SESSIONS

DAY 1 ✦ TUE, JUN 22ND

IQVIA Solution Summit

9:30am - 10:00am
Industry Only Solution Summit A

IQVIA has transformed the commercial compliance space with its innovative offerings. Beyond HCP Engagement Management, FMV, and Transparency Reporting technologies, our subject matter experts deliver comprehensive consulting and managed services. Join the IQVIA Commercial Compliance Consulting team and hear how our team of global experts can provide insightful guidance and support for Strategy & Analytics, Fair Market Value, Transparency Reporting, and more.

Participants

Samantha Hoffman - Associate Director, Client Services, IQVIA

John Moose - Principal, IQVIA

Mario Prohasky - Principal, IQVIA

Justin Will - Global Commercial Compliance Consulting and Managed Services Practice Leader, IQVIA

Johan Holm - Director, U.S. Transparency, Managed Services, IQVIA

Baker Tilly Solution Summit

9:30am - 10:00am
Industry Only Solution Summit B

Establishing fair market value (FMV) compensation is an essential activity for life sciences companies when complying with various global anti-bribery and anti-kickback regulations. Join Baker Tilly for an informative demonstration of fmvNOWTM, an online, on-demand fair market value (FMV) rate tool that helps life sciences companies quickly and accurately determine compensation rates for healthcare professionals and other stakeholders. Baker Tilly will be demonstrating this new tool that gives users access to country-specific FMV rates on-demand, provides regulatory and industry association guidance (where applicable), converts rates from a country's local currently to U.S. dollars or Euros, relies on documented methodology that is defensible to regulatory inquiries, and gives users access to Baker Tilly FMV specialists.

Participants

Mark Scallon - Principal, Baker Tilly US, LLP

Samantha Sutherland - Senior Manager, Baker Tilly

Darren Jones - Principal, Baker Tilly

Informa Connect and Chairperson's Welcoming Remarks

10:00am - 10:15am

Participants

Allie Spica - Senior Conference Producer, Informa Connect

Andrea Kocharyan - Vice President, Head of Legal & Compliance, Zealand Pharma US

Keeping Up with Industry Trends — Top Compliance Concerns Facing CCOs

10:15am - 11:00am

Take a deep dive into the topics and areas that keep top compliance officers up at night. Explore what is on their radar and why it should be on yours. Discuss how to institute a culture of compliance from the top and how it can act as a role model for the organization.

Participants

Moderator: Mark Scallon - Principal, Baker Tilly US, LLP

Panelist: Daryl Kreml - Chief Compliance Officer, Sage Therapeutics

Panelist: Ann Beasley - Chief Compliance Officer, Zai Lab

Panelist: Maria Ostrovsky - Chief Compliance Officer, Associate General Counsel, Deciphera Pharmaceuticals

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Conquering COVID-19 — Explore Best Practices and Lessons Learned for Compliance During a Pandemic

11:05am - 11:40am

Having lived in a pandemic for over a year now, highlight the top compliance challenges faced since March of 2020. How has compliance changed since the onset of pandemic and where are trends going in the future? What could compliance have done better?

Participants

Moderator: Emily Hodge - Partner, Choate, Hall & Stewart LLP

Panelist: Heather Golding - General Counsel and Chief Ethics & Compliance Officer, Sobi North America, Sobi

Panelist: David Ryan - Vice President, Chief Compliance Officer, Epizyme

Panelist: Emily Honig - Compliance Officer, Biogen

Panelist: Eric Teasdale - Ethics & Compliance Advisor, USBU PDT & HAE, Global Ethics & Compliance, Takeda

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TAKE TIME TO STRETCH

11:40am - 11:45am

PROSECUTOR PRESPECTIVES ● Zero-In on High-Priority Risk Areas for Biotech and Specialty Pharma

11:45am - 12:45pm

As settlements and investigations involving specialty pharmaceutical companies continue to dominate the headlines, hear what prosecutors who are spearheading the charge against healthcare fraud find noteworthy through recent settlements and areas of focus for enforcement efforts.

Participants

Moderator: Jane Yoon - Partner, Paul Hastings

Panelist: Anthony Scicchitano - Assistant United States Attorney, U.S. Attorney's Office for the Eastern District of Pennsylvania

Panelist: David Lazarus - Assistant United States Attorney & Unit Chief, U.S. Attorney's Office for the District of Massachusetts

Panelist: Jolie Apicella - Assistant U.S. Attorney, Chief, Health Care Fraud, U.S. Attorney's Office, Eastern District of New York

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IQVIA Solution Summit

12:45pm - 1:15pm
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Participants

John Moose - Principal, IQVIA

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Justin Will - Global Commercial Compliance Consulting and Managed Services Practice Leader, IQVIA

Mario Prohasky - Principal, IQVIA

Samantha Hoffman - Associate Director, Client Services, IQVIA

SESSIONS

DAY 1 ✦ TUE, JUN 22ND

Baker Tilly Solution Summit

12:45pm - 1:15pm
Industry Only Solution Summit B

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Participants

Mark Scallon - Principal, Baker Tilly US, LLP

Samantha Sutherland - Senior Manager, Baker Tilly

Darren Jones - Principal, Baker Tilly

INTERACTIVE SESSION ● Forecasting Priorities for 2021 and Beyond Based on Your Company's Size and Maturity Level

1:30pm - 2:15pm

Connect with likeminded companies and colleagues facing similar challenges to your own. ***Participants are encouraged to turn on their cameras*** to benchmark with peers for an engaging dialogue around emerging risk areas.

1. **Pre-Commercial Life Science Companies** *(M. Wetzel)*
2. **Small and Emerging Life Science Companies** *(A. Wilson, R. Khara)*
3. **Mid-Size and Large Life Science Companies** *(M. Joachim)*

Participants

Session 1 Facilitator: Matt Wetzel - Former Associate General Counsel & Chief Compliance Officer, GRAIL, Inc.

Session 2 Facilitator: Amy Wilson - Head of U.S. Compliance, MorphoSys AG

Session 2 Facilitator: Rahul Khara, PharmD - Vice President, Legal and Chief Compliance Officer, Acceleron Pharma Inc.

Session 3 Facilitator: Michael Joachim - Head of Ethics & Business Integrity, Specialty Care, Sanofi Genzyme

Invitation Only* — 3rd Annual Legal and Compliance Leadership Summit ● Hosted by Dovetail

2:15pm - 3:15pm

This Summit is designed to encourage an open exchange of ideas and strategies surrounding some of the most critical issues facing heads of compliance across the life sciences industry. The host facilitates discussions surrounding key questions, challenges and issues. Participants* benefit from exclusive networking with peers, sharing concerns and acquiring additional best practices for enriching their compliance programs.

**Participants must hold the title of Chief Compliance Officer, Vice President of Compliance, General Counsel or an equivalent compliance leadership position at a life sciences company (at the time of the conference). Invitations will be sent by the conference producer three weeks prior to the meeting. Final eligibility approval is at the discretion of Informa Connect.*

Participants

Eric Baim - Partner, Dovetail Consulting Group, LLC

Daina Selvig - Vice President, Chief Compliance Officer, Ardelyx

Silent Auditor: E. John Steren - Member of the Firm, Epstein Becker & Green, P.C.

Optimize Your Compliance Training: A Practical Approach to the DOJ's Guidance

3:15pm - 4:00pm
Topic Intensive A

During this session, the panelists provide practical approaches for aligning your compliance training with guidance from the Department of Justice as outlined in their publication Evaluation of Corporate Compliance Programs (June 2020). We examine the obvious (e.g., training based on risk) as well less-obvious factors that should be considered when devising compliance training plans.

We share practical examples to give you real-world guidance that you can apply immediately no matter the budget and internal capabilities at your company. Key takeaways include:

- Guidance for analyzing your compliance training needs.
- The effects of the forgetting curve on compliance – and how to overcome these effects.
- How to employ the Risk-Frequency Framework to make training decisions.
- How to apply the Compliance Training Portfolio model to optimize your time and budget.
- Practical ways to evaluate the effectiveness of your training.

Participants

Daniel O'Connor - Senior Vice President, PharmaCertify by NXLevel Solutions

Karen Snyder, JD - Associate Director, Ironwood Pharmaceuticals

Erica Powers - Compliance Officer, Head of Compliance Operations, Sage Therapeutics

Mergers and Acquisitions

3:15pm - 4:00pm
Topic Intensive B

- Navigate the role of compliance during a merger or acquisitions
- Evaluate internal controls during integrations
- Uncover relevant risk areas and overcome key challenges
- Assess the impact of CIAs during M&A integrations

Participants

Latarsha Stewart - Vice President, Head of Compliance U.S., Servier Pharmaceuticals

Scott Applebaum - Chief Legal & Compliance Officer; Senior Vice President, Regulatory Affairs, Trevena, Inc.

TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT

4:00pm - 5:15pm

SCHEDULE

DAY 1 ✦ TUE, JUN 22ND -

Compliance Congress for Specialty Products Virtual 2021

June 22 - 24, 2021
? VIRTUAL EVENT

TIME	INDUSTRY ONLY SOLUTION SUMMIT A	INDUSTRY ONLY SOLUTION SUMMIT B	TOPIC INTENSIVE A	TOPIC INTENSIVE B
9:00AM	**9:30am** - IQVIA Solution Summit	**9:30am** - Baker Tilly Solution Summit		
10:00AM	**10:00am** - Informa Connect and Chairperson's Welcoming Remarks **10:15am** - Keeping Up with Industry Trends — Top Compliance Concerns Facing CCOs	**10:00am** - Informa Connect and Chairperson's Welcoming Remarks **10:15am** - Keeping Up with Industry Trends — Top Compliance Concerns Facing CCOs	**10:00am** - Informa Connect and Chairperson's Welcoming Remarks **10:15am** - Keeping Up with Industry Trends — Top Compliance Concerns Facing CCOs	**10:00am** - Informa Connect and Chairperson's Welcoming Remarks **10:15am** - Keeping Up with Industry Trends — Top Compliance Concerns Facing CCOs
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SESSIONS

DAY 2 ✦ WED, JUN 23RD

Day Two Kick-Off

10:00am - 10:05am

Optimize and Mitigate Risk within Patient Interactions and Support Programs

10:05am - 10:45am

As scrutiny continues to increase around patient services and interactions, it is more important than ever that compliance teams ensure that plans are in place to reduce risk.

- Highlight the key considerations for specialty pharmaceutical manufacturers when interacting directly with patients
- Navigate the risk and merits of patient support activities and develop strategies for promoting appropriate business engagements with patient advocacy organizations
- Address the legal nuances and restraints with respect to travel assistance
- How to create a balance between program objectives and compliance

Participants

Moderator: Katherine Chaurette - Vice President, Healthcare Law and Compliance, Blueprint Medicines Corporation

Panelist: Lisa Shrayer - Head Therapeutics Counsel, North America, Vertex Pharmaceuticals

Panelist: Rahul Khara, PharmD - Vice President, Legal and Chief Compliance Officer, Acceleron Pharma Inc.

Panelist: Katherine Churchill - Corporate Counsel, Pfizer

Virtual First — Trends in Monitoring and Interactions

10:50am - 11:30am

- Mitigate privacy concerns when engaging virtual and explore the impact on auditing and monitoring
- Assess tools and systems that have eased in the transitions and sustainability of virtual engagements
- Further insights on e-detailing and engagement with HCPs

Participants

Moderator: Elaina McEwan - Senior Manager, Life Sciences Consulting Group, Paul Hastings

Panelist: Joy Dowdle - Partner, Life Sciences & Healthcare Practice, Paul Hastings

Brooke Nelson - Executive Director, Worldwide Compliance and Business Ethics, Amgen

Himani Shah - Executive Director, Head of Global Compliance Operations, Alexion Pharmaceuticals, Inc.

NETWORKING AND HYDRATION BREAK

11:30am - 12:30pm

Diversity and Inclusion Interactive Exchange

12:30pm - 1:30pm

Explore the topic of diversity and inclusion in the workplace and discuss the key barriers that continue to exist today. Join this interactive discussion to identify key strategies and resources on how to further inclusion and make sure D&I is a priority within your organization.

Participants

Latarsha Stewart - Vice President, Head of Compliance U.S., Servier Pharmaceuticals

Stefanie Doebler - Partner, Covington and Burling LLP

Best Practices Related to PAPs, Copays and Foundations

1:30pm - 2:10pm
Learning Lab 1

- Stay on the pulse of new guidance's, legislations and legal action taken on these programs
- Examine the impact of the legal actions, nuances and pain points related to programs
- Learn about industry best practices and analyze key PAP risk areas

Participants

Matt Wetzel - Former Associate General Counsel & Chief Compliance Officer, GRAIL, Inc.

Darren Jones - Principal, Baker Tilly

Compliant Frameworks for Medical Affairs and Commercial Interactions

1:30pm - 2:10pm
Learning Lab 2

- Hear about how the role of medical affairs is changing
- Discuss if and how companies are allowing more scientific exchange with HCPs and payors
- Define the firewalls that should be in place when working with medical affairs and commercial teams

Participants

Moderator: Chelsea Ott - Regulatory & Compliance – Senior Associate, MedPro Systems, LLC

Panelist: Yvonne Clark - Senior Corporate Compliance Counsel, Spark Therapeutics, Inc

Panelist: Christie Camelio - Chief Compliance, Ethics & Risk Management Officer, TG Therapeutics

Panelist: Bill Aprea - Head of Healthcare Compliance, Phatom Pharmaceuticals

Building in Safeguards and Assessing Risk of Nurse Educator Programs

2:15pm - 2:55pm
Learning Lab 3

- Identify compliant ways to measure nurse educator effectiveness and key considerations that impact program design
- Benchmark on best practices for training to ensure compliance
- Implement key monitoring and auditing programs to ensure appropriate interactions with patients

Participants

Keren Tenenbaum - VP & Assistant General Counsel, Head of Legal, Salix

State Drug Pricing Transparency — What's New and What to Do

2:15pm - 2:55pm
Learning Lab 4

- Dive into recent legislative and regulatory reform proposals and activity
- Highlight changes from the new administration and what executive actions may be in the pipeline
- Address methods for communicating new requirements to the organization and how to comply with changes

Participants

Donna White - VP, Compliance, Chiesi USA Inc.

Katherine Chaurette - Vice President, Healthcare Law and Compliance, Blueprint Medicines Corporation

Interactive Benchmarking on Speaker Programs Special Fraud Alert — What Do We Do Now?

3:00pm - 3:45pm

In November of 2020, HHS/OIG issued a special fraud and abuse alert related to speaker programs. As a result, companies are asking themselves, "Are speaker programs a thing of the past?" Across the industry, manufacturers are evaluating the risk and analyzing their own programs. Featuring live polling and real time industry benchmarking, uncover where specialty pharmaceuticals evaluate that risk and where the industry is going.

Participants

Moderator: Stefanie Doebler - Partner, Covington and Burling LLP

Panelist: Andrea Kocharyan - Vice President, Head of Legal & Compliance, Zealand Pharma US

Panelist: Patrick Mooty - Vice President, Compliance & Ethics, Sumitomo Dainippon Pharma America

SESSIONS

DAY 2 ✦ WED, JUN 23RD

TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT

3:45pm - 5:00pm

SCHEDULE

DAY 2 ✦ WED, JUN 23RD -

Compliance Congress for Specialty Products Virtual 2021

June 22 - 24, 2021
? VIRTUAL EVENT

TIME	LEARNING LAB 1	LEARNING LAB 2	LEARNING LAB 3	LEARNING LAB 4
10:00AM	**10:00am** - Day Two Kick-Off **10:05am** - Optimize and Mitigate Risk within Patient Interactions and Support Programs **10:50am** - Virtual First — Trends in Monitoring and Interactions	**10:00am** - Day Two Kick-Off **10:05am** - Optimize and Mitigate Risk within Patient Interactions and Support Programs **10:50am** - Virtual First — Trends in Monitoring and Interactions	**10:00am** - Day Two Kick-Off **10:05am** - Optimize and Mitigate Risk within Patient Interactions and Support Programs **10:50am** - Virtual First — Trends in Monitoring and Interactions	**10:00am** - Day Two Kick-Off **10:05am** - Optimize and Mitigate Risk within Patient Interactions and Support Programs **10:50am** - Virtual First — Trends in Monitoring and Interactions
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2:00PM			**2:15pm** - Building in Safeguards and Assessing Risk of Nurse Educator Programs	**2:15pm** - State Drug Pricing Transparency — What's New and What to Do
3:00PM	**3:00pm** - Interactive Benchmarking on Speaker Programs Special Fraud Alert — What Do We Do Now? **3:45pm** - TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT	**3:00pm** - Interactive Benchmarking on Speaker Programs Special Fraud Alert — What Do We Do Now? **3:45pm** - TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT	**3:00pm** - Interactive Benchmarking on Speaker Programs Special Fraud Alert — What Do We Do Now? **3:45pm** - TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT	**3:00pm** - Interactive Benchmarking on Speaker Programs Special Fraud Alert — What Do We Do Now? **3:45pm** - TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT

SESSIONS

DAY 3 ✦ THU, JUN 24TH

Day Three Kick-Off

10:00am - 10:05am

Cell and Gene Therapies — Compliance Considerations for Highly Complex, Potentially Curative Treatments

10:05am - 10:45am

- Analyze the current state of industry adoption for gene therapies, what is currently on the market, what is in the pipeline and the regulatory implications
- Assess the legal risks of these therapies
- Discuss current guidance's and enforcement from the FDA and other enforcement bodies

Participants

Meenakshi Datta - Partner, Sidley Austin LLP

TAKE TIME FOR VIRTUAL NETWORKING WITH COLLEAGUES AND VIEW ON-DEMAND CONTENT

10:45am - 1:00pm

Emphasize Data — Key Learnings from Recent Enforcement and Guidance

1:00pm - 1:40pm

- Uncover key findings and updates for the updated 2020 DOJ Guidance on Corporate Compliance Programs and how to apply those updates to your organization
- Highlight how the recent risk due to the Special Fraud Alert on Speaker Programs can be mitigated through data controls
- Explore the emphasis on testing and data and see how your program stacks up against peers

Participants

Moderator: Amy Pawloski - General Manager, Helio PDR, Helio Health Group

Panelist: Daryl Kreml - Chief Compliance Officer, Sage Therapeutics

Panelist: Alice Dong - Senior Manager, US Standards & Governance, Biogen

Panelist: Jonathan Light - Vice President, Associate General Counsel and Chief Compliance Officer, Paratek Pharamceuticals

Practical Approaches for Ensuring Data and Patient Privacy

1:40pm - 2:25pm

- Brief overview of HIPAA, CCPA and GDPR and how you might consider their applicability in the context of cell/gene therapy
- Special data privacy considerations in the context of cell/gene therapy development
- Understand how to work across your organization to protect it and ensure compliance
- Best practices and lessons learned

Participants

Sarah Soifer - Senior Director, Compliance & Privacy, Atara Biotherapeutics

Dan Goldstein - Co-Founder and Partner, Tueoris, LLC

Organizer and Chair Closing Remarks

3:05pm - 3:10pm

Participants

Allie Spica - Senior Conference Producer, Informa Connect

Andrea Kocharyan - Vice President, Head of Legal & Compliance, Zealand Pharma US

SCHEDULE

DAY 3 ✦ THU, JUN 24TH -

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2:00PM	
3:00PM	**3:05pm** - Organizer and Chair Closing Remarks

Disease Awareness Campaigns and Pre-Launch Activities

On demand

- Weigh the benefits of patient education and disease state awareness campaigns with the compliance risks
- Examine the legal issues related to "proactive" versus "reactive" presentations around disease state
- Address best practices with respect to unsolicited requests for information at speaker programs
- Understand approaches to working with payors pre-launch

Participants

Howard Dorfman - Founder, H.L Dorfman Pharmaceutical Consulting, LLC

Understand Risks in Payer Contracting and Specialty Pharmacy Distribution

On demand

- Examine best practices for drafting compliant payer contracts and effective strategies for operationalizing these contracts internally
- Address potential challenges connected to specialty pharmacy arrangements
- Explore trends in drug pricing and Medicare reform

Participants

Jesse Dresser, Esq., - Partner, Frier Levitt, LLC

Making the Most Out of Your Resources—Building a Compliance Program from the Ground Up

On demand

- Define the difference between legal and compliance
- Learn how to position your department to obtain more resources
- Identify how and where to leverage other functions within your organization

Participants

Dennis Barnes - Vice President, Global Governance, Risk and Compliance, Mayne Pharma

Aggregate Spend — Sunshine Act Expansion and Challenges of Vendor Spend Reporting

On demand

- Explore the impact of sunshine act expansion on data collection, analytics and monitoring
- Dive into industry standards for transparency reporting
- Utilize transparency data for compliance monitoring

Participants

Chelsea Ott - Regulatory & Compliance – Senior Associate, MedPro Systems, LLC

SCHEDULE

ON-DEMAND ◎ SESSIONS -

TIME	
8:00AM	**On demand** - Disease Awareness Campaigns and Pre-Launch Activities
9:00AM	**On demand** - Understand Risks in Payer Contracting and Specialty Pharmacy Distribution
10:00AM	**On demand** - Making the Most Out of Your Resources—Building a Compliance Program from the Ground Up
11:00AM	**On demand** - Aggregate Spend — Sunshine Act Expansion and Challenges of Vendor Spend Reporting