



# Merck KGaA, Darmstadt, Germany

## Policy Use, Care and Welfare of Laboratory Animals

### Introduction

Current international and national legislation and international pharmacopoeias mandate animal testing of medicinal compounds and chemicals during their development and prior to their approval for marketed use in humans.

Life science animal activities involve typically the animal by-products from live donor animals or from food-producing animals for the production of in vitro commercial products as well as the production of antibodies in animals. These activities are to be conducted in compliance with the applicable local/national legal requirements and Merck KGaA, Darmstadt, Germany standards where written agreements with the defined animal science and welfare criteria are in place, and in compliance with the local established ethical, scientific, quality, and regulatory standards.

Animal studies are required by law and are critically important to ensure

- (1) the safety of chemicals and pharmaceuticals,
- (2) the quality of biological drugs,
- (3) the efficacy of pharmaceuticals in animal research, and
- (4) in the production and quality control of biologics

At present, without animal research it is not possible to develop safe and highly effective drugs and chemicals.

Animal Research Activities are considered all activities involving animals, performed by Merck KGaA, Darmstadt, Germany or in the name of Merck KGaA, Darmstadt, Germany, e.g., in research, development, quality control, contract business and the production of or trade with materials.

This policy addresses our core commitments for the use, care and welfare of laboratory animals in the frame of animal research activities conducted by Merck KGaA, Darmstadt, Germany or on behalf of Merck KGaA, Darmstadt, Germany. All related activities are performed in compliance with all applicable legal requirements and our standards, and in compliance with established ethical, scientific, quality, and regulatory standards.



## Core Commitments

In line with the mission to create value and benefit to patients and consumers by developing innovative medicines and chemicals based on scientific excellence and the established ethical standards, we are committed to

- conducting animal research activities only if no other method or testing strategy is available for obtaining the result/product sought, not entailing the use of a live animal.
- applying established and fit-for-purpose practices, defined as a combination of best techniques, methods, people and science in the performance of animal research activities where they are unavoidable and cannot be replaced by alternative methods,
- following the highest ethical standards and to offering state of the art housing and husbandry conditions<sup>1/2</sup> in their care and use while continuously striving to improve these animal care and use conditions,
- promoting awareness of, and to performing continuous training on animal science and welfare to all people involved in animal research at Merck KGaA, Darmstadt, Germany,
- using alternative methods to aid drug discovery and preclinical development, along with processes to register chemicals, to control quality of biologics and to produce biologics, wherever possible,
- engaging actively in the development and implementation of methods and technologies to reduce, refine or replace animal experiments.

Wherever we conduct animal research activities, contingent on the local and international legislation, an expert (e.g., Animal Welfare Officer) or a team of experts (e.g., Institutional Animal Care and Use Committee, Animal Welfare Body) competent in animal science, welfare and compliance is appointed.

All our operative sites or external companies contracted by Merck KGaA, Darmstadt, Germany involved in animal research activities will seek, in accordance with applicable regional, national and international regulations, the ethical and scientific approval of animal research activities before their initiation.

At Merck KGaA, Darmstadt, Germany, animal welfare falls under the Group Function Animal Science and Welfare (EQ-A).

The Corporate Animal Welfare Officer

- governs, defines and ensures our strategy on Animal Science & Welfare,
- sets down the requirements we place on third parties who conduct animal research activities on our behalf,
- assures global corporate AS&W compliance to legislation and our commitments by controlling, executing and initiating independent AS&W audits at Merck KGaA, Darmstadt, Germany, CROs and partners,
- is the central and mandatory point of contact for annual reporting of AS&W related topics as well as interim reporting of AS&W relevant developments and incidents.

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<sup>1</sup> Directive 2010/63/EU on the protection of animals used for scientific purposes

<sup>2</sup> Guide for the Care and Use of Laboratory Animals: Eighth Edition Committee for the Update of the Guide for the Care and Use of Laboratory Animals; National Research Council



- manages advocacy of AS&W topics in relevant national and international bodies and associations.

EQ-A is supported by a steering committee (Group Animal Welfare Council) with direct reporting lines to the Merck KGaA, Darmstadt, Germany Executive Board (GL). Its mandate is to

- Decide on our Global Animal Welfare Strategy, Standards and Compliance Indicators
- Decide on global AS&W topics, define alignment on local AS&W topics
- Advice on potential threats and developments (new legislation) and decide on measures to be taken
- Decide on business critical AS&W related issues
- Approve scientific animal practices strategy

Know how in such fields is supported by the expertise and experience accumulated at Merck KGaA, Darmstadt, Germany, combined with active participation within national and international platforms, committees, associations, and initiatives in the laboratory animal science environment.

**For us, excellence and expertise in animal care, use and welfare are of high priority to provide the best quality of life possible to the laboratory animals. We also recognize that the quality of data generated from animal research activities is directly related to the well-being of the animals. Merck KGaA, Darmstadt, Germany is therefore committed to use those standards and practices in animal care, use and welfare best suited to effectively minimize pain, suffering and distress as follows:**

- 1) ensuring high quality and state-of-the-art housing and husbandry conditions for laboratory animals and continuously improving these conditions based on the criteria of established, state-of-the-art standards,
- 2) applying and actively promote the 3Rs (Reduction, Refinement and Replacement) in animal research activities,
- 3) promoting the validation and regulatory acceptance of methods to replace, reduce or refine animal research activities,
- 4) developing and fostering relevant and high level training and continuous education for all employees working directly and indirectly with laboratory animals,
- 5) selecting external partners based on their compliance with our high standards of animal welfare when they conduct animal research activities on behalf of Merck KGaA, Darmstadt, Germany or supply us with animals,
- 6) applying internal auditing systems to ensure compliance with the agreed animal welfare standards and the existence of appropriate documentation thereof,
- 7) actively contributing to auditing activities of internal animal facilities and external partners on animal welfare standards and compliance on a global level,
- 8) promoting, in addition to regular authority inspections, the development of external, independent assessments of our animal welfare programs and facilities,
- 9) contributing to a continuous, open and constructive dialogue on laboratory animal research and welfare with interested and involved stakeholders.

