DZIF/ BfArM / PEI Webinar Series

Preclinical Workshop on Small Molecules and Biologicals

September 2021

Wednesday, 15.09.2021, 3-5 pm (CET)

Session 1: Introduction & Regulatory Background

Topic	Speaker
Welcome & introduction, scope of the workshop	S. Goy (TPMO)
Brief summary of the previous workshops on: - Hit-to-Lead & Lead Optimization of Small Molecules and Natural Products - Biologicals: From R&D to GMP	M. Fürst-Wilmes (BfArM) S. Goy (TPMO)
General regulatory aspects Costs & timings of preclinical studies	M. Fürst-Wilmes (BfArM) S. Goy (TPMO)
Intersection of animal welfare and GLP, relevance of non-clinical studies in drug development, study protocol	P. Empting (Provivo Biosciences)
Discussion	

Wednesday, 22.09.2021, 3-5 pm (CET)

Session 2: Non-clinical development of small molecules

Topic	Speaker
Non-clinical safety evaluation of small molecules	A. Marzoll (BfArM)
Non-clinical GLP toxicology, efficacy and safety pharmacology studies	tbd (CRO Aurigon)
Discussion & lessons learned – Formulation development: - Development of BTZ-043 - Development of Corallopyronin A	F. Kloß & J. Dreisbach (HKI Jena, LMU München) K. Wagner (University Bonn)

Abbreviations: BfArM: Federal Institute for Drugs and Medical Devices, CARB-X: Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator, HKI: Hans-Knöll-Institute, LMU: Ludwig Maximilian University, OSRA: Office for Scientific and Regulatory Advice, PEI: Paul-Ehrlich Institute, TPMO: Translational Project Management Office

Wednesday, 29.09.2021, 3-5 pm (CET)

Session 3: Non-clinical development of biologics

Topic	Speaker
Formulation development	tbd (CRO Leukocare)
Non-clinical safety evaluation of biopharmaceuticals	G. Reichmann (PEI)
Non-clinical GLP toxicology, efficacy and safety pharmacology studies	tbd (CRO Charles River)
Case study from DZIF	G. Sutter (LMU München)
Discussion	

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