

26TH - 27TH SEPTEMBER AMSTERDAM, NETHERLANDS

# COMPLIANCE & TRANSPARENCY EXCELLENCE IN LIFE SCIENCES

CONNECTING THE DOTS OF VALUE-BASED STRATEGIES

EuroEvents is pleased to invite you to the inaugural edition of the Compliance and Transparency Conference for Life sciences, on 26th and 27th of September 2019 in Amsterdam, The Netherlands.

As heavy regulated industry, the companies are facing ever changing regulatory requirements. The industry players endeavour to better design and implement, assess and improve their programs to drive compliance into the Corporate DNA, Putting in place a holistic compliance program requires building a state-of-theart programs and practices, taking care of the all aspects of industry codes and regulatory requirements.

The new technologies promise to offer imminent value for the industry, at the same time pose challenge of adoption and adaptation of the existing programs and practices. The general shift towards these technologies is conditional on the robust evidence and understanding of the benefits their adoption. Nonetheless, industry leaders and early adopters have been testing and already put in place some of these solutions in their everyday operations.

Therefore, our Conference will give recognition to the best practices and offers a platform for open discussion and exchange of ideas on how to overcome the present-day challenges compliance professionals the life sciences industry are facing. Benefit from the learning, benchmarking and networking opportunities and adapt the best practices to your company specific needs.

Join us in very new home of the European Medicines Agency for a remarkable experience!

Sincerely,

Stefan Ristovski

Conference producer

#### **SPEAKERS**



**DETLEF GEIGES** 

Senior Director Compliance Assurance, Global Methodology & Europe & Russia/ Eurasia Lead, Astra Zeneca



LIESBETH BERGMANS

General Counsel EU Commercial, Teva Pharmaceuticals



**GABOR SULYOK** 

Head of Compliance Novartis



**MARTINE ZIMMERMANN** 

Global Head of Regulatory ffairs Alexion Pharma



**DANIEL SCHAFAGHI** 

Head of Global Compliance Program and Regions Management, Boehringer- Ingelheim



NATACHA UDO-BEAUVISAGE

Global Data Protection Officer, Servier

#### **SPEAKERS**



TETIANA ISAIEVA
Head of Compliance EEMEA
and Indian Subcontinent
Roche



ALEKSEJ DAINEKO

Head of Global Compliance & Risk Business
Partnering, LEO Pharma



ARIADNA QUESADA Ethics and Compliance Officer



JULIEN DURAND

Executive Director Compliance Amgen
& Chair of IFPMA Future Health
Technologies Commission, (invited)



THOMAS PFENNIG
Global Head of compliance
Bayer (invited)

## DAY I

**08:30** Registration & Welcome Coffee **09:00** Opening Remarks From the Chairman

## **SESSION I:** LATEST UPDATES ON THE REGULATORY LANDSCAPE

09:00 - 10:30

» OVERVIEW OF THE GLOBAL LANDSCAPE

09:00-09:30

MARTINE ZIMMERMANN, Global Head of Regulatory Affairs, Alexion Pharma

- » LIFE SCIENCE RISK STRATEGIES IN VUCA WORLD 09:30-10:00
- · How to build a strong risk culture through effective risk positioning
- · New and rising Risks...or...Opportunities
- Risk appetite: balancing of value creation and value protection

**TETIANA ISAIEVA**, Head of Compliance EEMEA and Indian Subcontinent, **Roche** 

» MDR & IVDR: CHALLENGES AND BEST PRACTICES 10:00-10:30

10:30 - 11:00 | Networking Break

# SESSION II: CULTURE OF CONTINUOUS IMPROVEMENT: SPECIFIC ASPECTS OF THE COMPLIANCE PROGRAMS

11:00 - 12:30

» CULTURE OF INTEGRITY: BALANCE BETWEEN VALUE-DRIVEN AND CONTROL-BASED COMPLIANCE

11:00-11:30

**ALEKSEJ DAINEKO**, Head of Global Compliance & Risk Business Partnering, **LEO Pharma** 

#### PANEL DISCUSSION 11:30-12:30

### COMPLIANCE CULTURE AND VALUES AS A COMPETITIVE ADVANTAGE

- The role of the board in building compliance culture
- Challenges of incorporating culture and corporate values in the dna of the company
- How to deal with cultural differences across world?

12:30 - 14:00 | Lunch Break

#### SESSION III: FROM REACTIVE TO STRATEGIC APPROACH: BUILDING A HOLISTIC COMPLIANCE PROGRAM

14:00 - 15:30

#### » HOLISTIC THIRD PARTY RISK MANAGEMENT

14:00 - 14:30

- Challenges
- Opportunities
- Conclusion & Outlook

DANIEL SCHAFAGHI, Head of Global Compliance Program and Regions Management, **Boehringer-Ingelheim** 

#### » THE (D)ART OF ASSURANCE

14:30 - 15:00

- Global vs. regional vs. local Monitoring
- Depth of Assurance
- Use of Data Analytics
- · Adaptive, risk-based Monitoring
- · Learning from Darts

**DETLEF GEIGES**, Senior Director Compliance Assurance | Global Methodology & Europe & Russia/Eurasia Lead, **Astra Zeneca** 

» IMPROVED TRAINING PROGRAMS AND ADOPTION OF E-LEARNING TOOLS 15:00 - 15:30\

**15:30 - 16:00** | Networking Break

#### SESSION IV: EFFECTIVE TRANSPARENCY PROGRAMS AS COMPETITIVE ADVANTAGE

16:00 - 17:30

- TRANSPARENCY IN DISCLOSURE OF PAYMENTS AND OTHER TRANSFERS OF VALUES CONSIDERATIONS, CHALLENGES AND BEST PRACTICES 16:00 16:30
- · Global transparency snapshot
- EFPIA new Code of Practice
- Key considerations in practice (roles and responsibilities, controls and monitoring, etc.)
- Key challenges (data privacy, outsourcing, etc.)

GABOR SULYOK, Head of Compliance, Novartis

#### PANEL DISCUSSION 16:30-17:30

#### TRANSPARENCY: BEYOND MONEY TRANSFERS

- Sponsorships and conferences participation
- Patient-data interactions data availability & more

END OF DAY I
Summary & Conclusions

## **DAY II**

**08:30** Registration & Welcome Coffee **09:00** Opening Remarks From the Chairman

# SESSION V: TECH GIANTS AND START-UPS: A NEW MARKET LANDSCAPE

09:00 - 10:30

- » OVERCOME BARRIERS FOR INNOVATION: REGULATORY, HR, FINANCIAL 09:00-09:30
- » COMPETITION LANDSCAPE: MERGERS & ACQUISITIONS IN EU COMPETITION LAW 09:30-10:00
- » THE IMPACT OF TECH GIANTS PENETRATING THE MARKET - WHAT SHOULD BE EXPECTED? 10:00-10:30

10:30 - 11:00 | Refreshments & Coffee Networking Break

# SESSION VI: DISRUPTIVE INNOVATION: APPLICATION AND CHALLENGES OF EMERGING TECHNOLOGIES

11:00 - 12:30

- » MANAGE THE EMERGING TECHNOLOGICAL RISK: OVERCOME THE CHALLENGES OF ADOPTION OF CUTTING EDGE TECHNOLOGIES 11:00-11:30
- » UNLOCK THE POSSIBILITIES OF BIG DATA AND ENSURING DATA PROTECTION 11:30-12:00
- further use of data
- · scientific research as compatible use
- patients expectations on further use
- transparency

NATACHA UDO-BEAUVISAGE, Global Data Protection Officer, Servier

- » BLOCKCHAIN FOR COMPLIANCE AND TRANSPARENCY 12:00-12:30
- Traceability within the supply chain,
- · Consent and clinical trial management
- · Real time red flags



# SESSION VII: MANAGING A PATIENT-CENTRIC ECOSYSTEM: THIRD PARTIES & MORE

14:00 - 15:30

- » INTERACTIONS WITH PATIENTS AND PATIENT ORGANISATIONS 14:00 14:30
- » DEALING WITH CHALLENGES OF PATIENT SUPPORT PROGRAMS 14:30 15:00

ARIADNA QUESADA, Ethics and Compliance Officer, AbbVie

PANEL DISCUSSION 15:00-15:30

PREVENTION OVER INTERVENTIONS: EFFECTIVE ABAC PROGRAMS

**15:30 - 16:00** | Networking Break

## SESSION VIII: FORETHOUGHTS ON COMPLIANCE AND TRANSPARENCY

16:00 - 17:30

- » SOCIAL MEDIA AS A RISING COMPLIANCE ISSUE 16:00 - 16:30
- Setting the stage
- Legal framework regarding Social Media Use
- · Do's and Don'ts

LIESBETH BERGMANS, General Counsel EU Commercial,
Teva Pharmaceuticals

» CONTINUOUS IMPROVEMENT OF SKILLS AND COMPETENCES AMONG THE COMPLIANCE PROFESSIONALS 16:30 - 17:30

Summary and Recap of the Conference
END OF CONFERENCE

