Clinical Research in Europe: What you need to know to successfully enter the EU Market

15 November 2018
New Delhi

Location
Indian International Centre
40 Max Mueller Marg
New Delhi 110003

Date
15 November 2018
11:30 am – 05:00 pm

India is taking on a greater role in global drug development. Clinical Trials are increasingly performed in India according to ICH-GCP and global quality standards.

This half day conference provides you with important information, knowledge and first-hand expertise to meet the challenges when conducting clinical trials in Europe. You will learn how to integrate the concepts and processes of European requirements into your drug development or medical device program as a proactive global approach.

Target Delegates invited: Leaders in the Biopharmaceutical, Biosimilar and Medical Device Industry responsible for Clinical Development, Pharmacovigilance and Regulatory Strategy, Representatives of Regulatory Authorities, Clinical Non-Profit Organizations.

lumis
Your clinical gateway to Europe

Program

11:30 am	Registration
12:00 – 01:00 pm	Welcome Lunch and Networking
01:00 – 01:15pm	Introduction to the program and Inauguration (Representative from Indian Regulatory Authority invited)

01:15 – 01:45 pm

Module Regulatory

European requirements when conducting clinical trials

Heike Schoen, Managing Director Lumis International GmbH

- Understand the diverse European regulatory landscape
- Get to know the preconditions to conduct clinical trials in Europe
- Learn what needs to be considered for clinical trial data to be submitted to European Regulators

Heike Schoen
is Executive Manager with more than 25 years of experience in general management, clinical operations and business development gained in several CROs and biotechnology companies. She has in-depth knowledge of international clinical drug development processes and regulatory requirements from First in Human clinical trials to market access. With her company LUMIS International she supports especially Biopharmaceutical, Biosimilar and Medical Device companies outside of Europe to enter the European market.

01:45 – 02:15pm

Module Legal

Clinical Drug Development in Europe – General legal considerations

Myrthe Trompert, CEO Salvius legal B.V.

- Contractual: the challenges of contracting
- Informed Consents and its process
- Data Privacy Rules

Myrthe Trompert
Myrthe has been working as a lawyer in the clinical research industry for more than 20 years, including in the role of Senior Legal Counsel responsible for contract management in all countries (except USA/Canada) for a global CRO. Since 2010, Myrthe has been the CEO and Director Legal Consultant of Salvius Legal, a company specializing in contract management support for the clinical trial industry. As such, she has gained a thorough understanding and knowledge of clinical trial processes and the requisite contractual and regulatory requirements for performing clinical trials in Europe and the rest of the world.

02:15 – 04:00 pm

Module Quality

Inspection readiness: what does this mean for European Inspectors?

Nancy Meyerson-Hess, Chief Compliance and Regulatory Officer, eMQT, Emerging Markets Quality Trials

- Oversight obligations
- Quality Assurance activities
- Quality Management and Quality Control activities
- Centers of Excellence for clinical trials: what are these?

Nancy Meyerson-Hess
has over 30 years of experience in leading global clinical research teams in pharmaceutical and contract research organizations. She has focused on providing best practices for success in global clinical research, including emerging regions, in areas such as Good Clinical Practice and Inspection Readiness. In addition, she has extensive experience in patient-centered activities and solutions.Nancy is Chief Compliance and Regulatory Officer at eMQT Emerging Markets Quality Trials, a non-profit targeting healthcare research in Africa. Nancy is an Expert Partner at admedicum Business for Patients, an organization specialized in patient focus and engagement. She also provides support as a consultant in clinical research with a focus on clinical trials and outsourcing through quality and process improvement.

03:00 – 03:30 pm

Networking Tea

04:00 – 04:30 pm

Module Drug Safety and Pharmacovigilance

Product Safety Monitoring in Europe After Approval

Dr J Vijay Venkatraman, Managing Director & CEO, Oviya MedSafe

- Overview of EU Pharmacovigilance Regulations (Post-Marketing)
- Product License Types and Pharmacovigilance Obligations of Marketing Authorization Holder (MAH)
- Medical Literature Monitoring by European Medicines Agency: Process and implications for MAH
- Role of EU Qualified Person for Pharmacovigilance (QPPV) and Local Responsible Person (LRP) in some European countries

Dr J Vijay Venkatraman
is a Diabetologist, Drug Safety Physician and Entrepreneur, with almost 2 decades of experience. He holds a MBA degree in Services Management. He is the first Indian to have been conferred the Fellowship of the Pharmaceutical Information & Pharmacovigilance Association (PIPA), UK. Dr Vijay founded Oviya MedSafe, a global Pharmacovigilance consulting & Drug Safety services providing company in 2012 and has functioned as its Managing Director & CEO since then. Dr Vijay holds several honorary leadership positions in professional associations in the pharmaceutical and health care domains. He has been awarded by the Indian Medical Association.

04:30 – 05:00 pm

Wrap up and feedback

How to register

As the number of seats is limited, please register your participation with our organizing partner **Oviya MedSafe** via e-mail to **info@oviyamedsafe.com**

Registration is free of cost but mandatory for all delegates.
Please contact **Mr Karthik on +918220763222** for registration/enquiry

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www.iicdelhi.nic.in

Organisation

Organized by Lumis International GmbH
Co-organized by Salvius, eMQT, Oviya Medsafe

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