vivo Science provides services focussing on safety toxicity, immunological and customized extended studies for biologicals, small molecules and chemicals.

Study protocols are individually adapted to your technical document and follow the recent guidelines of EMEA/CPMP or corresponding FDA, ICH or OECD guidelines.

Our studies will be performed in full compliance to GLP or GMP.

Do you produce biogenerics like EPO or G-CSF according to European Pharmacopoeia? Do you intend to develop new biologicals to the point of marketing authorization?

Ask our study directors for a customized in-vivo bioassay. We´ll develop and validate your assay - fast and reliable.

...choose a CRO dedicated to the immune system...

vivo SCIENCE
GmbH
Fabrikstr. 3
48599 Gronau / Germany

Call our scientific managers:

Dr. André Rademaekers

Specialized in microbiology and immunology, expert in developing customized immunological assays. Test Facility Manager.

Dr.-Ing. Frithjof Wollbold

Physicist and engineer with wide experience in precision measurement. Director of GLP / GMP quality management.

✆ ++49 +(0)2562 8170- 0

www.vivoscience.de

Order a GLP immuno-assay - tailored individually to your needs

VIVO
SCIENCE GMBH

Safety and Toxicity

Immunotoxicity

in vivo assays

vivo SCIENCE
GMBH

Immunogenicity

Immunogenicity testing is especially recommended by the EMEA and FDA in case of biotechnology derived drugs.

in vivo
- measurement of DTH responses
- active and passive cutaneous anaphylaxis
- local lymph node assay

ex vivo
- antigen dependent proliferation of primed lymphocytes
- antigen dep. cytokine production of primed lymphocytes
- quantitation of antigen-specific antibodies
- quantitation of antigen/allergen-specific IgE (ELISA)
- detection of glomerular immune complexes
- detection of autoantibodies

Safety and Toxicity

Standard Toxicity Studies in rodents,
e.g. to use for the registration with REACH

- OECD 402 Acute Dermal Toxicity
- OECD 407 Repeated Dose 28-day Oral Toxicity Study
- OECD 408 Repeated Dose 90-Day Oral Toxicity Study
- OECD 410 Repeated Dose Dermal Toxicity: 21/28-day Study
- OECD 414 Prenatal Developmental Toxicity Study
- OECD 415 One-Generation Reproduction Toxicity Study
- OECD 420 Acute Oral Toxicity - Fixed Dose Method
- OECD 421 Reproduction/Developmental Toxicity Screening
- OECD 423 Acute Oral toxicity - Acute Toxic Class Method
- OECD 425 Acute Oral Toxicity: Up-and-Down Procedure

vivo Science has validated a stepwise approach for immunotoxicity testing. This approach is in full compliance with immunotoxicity testing guidelines issued by EMEA and FDA, especially to ICH guidance S8.

Tier I
Immunopathology
- Blood counts (total and differential)
- Cellularity of lymphatic organs (flow cytometry)
- Wet organ weights (lymphatic); body weight & temperature
- Histopathology (lymphatic)

Humoral immunity
- Total serum protein, albumin: globulin ratio
- Immunoglobulin isotype distribution (IgM, IgG, IgA, IgE)
- Hemolytic complement-activity

Cellular immunity
- Natural killer cell (NK) activity
- Mitogen stimulation assay
- Phagocytic activity

Immunotoxicity

Tier II
Humoral immunity
- Kinetics of humoral responses against T-dependent antigens
- Kinetics of humoral responses against T-independent antigens

Cellular immunity
- Primary and secondary mixed lymphocyte reaction (MLR)
- DTH reaction
- CTL-activity against allogeneic tumor cells

Host defense
- Syngeneic tumor models (growth / regression / metastasis)

In vivo monitoring of human or veterinary drugs, biopharmaceuticals, chemicals and other compounds:

- acute & subchronic toxicity
- repeated dose toxicity
- immunotoxicity
- immunogenicity
- sensitisation / allergenicity
- local tolerance
- efficacy / potency
- biosimilarity
- bioavailability
- virus safety

- and more! Take full advantage of our expertise and equipment like biosafety level 2 labs supplied with IVC's for the handling of GMO's and infectious substances. Upon request, we either perform your entire project or act as PI for study parts.
Our start to finish service includes designing the study protocol, performing the entire animal-related project like the technical, surgical and histopathological work up to the final report.

in vivo bioassays

According to European Pharmacopoeia, vivo Science has validated GMP compliant procedures for virus-safety tests of cell lines and other pharmaceutical products. We provide potency testing, e.g. for recombinant Erythropoietin (EPO). GMP-tests for other biogenerics (e.g. G-CSF) on request.

Biologicals: specialized in-vitro assays determine the predictivity of test results from simian-models for safe clinical application