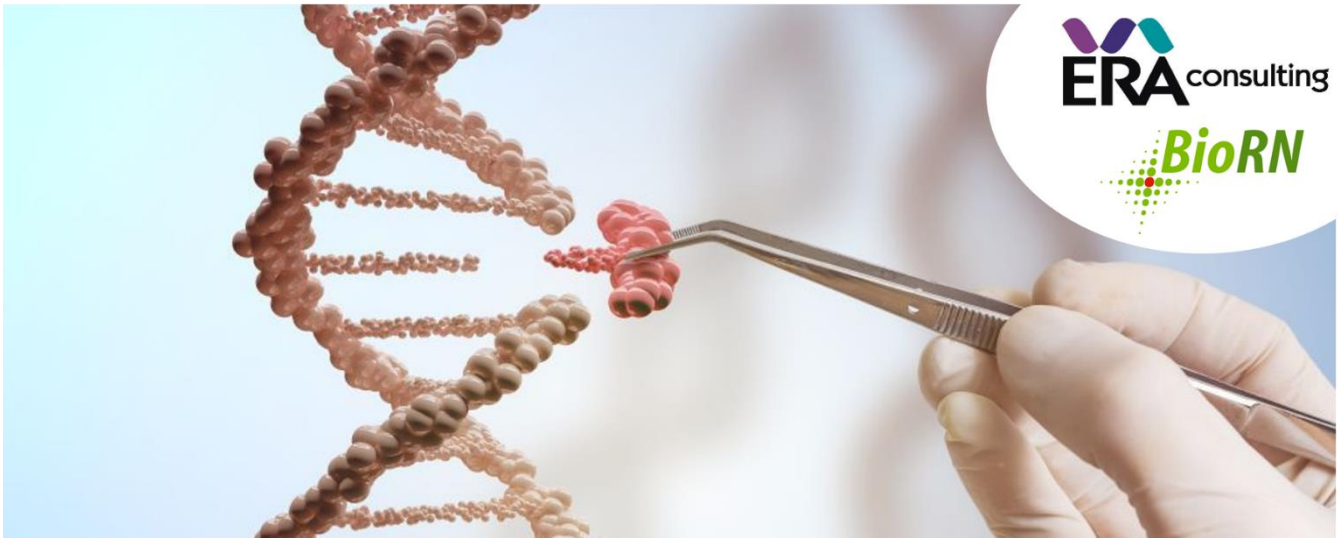
Pathways to Pre-Clinical Development Success: Focus on Biologics and ATMPs



When: November 15, 2018

Where: Heidelberg, Technology Park, Conference Center (Im Neuenheimer Feld 582)

This event will introduce technical and regulatory strategies for pre-clinical development, with a focus on biologicals and advanced therapy medicinal products (ATMPs). The sessions are designed to provide attendees with a regulatory scientific approach for successful translation of biologicals and ATMPs into the clinic. We will aim to provide an understanding of pre-clinical development pathways and requirements for biologicals and ATMPs leading to the most expedited regulatory strategy in Europe, the US and beyond. Potential challenges in the development and registration of these products will also be discussed, to provide practical advice as well as highlight key aspects determining successful regulatory submissions.

Programme:

13:45 – 14:00	Registration
14:00 – 14:05	Introduction by BioRN
14:05 – 14:35	**A Regulatory Strategy Adds Value in Pre-clinical Development - Dr Veronika Alt**
14:35 – 15:05	**Quality Counts in Pre-clinical Development for Cell and Gene Therapies – Dr Dianne Jackson-Matthews**
15:05 – 15:30	Afternoon Tea
15:30 – 16:30	**Critical factors in Successful Pre-clinical Testing - Dr Lesley Earl**
16:30 – 17:30	Reception/Networking

Register by sending your data to az@biorn.org

Biographies:

Dr Dianne Jackson-Matthews, BSc, PhD, RAC
Chief Scientific Officer, ERA Consulting Group/Director of Regulatory Affairs (Australia)

Dianne has over 25 years of experience in pharmaceutical product development, spanning the areas of drugs, biotech/biologics/biosimilars and cell/gene therapies in the US, Europe and Australia. She has experience in development of regulatory and technical strategies, conducts regulatory agency interactions worldwide, prepares regulatory documentation and submissions, and performs regulatory and technical due diligence assessments supporting funding and licensing opportunities for the investment community and the industry. Prior to joining ERA in 2001 as the Director of the Washington DC office, Dianne was the Director of Regulatory Affairs at a biotech company in New Jersey, where she gained extensive experience with biotechnology products over a 12 year period, covering GMP production, GLP and GCP testing, and regulatory affairs. She also has 6 years' experience with in vitro diagnostic device development in the US. Dianne has held an Adjunct Associate Professor position at the University of Queensland, Australia, since 2010.

Dr Lesley Earl, BSc, PhD, ERT
Associate Director, Nonclinical, ERA Consulting (UK)

Lesley provides expert regulatory and scientific advice with respect to human health to companies seeking development through the regulatory processes in the biopharmaceuticals sector. She has over 25 years' experience in hazard characterisation and risk assessment in the pharmaceutical, agrochemical, chemical and food sectors. Lesley has worked as a senior toxicologist with multi-national companies in the fast-moving pharmaceuticals, foods and consumer goods sectors. She has contributed to the international validation and acceptance of in vitro test methods such as skin and eye irritation/corrosion and phototoxicity and is keen to use appropriate strategies for reducing animal testing. Lesley has a PhD in Toxicology from University College, London and a BSc in Toxicology from the University of Surrey. She has over 25 peer reviewed papers and book chapters and has presented posters and platform presentations at many international and national scientific meetings. Lesley is a European Registered Toxicologist, a Fellow of the British Toxicology Society and a member of the UK In Vitro Toxicology Society.

Veronika Alt, Dipl.-Chem., Dr. rer. Nat
Senior Consultant & Head of eCTD, ERA Consulting GmbH

Veronika Alt joined ERA in 2007 and established ERA's eCTD group. Veronika is the head of ERA's eCTD group and has over 10 years' experience in regulatory affairs, including compilation and submission of eCTDs for various jurisdictions. In addition Veronika has a thorough understanding of CTD requirements, including timing for submission deadlines and different requirements for the jurisdictions. As Senior Consultant Regulatory Affairs, Veronika is highly experienced in guiding clients through regulatory challenges pre- and post-approval using her deep scientific and technical expertise. Authoring of quality (CMC) and administrative Modules for MAAs, BLAs, INDs, IMPDs and preparation of various other regulatory documents for (biological) human medicinal products are Veronika's responsibilities. Veronika works on the life-cycle management of several MAAs and successfully completed many post-marketing variations for biological medicinal products. Veronika is also part of EU Agent team and responsible for compilation and submission of CTAs and MAAs as well as requests for Scientific Advice Meetings with different competent authorities. Veronika has a scientific background with a doctoral degree in technical chemistry (biotechnology) and many years of experience in purification and analytical method development and validation of various components, including peptides and proteins