

EXPLORE YOUR OPTIONS WITH OUR....

EVALUATION OF IMMUNE PROPERTIES

SPI-BIO develops, manufactures and markets EIA kits (based on a patented technology) for **xenobiotics & biomarkers**.

This results from a close and long-term co-operation with the French Atomic Energy Commission (CEA) since 1991.

SPI-BIO is also a Drug Development Services Company that proposes scientific expertise and tools for your pharmaceutical research (pre-clinical and clinical phases):

Pharmacology - various investigation fields

- AIDS (HIV), TSE (prions),
- Vaccines & adjuvants;
- Neuro-degenerative disease (e.g. Immune response in multiple sclerosis);
- Allergy;
- Inflammation.

Pharmacokinetics & Metabolism - GLP studies

- Animal & human pharmacokinetics;
- Intracellular pharmacokinetics;
- In vivo & in vitro metabolism profile;
- Alternative in vitro models (human BBB, transporters, CYPs).

Bioanalysis for NCEs, peptides, polypeptides, proteins & oligonucleotides

- GLP development, validation of assays & drug measurement;
- Various techniques such as, HPLC-MS/MS, Immunoassay, competitive hybridization.

Microbiological safety (HIV & prion)

- Assessment of manufacturing & purification processes as well as detergents & sterilisation steps.

Biotransformation platform for the generation & production of NCE and metabolites

SPI-BIO along with Ellipse pharmaceuticals form the Bertin Pharma Biotech Division ready to shape a project in accordance with Biotech and Pharmaceutical companies' needs:



Innovation & Services in Pharmaceutical Development (Original Drug Delivery Systems, New Products & Processes).

Besides, **bertin technologies** is also your partner for designing and manufacturing laboratory equipment for Life Science Laboratories & Environment surveillance.

SPI-BIO offers its expertise for evaluation of biological effects of **new immunomodulatory compounds, and of adjuvant or vaccinal solutions on the immune system and of the neutralisation of biological effects** in volunteers treated with one of these compounds.

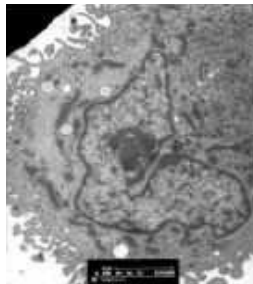
These studies are undertaken in close cooperation with the sponsor. They are realised according to a protocol approved by all parties. All expertises follow a precise time-table. At the end of the assessment, a meeting is organised to discuss the experimental conditions and the data obtained. These are synthesised in a final report reviewed by the sponsor.

Immunomodulatory compounds for the following therapeutic categories:

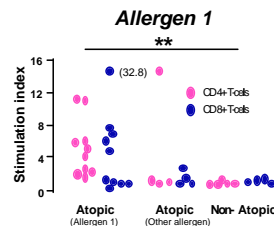
Autoimmune disorders (e.g. Multiple sclerosis)
Infectious diseases (HIV, Hepatitis B & C)
Cancer
Allergy & Asthma
Chronic Inflammation
(Atherosclerosis, cardiovascular diseases, diabetes, obesity, ...)

Indeed our scientists have several years of experience in the characterization of innate & adaptive immunity and in the evaluation of immunomodulatory properties of drugs, vaccines, and adjuvants:

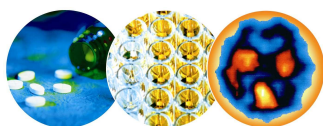
- Using primary cultures or cell lines as *in vitro* models,
- Using cynomolgus monkeys as *in vivo* model,
- During immunological follow-up of clinical trials (phase I to III).



Primary human macrophage in electronic microscopy



Proliferative responses of CD4+ and CD8+ T lymphocytes in response to an *in vitro* stimulation with the allergen 1



SPI-Bio & Ellipse PHARMACEUTICALS:
BERTIN PHARMA BIOTECH COMPANIES

METHODS

The researchers operate if necessary, in an extensive biosafety level 3 suite of laboratories. They handle a wide range of techniques. Several of these techniques have been developed or improved for the experimental purposes outlined above.

- Specific T lymphocyte response against mitogens, antigens, peptides, vaccines or allergens (proliferative response, ELISPOT),
- Immunophenotyping (Flow cytometry),
- Biological activities of antigen presenting cells such as dendritic cells & macrophages (human models), EIA, RIA of cytokines or other cell factors such as histamine, eicosanoids, GSH, etc.,
- mRNA expression by quantitative RT-PCR (cytokines or other cell factors),
- Natural killer (NK) & cellular T lymphocyte (CTL) activity,
- Neutralisation tests directed against administered compounds,
- Microarray technologies (multiple cytokine protein array & multiple inflammatory gene array),
- "Chemotaxis assay", ...

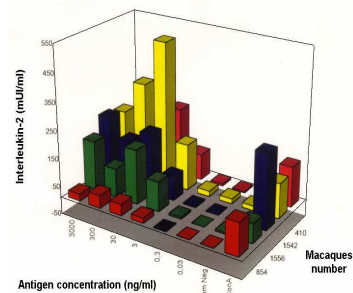
BIOLOGICAL MATERIAL

CELLS FOR CULTURE & CO-CULTURES

- Peripheral blood mononuclear cells,
- Peripheral blood lymphocytes,
- Monocytes,
- Monocyte-derived macrophages,
- Monocyte-derived dendritic cells,
- Endothelial cells,
- Astrocytes,
- Keratinocytes.

BIOMARKER ASSAYS

The level of knowledge and experience of SPI-BIO can help you to find the optimal biomarker assay and to offer you full integrated biomarker support from development of new assays, full validation under GLP for PK/PD studies to kits ready-to-use.



IL-2 in SIVmac-infected cynomolgus macaques, treated or not by HAART

RELATED SERVICES

Evaluation of anti-inflammatory drugs
Intracellular measurement of drugs in HIV and cancer therapy
P-glycoprotein and other ABC transporters

Evaluation of anti-retroviral molecules
Evaluation of anti-prions molecules