



Supplying the future – achieving regulatory, development and drug safety goals

Symposium

20 years of YES

September 24th, 2014

9.00 h – 17.00 h

08:30 **Registration**

09:00 **Breakfast reception**

09:30 **Welcome**



Event Location

Frankfurt Stock Market
Frankfurt am Main – Plenarsaal
Börsenplatz 4, 60313 Frankfurt

09:45 **Deeper or wider – pharma value chain reconfiguration**

- *Megatrends in Pharma / Healthcare*
- *New Business Models and strategies*
- *Digital Revolution in Healthcare*

*Dr Hari Sven Krishnan,
COO Digital & Adjacent
ProSieben Sat.1 Media AG*

10:15 **How to harness strategic outsourcing in clinical development - a case study from global pharma**

- *The change process, objectives and ownership*
- *Definition of core and non-core competences*
- *3 crucial phases of the change process*

*Dr Thomas Lander,
Managing Partner
Lander Goette Biopharmaceutical Consulting GbR*

11:00 **Coffee Break**



11:15 **Make or buy – outsourcing pharmacovigilance services**

- *PV performance parameters*
- *Strategic considerations*
- *Customized decision*

*Dr Joachim Maus,
MEDA Pharma GmbH & Co. KG*

12:00 **Staff lease or Business Process Outsourcing – fits and misfits**

- *Definition and differentiation*
- *Advantages and disadvantages*
- *Summary and outlook*

*Tim Luchtenberg,
Expert in Labour and Social Law
HessenChemie,
Association of Chemical
and Related Industry Employers*



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12:30 **Lunch Break**

13:30 **Challenges and global trends in the pharma and medical device industry**

- Changing healthcare environments
- Global trends in the pharmaceutical and medical device industry
- Challenges of the pharmaceutical and medical device industry

*Jürgen Reinisch,
Corporate Sector Analyst
Commerzbank AG*

14:15 **Asia-Pacific pharma market: Keeping up to date with the development in the pharma and outsourcing industry**

- Current and Future Market Overview of India and selected APAC countries
- Notable trends in the Indian Pharmaceutical Industry
- Alliances and emerging markets: Way Forward

- Growth drivers in India and Asian pharma industry.

*Ashish Dasgupta,
General Manager
YES India*

15:00 **Coffee Break**

15:15 **Drug Development in the US - Similarities & Differences to the EU**

- The changing landscape of US regulatory policy: Considering critical success factors for the largest global pharmaceutical market.
- The Prescription Drug Users Fee Act (PDUFA), What to expect, and options to accelerate development.
- The Biologics Price Competition and Innovation Act (BPCI Act). US views on biosimilar development.
- From Hatch-Waxman to The Generic Drug Users Fee Act (GDUFA), Everything you wanted to know about generic drug development but were afraid to ask.

*Tom Fritz,
General Manager
YES Group US*

16:00 **The Brazilian Healthcare Market – why and how to access?**

- Regulatory fundamentals for the healthcare sector in Brazil

*Stephan Fontanel,
Vice President
YES Brazil operated by Mandala*

16:45 **Conclusion**

17:00 **Get Together**

The event is recognised by the Hessian State Pharmacists' Association as an advanced training course worth 7 credit points.

If you wish to arrive the day before, you can book your accommodation via the link below – the hotel allocation is available until 26.8.2014, and may only be booked through the reservation system.

http://www.frankfurt-tourismus.de/cms/tourismussuite/soko/yes_en.html

If you have any booking queries, please contact Ms Fotini Kaldi:

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Biographies

Dr Thomas Lander

is owner of Lander Goette Biopharma Consulting. He has over 20 years of experience from senior executive positions including Medical Director Europe at GlaxoWellcome Plc, and Executive VP Global Clinical Development at Merck KGaA. He held senior positions with major international pharmaceutical companies (Boehringer Ingelheim, NovoNordisk, Bristol-Myers-Squibb, GlaxoWellcome, GSK, Merck KGaA). He was Managing Director of CureVac, a German mid-size biotech company.

Dr Hari Sven Krishnan

started his professional career as consultant at McKinsey&Co. Thereafter, he has been working with Novartis as CEO Novartis Denmark, Head of Marketing Germany and as CEO Novartis Pharma Russia. After having worked for Seven Ventures AG Hari Sven Krishnan is working with ProSieben Sat.1 Media AG as COO Digital & Adjacent.

Jürgen Reinisch

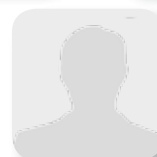
is Sector Analyst for Healthcare/ Pharmaceuticals in the Group Risk Management Department at Commerbank AG. He has long-term experience in industry and corporate analysis. Commerbank is a leading bank in Germany and Poland with world-wide presence in all major markets. In total, Commerbank boasts nearly 15 million private customers, as well as 1 million business and corporate clients.

Dr Joachim Maus

joined the pharmaceutical industry as Head of Human Pharmacology at Asta Medica, later Viatrix. For 10 years Joachim Maus works at Meda Pharma as Head of Clinical Research, Director Clinical Development and most recently as Acting Executive Vice President Scientific Affairs covering Clinical Development, Drug Regulatory Affairs, Pharmaceutical Development and Quality Assurance.

Troy Ignelzi

is Senior Vice President-Business Development of YES Group, LLC. He has worked for more than 20 years in finance and business development with start-up and established companies to raise capital (including three IPOs), identify partnership and funding opportunities, and negotiate license acquisitions. Mr Ignelzi also has lead operations for pharmaceutical companies, establishing large infrastructures to support strategic acquisitions.



Stephan Fontanel

is co-founder of YES Brazil as well as founder and Vice President of Mandala. He has 20 years of experience in business development and sales on the Latin American Market, especially on the Brazilian Market. His track record includes experience with a software company subsidiary in Latin America, being a commercial director for a start-up, a director of trade marketing for L'Oréal Group Brazil, and a founder and director of a hospitality and tourism center in Amazonia.

Tom Fritz

is Managing Director of YES Group, LLC. He has been successful in founding and operating two companies, ImaRx Pharmaceutical Corp. and Fritz Consulting Group. Later on, Tom Fritz joined Swiftwater Group, LLC (now called YES Group, LLC) as Managing Partner. He has gained deep expertise in pharmaceutical operations management, clinical and regulatory strategy, technical and operational due diligence, and operational set-up and restructuring.

Tim Luchtenberg

studied law in Cologne and Geneva and is now a lawyer in the fields of employment and social law at HessenChemie Association of Chemical and Related Industry Employers. After having worked with several international chambers Tim Luchtenberg gained experience by working in the legal department of a German industrial service provider.

Ashish Dasgupta

is Managing Director of YES Regulatory Healthcare Services India Pvt Ltd. He possesses more than thirty years of experience in clinical research and pharmaceutical generic development. In the past, he had been responsible for establishing Lambda Therapeutic Research, one of the largest CROs in India. Over the last decade, he had multiple senior leadership positions in Lambda and Jubilant Clinsys with strategic, operational and organizational mentoring responsibilities.