




ANIMAL WELFARE - POLICY



At Formycon, we are committed to ensure that all our products are safe, effective, and efficient. All our products are developed in full compliance with regulatory standards. Although regulatory guidelines of the main regulatory authorities such as the EMA, FDA and PDMA allow for the waiver of animal studies based on analytical data for the development of biosimilars, in rare cases and due to regional standards, it is required that our products are tested on animals before clinical studies on humans can be initiated.

It is Formycon's ambition to minimize or, opt out of animal studies for research by implementing alternative research methodologies like in-vitro or ex-vivo testing or computer modelling wherever feasible. Formycon conducts animal studies only when requested by health authorities. In such cases, we engage external service providers to carry out the studies on our behalf. We expect our business partners who are commissioned with such studies to comply with the ALAAC standards (Association for Assessment and Accreditation of Laboratory Animal Care) or similar regional guidelines. If animal studies are required, Formycon will

ensure that these studies are conducted with the highest ethical and scientific quality standards of animal welfare, adhering to the internationally recognized 3Rs principles:

- **Replacement** - studies on animals are replaced with alternative methods
- **Reduction** - the least number of animals possible will be used for the study
- **Refinement** - through improved methods, animal welfare is increased

Formycon recognizes that the testing on animals carries a special kind of responsibility. For this reason, Formycon does not only comply with all laws and regulations on animal testing but has also adopted this Policy to ensure their respectful and ethical treatment.

Purpose

This Policy outlines the guidelines and procedures to govern all activities related to animal use by Formycon or on behalf of Formycon.

Review and updates

This Policy will be periodically reviewed and updated to reflect changes in laws, regulations, and best practices related to activities using living animals. Employees will be notified of any updates to the Policy and must comply with the revised provisions.

Scope

This Policy applies to all employees of the Formycon AG and its subsidiaries.



Principles

- Formycon only conducts studies with animals when scientifically justified and/or required by health authorities.
- Formycon fully supports the replacement of animals with non-animal alternatives wherever feasible, while meeting our obligations to patients and the expectations of regulatory agencies.
- Before each animal study, careful evaluation takes place, especially regarding the purpose of the study, the effects on the animals and the reasons why results cannot be obtained otherwise. The study will only take place, if animal testing is required by mandatory regulations or results cannot be achieved through an alternative method.
- All animal studies carried out on Formycon's behalf must adhere to this Policy and set of Standards. Moreover, all employees that partake in animal studies on behalf of Formycon must be properly trained and qualified in the conduct of animal studies.
- All Formycon sponsored animal studies must meet or exceed applicable national laws, regulations and accreditation guidelines for the care and use of animals in research.
- Unnecessary harm, stress or pain to the animals must be avoided. Furthermore, animals are to be kept with optimal housing, including environmental enrichment, hygiene, and qualified and independent veterinary care.
- Formycon will only use animals that were bred for the purpose of testing and were acquired through Animal Using Vendors (AUV) that are compliant with national laws.
- As strong adherents to the 3Rs concept, we acknowledge the importance of animal welfare, including the respectful and ethically correct treatment of animals, and support the development of alternative research methods.

Policy breaches

Breaches of this Policy will result in remedial, corrective, or disciplinary actions up to and including termination of employment or supplier contract. Actual or suspected incidents of misconduct should be reported. For this purpose, our Whistle-blower tool can be used. Please see our Whistle-blower Policy (GUI-00019) for further information.

