



2023 PCF Annual Members Meeting

Intercontinental Hotel Times Square, NYC

Pre-Meeting Workshops – March 6, 2023

Advance Registration is Required

Pending Compliance Certification Board (CCB) Credits

Workshop # 1:

Compliance 101 Bootcamp

12:00- 5:00pm

New to Compliance? Want a Refresher in US Healthcare Compliance? Come join us!

Gain a foundational overview of the U.S. regulatory landscape, the healthcare laws & regulations which govern the pharmaceutical industry. Understand the compliance program framework through the review of the OIG's seven elements of an effective compliance program. Discuss ways to measure compliance effectiveness through monitoring and risk assessments. Participate in Case Study review and discussions.

Hear practical approaches and lessons learned from our experienced PCF Member Faculty

Don Carter

Former Director, Commercial Compliance, Alnylam Pharmaceuticals

Terri Ledva, MS

Chief Compliance Officer, Aurobindo

Erica Powers

Head of US Commercial Compliance and Compliance Operations, Sage Therapeutics

Workshop # 2:

Countdown to Launch: A Compliance Readiness Product Playbook

1:00- 4:30pm

In this session we'll provide a roadmap which compliance teams can use when supporting the launch of a new product or entering a new therapeutic area no matter the size or maturity of your company. You'll walk away with a practical list of tactics for before, during and after the launch to ensure you are proactive and prepared to support your business partners.

Topics areas to be discussed:

- How and what to consider when engaging with business partners for a new product launch or new therapeutic area with/without co-promotion partners
- How to perform a compliance and risk analysis of a new product and related business tactics, with examples across different types of products
- Creating your list of compliance tactics before, during and after launch
- What compliance controls need to be in place and how will this be measured
- Understanding nuances to be considered based on the maturity of your organization
- How to communicate up and out about your plan to get the support you need

We will also dig into a few of the more complex issues, including the introduction of new field-based roles, new patient support models, and navigating in the rare disease space

A compliance checklist will be provided to all attendees for reference after the workshop.

Terra Buckley, JD

Vice President, Head of Compliance Advisory Services, MedPro Systems

Vice President, Head of Compliance, Mesoblast

Dhara Moro, CPA, CFE

Associate Director, Compliance, Sage Therapeutics

Ed Sleeper

Former Global Ethics & Compliance Officer, HUTCHMED