

# Enabling Innovation & Technology Organisations in Life Sciences



**GALILEO**  
RESEARCH

Your R&D Team Extension

# Pharmaceutical

- ▶ *In silico* Predictions
- ▶ *In vitro* and *in vivo* Pharmacology
- ▶ *In vitro* and *in vivo* ADME
  - Biological Barriers Permeability
  - Stability
  - Binding
  - CYP<sub>450</sub> interactions
  - Pharmacokinetic
- ▶ *In vitro* and *in vivo* Toxicology
  - Single and Repeated Systemic Toxicity with toxicokinetics
  - Genotoxicity
  - Reproductive Toxicity
  - Local Tolerance
  - Cytotoxicity
  - Immunotoxicity

# Pharmaceutical

- ▶ Molecular Analysis
  - mechanisms of action
  - target identification
  - protein expression
  - gene expression
- ▶ Sensitization (Mouse Local Lymph Node Assay)
- ▶ Regulatory toxicology (GLP compliant)
- ▶ Management and Planning of the non-clinical phase
- ▶ Regulatory Support
  - CTD
  - Expert Report
  - PDE

# Medical Devices

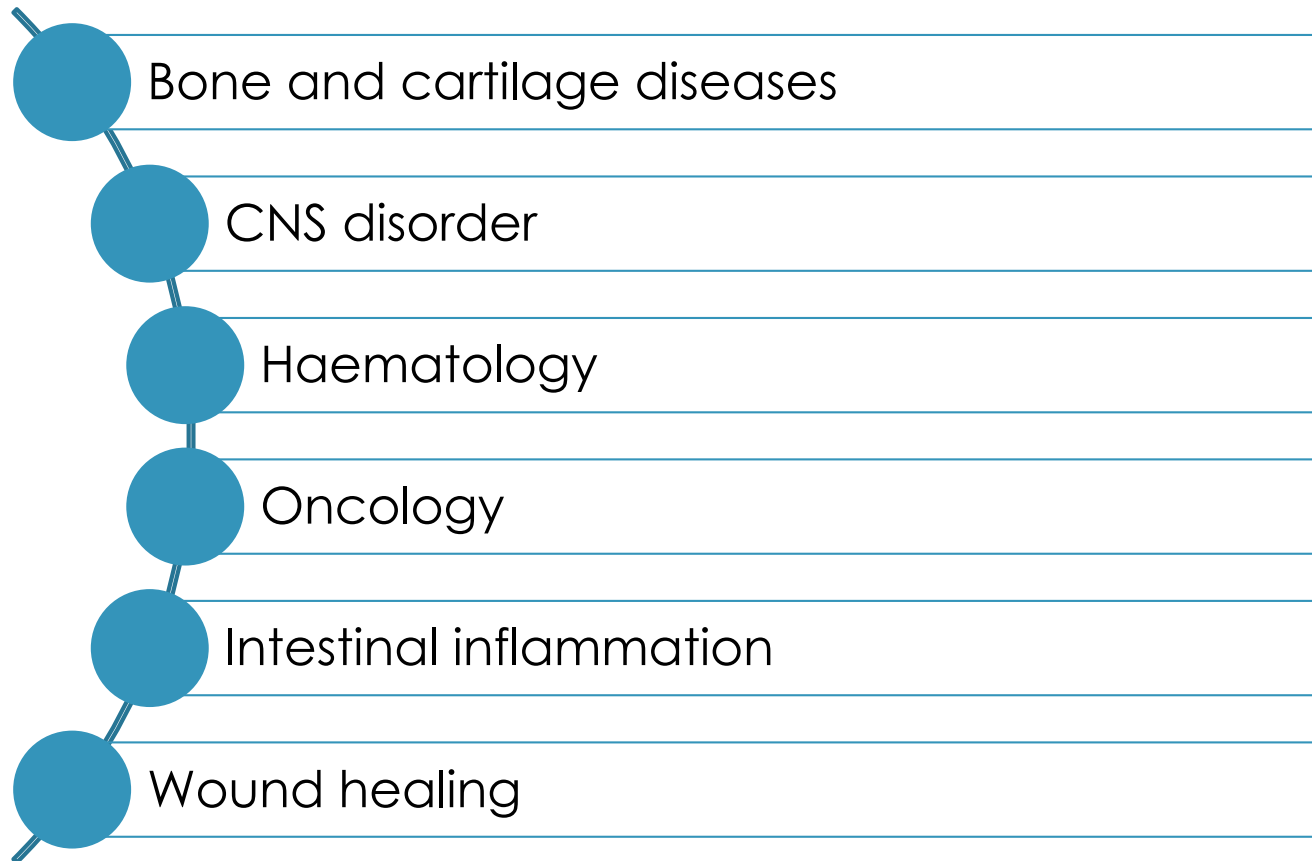
Biocompatibility Plan, Testing (GLP) and Report according to ISO 10993-1 series within a Risk Management Process

- ▶ Genotoxicity
- ▶ Reproductive and developmental toxicity
- ▶ In vitro cytotoxicity
- ▶ Implant toxicity (clinically relevant implantation site)
- ▶ Bio-Degradation
- ▶ Irritation and skin sensitization
- ▶ Systemic Toxicity
- ▶ Sample preparation
- ▶ Toxicokinetic
- ▶ Immunotoxicology

# Novel food, Food supplements and Botanicals

- ▶ *In vitro* and *in vivo* Potential Benefits Assessment
- ▶ *In vitro* and *in vivo* Safety Assessment
- ▶ *In silico* Prediction
- ▶ Regulatory *in vivo* Toxicological Data collection to support approval from EFSA - including genotoxicity, information on absorption, distribution, metabolism and excretion (ADME)

# Key Therapeutic Areas



# A History of Success

- ▶ Hyaluronic acid platform
- ▶ Implanted Medical Devices (bio-polimers)
- ▶ Botanicals
- ▶ Molecular biology
- ▶ Novel food
- ▶ 3D-reconstructed human tissues in vitro
  - Irritation
  - Absorption
  - Efficacy
  - Histology
  - Immunohistochemistry



Close to 100% regulatory submission compliance

**Thank You!**



Your R&D Team Extension

