7th Annual
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CONFERENCE

Corporate Compliance & Transparency in Life Sciences

20 & 21 February 2019, Zurich
This Year’s Highlights:

30+ Speakers
120+ Attendees
2 Dedicated Streams
C-Level Debate Session
New Tech Player Session
10+ Hours of Informal Discussions
“Know Your Peers” Cocktail Reception

Pharma Stream
Focus:
- Ethical interaction with patient organizations and individual patients via different channels
- Value-based compliance
- Automation and big data analytics in compliance
- Transparency & compliance for the growing amount of RWE data in outcomes-based healthcare
- Compliance landscape for AI, social media and digital health
- Behind the curtains – an effective ABAC program
- Compliance framework for scientific exchange with HCPs

Focus on Medical Devices & Diagnostics:
- How the phasing out of direct Sponsorship to HCPs has affected us
- First experiences after adopting the new MedTech Europe Code of Ethical Business Practices
- Insights into the transparency of educational grants
- Critical considerations for compliance with EU MDR & IVDR

Key takeaways:
- Critical insights to transparency in Pharma & MD&D
- Where compliance stands in the digital world
- Embedding ethics and compliance into the corporate DNA
- Tips and tricks for addressing compliance in high risk areas
- How to integrate ABAC processes to ensure third party compliance
- Progress in GDPR compliance and its re-enforcement after implementation
- Compliance framework examples to interact with individual patients throughout the whole product life-cycle
- Tips to compete with the new tech players entering the healthcare market
- Learning from digital tech companies and their compliance strategies
- Utilizing the full potential of big data analytics and automation in compliance
- Future developments of three disclosure codes in the Life Sciences sector
- Experience on disclosing on professional conference organizers
- Best practices to identify promo vs. non-promo activity in the scientific exchange with HCPs
- Understanding of the compliance landscape for RWE data and outcomes-based healthcare
of attendees intend to attend again

of attendees recommend the event

of attendees appreciated the networking opportunities

Testimonials from previous Pharma Compliance Events:
“Very good presentations, interactive sessions, diversity of topics regarding the same subject. Excellent!”
Mihaela Scarlatescu, A&D Pharma, Romania

“Great networking. Very informative, with a lot of practical examples from industry and patients.”
Marina Relly, Newport Pharmaceuticals, Ireland

“Reflected on current industry issues in a pragmatic way with knowledgeable speakers.”
Savvas Palaistis, UCB, Greece

“I enjoyed very much the part of the congress that I attended and I believe you are totally on the right path. Fleming has a good reputation among compliance professionals, so keep it that way.”
Efi Gkika, Baxter, Switzerland
Speaker Line Up:

**Pharma & Biotech Speakers:**

- **Brett Hudson**
  Novartis, Switzerland
  Head of Integrity & Compliance

- **Nicolas Honhon**
  UCB, Switzerland
  Ethics and Compliance Head EMEA

- **Fausto Massimino**
  Roche, Italy
  Director Legal & Compliance

- **Thomas Roth**
  Boehringer Ingelheim, Germany
  Global Data Privacy Officer

- **Jolanta Wyszynska**
  Astra Zeneca, Poland
  Vice President Compliance Europe & GBS

- **Martin Fürle**
  Daiichi Sankyo, Germany
  General Counsel and Chief Compliance Officer

- **Caroline Kelly**
  Grunenthal, UK
  Head of Compliance

**Patient Speakers:**

- **Jan Geissler**
  EUPATI, Germany
  Director

- **Ananda Plate**
  Myeloma Patients Europe, Belgium
  CEO

**Pharma & Biotech Speakers:**

- **Klaus Geldsetzer**
  Santen, Germany
  Chief Compliance Officer

- **Karolina Czernicka-Kuhl**
  Vertex Pharmaceuticals, Germany
  Director Legal and Compliance DACH, Eastern EU & Middle East

- **Antonis Roussos**
  Astellas, Greece
  Senior Director Ethics & Compliance, Privacy Lead for EMEA

- **Thomas Hauser**
  Navigant, UK
  Director Life Sciences Governance, Risk Management & Compliance

- **Kathryn Higgs (TBC)**
  Transparency International, UK
  Director – Business Integrity Programme

- **Jolanta Wyszynska**
  Astra Zeneca, Poland
  Vice President Compliance Europe & GBS

- **Dumitru Uta**
  Eli Lilly, Romania
  Ethics and Compliance Director, South Eastern Europe

- **Artem Kardashevskiy**
  Novartis, Czech Republic
  Compliance Team Lead, Anti-Bribery Due Diligence

- **Martin Fürle**
  Daiichi Sankyo, Germany
  General Counsel and Chief Compliance Officer

- **Caroline Kelly**
  Grunenthal, UK
  Head of Compliance
Medical Devices & Diagnostics Speakers:

**Bernhard Fischer**  
Johnson & Johnson Medical, Germany  
Healthcare Compliance Officer

**Mirko Lalatovic**  
Fresenius Medical Care, Germany  
Head of Compliance Central and Northern Europe (CENE)

**Daniel Köhnen**  
Cardinal Health, Germany  
Head of Compliance – DE, AT, CH, Central

**René Neubauer**  
Fresenius Medical Care, Germany  
Director Healthcare Law

**Elena Gilardi**  
Diasorin, Italy  
Senior Corporate Legal Affairs Manager

**Dominik Lysek**  
credentis, Switzerland  
CEO

**Wolfgang Werner**  
Biovotion, Germany  
Senior Vice President Regulatory & Quality

**Enno Behrendt**  
Siemens Healthineers, Germany  
Head of Healthineers Diagnostics Imaging and Services

**Gérald Hucky**  
Sonova, Switzerland  
Head Group Compliance

**Lori Russell**  
bioMerieux, France  
Global Ethics and Compliance Officer

**Frida Berlin**  
Elekta, Sweden  
Corporate Compliance & Integrity Officer
DAY 1
20 February 2019

8:00  Registration & Morning Coffee

9:00  Opening of the Conference & Organizational Introduction

9:05  Welcoming Note from the Chairman

9:10  Speed Networking

9:15  KEYNOTE: Tackling the Present, Shaping the Future
- Where do we see our businesses in 5 years?
- Self-regulation vs. legislation – compliance gaps and future development
- Three disclosure codes – vision and progress
- Insights into local strategies

9:30  CASE STUDY: New Generation of Compliance in the Digital World
- How AI, machine learning and automation is transforming compliance programs
- Blockchain technology to improve efficiency and safety
- Ensuring regulatory compliance during the transformation

10:00  CASE STUDY: Rise of New Tech Players
- Compliance landscape for the new digital players entering the healthcare market
- What life sciences can learn – how to apply it in strictly regulated environments
- Examples of compliance with the new tech players and their compliance framework

10:30  Coffee & Networking Break

11:00  CASE STUDY: Ethical Interaction With Patient Organizations and Individual Patients
- What is the public perception of our company?
- Compliance in the very early stages of interactions
- Optimizing interactions in a highly regulated environment
Fausto Massimino, Roche, Italy
Director Legal & Compliance

11:00  CASE STUDY: MedTech Code of Ethical Business Practices – After the Implementation: Maintaining an Effective Compliance Program
- Developing compliant relationships with HCPs and HCOs
- Translating the code into practice – what are we doing differently?
- Differences in local jurisdictions – how is it affecting our business?
**CASE STUDY: Engaging with Patient Organisations – How Do It Right**
- How can we make digital interactions fully comply with HCPs?
- Best practices to identify promo vs non-promo activity in the scientific exchange with HCPs
- Interactions on social media

**Karolina Czernicka-Kuhl**, Vertex Pharmaceuticals, Germany, Director Legal and Compliance DACH, Eastern EU & Middle East

**CASE STUDY: From Rules To Habits: Building A Culture Of Integrity**
- How to empower and enable ethical conduct by giving more regard to human behavior and decision-making.
- Shifting perspective towards a more realistic and scientifically up-to-date view on cognitive biases and the impact of context.
- The crowd view: Towards a culture of ethical leadership

**Enno Behrendt**, Siemens Healthineers, Germany, Head of Compliance Diagnostics Imaging and Services

**CASE STUDY: Measuring the Efficiency of Compliance Programs**
- What are the markers and indicators of an effective compliance program?
- Establishing appropriate metrics to assess the state of ethics and compliance programs
- Developing benchmarks by which we can measure the progress

**Dumitru Uta**, Eli Lilly, Romania
Ethics and Compliance Director, South Eastern Europe

**CASE STUDY: Compliance strategies for the new requirements on RWE data in outcomes-based healthcare**
- Integrating data from multiple sources to make RWE more central
- How should collecting, analyzing and reporting real-world data be done?

**Nicolas Honhon**, UCB, Switzerland
Ethics and Compliance Head EMEA

**CASE STUDY: Transparency Disclosure – Months after MedTech**
- In what way has it affected our business?
- Main challenges of new transparency for educational grants
- First impressions of HCPs and the general public on the transparency initiatives
- Examples of first outcomes

**Bernhard Fischer**, Johnson & Johnson Medical, Germany, Healthcare Compliance Officer

**THINK TANK: Supporting Third-Party Medical Education According to the MedTech Code**
- New relationships with HCPs and HCOs
- Transparency of educational grants – where do we stand?
- Best practices – what worked for us? Where did we make a mistake?

**CASE STUDY: Emerging, High Risk Areas in Compliance**
- Development and implementation of a monitoring plan
- Assessing each high-risk area in terms of risk, probability of risk exposure and potential compliance impact from the risk area
- Determining adequacy of internal controls (e.g. policies and procedures)

**Mirko Lalatovic**, Fresenius Medical Care, Germany, Head of Compliance Central and Northern Europe (CENE)

**CASE STUDY: Third-Party Due-Diligence**
- A sustainable approach to mitigate the specific risks of third parties in the MedTech industry
- Management of stakeholders in Due Diligence processes
- Managing issues and investigations

**Daniel Köhnen**, Cardinal Health, Germany
Head of Compliance – DE, AT, CH, Central
DAY 1
20 February 2019

15:00 THINK TANK: Reducing Risks and Achieving Third-Party Compliance for the Pharmaceutical Industry
• Effective management of third parties, complying with regulations and improving collaborations
• Creating a single, accurate view of third parties across multiple data sources
• Understanding compliance risks related to mergers & acquisitions

15:00 THINK TANK: How to Handle Multi-National Jurisdiction Requirements
• Mapping global transparency compliance
• Post-Brexit application of EU laws
• Creating a contingency plan in the event of non-compliance

15:30 Afternoon coffee break

16:00 CASE STUDY: Behind the Curtains – an effective ABAC program
• What we can do to prevent bribery – establishing a strong compliance programs
• What is the appropriate response to potential abuses?
• Tools used to detect and predict non-compliant behavior
Lori Russell, bioMerieux, France, Global Ethics and Compliance Officer

16:00 CASE STUDY: Anti-compliant Behavior in Healthcare
• Understanding the nature of corruption – what it is and where it goes on
• Managing conflicts of interest
• Standardizing the code of conduct in emerging markets
Artem Kardashevskiy, Novartis, Czech Republic, Compliance Team Lead, Anti-Bribery Due Diligence

17:00 Evaluation of Day 1 and Conclusions

17:30 Cocktail Reception
Speakers and Delegates are cordially invited to a networking reception
## DAY 2
21 February 2019

### 8:30
Morning Coffee & Networking

### 9:00
Opening Remarks from the Chairman

### 9:10 **C-LEVEL STRATEGIC PANEL: Assessing Your Organizational Compliance Culture**
Optimizing a compliance function with the organizational structure – what is the optimal structure in large vs. small and niche companies?
- What are your biggest concerns about the company’s compliance program?
- Regulatory developments and enforcement actions that impact the company’s businesses
- What is the company doing to engender a compliance culture?
- Do employees feel comfortable raising compliance issues with their managers or directly to the compliance department?

**Martin Fürle, Daiichi Sankyo, Germany, General Counsel and Chief Compliance Officer**

### 9:40 **CASE STUDY: Winning With Compliance**
- Building modern, efficient and agile compliance programs
- Determining actions necessary to avoid, mitigate and remediate risks
- Utilizing big data & advanced analytics to improve compliance
- Self-learning algorithm to detect and monitor fraud

**Gerald Hucky, Sonova, Switzerland, Head Group Compliance**

### 10:10 **CASE STUDY: Building an Ethics Culture Across a Global Brand**
- Current pressures for change in business ethics
- Future business practices driven by values embedded in company culture

**Thomas Hauser, Navigant, UK, Director Life Sciences Governance, Risk Management & Compliance**

### 10:30 Coffee & Networking Break

### Pharmaceuticals & Biotech

#### 11:00 **CASE STUDY: Transparency and Disclosure of HCP Payments**
- How GDPR influenced disclosure and the way we collect, store and disclose data
- New countries with disclosure requirements (South Korea)
- Managing sponsorship of conferences
- Indirect HCP interactions and responsibility of compliance

**Klaus Geldsetzer, Santen, Germany**

**Chief Compliance Officer**

#### 11:30 **CASE STUDY: Soft Skills for Compliance Leaders – Compliance Meets Business**
- Developing the skills needed to negotiate with businesses and bringing added value
- Compliance in digital business – acquiring the right skills
- Soft and digital skills in compliance

**Caroline Kelly, Grunenthal, UK**

**Head of Compliance**

### Medical Devices & Diagnostics

#### 11:00 **CASE STUDY: The New European Regulatory Landscape – MDR & IVDR**
- What is the impact for industry?
- How do different countries interpret and implement the directives in different ways?
- Going from Directive to Regulation – what does it mean?

#### 11:30 **CASE STUDY: Key Issues for Compliance with the EU MDR & IVDR**
- What are the new transparency principles under the new regulations?
- Development and implementation of proactive and pragmatic MDR compliance
- Transparency through EUDAMED

**René Neubauer, Fresenius Medical Care, Germany, Director Healthcare Law**

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12:00 **THINK TANK: Best Practices for Compliance Monitoring Programs**
- Monitoring and auditing with limited resources
- Management’s oversight of company compliance initiatives
- Maximizing the efficiency and value of risk mitigation activities
- Documenting the effectiveness of compliance programs

12:00 **THINK TANK: How will the MDR & IVDR Disrupt and Transform the Industry?**
- How aware is the wider organization and senior leadership of the mandatory changes?
- What are the costs and resource implications of new regulations in our business?
- How is the supply chain affected?
- To what extent will big, medium and small companies be affected?
  **Dominik Lysek, credentis, Switzerland, CEO**

12:30 Lunch

14:00 **CASE STUDY: Compliance Framework In the Digital Age**
- Rise of digital health, mHealth and AI & its impact on a compliance framework
- Approaches and steps to achieve compliance and the highest ethical standards in the use of digital interactions, AI and other disruptive technologies
- Big data and analytics – how we work with data and achieve compliance with legislation
  **Wolfgang Werner, Biovotion, Germany, Senior Vice President Regulatory & Quality**

14:30 **CASE STUDY: Regulatory Compliance and Cyber Threats: Industrial Security in the Life Sciences**
- Leveraging benefits of big data while minimizing security risk
- Implementing best practices for industrial systems
- Managing the security operational sides of the equation
  **Antonis Roussos, Astellas, Greece, Senior Director Ethics & Compliance, Privacy Lead for EMEA**

15:00 Afternoon Coffee & Tea

15:30 **CASE STUDY: After GDPR: What’s Next?**
- Modifications in different jurisdictions
- Tackling gray and uncertain areas
- Operationalizing your data
- Authorities’ acceptance of companies’ new processes and the general public perception
- HCPs view on GDPR
  **Thomas Roth, Boehringer Ingelheim, Germany, Global Data Privacy Officer**

16:00 **WORLD CAFE: Navigating Life Sciences Privacy Risks: GDPR and beyond**
- Which customer data are safe to use while using marketing promo materials?
- What are the changes in how customer services and legal departments operate?
- Protecting the security and privacy of personal information as a top priority
  **Elena Gilardi, Diasorin, Italy, Senior Corporate Legal Affairs Manager**

16:30 Final Note from the Chairman & Farewell
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