



Laboratory animal research is indispensable to the discovery, development, manufacture and marketing of innovative medicines that treat and prevent disease.

Our company is dedicated to the ethical and responsible treatment of all animals used in the development of medicines and vaccines. Decisions regarding animal care, use and welfare are made by balancing scientific knowledge and regulatory requirements with consideration of ethical and societal values.

Any investigator proposing a study that may involve discomfort or distress, even if it is relieved by analgesics or anesthetics, must perform a literature search to assure that there is no viable alternative methodology. It is important to note that a large variety of nonanimal (in vitro, or test tube) studies are performed at our company prior to or instead of animal studies. Research animals are used only to address important scientific questions or fulfill a regulatory requirement. Animals involved in research within MRL are all bred specifically for research purposes.

To promote our commitment, we subscribe to the “3 Rs”—replacement, reduction and refinement—for animal-based research.

In our research laboratories, 96.8 percent of the research animals are rodents. The care and use of laboratory animals in biomedical research is highly regulated. In general, the regulations govern housing, feeding, veterinary care, and research project review conducted by the Institutional Animal Care and Use Committee (IACUC)/Ethical Review Committee (ERC), as well as unannounced government inspections. Our animal facilities are staffed with veterinarians and professional animal care technicians trained and certified as research-animal experts.

ANIMAL RESEARCH OVERSIGHT

Animal research is highly regulated and monitored by the government, and is also internally monitored by our Quality Assurance (QA) Animal Welfare department. The QA Animal Welfare audit program is a comprehensive, risk-based audit and oversight program function designed to ensure that the Animal Care and Use Program at each research site meets relevant, local standards and is in compliance with all applicable legal requirements covering animal research.

Additionally, all of our company sites hosting animal-based research have active and engaged IACUCs or ERCs that review,

approve and monitor research studies. The committee membership includes veterinarians and scientists knowledgeable in animal-based research and, often, nonscientists and community members. Committees review proposed animal studies and animal care facilities and investigate, as appropriate, any research-animal welfare concerns. The IACUCs/ERCs regularly communicate with and provide status reports to our company's institutional officials regarding animal welfare compliance.

Global policies and guidelines governing appropriate animal research practices are in place and are kept up to date. These standards for the care and use of animals in studies meet or exceed applicable local, national and international laws and regulations.

U.S. regulations and annual inspection results can be found [here](#).

The European Directive 2010/63/EU can be found [here](#).

As further evidence of our commitment to the highest level of animal care, our research sites voluntarily secured a third-party review and accreditation of our animal research programs and facilities by the [Association for Assessment and Accreditation of Laboratory Animal Care International](#) (AAALAC), an external, independent organization.

As of the end of 2016, all of our MRL research facilities were accredited by
AAALAC.

Our scientists whose work involves research animals are trained to perform the duties required. Training includes review of regulations and policies, instruction on how to search for animal research alternatives, explanation of the role of the IACUCs/ERCs and training on how to raise concerns about misconduct. Qualified veterinarians work with the scientific staff to consult on and assist with all animal-related research projects. Our company places a high value on its animal welfare stewardship responsibility; violation of these policies is grounds for employee disciplinary action, up to and including dismissal.

CONTRACT RESEARCH

We perform due diligence on and monitor contract laboratories that perform animal studies on our behalf to ensure that our company's expectations for animal care and use and regulatory compliance are met. All agreements with contract laboratories include terms regarding our company's expectations for animal care and use as well as regulatory compliance. Additionally, animal research conducted at contract laboratories is subject to protocol review by a company's IACUC/ERC or an equivalent committee. Noncompliance with regulations or standards can lead to termination of the relationship.

SUPPORT FOR ANIMAL SCIENCE AND RESEARCH ANIMAL WELL-BEING

We also advocate for the development of best practices and dissemination of information by supporting and participating with nongovernmental organizations to foster a greater understanding of biomedical research, advancements in research-animal science and the development of alternatives to animal use.

REPLACEMENT, REDUCTION AND REFINEMENT

We are committed to the philosophy of using the best scientific methodologies and animal alternatives whenever possible or permissible by law. To promote this commitment we subscribe to the “3 Rs”—replacement, reduction and refinement—for animal-based research.

Replacement — using nonanimal systems or less-sentient species (e.g., cell cultures, computer modeling, bacterial assays, and fly or worm models). Our scientists have access to specialized software that searches the scientific literature for viable alternatives to animal research. In addition, the company employs information specialists in our research library, trained by the Animal Welfare Information Center of the U.S. National Agricultural Library, to assist our scientists in identifying potential animal alternatives. We also have extensive in vitro expertise and investments, including an in vitro department that develops and utilizes nonanimal research methods (cell cultures) in the discovery and development of new medicines and therapies, and experts in computer modeling and simulation.

Reduction — using the minimum number of research animals necessary to obtain valid scientific data. Sophisticated animal models that yield precise data, such as telemetric monitoring models that monitor ECG and blood pressure, reduce the number of animals needed. In addition to state-of-the-art data collection and sharing systems, we have statisticians on staff who advise on study design and analysis in order to minimize the number of animals included in a study.

Refinement — minimizing distress or discomfort. Our scientists conduct extensive literature reviews to choose the best scientific models and design the most effective studies. When animals are required for a study, anesthetics, analgesics and tranquilizers are used whenever possible to minimize or eliminate potential pain or distress.

Our company’s Animal Welfare group collects, promotes and internally disseminates information on the principles and practice of the 3 Rs. Training on the 3 Rs is part of staff orientation for animal research. It is our responsibility to use the most appropriate methodology and to aggressively seek scientifically valid 3-R approaches to animal research. As an example of the third R, refinement, we have created a world-class imaging department that allows scientists to view cancers and other pathologic diseases in animals and monitor the long-term effectiveness of new treatments in a noninvasive manner. In addition, we have voluntarily made the decision not to use chimpanzees (nor to fund their use directly or indirectly in studies by external research partners) in biomedical research in the foreseeable future. Recent scientific advances now allow researchers to use alternative methodologies that in many circumstances replace the need for chimpanzees in biomedical research.

INTERNAL ANIMAL ALTERNATIVE AWARD

Since 1994, in support of the 3-R philosophy, we have presented an Animal Alternative Award annually to the team or teams of our company’s scientists that develop new techniques to support the alternative principle and publish their work to share innovations with the greater scientific community. Awards have been given for developing and utilizing an in vitro liver screening assay, reducing the number of animals used by utilizing sophisticated telemetric monitoring, replacing a dog model with a guinea pig model, and applying imaging techniques such as MRI to reduce the number of animals needed for tumor studies.