

News and Notes

from

CBI's 13th Annual Pharmaceutical Compliance Congress

CBI's [13th Annual Pharmaceutical Compliance Congress](#), held at the Ritz-Carlton in Washington DC, offered an impressive lineup of industry luminaries and government regulators discussing a wide range of compliance-related topics.

While some of the discussions didn't offer much in the way of groundbreaking information (tone at the top, embed compliance in the businesses, relationships matter, etc.), the concepts presented were critical for any attendees new to their role or the world of life sciences compliance in general.

Embed Compliance into Business Practices

There was the expected emphasis on the concepts of embedding compliance into business practices and gaining buy-in from the C-suite. One panelist even mentioned that when asked to join her current company, she insisted that she be a member of the North American leadership team and therefore have direct access to the business leaders. As another speaker put it, "relationships matter, and you have to speak the language of the businesses in their terms."

Tie Compliance to Incentives

One compliance officer from a small pharmaceutical company referenced the need to make sure sales incentive is tied to compliance, to make the concepts and policies more meaningful – a concept that was considered revolutionary in the industry just a few years ago. She added that sales management needs to own

the compliance metrics in order for there to be lasting and real change. The same global officer touched on the challenges of doing business globally and the need to have tough conversations about spending caps. "You will get pushback," she stressed, "but don't compromise. There's no need to take that kind of risk."

Transparency: Think Globally, Act Locally

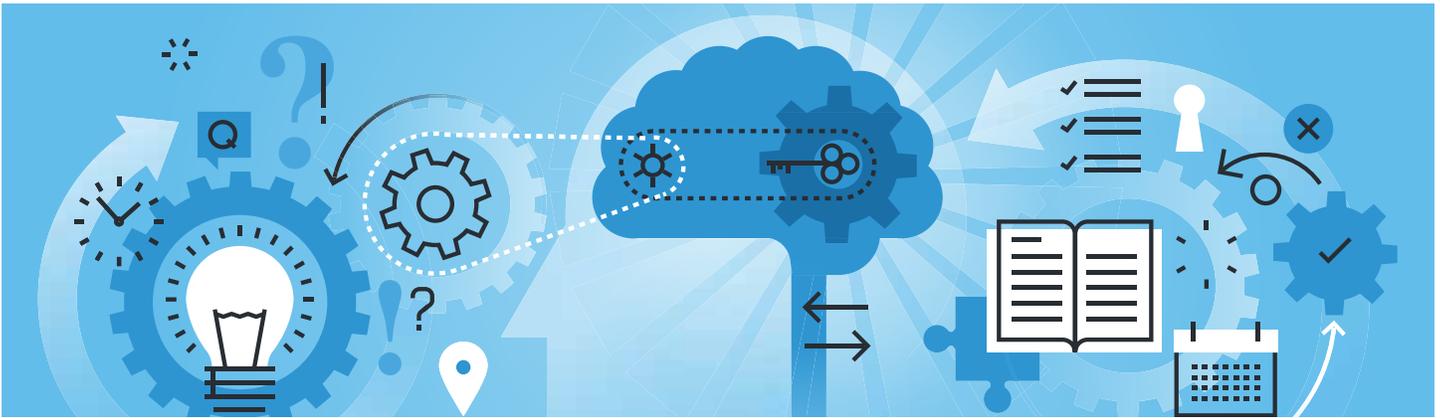
Continuing on the global front, presenters reviewed the merits and details of global transparency codes like EFPIA, while touching on upcoming movements toward laws and guidance. When dealing with global regulations and codes, the potential for confusion reigns. For example, when providing meals to HCPs from various countries, one panelist advised audience members to use the lowest common denominator for the meal limit, BUT, don't forget to take Loi Bertrand into consideration if an HCP happens to be from France.

In addition, panelists stressed that companies can't fall into the trap of thinking that because they are familiar with the rules around the Sunshine Act and Open Payments, they can roll right into global reporting. As one speaker from a large pharmaceutical company suggested, you have to look at it differently. "If you approach it like you approach Open Payments, your credibility will be challenged."



Yates Memo and Individual Culpability

Among the regulators and defense attorneys who spoke during the conference, one common theme was the Yates Memo, and the affect it has (or is some cases, doesn't have) on how investigations are conducted and cases prosecuted. The Memo, which is named for Department of Justice Deputy Sally Quillian Yates, was released in September of 2015. It [generally states that](#)



the DOJ will increasingly target individuals in corporate crimes. A number of the regulators stressed that while the Memo is significant in its scope, it will not necessarily change how their offices pursue pharmaceutical and medical device cases. During the U.S. Healthcare Fraud Enforcement Panel, one US Attorney said it “codifies what they have already been doing in her office” and another commented that he asks his prosecutors to always look at individual culpability in each case.

Innovations in Training

As a compliance-focused learning company, we at PharmaCertify™ pay close attention to presentations and commentary with a slant toward training. It’s been a slow process, but based on the information and concepts presented in this and other recent conferences, it’s clear to us that companies are integrating exciting and novel techniques into their curriculums. Innovative compliance departments are adding micro-learning solutions and app-based tools in an effort to raise the level of engagement among their learners, which is music to our ears.

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One company representative detailed the planning process and upfront analysis she and her colleagues conduct to ensure that training concepts meet the needs of the business as well as the compliance department. Once those needs are identified, they look for unique ways, including a healthy dose of humor, to make their messages stick. She and her co-presenter reviewed the details of the compliance app recently launched across the company, which uses self-produced video sequences, with compliance department employees as actors, to communicate the concepts. While we agree that technique can help to

“humanize” compliance, as we warned in [another recent blog post](#), you need to be careful that bad acting doesn’t distract from the important messages.

CASTING YOUR COMPLIANCE TRAINING VIDEOS

EMPLOYEES

VS.

PROFESSIONAL ACTORS

<p> Cost-effective</p> <p> Understand the language</p> <p> Builds rapport with audience</p>	<p>More convincing </p> <p>Employees stay productive </p> <p>Audience focused on message </p>
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THE VERDICT: IT DEPENDS

- Can you keep the scenes brief?
- Can you afford to pull employees away from core duties?
- Does your budget limit the use of professionals?
- Is the value of recognition worth the risk of bad acting?

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While this year’s Pharmaceutical Compliance Congress featured much of the same themes as recent conferences, the ever-evolving world of life sciences compliance always offers new twists and turns for those tasked with ensuring their individual companies remain in alignment with the latest rules and regulations. These conferences offer attendees the invaluable opportunity to learn best practices, tips, and updates directly from their peers and government regulators from around the world. They shouldn’t be missed.

See you at the next conference!