

Pre-Seminar: Introduction to healthcare compliance in medical education activities

Hilton Copenhagen Airport Hotel, March 7, 14.00 – 17.00
In association with ETHICS

Learning Objectives:

- No detailed knowledge of healthcare regulation will be assumed.
- Provide a sound basis for understanding the regulatory and compliance requirements for healthcare companies which affect their support and participation in medical education, conferences and congresses, advisory boards etc.
- Provide insight and understanding into the reasons for the current high concentration on healthcare compliance by companies.
- Describe and explain the various codes and regulatory controls that may affect the activities of healthcare companies. Understand the implications for all parties (including congress organizers, medical societies, healthcare companies etc) involved in healthcare conferences and meetings.
- Submit your queries in advance so these can be covered during the session.

Recommended for:

- Pharmaceutical and medical device company staff who are new to working in the conference and meetings arena
- Medical society staff who interact with healthcare companies on arrangements for meetings
- Conference organising company staff
- Venue staff
- others involved in healthcare conferences

Tutors:

- Sue Egan (independent, ETHICS)
- Martin Hess-Janorschke (Roche, IPCAA)
- Dominique Laymand (ETHICS, Ipsen)
- Arthur Muratyan (ETHICS, Eucomed)
- Dave O'Shaughnessy (ETHICS, Quintiles)
- Paul Woods (independent, IPCAA)

Programme format:

- There will be 3 sessions of approximately 1 hour each.
- In each an introductory presentation will be given by one of the tutors followed by an interactive discussion between delegates and the tutors.
- The discussion will be based on the subject matter of the presentation and will incorporate queries and topics which delegates will be invited to submit in advance of the meeting.
- Pre-prepared scenarios will be utilized in the discussion session to illustrate the practical application of rules and procedures.
- The tutor who developed them will introduce the scenarios.
- All tutors will contribute to all sessions.

Session Overview:

Session 1 - **The Why, What and How of healthcare compliance**

- o Why Compliance Programmes and organisations have developed so much over recent years?
- o Why is this area so important to the healthcare industry and why are meetings (congresses/ medical education/ advisory boards etc) a special focus for compliance and ethics programmes?
- o What, in essence, is an industry compliance programme and how does it affect other players in the healthcare education world?

Session 2 - **Who's Who? The pieces of the jigsaw**

- o Describe the various bodies, codes and regulations that affect company involvement in the meetings and medical education sector.
- o Introducing different bodies like EFPIA, Eucomed (Ethical MedTech), IFPMA, national codes, etc...and talk about Self-Regulation etc...
- o Cover key laws and regulation European (advertising, competition) and national (bribery act, FCPA). Explain why these are important and what practical influence they have on meetings

Session 3 - **What's hot and why?**

- o This session addresses specific questions delegates would have submitted in advance and some 'hot topics' in Compliance today.
- o Rather than tackling the latest developments and the fine points of contention (which will be covered in the main seminar) we will step back and describe why these issues are important and how we have come to the current positions.