Heike Schoen, Clin Pharmacol Biopharm 2018, Volume:7
DOI: 10.4172/2167-065X-C1-027

6th European Biopharma Congress

September 18-19, 2018 | Amsterdam, Netherlands

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Operational and legal challenges for biopharmaceutical and biosimilar companies conducting clinical trials in Europe

The implementation of the new ICH E6 R2 GCP guideline has created confusion, contradictory opinions about what is necessary to be implemented as sponsor oversight in clinical trials to fulfill the requirements. Sponsor oversight in general is not new, of cause, but the details to mandatory perform oversight activities and to manage compliance for all clinical trial activities have raised lots of discussions with different opinions and solutions. One important step in sponsor oversight is the selection and management of CROs and vendors. The key in CRO/vendor-selection is not only the experience with the specific indication of the CRO, however of same importance is to consider the company cultures to achieve the best alignment within the two or more parties and to define clear responsibilities and expectations. Finally when it comes to define the different involvement of the stakeholders in a clinical trial the legal aspects have to be carefully considered, not only for the sponsor-vendor relationship but also the site contracts and the different requirement of the respective countries within Europe. Another challenge for the majority of the smaller sponsors is the set-up and maintenance of clinical trial oversight management and the use of effective tools, to implement a clinical quality management system and to train clinical development department team. This suggested session should consist of three topics and three speakers include: Selection of vendors and CROs; legal aspects to conduct clinical trial in Europe; effective oversight management in clinical trials.

Biography

Heike Schoen is the Managing Director of LUMIS International GmbH, Germany. She is a Cofounder and Managing Director of LUMIS International GmbH. She has worked in leading positions in clinical research for more than 20 years. Her experience ranges from conducting national and international Phase I clinical trials all the way to registration and post marketing activities as well as business development within contract research organizations (CROs) and the biotechnology industry. Her previous positions included Operational and General Management. She holds a Master's Degree in Psychology and a Master's Degree in Business Administration.

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