



→ Business activities

Potential OECD studies

NewLab BioQuality GmbH offers you a range of standard studies using rodents in accordance with OECD guidelines.

The following studies can be performed ASAP in-house:

- 402 Acute Dermal Toxicity (Updated Guideline, adopted 24th February 1987)
- 407 Repeated Dose 28-day Oral Toxicity Study in Rodents (Updated Guideline, adopted 27th July 1995)
- 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents (Updated Guideline, adopted 21st September 1998)
- 410 Repeated Dose Dermal Toxicity: 21/28-day Study (Original Guideline, adopted 12th May 1981)
- 420 Acute Oral Toxicity – Fixed Dose Method (Updated Guideline, adopted 20th December 2001)
- 423 Acute Oral Toxicity – Acute Toxic Class Method (Updated Guideline, adopted 20th December 2001)
- 425 Acute Oral Toxicity: Up-and-Down Procedure (Updated Guideline, adopted 20th December 2001)

Do you have any special questions?
Please feel free to ask and challenge us

→ Contact

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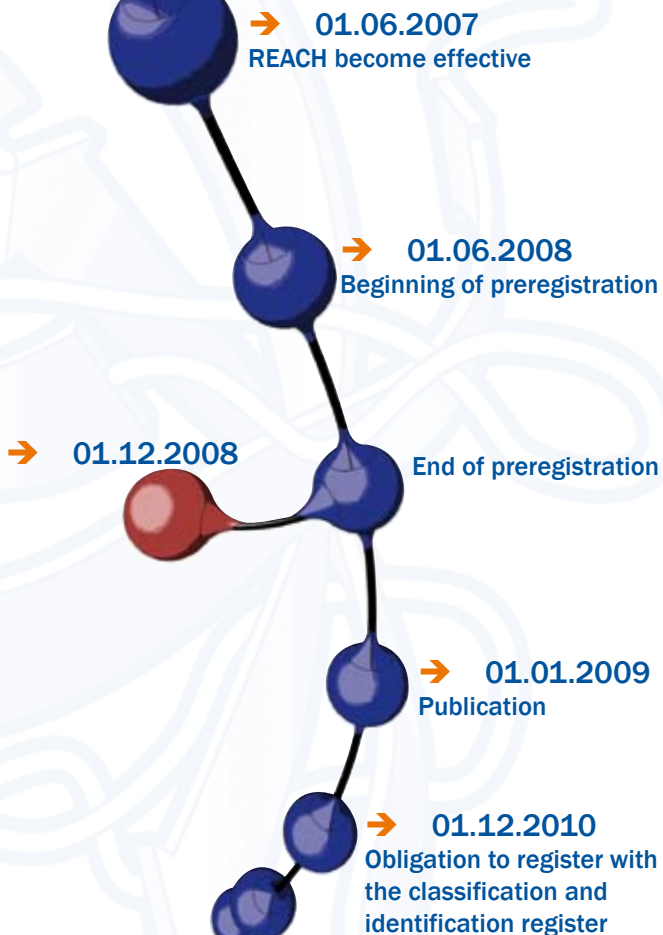
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→ How to find us

You will find NewLab BioQuality GmbH in the Wirtschaftszentrum Gronau (WZG) on the 2nd floor, sections C and B. The WZG is located about 100m from the Gronau train station.



→ REACH
The new
EU-Chemicals law





→ Reach

What is REACH and what do you have to do to comply with its regulations?

In order to increase the safety of humans and the environment, the new registration, evaluation, and authorization of chemicals – REACH – was created effective July 1, 2007. This decree has to be implemented in all EU states immediately.

What does REACH mean for you as a producer, importer, or downstream user in the marketplace?

In short: You are responsible for the safety of your product or imported product, even for products you use as an end user, and therefore you have to generate corresponding data on environmental safety and potential effects within the scope of the decree. This means that in the future you may only produce, distribute, and use substances if they have been awarded the necessary regulatory approval.

In vivo toxicity studies according to OECD guidelines

For the majority of chemicals and substances already on the market, insufficient data are available concerning toxicity. In order to fulfill the registration requirements of REACH it is necessary to generate these data for regulatory approval. In contrast to the registration of pharmaceuticals, a study on rodents, usually rats – following applicable animal protection guidelines – is sufficient.



Where is the challenge?

For example, did you know that a conformity study takes considerably more time than stated in the OECD guideline?

A 28-day toxicity study, as will soon be demanded for your products, may take up to five months between closing the contract and issuing the final study report. In such a case, you would be supported by NewLab BioQuality GmbH with their extensive expertise and experience in the field of in vivo studies.

From the generation of a study plan to the planning of the in vivo phase, the actual performance of the study, and the issuing of the final study report, you receive optimized planning and a personalized supervision from us.

→ Certification and Service Spectrum

GLP

NewLab BioQuality GmbH is certified according to the requirements of Good Laboratory Practice (§19, paragraph 1, Chemicals Law) for the following categories

- Category 2

Studies for the analysis of toxicological properties

- Category 9

Immunotoxicology and immunogenicity in vitro and in vivo

The certificate conforms to international guidelines including the OECD and the Chemicals Law, currently ENV/MC/Chem(98)17 effective April 22, 1999.

NewLab BioQuality GmbH is your partner in all three central areas in the characterization of substances and the preclinical development of components

- quality
- safety
- efficiency

up to regulatory approval.



GMP

Since June 2007, NewLab BioQuality GmbH has been accredited for virus safety studies in Good Manufacturing Practice.