pharmacertify
by NXLevel Solutions

NOTES & NEWS

from the

Seventeenth Annual Pharmaceutical and Medical Device Compliance Congress

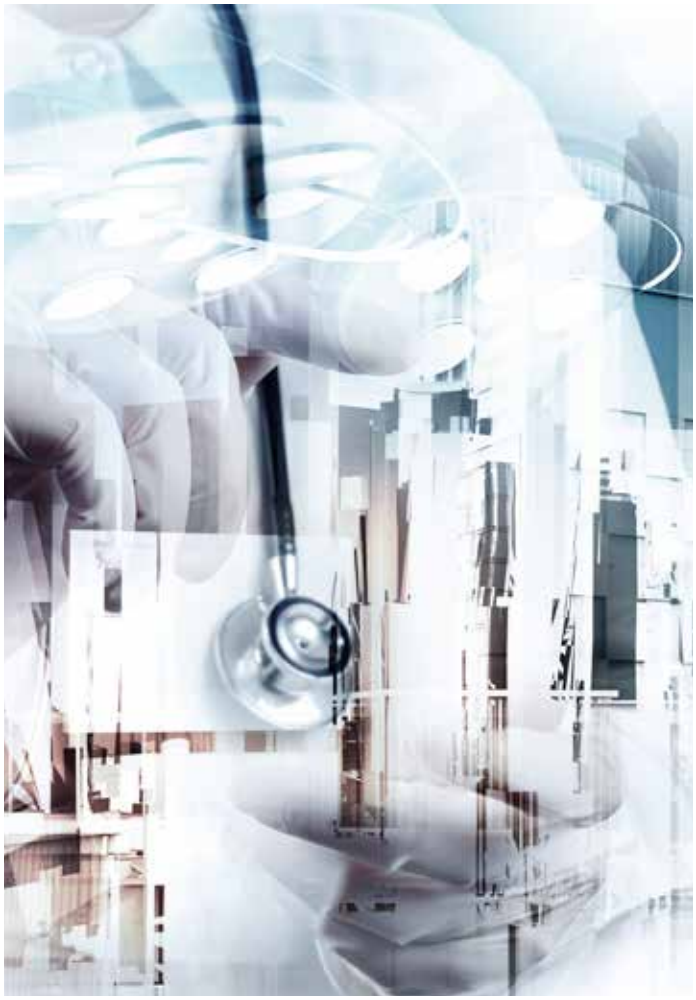
If the overriding theme of the *Seventeenth Pharmaceutical and Medical Device Compliance Congress* could be summed up in three phrases, they might be "partnering with the businesses," "a seat at the table," and "a principles-based approach to compliance." On that last one – note the change from "values-based approach" to "principles-based approach."

Watching recent conferences (and the industry in general) evolve to the point where these themes are at the forefront is refreshing and encouraging. As someone who has worked in life sciences compliance training for ten years, I've looked forward to the shift to an all-inclusive approach that considers all ideas and voices in the organization, and ultimately leads to the creation of more valuable and engaging compliance training. Below are a few of my observations and highlights from this year's conference. The conference organizers offer the opportunity to purchase an archive of individual sessions or the full conference at www.pharmacongress.com. You can preview video clips of those sessions at www.pharmacongress.com/post-con-individual.html.

CCO Roundtable

The *Chief Compliance Officer Roundtable* on Day 1 featured industry leaders sharing lessons on building and executing a modern and effective compliance program. The panel included representatives from both the pharmaceutical and medical device industries and the conversation focused on two concepts: the practice of thinking from a perspective of risk (the "gestalt of risk," as one panelist defined it), and the need to focus on what is meaningful to the business when developing and executing a compliance example. One speaker used the example of monitoring sample dates, and how that practice is not necessarily worthwhile to the business. That same panelist emphasized the need for hiring individuals with business experience when staffing compliance positions. Another looked at compliance training as what employees "should stop doing based on prioritized risk."

Finally, one panelist stressed "prevention" over "detection" and how his staff uses data analytics to help identify problems based on the area of risk. "Defining guardrails, and risk tolerance, is necessary to get out in front of the issues," he said.



FCPA Enforcement

During the FCPA Enforcement Panel, Joseph Beemsterboer, JD of the Department of Justice, Terry Price, JD of the SEC, and Gejaa Gobena, JD, of Hogan Lovells, discussed the growing number of cases related to the Foreign Corrupt Practices Act. To this point in Fiscal 2016, 24 FCPA cases have been filed, 6 of them against pharmaceutical companies. 85-90% of the 24 cases were related to conduct in China. Pharmaceutical and medical device industries represent such a significant portion of these cases because large numbers of their employees must interact with foreign officials, according to one of the presenters.

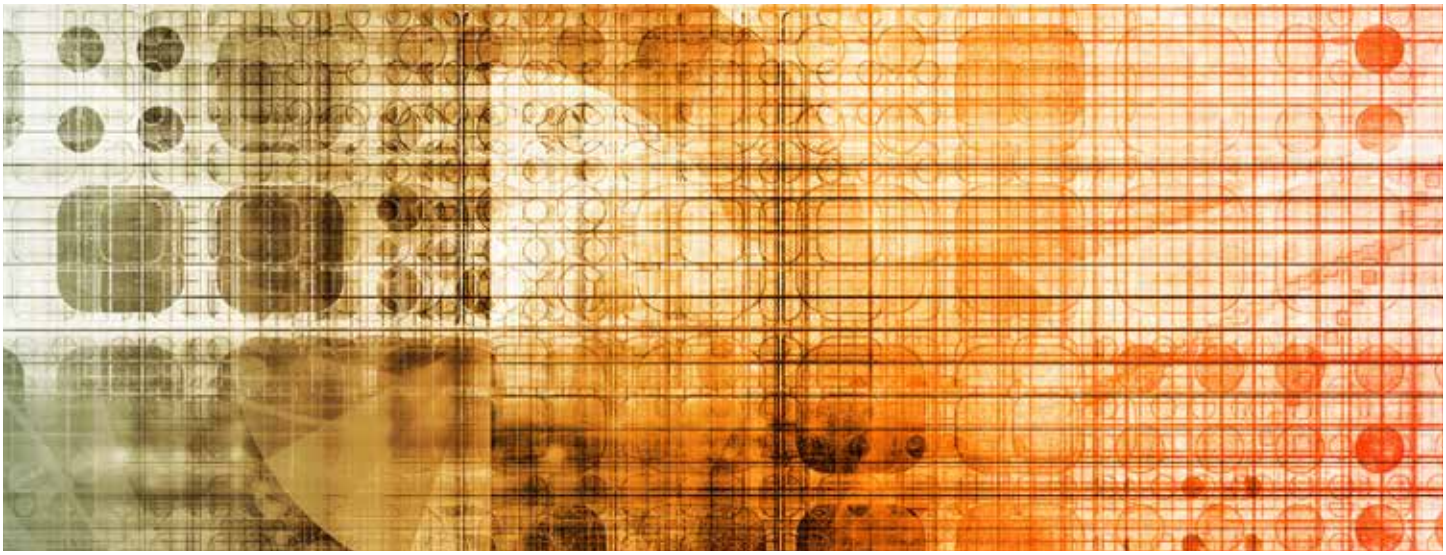
Anti-bribery

Day 2 opened with a much-anticipated session titled *Behind the Bribe: Multiple Real-World Perspectives on How Foreign Bribery Occurs, Is Investigated, and Could Be Prevented*. Regulators emphasized that anti-bribery remains an area of focus, "we are still seeing the same behaviors, and issues with gifts, travel, and entertainment," according to one panelist. The FBI representative made it clear that the Agency is "committed to going after global bribery" and the "storm that is coming" will focus on the prosecution of individuals. "Culture is critical," he said, "just publishing a video from the CEO doesn't cut it anymore."

The panel included former executive, Richard Bistrong, who spent time in prison for conspiring to bribe officials to win contracts from the United Nations, and spent 2.5 years as a government witness. Mr. Bistrong stressed the need for diligence as foreign cultures can be misleading. Distributors will often sign FCPA documents, then do something else in the practice. "Don't let get the business done, drown out how to get the business done," was one of his key points.

First Amendment Update

During the *Truthful and Non-Misleading Communications and Recent First Amendment Cases* session, a panel of industry attorneys discussed and debated the ambiguity regarding off-label promotion in FDA policy. After revealing the reasoning behind the FDA's policy (patient safety and advancement of science), a lively discussion led to speculation that the Agency's recent public hearing and announcement in the Federal Register signals gridlock and tension among leadership. This lack of direction is what led companies such as Amarin and Pacira to believe they needed to litigate their cases, according to one attorney. The session closed with the moderator asking each panelist if he or she thought the FDA would publish any clear guidance in the next year. The responses ranged from "I just don't know," to "highly unlikely," to "no, they're not." Don't expect clarification anytime soon folks.



Managed Markets

The *Compliance Considerations for the Managed Markets Business* opened with panelists first defining their definition of managed markets and how it differed for each of their companies. The bottom line was that no matter the particulars, it is defined as the functions responsible for "ensuring patients have access to the therapies the physicians write." One industry representative said her company defines healthcare professionals to include anyone paying for the products, and another included anyone who can influence prescribing decisions – making compliance policies and the regulations pertinent to the managed markets business.

The expanded movement to the use of specialty pharmacies creates more risk, according to the panel, and companies are thinking about those issues in more detail after Novartis' Corporate Integrity Agreement was made public. Pharmacy Benefit Managers (PBMs), Patient Assistant Programs (PAPs) and Reimbursement HUBs were covered as well, with the panelists stressing that government is starting to examine the relationships established through these entities, and companies need to be aware that laws never meant for managed markets are now being applied to that sector of the industry. As an example, one panelist mentioned, "the data that goes back and forth with charities is a risk area, and measures need to be put in place to ensure it is not used inappropriately by anyone involved with the data." The session ended with a compelling question from the audience, "how do you ensure copay cards aren't used for off-label purposes?" The answer came down to extensive monitoring to make sure that anyone who was supposed to be excluded was indeed excluded.

Compliance Training

As the compliance training division of NXLevel Solutions, the PharmaCertify™ team is always eager to attend sessions such as this conference's *What's New for Training Programs*. Since our mission is to help life sciences companies strengthen their compliance cultures and reduce risk, we are always encouraged to hear pharmaceutical and medical device professionals espousing techniques that support that goal. This session was no exception. While each company varied in the particular details, the panelists' remarks made it clear that a true movement toward a blended approach to compliance, spread across a learner's timeline, is growing. As one professional described it, "training to the right people, with the right content, the right amount of times."

While panelists varied on the degree of live training over computer-based training, most agreed that the use of small vignettes, or small "bursts of information," as one described them, are critical. The live training options included a Family Feud type game rolled out on a regular basis to streaming scenarios. The millennial generation was referenced, and the need for mentoring programs and live training that makes millennials' transition into the industry a more compliant one.

Training content was a focal point, with one panelist stating "you have to make the content relevant, so people can do their jobs," as he stressed the need to survey the learners on what else they actually want to learn about, along with questions about whether or not they feel more knowledgeable and if they have the support of their managers.

And let's not forget about culture and tone of the organization – at the top, middle, and bottom. For example, training needs to emphasize that employees should feel comfortable reporting violations and asking questions.

The PharmaCertify™ compliance training professionals and subject matter experts are always anxious to discuss your compliance training curriculum and plans. To discover how we can help evolve your approach to training, contact Dan O'Connor at doconnor@nxlevelsolutions.com or visit www.pharmacertify.com to learn more about our products and services.

Compliance 2.0

It's time for "partnering with the business" and "a seat at the table!" During the *Compliance 2.0: Shared Ownership of Effective Compliance Across Business Functions* presentation, six panelists (representatives from compliance and business) detailed case studies on how their companies made compliance concepts and programs more concrete and effective. Throughout each example, the importance of bringing the business into the planning from the start was stressed. One team who used the development of a new monitoring tool as their example said, "you have to know and understand the business in order to build a tool that meets their needs as well as your needs."

One particularly interesting panelist was recently added to his company's compliance team from the field, as part of the organization's efforts to foster a strategic relationship between the business and compliance. He represented a compelling example of how that type of program is an opportunity to "infuse ethics and compliance into the company when the business pulls him back," as he effectively put it. As another eloquently stated, "we have to raise our business partner's compliance IQ and we can't do that by ourselves."

"Access to leadership" was referenced as a key component of Compliance 2.0, as more than one panelist discussed the need for those involved to feel comfortable questioning everything from leadership as the initiatives got started.

> **"Transparency isn't just TOV data, it refers to sample data as well"**

Beyond Transparency

My final breakout session was *Beyond Transparency: HCP Interaction Risk Management*. The session was centered on the use of data and how the transparency data can be used to track issues, then leveraging the auditing results to enhance policies and create more training. One panelist addressed it succinctly when he said, "our goal is to get to the point to where we use data to identify issues faster." Another used the example of speaker programs and how the data could be used to raise questions about the number of times an individual HCP attended a speaker program, and raise the question of whether that was a concern.

The audience was reminded that "transparency isn't just TOV data, it refers to sample data as well, and there is a need to overlay sample data with TOV data to reveal more than occasional interactions with one HCP."

With representatives from both large and small companies on the panel, much of the discussion centered on the tools needed to keep the data organized and up-to-date. One panelist summarized it nicely, "when you do your hiring, make sure you find a person with excellent Microsoft Excel skills."

The Evolution of Compliance Training

The first presentation during the closing plenary session, *Driving the Evolution of Compliance Programs into Systems Supporting Business Integrity*, covered the oft-referenced theme of a "principles-based approach to compliance." Representatives from three different companies touted the benefits of moving away from a "rules-based approach."

As a foundation, in a principles-based system, decisions are not based on policy, but more on how individuals think and make decisions. "They need to be given the skills to make decisions," according to one Vice President of Compliance, and "they need to be empowered to make those decisions and it's a cultural shift for all stakeholders." This is approach requires "a high level of trust and respect by leadership for the rank and file," one panelist noted; and, he pointed out, writing shorter and more concise policies associated with such an approach takes discipline and time –quoting Winston Churchill, he referenced, "I would have written a much shorter speech if I had the time."

The shift isn't an easy one and the panelists stressed the need to "get leadership's buy-in and help them see that a rules-based policy was holding the company back and the new policy will help patients, caregivers, and shareholders." When an audience member asked "what kind of practical training would you offer to support such a shift," the panel responded with "go back to the guiding principles of honor, trust, and integrity."

Summary

While we weren't able to attend all the sessions at the *Seventeenth Annual Pharmaceutical and Medical Device Compliance Congress*, we couldn't help but be impressed with the level of content the conference provided to an audience hungry for any best practices and advice they could garner from their colleagues and subject matter experts. From a vendor standpoint, the foot traffic on the exhibit floor was steady and we appreciated the unique opportunity to engage current and prospective clients in meaningful conversation about their compliance programs and how we can help strengthen their compliance culture and reduce risk.

I welcome your thoughts and feedback. Please contact me at smurphy@nxlevelsolutions.com.

Thanks for reading and stay compliant!

Sean Murphy,
PharmaCertify™ Product and Marketing Manager