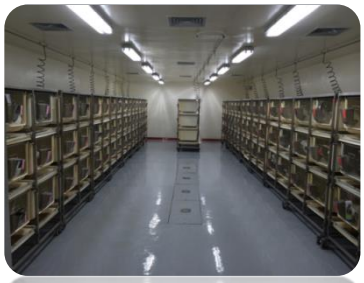
biocameltec
SPM

More than a CRO

we are your partner to bring your R&D projects to clinical

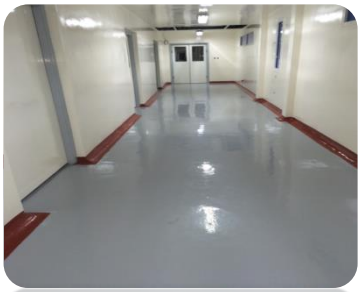
Discovery → Lead Candidat Selection → Pre-Clinical Dev. → Clin. PhI → Clin. PhII → Clin. PhIII → FDA Rev./Approv.

SPM acts effectively in these steps



SPM-Biocameltec is an R&D service provider for

- ❑ Pharmaceutical Industry.
- ❑ Biotech Companies.
- ❑ University Researchers.
- ❑ Government Agencies.



SPM-Biocameltec provides high quality R&D services across a number of disciplines including

- ❑ Pharmacology.
- ❑ Toxicology.
- ❑ Antibody development and production.

SPM-Biocameltec offers a wide variety of animal species such as rabbits, dogs, cats and other largest animals such as sheeps, horses, camels, swines..

SPM-Biocameltec's mission is to offer the highest quality R&D services within short deadlines to advance our customer projects in a timely and cost effective manner. Our work with animals is carry out strictly in accordance with the local national regulations and legislation and the code of ethics and guidelines of our customer countries of (e.g. 2010/63/EU).

SPM-Biocameltec *in vivo* DMPK

Characterizing the relationship between the pharmacokinetics (PK, concentration vs. time) and pharmacodynamics (PD, effect vs. time) is an important tool in the discovery and development of new drugs in the pharmaceutical industry.

At SPM-Biocameltec we propose PK and PD studies to support early stages drug discovery process.

❑ **Drug Disposition/Pharmacokinetics (ADME)**

To evaluate the bioavailability, tissue distribution, active metabolite formation, and elimination of test materials.

❑ **Pharmacodynamics**

To evaluate the relationship between drug concentration and the resulting effect, including the time course and intensity of therapeutic and adverse effects.

❑ **In Vivo Topical Absorption Studies**

To study percutaneous absorption of drugs or environmental contaminants.

- **Duration**: 6 to 72 hours.
- **Animals**: Rabbit, Dog, Swine or other species (upon customer request).
- **Dose and route of administration**: Various according to client conditions.
- **Parameters:**
  - **PK:** AUC, Cmax, Tmax, $T_{1/2}$ ...
  - **PD:** Kinetic of therapeutic (or adverse effects) apparition
  - **Topical Absorption:** Absorption rate (quantitation in blood, urine, feces, vaginal fluids, and tissue samples).

SPM-Biocameltec *in vivo* Toxicology

To achieve toxicological studies **2 species are required**, one of them is **rodent** such as mice and rats and the other specie must be **non-rodent**.

SPM Biocameltec allows you **to complete your toxicological** studies and propose several species such as dogs and rabbits and other non-rodent species.

- ❑ **Acute Toxicity** , to evaluate, the LD50, the MTD, NOEL, potential target organs for toxicity, reversibility of toxicity, and the selection of doses for repeated-dose toxicity tests.
- ❑ **Subacute Toxicity (Repeated Dose)**, to determine toxicity after repeated administration of the test material and to help establish doses for subchronic studies.
- ❑ **Subchronic Exposure**, to identify NOEL and specific organs affected, characterize dose-response relationships following repeated doses and predict a reasonable and appropriate dose for chronic exposure studies (MTD).
- ❑ **Chronic Exposure**, to evaluate the cumulative toxicity of chemicals and to assess carcinogenic potential.

- **Duration**: A few days to 12 months.
- **Animals**: Rabbits or dogs. Other species are also feasible upon request.
- **Dose and route of administration**:
  - **Acute Toxicity:** Single administration by oral or other route of administrations.
  - **Subacute Toxicity:** 3 to 4 doses given by the same route as acute toxicity tests.
  - **Subchronic :** At least 3 doses given by the same routes as previous toxicity tests (the lowest producing no apparent toxicity and the highest producing toxicity but less than or equal to 10% mortality).
  - **Chronic Exposure**: For non-rodents species including dogs, 12 months or longer (or up to 10% of species' lifespan).
  - **Parameters:** Weight change, clinical pathology, signs of toxicity, gross necropsy and mortality.

SPM-Biocameltec Pathological Models and Naturally Diseased Animals

❑ Rabbit Models

SPM-Biocameltec offers dyslipidemic and atherosclerotic rabbit models for the evaluation of therapeutics.

- **Casein-induced dyslipidemia** in New-Zealand rabbits.
- **Cholesterol-induced atherosclerosis** in New Zealand rabbits.

❑ Naturally Diseased Dogs and Cats

- Cancer Diseases
- Inflammatory and Autoimmune Diseases
- Metabolic Diseases
- Cardiovascular Diseases
- Neurological Diseases
- Infectious Diseases
- Urinary System Diseases.

❑ Supported animals

- Hospitalization
- Chemotherapy treatment.
- Clinical monitoring
- Blood sampling and harvesting of tissues/organs
- Tests: Biochemistry, Radiography, Ultrasound, Anatomopathology

❑ Available Samples

- Biopsies
- Tumor masses
- Blood and derivatives
- CSF
- Urine

SPM-Biocameltec Conventional Polyclonal Antibody Production

- **SPM-Biocameltec offers** laboratories and animal facility both with state-of the art equipment as well as animal housing with conditions that meet the highest international standards for antibody development and production.
- **SPM-Biocameltec** has a **high capacity** of producing polyclonal antibodies. We offer a **cost-effective service** and are able to produce **large batches** of immune-serum (**more than 100 Liters**).
- **Custom polyclonal antibody production** is accomplished using a wide variety of species. We are able to provide immune-serum from: Rabbit, Goat, Chicken, Sheep, Donkey, Horse …

Example of Standard Protocol

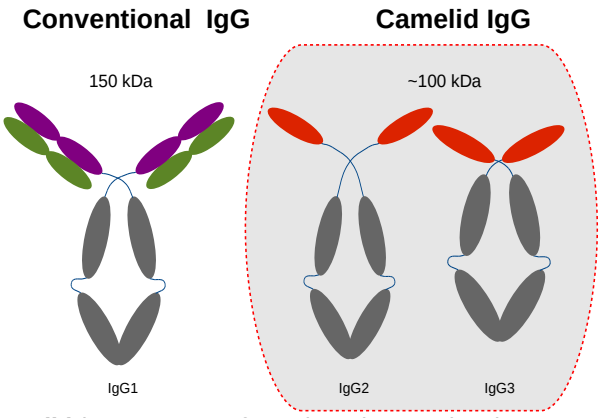
	Rabbit			Chicken	Goat
Duration	55 Days	67 Days	90 Days	90 Days	90 Days
Pre-immune Bleed & 1st immunization	0	0	0	0	0
Boost #1	14	14	21	14	21
Boost #2	28	28	42	28	42
Bleed #1	35	35	53	55	53
Boost #3	-	42	63	55	63
Bleed #2	-	53	74	70	74
End of Protocol (final bleed)	55 Days	67Days	90 Days	90 Days	90 Days

- **Other services**

- Antibody purification and characterization: Immune-serum titration, IgG precipitation and purification of specific antibodies.
- Other biological products: Blood and its derived components (erythrocytes, plasma & serum, reticulocyte lysate system…) from different animal species (horse, sheep, camel, goat, rabbit…).

SPM-Biocameltec HcAb Antibody Production

❑ **SPM-Biocameltec proposes** the production of unconventional antibodies called **HcAb** for *heavy chain only antibodies* from camelids (polyclonal immune-serum and whole lymphocytes for the engineering of nanobodies)

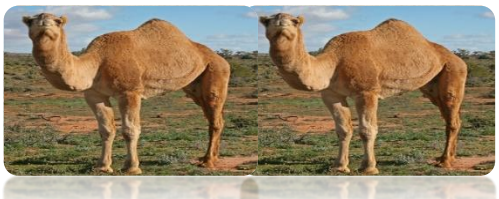


IgG from camelid *have a MW of 100 kDa (conventional IgG; 150 KDa), and there antigen binding domain represents only* ***12 -15 kDa****. This characteristic (lower MW) gives to camelid antibodies there unique properties: to* ***recognize inaccessible epitopes****, to* ***penetrate tissues and cells easily****, and to* ***resist to large pH*** *and* ***temperature variations****.*

For all these reasons camelid antibodies are attracting a lot of interest as potential therapeutic and diagnostic tools

Standard Protocol of Immunization

- **Protocol duration: 84 days.**
- **Antigen: 2mg /dromedary.**
- **Number of Immunizations: 4/animal.**
- **Non-immune sample: 20ml.**
- **Immune-serum Production: 2 samples called sample of production (500 ml minimum).**
- **Control: intermediate sampling from the 2^{d} immunization and the final sampling for IgG production could be performed if needed for the determination of the optimal immune-response**



Protocol Work Flow

- **Day 1: pre-immunization sampling and injection of Freund's adjuvant**
- **Day 21: the first antigen injection**
- **Day 42: the second antigen injection**
- **Day 53: sampling for test**
- **Day 62: the third antigen injection**
- **Day 71: the 1st immune-serum « production »**
- **Day 76: the forth antigen injection**
- **Day 96: the 2^{d} immune-serum « production »**
- **Animal housing: dromedaries are maintained and could be re-immunized (once/month) if needed for a long term antibody production**

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To speedup your science

For more information about SPM-Biocameltec,

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www.biocameltec.com

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