evotec

#RESEARCHNEVERSTOPS

Formulating your way to successful toxicology studies

- **Bespoke solutions** in support of toxicological investigations based on study design needs and compound physico-chemical properties
- **A dedicated team** of pre-clinical formulators with an in-depth understanding of complex bioavailability issues
- **Integrated formulation support** into early tox phase and GLP IND-enabling studies
- **Proven track record** in designing formulations that can be used to support both GLP tox and FIM studies

Areas of expertise

Early Formulation

Material Science – Solid Development

DMPK

Toxicology

Contact our experts

info@evotec.com | www.evotec.com

Rely on comprehensive, integrated capabilities with proven expertise

- An experienced team of pre-clinical formulators and DMPK/Toxicology experts working in synergy
- Services offered include solid form screening such as salt, co-crystal, polymorphism
- Pre-clinical formulators use their knowledge of excipient tolerability to design well tolerated, complex vehicles for challenging water insoluble compounds with bioavailability issues based on species, route of administration and dose requirements for toxicology assessment
- Effective use of formulation approaches in GLP studies:
  - Solutions (using solvents, pH adjustment, surfactants and/or cyclodextrins)
  - Suspensions (using micronized API or nanosized API obtained by nanomilling or solvent-antisolvent precipitation)
  - Amorphous solid dispersions (by spray drying, hot melt extrusion and emulsification approaches)
  - Lipid based systems
- Knowledge gathered during early formulation stage as starting point for clinical formulation development

In vitro, in vivo, in silico models

- *In vitro* dissolution/re-precipitation models to guide formulation development tailored to each animal species both for oral and parenteral compounds
- Fit-for-purpose PK study to assess *in vivo* formulation performance
- *In silico* human prediction model set up based on physico-chemical properties and DMPK data
- Model can be refined as new data is generated; this improves chances of selecting the best compound and formulation for FIM studies and reducing the number of animal studies

One single, unified, collaborative team from preclinical to clinical formulation

- Evotec provides cost and time effective seamless development solutions from early candidate selection to cGMP clinical manufacture according to the highest quality standards