

ARTIFICIAL INTELLIGENCE for Life Sciences Compliance

Modernize Compliance Programs, Risk Management, Data Privacy and Analytics

June 3-4, 2024 | The Inn At Penn | Philadelphia, PA

Essential Discussions

- · Create a culture of ethics and compliance in the age of AI
- Examine Al implementation across discovery, development and commercialization
- Identify data privacy risks and Al governance strategies
- Monitor legislative changes regarding data privacy, ethics and bias and liability
- Modernize risk identification and compliance monitoring
- Realize the potential of predictive analytics

Featured Speakers



Vice President, General Counsel,
Compliance and Privacy Officer
Align Technology



Christie Dougherty
Associate Director, Ethics &
Compliance, Global & US Privacy,
Alnylam Pharmaceuticals



Rebekah Latchis Global Chief of Staff, Governance & Planning, Office of Ethics and Compliance



Amie Phillips Pablo Vice President Corporate Compliance & Privacy Officer Novo Nordisk



Amy Wilson
VP, Chief Compliance Officer
Esperion



Alicia Opal-Bonaire Vice President, Head of Compliance Sumitomo Pharma America



Timothy Roberts
US Compliance &
Privacy Officer
Ferring Pharmaceuticals



Bill Reid
Security Advisor to Healthcare
and Life Sciences,
Office of the CISO
Google Cloud



Distinguished Speaking Faculty



Conference Chair
Gina Nese
Vice President, General
Counsel, Compliance and
Privacy Officer
Align Technology



Rebekah Latchis Global Chief of Staff, Governance & Planning, Office of Ethics and Compliance **Medtronic**



Amy Wilson VP, Chief Compliance Officer **Esperion**



Timothy Roberts
US Compliance & Privacy
Officer
Ferring Pharmaceuticals



Stan Kachnowski Director, Digital Health Program Columbia Business School



Christie Dougherty Associate Director, Ethics & Compliance, Global & US Privacy Alnylam Pharmaceuticals



Arjun Arora Principal Consultant **Socha Solutions**



Robert A. Wells Shareholder Baker, Donelson, Bearman Caldwell & Berkowitz, PC



Sarina Rivera Associate General Counsel **Genentech**



Isha Arora Founder & CEO Ingen



Amie Phillips Pablo Vice President, Corporate Compliance & Privacy Officer **Novo Nordisk**



Alicia Opal Bonaire, Vice President, Head of Compliance Sumitomo Pharma America



Bill Reid Security Advisor to Healthcare and Life Sciences, Office of the CISO Google Cloud



Lauren Hickson Associate Compliance Officer, Global Risk, Analytical and Operational Excellence **AbbVie**



Sean Collins Global Transparency Lead argenx



Joel Nichols Senior Vice President, Digital Systems **Tessera Therapeutics**



Mike O'Connor Partner **Helio**



WHY ATTEND

ARTIFICIAL INTELLIGENCE for Life Sciences Compliance is a groundbreaking event for compliance and privacy peers to exchange perspectives on the challenges and opportunities involved in managing expanding responsibilities and priorities in the era of Al. It provides upto-the-minute information about how AI is being leveraged across life sciences and the impact of rapidly evolving legislative developments. This is an Indispensable opportunity to strategize tactics to modernize compliance programs, risk identification and predictive analytics.

WHO ATTENDS

- Compliance
- Ethics
- General Counsel
- Data privacy
- Data analytics
- · Data security
- · Data integrity
- · Compliance monitoring
- HCP engagement
- Risk management
- · Artificial intelligence
- Auditing
- Legal/regulatory





















DAY ONE, JUNE 3, 2024

8:30 Conference Chair's Introduction and Welcome
Gina Nese, Vice President, General Counsel, Compliance and Privacy Officer,
ALIGN TECHNOLOGY

8:45 PANEL- Create a Culture of Ethics and Compliance in the Age of Al – Part 1

Exchange perspectives on how to manage expanding responsibilities and priorities in the era of Al.

- Assess the impact of AI implementation on compliance roles
- · Identify current, evolving challenges
- Discuss the vision for keeping organizations safe while embracing innovation

PANELISTS:

Rebekah Latchis, Global Chief of Staff, Governance & Planning, Office of Ethics and Compliance, MEDTRONIC

Amy Wilson, Vice President, Chief Compliance Officer, **ESPERION** Timothy Roberts, US Comp liance & Privacy Officer, **FERRING PHARMACEUTICALS**

9:45 Update on Al Implementation in Pharma, Biotech and Medical Device

Gain an understanding of how AI is being leveraged across life sciences.

- Explore where Al technologies are being utilized across drug discovery, development and commercialization
- Examine areas of successful Al implementation
- Discover the potential for future innovation

Stan Kachnowski, Director, Digital Health Program, COLUMBIA BUSINESS SCHOOL

10:30 *Networking Refreshment Break*

11:00 Modernize Your Compliance Program With Al

A growing number of priorities can take compliance officers away from concerns of higher value that deserve greater attention. Learn about the potential to leverage artificial intelligence to automate efficiencies in compliance monitoring, risk identification, training and more.

- Highlight the efficiencies that AI can bring to compliance monitoring
- · Identify and mitigate risk in real time
- Open up new pathways of communication with business partners
- Assist with delivery of relevant training on existing and new policies
- Understand what OIG is looking for

Mike O'Connor, Partner, HELIO

11:45 **CO-PRESENTATION | Identify Data Privacy Risks and Al Governance Strategies**

While responsible AI principles inform governance frameworks, turning those principles into practice remains challenging. This session discusses compliance, privacy risks, and responsible AI governance strategies using real-world examples.

Identifying compliance & privacy risks

- Leverage existing policies and procedures as part of the foundation for Al governance
- Put policy to practice: chatbots, talent acquisition, localization, and more

Christie Dougherty, Associate Director, Ethics & Compliance, Global & US Privacy, ALNYLAM PHARMACEUTICALS

Arjun Arora, Principal Consultant, SOCHA SOLUTIONS

12:30 *Networking Luncheon*

2:00 Legal and Regulatory Update on Al Policies Impacting Industry

The current legal and regulatory landscape around Al in life sciences will evolve rapidly. Find out about current and potential areas for rapidly evolving legislative developments

- Unravel EU AI Act
- Explore FDA regulatory framework for AI
- Monitor legislative changes regarding data privacy, ethics and bias and liability

Robert A. Wells, Shareholder, BAKER, DONELSON, BEARMAN, CALDWELL & BERKOWITZ, PC

2:45 INTERACTIVE DISCUSSION GROUPS

Optimize peer-to-peer learning by crowdsourcing solutions to common challenges surrounding AI in life sciences compliance. The connections you make will become a valuable takeaway.

Group 1 Leverage AI for Compliance Monitoring and Risk Identification

Compliance monitoring will evolve with the dynamic nature of new technology implementation.

- Evaluate needed changes to current monitoring and auditing
- Use dashboards to rapidly act on risk identification
- Examples of current use of AI for enterprise-wide risk identification
- · Leverage monitoring data for decision making

Group 2 | Establish IP Protections for Inventorship and Ownership

- Recognize potential legal liabilities regarding innovation and IP.
- Determine impact of AI on IP
- Anticipate varying needs for future IP protections

Group 3 | Pinpoint Data Privacy Risks and Methods to Protect the Confidentiality of Patient Data

Take the opportunity to brainstorm around analyzing data acquisition, collection and monitoring to ensure patient safety.

- Underscore sources of bias in AI regarding data collection
- · Address anonymization of sensitive data
- Grasp protection for patient data, data rights and consent

3:45 Networking and Refreshment Break



4:15 **Drive Digital Transformation While Ensuring Compliance and Security**

New data models and artificial intelligence are enabling innovation in drug discovery at a rapid pace and most things are a work in progress. Obtain insight into evolving data strategy, data sources and security.

- · Find out how AI is being used in R&D
- What are the key structural components that are needed to make an AI strategy successful
- Consider realistic expectations for transformative change and how that may impact ethics and compliance

Joel Nichols, Senior Vice President, Digital Systems, TESSERA THERAPEUTICS

5:00 Close of Day One

DAY TWO, JUNE 4, 2024

9:00 Conference Chair's Opening and Review of Day One Gina Nese, Vice President, General Counsel, Compliance and Privacy Officer, ALIGN TECHNOLOGY

9:15 Create a Culture of Ethics and Compliance in the Age of AI - Part 2

Continuing the discussion which began on the first day of the conference, dive deep into considerations for modernizing compliance management.

- Gain approaches for changing compliance policies to reflect AI
- Communicate tenets of ethics and compliance culture throughout the organization
- Integrate your company's core mission with Al implementation

Panelists:

Sarina Rivera, Associate General Counsel, **GENENTECH**Amie Phillips Pablo, Vice President, Corporate Compliance & Privacy Officer, **NOVO NORDISK**

Alicia Opal Bonaire, Vice President, Head of Compliance, SUMITOMO PHARMA AMERICA

10:15 **Governance Practices to Manage Security, Privacy and Compliance Risks of Al**

New risks will continue to emerge surrounding the use of AI. Explore frameworks and support for identifying and managing risks.

- Identifying and classifying emergent AI risks within Life Sciences
- Explore a framework, Secure AI Framework (SAIF), as a means to organize the governance approach
- Illustrate this governance model with an example use case
- Appraise AI in software as a medical device
 Bill Reid, Security Advisor to Healthcare and Life Sciences, Office of the CISO,
 GOOGLE CLOUD

11:00 Networking Refreshment Break

11:30 PANEL Improve Compliance Programs With Predictive Analytics and Risk Management

Realize the potential of AI to enhance predictive analytics for next gen compliance programs.

- Understand the benefits of predictive analytics
- Discuss ideas for offering insights that provide more comprehensive risk management
- Assess compliance risks on a prospective basis

Panelists:

Lauren Hickson, Associate Compliance Officer, Global Risk, Analytical and Operational Excellence, ABBVIE

Isha Arora, Founder & CEO, INGEN

Sean Collins, Global Transparency Lead, ARGENX

12:15 Networking Luncheon

1:30 Modernize Your View on Data Technology Infrastructures

Digital technology roadmaps are changing to incorporate generative and traditional Al. Gain perspective on how these changes shift the view on business decision making and compliance programs.

- Examine compliance issues related to data collection and management
- Assess potential initiatives to guide compliance excellence and data integration
- Investigate ideas for monitoring data integrity and privacy

2:15 PANEL-Prepare to Report to Tech Committees and Audit Boards

Compliance and privacy executives are familiar and experienced with internal and external reporting. Learn more about how to prepare for and keep pace with increasing demand for communication related to Al and compliance.

- Discuss evolving need for reporting
- Determine which new parties may require information
- Examine what type of information boards and committees are looking for

PANELISTS:

Gina Nese, Vice President, General Counsel, Compliance and Privacy Officer, ALIGN TECHNOLOGY

3:00 Close of Conference

CO-LOCATED WITH

The 3rd Transparency and Aggregate Spend Summit



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