

Benefit from our experience and laboratory capabilities, which include modern animal facilities and biosafety 2 laboratories required for testing GMO's and infectious agents. Our service can include designing the required study, on through to performing the entire test and producing a GLP-compliant final report. In the case of testing for adventitious agents, we provide a GMP-compliant certificate of analysis. The entire project is performed in close collaboration with our clients to ensure that their requirements are fulfilled.

Vivo Science performs studies focusing on safety toxicology, immunotoxicity, as well as immunogenicity studies and testing for adventitious viral agents. We have experience in working with chemicals, small molecules and biologicals including biosimilars and advanced therapy medical products. Please contact us to discuss your particular requirements.

We can develop and validate customized assays  
– fast, reliable and Q2R1 compliant.

– more than just Immunology...

**VIVO**  
SCIENCE

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**VIVO**  
SCIENCE

- Immunotoxicity
- *in vivo* assays (GLP+GMP)
- non-clinical safety and toxicity



vivo Science – more than just Immunology...

# vivo Science

vivo Science is a privately owned, independent CRO focused on immunology and toxicology studies, as well as adventitious virus testing.

Regulatory agencies such as the FDA or EMA have developed guidelines to ensure the safety of new drug candidates. These include, among others, testing for immunotoxicity (ICH-S8) and immunogenicity (ICH-S6). vivo Science offers assays as required by these guidelines using both *in vitro* and *in vivo* methods that are GLP-compliant.

**vivo Science also performs the immunological testing and the standard toxicity testing required for medical products.**

**In addition, we perform the required OECD-compliant testing for REACH.**

## Specific capabilities

### • Immunotoxicity

- Standard toxicity
- Functional assays
- Immunophenotyping
- Host resistance
- Tumor models
- Specific humoral immunity
- ADCC/CDC

### • Immunogenicity

- Delayed-type hypersensitivity response
- Active / passive cutaneous anaphylaxis
- Antigen-dependent primed lymphocyte proliferation
- Quantification of antigen-specific antibodies
- Cytokine arrays
- Detection of auto-antibodies and anti-drug antibodies

### • OECD-compliant testing for the REACH program

- 28-day and 90-day repeat-dose oral testing
- Reproduction and developmental toxicology
- Combined repeat-dose toxicology screening testing

...more upon request

### • Experience includes, for example

- Testing of biologicals including biosimilars
- Pharmacokinetic and pharmacodynamic testing
- Immunoefficacy of therapeutics
- Potency assays for vaccines and growth factors
- Developing a variety of customized assays

**– more than just Immunology...**