



02
Days



Inspiring Keynote



Case Studies



**Multiple
Tracks**



20+
Speakers



FDA Presentation



25+
Key Areas



Expert Panel Discussions

ComplianceOnline Pharma Summit 2016

Risk Control & Compliance

Philadelphia, PA | June 16-17, 2016

ComplianceOnline
PHARMA
SUMMIT 2016

SPEAKERS



Tom Loker

Businessman | Author | Speaker, Startup Consultant and Advisor SYDK.ORG, Contributor to California Political Review



Michele Sharp

Sr. Director Regulatory Affairs at Eli Lilly and Company



Robert Popovian

Sr. Director, US Government Relations at Pfizer Pharmaceuticals



Josh Stein

CEO & CO Founder, AdhereTech



Darin Oppenheimer

Regulatory Affairs Expert, Global Medical Device Regulations & Licensure Authority, Strategic & Engaging Leader, Baxter Healthcare Corporation



James Vachon

Associate Director, Takeda Pharmaceuticals International Co



John Kelly E

Healthcare, Compliance and Government Investigations Attorney at Bass, Berry & Sims



Jeff Gibbs

VP Internal Audit (Chief Audit Executive) at Biogen Idec



Dr. Ron Weissman

Chairman, Software SIG, Band of Angels



Terri Jollymour

Sr. Director, Operations Readiness & Convergence Johnson & Johnson Corporate Supply Chain Quality & Compliance



Rick Williams

Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics

AGENDA

DAY 01 - JUNE 16, 2016

Note: This program may be subject to alterations and additions.

08:00 - 09:00 am	Registration and Breakfast
09:00 - 09:05 am	Intorduction to ComplianceOnline & Summit
09:05 - 09:30 am	Future of Healthcare, NOT Embodied by Government Reform - Inspirational Keynote Thomas Loker Businessman Author Speaker, Startup Consultant and Advisor SYDK.ORG, Contributor to California Political Review
09:30 - 10:00 am	FDA Approval Licensing Process for Products Containing Novel Adjuvant FDA Invited
10:00 - 10:30 am	FCPA and Internal Control Issues Across Pharmaceutical Industry John Kelly E Healthcare, Compliance and Government Investigations Attorney at Bass, Berry & Sims
10:30 - 10:45 am	Networking Tea/Coffee Break
10:45 - 11:15 am	Drugs Patent & Trademark FDA Invited
11:15 - 11:45 am	Pharmacovigilance Audit Strategy
11:45 - 12:15 pm	Risk-Based Monitoring Implementation FDA Invited
12:15 - 12:30 pm	Sponsorship & Speaking Opportunities
12:30 - 01:30 pm	Lunch Break

TRACK A - SESSIONS

TRACK B - SESSIONS

01:30 - 02:10 pm	Drug Safety Regulatory Update and Outlook	Demonstrating Value to Attract New Investments Dr. Ron Weissman Chairman, Software SIG, Band of Angels
02:10 - 02:50 pm	Process and SOP Compliance Darin Oppenheimer Regulatory Affairs Expert, Licensure Authority, Strategic & Engaging Leader, Baxter Healthcare Corporation	Challenges Associated with Stakeholders Amidst Mergers & Acquisitions Rick Williams Partner, Newport Board Group New England Practice, Chairman of Point Care Technology, Board member of Amorphex Therapeutics
02:50 - 03:05 pm	Networking Tea/Coffee Break	Networking Tea/Coffee Break
03:05 - 04:00 pm	Vendor Governanace / Supply Chain Management	

DAY 02 - JUNE 17, 2016

Note: This program may be subject to alterations and additions.

 08:00 - 09:00 am Breakfast and Networking

 09:00 - 09:50 am **FDA's View on Domestic Manufacture of APIs in the Country**
FDA Invited

 09:50 - 10:35 am **Quality System Management and Changing Regulations**
Michele Sharp
Sr. Director Regulatory Affairs at Eli Lilly and Company

 10:35 - 11:05 am **eHealth System**

 11:05 - 11:25 am Networking Tea/Coffee Break

 11:25 - 11:55 am **How Does the FDA Monitor Off Label Drug Administration**
FDA Invited

 11:55 - 12:10 pm **Sponsorship & Speaking Opportunities**

 12:10 - 12:30 pm **Clinical Trials--Assessing Safety and Efficacy for Diverse Population**

 12:30 - 01:30 pm Lunch Break

TRACK A - SESSIONS

TRACK B - SESSIONS

 01:30 - 02:15 pm **Standardizing Packaging & Labelling Globally**
Robert Popovian
Sr. Director, US Government Relations at Pfizer Pharmaceuticals

Cloud Based Drug Design & Development
Josh Stein
CEO & CO Founder, AdhereTech

 02:15 - 03:00 pm **Auditing R & D - Key Risk Areas in Preclinical Development Clinical Development, including Use of CRO's**

Evolving Payment Models and Regulatory Consideration
James Vachon
Associate Director, Takeda Pharmaceuticals International Co.

 03:00 - 03:20 pm Networking Tea/Coffee Break

 03:20 - 04:00 pm **Current Challenges with Orphan Drug Development**

Strategic Survey for "ComplianceOnline Pharma Summit 2016 – Risk Control & Compliance":

We are seeking suggestions from the pharma/biotech community in preparation for the Agenda of this Summit. This survey asks your opinion on what's important to you and what we should include.

[Click here to start the survey!](#)

Registration Form

Registration Information:

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Summit: ComplianceOnline Pharma Summit 2016 - Risk Control & Compliance

Date & Location: Philadelphia, PA | June 16-17, 2016

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