PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

NON-CLINICAL DEVELOPMENT

Non-clinical development includes providing advice to clients in terms of non-clinical study requirements to support various phases of clinical development of active drug substance and subsequent marketing authorization. This includes types of pharmacology, pharmacokinetics, and toxicology studies; their timing/sequence, and an outline of the study design.

What We Offer

- Non-clinical data review & gap analysis
- Develop non-clinical evaluation strategy
- CRO selection, outsourcing, study monitoring and report review
- Non-clinical studies - plan, budgeting and timeline
- Regulatory authority briefing package & questions for US FDA, pre-IND meetings & EU scientific advise meeting
- Compiling & integrating study data into CTD modules.
- Drug metabolism, pharmacology, and toxicology study design
- Literature-based qualification of excipients & impurities

Our Experience

- Differentiated Products [505(b)(2)] / Hybrid Applications
- New Chemical Entities
- Small Molecules
- Peptides
- Biologics
- Biosimilars
- Vaccines
- Cell Therapy
- Gene Therapy
- Drug-Device Combinations

Non-Clinical Support to Medical Device Development

- Biocompatibility evaluation strategy
- Design of biocompatibility studies
- Risk assessment of extractables
- Studies of extractable and leachable evaluation
- Risk assessment and derivation of Tolerable Intake (TI) and Tolerable Exposure (TE)
- Exposure determination & Margin of Safety (MOS)

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