Setting the Stage: Ten of the Toughest Compliance Questions in Medical and Clinical Affairs

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Ten of the Toughest Questions

- What are the appropriate roles of Medical Affairs, the Legal Department, and the Compliance Department on drug safety and advertising issues?
- What about distribution of journal reprints by sales force personnel?
- Are preceptorships a valid sales training tool?
- What can and should companies do with respect to incentive compensation?
- What can and should companies do to separate educational and research grants sales and marketing?
- What has been the fallout from the NY Attorney General's investigation involving publication of clinical trial results?
- What can and should companies do to monitor and audit their medical and clinical activities?
- As manufacturers continue to respond to the trend toward a consumer-directed healthcare system, what are the risks and how can companies address these risks?
- What trends do you see with respect to compliance risks outside the United States?
- What are the new and emerging risk areas that companies will face 5 to 10 years from now?

Within a pharmaceutical manufacturer, what are the appropriate roles of Medical Affairs, the Legal Department, and the Compliance Department with respect to drug safety issues?

What are the appropriate limits with respect to the distribution of journal reprints by sales force personnel?

Are preceptorships a valid sales training tool or are they an inappropriate technique to build relationships with doctors and/or promote a company's products?

What can and should companies do with respect to incentive compensation and the risks this creates for inappropriate sales and marketing activities?

What can and should companies do to respond to the HHS OIG's suggestion that the award of educational and research grants should be separate from the sales and marketing function?

What has been the fallout from the NY Attorney General's investigation involving publication of clinical trial results?

What can and should companies do to monitor and audit their medical and clinical activities?

As manufacturers continue to respond to the trend toward a consumer-directed healthcare system, what are the risks for medical and clinical affairs and how can companies address these risks?

What trends do you see with respect to compliance risks outside the United States and what should companies do to address these risks? Can and should companies move to the adoption of "global" standards of conduct?

What are the new and emerging risk areas that companies will face 5 to 10 years from now?

"The views expressed during the course of this presentation are those of the participants and are not necessarily those of their respective companies/firms. Moreover, the comments of the participants provide general insights and do not constitute, and should not be relied upon, as legal advice."