

SPARK

BERLIN

LECTURE SERIES

Spark is an initiative created at Stanford University, to overcome challenges associated with translation of academic discoveries. And now in Berlin!



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SEPTEMBER 26TH

NEXT SPARK

EDUCATIONAL FORUM

FROM RESEARCH TO THE REGULATED WORLD

– THE DO'S AND DON'TS IN EARLY DEVELOPMENT

5:00 – 7:00 PM

VIRCHOWWEG 6

CCO AUDITORIUM

PROF. MICHAEL HILDEBRAND, *Friedrich-Schiller University Jena*,
founder and managing director HILDEBRAND PHARMA CONSULTING

After a short overview of the drug development process, Prof. Hildebrand will focus on the different relevant topics of pre-clinical development. A comprehensive review of pharmacodynamic models, safety pharmacology, toxicology, and pharmacokinetics will be provided. The compound and its formulation needs to be addressed from the beginning. Differences between small molecules and biologicals will be described. The relevant guidelines will help in all areas to design the right experiments and studies. The role of animal models and the selection process will be discussed in more detail. Awareness should be generated that individual project aspects play an important role and should be thoroughly described and evaluated. Defining the targets and constraints of the development is a corner stone for future activities and helps to clarify your own position and the discussion with external partners. Smart development strategies will help to generate the data needed for the next development step. The role of regulatory scientific advice, consultancy and outsourcing partners will be exemplified.

Prof. Michael Hildebrand is a pharmacist by training, with a long track record working for Schering AG. Since 2006 he holds a professorship of industrial pharmacy at the Friedrich-Schiller University in Jena. In 2008 he founded and since manages Hildebrand Pharma Consulting. He is also a board member of the Conelis network since 2011.