:41.134***: Sure. Thanks, Cassie. I'm happy to be here today presenting on this topic of compliance. Megan and I first spoke about this at the inaugural ISMPP Academy back in the fall of 2023, and there were some really good discussions surrounding this topic, and I actually learned a lot at that particular session. So, just a little bit of my background. Currently, I am lead of publication standards at Sanofi, and our team sits within the chief medical officer office, So I'm not compliance per se. However, we are responsible for the publication processes, publication management, platforms and systems and the publication SOP. And that is a company wide. We touch on all, all areas of the company. I have about 30 years experience developing scientific publications for the pharmaceutical industry. I've worked in both the medcomms agency side as well as pharma. I'm happy to be here today.

Megan Weigel ***02:01.065***: Hi, I'm happy to be here with both of you today. My name is Megan Weigel. I'm a medical policy advisor focusing on medical communications at Bristol-Myers Squibb. And I just wanted to note before I kick off that everything that I will mention or say today is on my own behalf and not on behalf of Bristol-Myers Squibb.

I started in the industry about 10 years ago working for medical communication agencies, doing project management for a variety of different pharmaceutical companies. I switched over to the pharmaceutical side back in 2019 in more of a publications compliance role, doing monitoring, and eventually switching over to advising on not only company policies and processes for good publication practices, but also industry best practices.

Cassie Stox ***02:59.453***: I'm really excited to get the opportunity to speak to you both and have a conversation about compliance. So to start us off, can you tell me, why do publications compliance teams exist within organizations?

Merry Saba ***03:13.737***: I'll start off on this. First of all, if anyone wants a really more in-depth background on this, they can refer to the podcast that's being released in March, Navigating the Non-Negotiables, where there's a really good description of sort of the history of publication compliance, what happened in the industry 20, 30 years ago that led to companies and professionals to recognize that there was a need for some guidelines and standards. And that was really the birth of good publication practice, as well as sort of integrating that with ICMJE. And so we've learned the lessons from the past where things were not always transparent. It wasn't always best practices being followed. So that's really why compliance, I believe, exists today. And we're here to sort of guide the process, make sure that our colleagues are compliant, able to do their jobs, but also to do it compliantly. Megan, I don't know if you have something you want to add on top of that.

Megan Weigel ***04:41.451***: Yeah, I definitely agree with you. I think that, as you mentioned, 20, 30 years ago, there was a lot of misconduct that was happening in the industry. We know that there was ghostwriting, guest writing, guest authorship. There was no reporting of transfers of values to physicians, and that led to a lot of misconduct. Our industry was under a lot of scrutiny. And I think that folks who are new into the profession don't always know that background and know that history. Compliance teams really exist so that they can protect the company and protect the employees of that company and make sure that the publications that are coming out are transparent and compliant and follow those best practices that the industry has really established.

Cassie Stox ***05:38.037***: Thinking about now, 2024, there has been such an evolution in the role of compliance. So just wondering, what are some trends that either of you have been noticing in the industry?

Merry Saba ***05:56.404***: Well, I think first I would say that the industry is moving faster than our SOPs. We have a lot of good guidance out there. I think the GPP that came out in 2022 tried to address a lot of the evolving topics, but I think the foundation is there with GPP. But things like AI, when I think of not even a year ago when I was at the ISMPP annual meeting, the discussions there about AI and the use of AI, responsible use of AI, how that's evolved to what we talked about at the Academy in the fall to now. You know, it's really, it's moving fast. So I think on a lot of these newer initiatives, whether it's preprints or AI or any of the other publication tactics and strategies that teams are eager to use and to explore, we have to really remain very agile. So I don't know, Megan, what your experience has been with this?

Megan Weigel ***07:07.018***: Yeah, I think that you add such a great point that things are moving so much faster than the SOPs and the standards and the guidance documents can really keep up with. You know, a lot of the issues that I've observed are around, I mean, copyright is always a big one. That's not new, but it's always there. Like you mentioned the use of preprint servers, and that can have copyright implications tied in with it.

I think that there's also new challenges we see with different kinds of publication extenders, whether those are digital enhancements that are offered from a congress or a journal, as well as

even things like the plain language summaries and the involvement of patients as authors and things of that nature.

Cassie Stox ***08:04.289***: So as communicators are coming to you with extender ideas, are there common issues that you're seeing that you're running into that's hindering them from being able to use them? Or is it a bit of a variety of considerations?

Merry Saba ***08:24.626***: I think from my perspective, we would always want to ensure that whatever those digital extenders or enhancements, when they're being used, that they're always reflecting the content of the original publication. We never want to add extra, you know, data or extra things into those extenders that are not originally in that publication. And that, you know, they're already following the appropriate review and approval steps within that company.

Megan Weigel ***09:00.192***: I think one of the things that I see, too, is that there are some questions. The teams, right, they're just building their experience doing these. There are questions about what's the right review process for this. Who do I have to involve in this? Where can this live? How can people find it? Those are the kinds of discussions that we often have.

Cassie Stox ***09:26.223***: So thinking about, preparing for those kinds of conversations and those discussions, that dynamic between medical communicators and compliance, what are some ways that maybe medical communicators could think differently about that dynamic and how they come to compliance?

Merry Saba ***09:49.023***: Well, I would say, you know, bring us in early and have a discussion about these things. Because as I indicated, and I think this is true probably for Megan as well, we are not doing publications ourselves, right? We're the compliance people. I need to understand what some of these initiatives are that people want to pursue or are considering pursuing. because it, so it helps to have that discussion early on so we can talk about what the risks may be to doing certain activities so that I can fully understand what they want to deliver and to whom and how. I think it's really important to have those discussions up front.

I think sometimes people look at compliance as the police so they don't necessarily want to talk to us first. They figure maybe we'll catch them downstream. But it's always better to have those early conversations. Because I think our goal is to help our colleagues to be a resource. to sort of have that expertise in publications and good publication practice and share that with them. And they can share their knowledge about all the current trends in different types of publication extenders and different places that they plan to sort of go with their publications.

Megan Weigel ***11:27.565***: Yes, Merry, I think that we've laughed a lot about how sometimes folks can view us as the compliance police or, you know, that we're going to try to get them in trouble or catch them in something. And that's really not the role of a publications compliance person in a company. I think that they really exist in order to help their colleagues find a way to move forward compliantly with what they want to do, not to hinder them in doing something. We know that there's a lot of risk around the pharmaceutical industry as a whole, and publications

can be under extra scrutiny. So viewing your compliance counterparts as a resource to use rather than someone who's going to hinder you from moving forward, I think is a really good mindset shift to have.

Cassie Stox ***12:31.188***: I actually have some experience working with some of my clients on the agency side where we were trying to get some new and novel extenders or channels approved. And we saw lots of success by starting early and going in and talking to compliance. One of my goals was to just understand what those guardrails are from compliance so that we can go back and make tweaks. And we did have to make some adjustments. And I think that's important to keep an open mind, go in with the mindset that you want to collaborate and the role of compliance, we saw them as someone that's going to help us do what we want to do, but do it compliantly.

We had some success with that approach and we're able to work together to really adjust what we wanted to do to make sure it's compliant and then get it approved. And after we piloted that one channel with one asset, we now have a success that we can build on for other assets or other manuscripts as they come across. And we know we have a better idea now from the beginning of what our guardrails are and what we need to do to stay within those. Then again, that dialogue has been opened now with compliance and we can bring them in early. So yeah, we have seen success. I hope that others would also give this a try. Go in with an open mind and hopefully you would see success as well.

Merry Saba ***14:07.536***: As I mentioned earlier, I'm not in within the compliance department per se, but I'm sort of a pubs process expert. A lot of times, for these discussions, you may need to pull in different people. You may need to have someone from legal. You may need to have, in our case, someone from compliance. And just to make sure that everyone's aligned, that it's great to get the different perspectives. Because what I might perceive as a risk, someone else may not. They may be able to talk me out of it based on their experience. or just bring in different ideas. So having those discussions early on. And I'm finding that more and more we're seeing that with our publication leads within the organization, where they reach out proactively to try to understand how they can move forward with certain things, given the various things that are in our SOP and knowing what the environment's like.

Megan Weigel ***15:20.681***: Yeah, that's such a good point because there are certain times where if folks come too late in the process, that's when sometimes the answer might be a no. When folks come early on and they bring the compliance person in from the beginning and you have those discussions, you can kind of shape the process moving forward to be compliant. But when you come too late, sometimes you might be too far in the process. So, it makes it much more difficult to find a path forward. Like you've both been stressing, coming early and coming with all of the details and coming with an open mind is the best way forward.

Cassie Stox ***16:10.308***: We even have success treating it a little bit as a concept review, where you're coming in with, here's the channel, here's the asset, here's our concept that we want to do, and then think through all the considerations and make adjustments. So definitely

understanding all the details so you can answer all the compliance questions, but also kind of keeping it a little bit loose, understanding that there may be opportunity to make adjustments in the actual asset.

That was a situation we ran into. We wanted to use a different publication and we had to go back to the original manuscript instead. And so that was just, we needed that flexibility to understand compliance's view, but then also still fulfill on our goal for the project. If we were going to talk about any key takeaways or words of encouragement for our listeners, what would you offer from your perspective?

Merry Saba ***17:23.133***: I'll start. I think what we talked about early on, understanding a little bit of the history of scientific publications within the pharmaceutical industry, is important, so it's good to be educated on that so that you understand why compliance exists. We're not here to keep you from doing things, right? We're here to sort of facilitate keeping everyone on the quote, unquote, right path, right? So I think, first of all, understanding why compliance exists, and then also knowing within your organization, because every company and agency is set up differently, know who the pubs publication process experts are within your organization. So that if you do have a question, who owns the SOP? So you know who to reach out to if you have questions, if it's not crystal clear to you. I think knowing who those experts are within your own organization will help quite a bit.

And then, of course, know your own company's SOP. I don't think there's a lot of difference. I mean, from company to company, there's a lot of similarities, because I think that the SOPs, at least the ones that I've seen, are all built on good publication practice, ICMJE, and all the industry guidance for publications. But there will be slightly minor differences, right? So maybe it is some little change that's different from the company, let's say you worked at another company previously, and you find something a little different, but they're all very similar, but really know your company's SOP. And I have to say on a personal level, I really enjoy it when I get an email with a question, and they've sent a screenshot of the section of the SOP, and they're asking for clarification on that because it really shows that they're, first of all, they're doing their due diligence. They have a question about it. It might be something that we need to look to update in our SOP. So, it's really, for me, it's very gratifying to have people refer to the SOP. And then, of course, you know, knowing GPP and ICMJE, keeping up to date on those. For anyone who's developing publications or leading a publication team, I think those are critical.

Megan Weigel ***20:12.093***: Yeah, Merry, I think you hit most of the top points. The only thing I would add is just to say, view those publication compliance folks as a resource, not as someone who's going to hinder you or who's going to get you in trouble. Really utilize them. Go to them early, go to them often. They would rather have you come and ask the question, then come later and ask for forgiveness. So really create that relationship with them from the start and bring them in whenever you can.

Cassie Stox ***20:48.444***: Thank you, Megan and Merry. This has been a very interesting conversation, but we are out of time for today. If you're interested in more information about the

compliance aspect, please listen to the Navigating the Non-Negotiables InformED podcast released in March.

Thanks for listening to InformED from Medical Communication 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. Join ISMPP today to become part of our community, 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-.org to learn more. I'm Cassie Stox.