



6TH ANNUAL LIFE SCIENCES

COMPLIANCE CONGRESS FOR SPECIALTY PRODUCTS

Emerging Trends, Best Practices and Benchmarking for Managing Risks Associated with Complex, High-Touch Therapies

September 22-24, 2020 • Boston, MA

The life sciences industry's must-attend conference catered to the unique legal and compliance challenges for specialty pharmaceutical companies focused on rare, ultra-rare and orphan diseases.

FEATURING ALL-NEW AND BETTER-THAN-EVER CONTENT!

**Invitation-Only Legal
and Compliance
Leadership Summit**

**Pain Points Roundtable —
Small group discussions based
on company size and maturity**

**Specialty Pharma
in the Digital Health Era
Panel Discussion**

**Cell and Gene Therapies
Learning Lab — What does
compliance need to know about
these breakthrough therapies?**

JOIN THE COMPLIANCE COMMUNITY FOR DYNAMIC DISCUSSIONS ON:

- Enforcement trends surrounding specialty pharma and biotech companies
- Patient interactions — Shedding light on potential gray areas
- Weaving compliance into the organizational culture from the beginning and during transitions
- Legal issues surrounding disease state education and pre-launch activities
- Current and pending state drug pricing issues
- Advanced strategies in monitoring and auditing
- Compliance training with limited resources
- Key considerations for charitable donations and grants
- Ensuring compliance in value-based contracts
- Global compliance programs and high-risk markets
- Evolving state pricing transparency requirements



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AGENDA AT-A-GLANCE

DAY ONE • TUESDAY, SEPTEMBER 22, 2020

12:00 *Conference Registration and Continental Breakfast*

1:00 *Co-Chair's Welcome and Opening Remarks*

1:15 **Advisory Board Panel • A Conversation Around the Future of the Biotech Industry in Boston**

2:00 **Industry Roundtable • Overcoming Limitations to Build Ethics and Integrity into the Heart of the Organization**

2:45 *Networking and Refreshment Break*

3:15 **CHOOSE BETWEEN TWO COMPREHENSIVE BREAKOUTS (A-B)**

A. Scaling Up Compliance Operations for the Business's Expanding Global Aspirations

B. Best Practices for Disease State Awareness and Other Pre-Launch Activities

4:00 **CHOOSE BETWEEN TWO COMPREHENSIVE BREAKOUTS (C-D)**

C. Standardizing Global Compliance Monitoring and Auditing Best Practices

D. Key Strategies for Preparing for Product Launch Day One

4:45 *Close of Day One | Welcome Reception Commences*

DAY TWO • WEDNESDAY, SEPTEMBER 23, 2020

8:00 *Continental Breakfast*

8:45 *Co-Chair's Review of Day One*

9:00 **Highly-Acclaimed Enforcement Panel • Prosecutor Perspectives — Zero in on High-Priority Areas for Biotech and Specialty Pharma**

10:00 *Networking and Refreshment Break*

10:30 **Transparency and Aggregate Spend — Expansion of the Sunshine Act**

**Invitation-Only
2nd Annual Legal & Compliance
Leadership Summit**

11:15 **Federal and State Drug Pricing Transparency Legislation — What's New and What to Do**

12:00 *Networking Luncheon*

AFTERNOON DEEP-DIVE — NAVIGATE THE RISKS AND REWARDS OF SUPPORTING AND PARTNERING WITH PATIENTS

1:15 **Patient Interactions — Assessing the Nuances and Building in Safeguards**

2:00 **Overcome the Hurdles of Patient Advocacy and Education**

2:45 *Networking and Refreshment Break*

3:15 **Smaller Populations, Bigger Risks — Protecting Patient Privacy**

4:00 **Gain Insights into Tightening Controls for Patient Assistance Programs and Support Services**

4:45 *Close of Day Two | Welcome Reception Commences*

DAY THREE • THURSDAY, SEPTEMBER 24, 2020

8:00 *Continental Breakfast*

8:30 *Co-Chair's Review of Day Two*

8:45 **Panel Discussion • Wearables, Apps and Social Media — Specialty Pharma in the Digital Health Era**

9:30 **Cell and Gene Therapies Learning Lab — Compliance Considerations for Highly Complex, Potentially Curative Treatments**

10:15 *Networking and Refreshment Break*

10:45 **Specialty Café and Conversations • Forecasting Top Risk Priorities for 2021 Based on Your Company's Size and Maturity Level**

12:00 *Networking Luncheon*

1:00 **Proactive Approaches for Field Force Compliance**

1:45 **Ramp up Resources for Mergers, Acquisitions and Joint Ventures**

2:30 *Final Thoughts and Close of Conference*

SIX YEARS OF POWERFUL PROGRAMMING FOR THE INDUSTRY:

“The speaking faculty scope and depth provided an outstanding view of specialty compliance risks and tools to minimization.”

— Director, Government Programs and Commercial Compliance, **Prometric Biotherapeutics**

“I found the agenda and panel discussions highly informative and relevant.”

— Ethics & Compliance Officer, **Merck**

“This is the only conference that focuses on compliance for specialty products. The unique forum provides a great opportunity to share best practices and benchmark programs.” — Chief Compliance Officer, **Haemonetics**

“Excellent content and presentations. The presenters were well informed and facilitated thoughtful conversations with audience members. I will be back!”

— Associate Director, Compliance Operations, **Helsinn Therapeutics**

“Great information for someone starting out in specialty pharma.”

— Associate Director, Compliance, **PTC Therapeutics**

WHO SHOULD ATTEND

You will benefit from attending this conference if you work at a specialty pharmaceutical or biotech company and have responsibilities in the following areas:



This conference will also benefit law firms, consultants and service providers focused on compliance.

Want to Get Involved? Meet the #SpecialtyCompliance Team:

Speaking Opportunities:



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**Disclaimer: This is preliminary conference information. Topics and agenda are subject to change without notice. For up-to-date information, visit www.cbinet.com/specialtycompliance.*