Innovation Drives Risk Mitigation in the Field: Guidance from a Compliance Expert

Executive Summary

In an effort to mitigate compliance risk, many life sciences companies have implemented policies that limit or restrict the ability for field reps to capture notes about their interactions with healthcare professionals. The stance against using "free text" can limit account plans' effectiveness, insights that can drive decision making, and opportunities to identify potential issues or violations.

Veeva interviewed Michael Shaw, an experienced compliance expert, for his perspective on how compliance can better enable business through technology that advances compliance management. Michael has over 25 years of experience in the pharma industry, including leadership roles in ethics and compliance at GSK and Novartis.

What is the role of a compliance executive in the pharma industry?

Compliance professionals have two areas of responsibility. One is to promote an ethical culture. The other is to oversee a framework of compliance controls.

To do that effectively, especially in pharma, you need to have a deep understanding of the business so you can understand the organization's strategy and objectives, then tailor practical compliance controls to support and enable the business to be as competitive and compliant as possible.

How do pharmaceutical companies ensure the field is compliant with policies?

When it comes to the field, other than policies and training, you want to have some way to confirm that people are following the policies. Ride-alongs are an effective means either for a manager or the compliance team, but you can't be with a representative at every interaction.

One thing compliance teams have done is to monitor field interactions through systems like Veeva CRM to review what's being captured in the post-call notes to see how those interactions are taking place. But one of the problems with enabling free text is that it opens the door to the human factor, which could result in careless documentation that creates risk. Even if you have the most legitimate, exquisite interaction between a pharma representative and a healthcare professional, if an individual is careless about how they document an interaction, it could look like something more violative took place. This documentation is enduring and could be used by prosecutors to conclude violations of policies or laws took place.

Accordingly, rather than taking the risk of permitting careless documentation in free text fields, some companies have chosen to either limit or eliminate free text.

Do you see a lot of organizations unlocking free text?

Yes, I do see it being more frequent. From personal experience from companies I have served and companies served by colleagues, I see more and more companies using it.

For companies that are still using drop-down boxes only, what's disrupting that approach in the marketplace?

If you limit or eliminate the ability for someone to capture what happened in an interaction, there will inevitably be unsanctioned ways that people will document what transpired.

No matter what business you're in when you go to a business meeting, someone will have a notebook to capture key discussion points, actions, and follow-ups from the meeting. Often, if you don't enable a free text option, people will capture the information in notebooks, phones, iPads, or apps in a decentralized and ungoverned way.

A number of different business objectives could require coordination across teams in the field that can necessitate a centralized mechanism to capture documentation about accounts and customers. If I were in the field, this would allow my teammates to know what happened in any given interaction, what the follow-ups will be, what to build on in the next discussions, etc. By unlocking this free text, you could deliver better customer service.

Another compelling reason is that pharma companies' insights and analytics groups are just getting bigger, more powerful, and more dynamic. I see the interactions being captured in the field as offering valuable insights to the company about the essence of the interactions taking place with healthcare professionals and accounts.

Finally, especially in the post-COVID-19 world, more digital interactions are taking place every day. Without monitored free text, it's particularly hard to create personalized emails to texts to doctors.

What are your thoughts on the manual monitoring of free text?

Historically, the way we have monitored free text notes was to pull a large sample of the notes multiple times a year and manually review them to see how policies are being followed. This sample could be as large as 100,000 post-call notes. The key challenge with this approach is that you can easily miss something important. A manual review of large quantities of notes is also a boring and burdensome job. Over time, I think manual monitoring of free text will be replaced by technology-enabled monitoring, assuming it is effective and affordable.

What about technology-enabled monitoring of free text like keyword matching or phrase matching?

That's changed the game for both enabling free text as well as enabling better compliance. The more targeted the word and phrase searches are, the better you can identify potentially problematic behavior.

That doesn't mean it's going to be perfect. There are always going to be false positives. However, technology reduces the workload it streamlines the backend process. It also allows you to monitor all free text entries in a targeted manner vs. just a sample.

How would you like to see monitoring capabilities advance in the future?

There are many nuances to off-label promotion risk. I do not believe we are in a Terminator 2 / Skynet kind of situation where the computers are going to become so smart that they're going to get the monitoring right every time. However, that learning could likely make targeting better and reduce false-positives. If artificial intelligence learns which words or phrases are rejected by compliance, legal, or business functions, then the artificial intelligence can hopefully learn, in those instances, and identify that type of language in the future. So, to me, that will do better on risk mitigation and business insights.

Technology could also provide some real-time coaching. Just as auto correct and suggestions for complete sentences with merely the beginning of a few words in email or documents, a similar function could be employed for CRM systems. So, think about a world where you're a field representative, you're typing up your interaction, and artificial intelligence reminds you to capture important information from interactions, highlight pull-through of strategic objectives, or flag potentially problematic behavior to be corrected with a healthcare professional? With more of that real-time response, you mitigate risk in real-time and minimize the kind of follow-up that needs to happen both on the compliance side and the business. I think that could be fantastic.

Also, I have been doing some work in behavioral science. I think the way prompts could work from a behavioral science standpoint is to reinforce the business objectives in those interactions. Getting these real-time prompts can be more useful to drive behavior change than if only done through policies or training or national sales meetings.

Any final thoughts?

I've always believed that monitoring should not be seen as a policing mechanism. It should be seen as an enabler. I can't tell you how many times in my last role that I heard the following, "Hey, we could do this new business practice only if we do backend monitoring on it."

So, in a way, companies are starting to be comfortable taking on certain business risks. And, when I say business risk, it really comes down to execution risk. The proposed activity is legitimate, but you still have to be careful because if executed poorly, significant risks may be tied to it. This punctuates our discussion about free text.

You can use free text in CRM systems to capture valuable insights and harness those insights. However, the human factor and execution risks are present. So, you need to do some kind of backend monitoring to make sure that people are capturing appropriate interactions consistent with company policy. Frankly, I get excited by the business insights that come with free text. So, I don't think it's just about compliance backend monitoring. I think it's bringing insights to the business in some kind of real-time fashion so business leaders can take action on trends, whether that's business trends or compliance risk.

Veeva Perspective

The ability to capture free text notes is essential for account coordination and critical to the future of commercial operations. Allowing free text notetaking without oversight is risky but restricting the field entirely from capturing notes can result in missed opportunities. Technology solutions, such as **Veeva CRM Approved Notes**, can help ensure compliance in an efficient way.

About Michael Shaw

Michael Shaw is a results-driven leader with a proven track record of leading compliance programs and major organization transformations. Michael is currently the Global Head of Risk & Compliance at ZS Associates, where he is helping clients unlock a new level of innovation, performance, and patient outcomes by better navigating risk. Michael has over 25 years of experience in the pharma industry, including roles as Vice President of Ethics and Compliance at GSK and Global Head of Ethics and Compliance at Novartis Oncology. Prior to entering the pharma industry, Michael was a Director in Pricewaterhouse Coopers' Global Pharma and Health Sciences Practice and was Senior Counsel with the Office of Inspector General of U.S. Department of Health and Human Services.