

Valneva's Policy on Animal Welfare

Effective Date: January 2025

1 Applicability / Scope

This policy applies to all Valneva employees, particularly those involved in research and development, quality control, and any other department where animal care or use is necessary. It also extends to external partners and collaborators, such as pre-clinical Contract Research Organizations, suppliers, and other stakeholders engaged in research activities involving animals.

Valneva is committed to ensuring that ethical animal welfare practices are upheld throughout its upstream value chain. This includes partners involved in the supply of animals, equipment, and materials critical to our research and development activities.

By establishing clear standards for all internal operations and collaborations, this policy reinforces Valneva's commitment to the highest standards of animal welfare, regulatory compliance, and ethical responsibility.

At Valneva, we are dedicated to the development and delivery of innovative vaccines that address significant unmet medical needs. This often necessitates the use of animal research in circumstances where alternative methods are unavailable or insufficient. In particular, the development and manufacture of vaccines involve complex immunological processes that cannot yet be fully replicated by alternative methods. The interaction between vaccines and the immune system requires *in vivo* testing to ensure both safety and efficacy during research and development, as well as to support the manufacturing process, including release testing. While Valneva is committed to adopting alternative methods wherever possible, animal testing remains mandatory to ensure that only safe and effective vaccines are provided to humans.

We acknowledge the essential role that *in vivo* testing plays, as required by regulatory authorities, in confirming the safety and efficacy of our products for human health.

Valneva takes great pride in operating its own state-of-the-art animal facility for internal testing, which allows us to maintain direct influence over the highest standards of animal welfare, quality, and regulatory compliance. Valneva is equally committed to employing highly trained, skilled, and motivated staff who are dedicated to maintaining and improving these standards. This ensures that the majority of our testing is conducted in-house, with external animal testing only performed in rare cases, e.g. when a new animal model is too complex to implement within the needed time frame.

2 Purpose / Definitions

Valneva's animal welfare approach is guided by stringent ethical standards and legal requirements to ensure humane treatment and compliance with all relevant laws.

Commitment to Compliance: Valneva ensures that all animal research activities are conducted in full compliance with applicable international, regional, and national regulations governing the use and welfare of animals in scientific research, including national laws such as the Austrian Tierversuchsgesetz 2012 and Tierversuchs-Verordnung 2012, as well as international regulations like the EU Directive 2010/63/EU. In addition to

adhering to legal requirements, Valneva strives to exceed regulatory expectations, actively engaging with public authorities to uphold the highest standards of animal welfare. We are committed to continuous improvement and rigorous compliance monitoring to ensure the ethical treatment of animals across all our scientific endeavours.

Commitment to the 3Rs Principles: Valneva’s approach to animal welfare is centered on the internationally recognized 3Rs principles:

Replacement: Valneva prioritizes the use of alternative scientific models, such as computer simulations and *in vitro* methods, to replace animal testing where feasible. Animal testing is conducted only when absolutely necessary and required by regulatory bodies.

Reduction: We minimize the number of animals used in research by applying advanced study designs and statistical methods to achieve reliable scientific results with fewer animals.

Refinement: Valneva continuously seeks to refine animal care and handling procedures, ensuring the highest possible standards of housing, veterinary care, and humane treatment, integrating the latest advancements in animal welfare practices.

Commitment to a Culture of Care: At Valneva, we are committed to fostering a culture of care that extends beyond compliance with regulatory standards. This culture emphasizes the ethical responsibility of every employee to prioritize animal welfare in all aspects of research and care. By promoting open communication, continuous education, and shared responsibility, we aim to create an environment where animal welfare is central to all operations. This commitment is reflected in the roles of every individual involved, from senior manager to animal technician, ensuring that all decisions and actions support the ethical and humane treatment of animals.

By incorporating these principles, Valneva not only complies with regulatory mandates but also actively works to advance scientific research while promoting the ethical and humane treatment of animals.

Abbreviation / Term	Explanation / Definition
Animal Welfare	“The welfare of an individual is its state as regards its attempts to cope with its environment. Welfare includes feelings and health and can be measured scientifically. It is a biological concept, quite different from rights, and refers only to living animals” ¹ .
EC	Valneva’s Executive Committee
CRO	Preclinical Contract Research Organization, specifically excluding clinical CROs in the context of this document
DOR	Detailed Operational Requirement
EU	European Union
FELASA	Federation of European Laboratory Animal Science Associations
GV-SOLAS	German Society for Laboratory Animal Science
GxP	GxP is the abbreviation of “Good x Practice”. The “x” in GxP stands for the field the guidelines and regulations applied to, e.g. GMP – Good Manufacturing Practice.
HR	Human Resources Department
R&D	Research and Development
SOP	Standard Operating Procedure
WI	Working Instruction
QA	Quality Assurance Department

¹ M. Broom (2017). *Animal Welfare in the European Union (PE 583.114 EN)*. Policy Department for Citizens’ Rights and Constitutional Affairs. [https://www.europarl.europa.eu/RegData/etudes/STUD/2017/583114/IPOL_STU\(2017\)583114_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/STUD/2017/583114/IPOL_STU(2017)583114_EN.pdf)

Abbreviation / Term	Explanation / Definition
3R	In the “3Rs principle” the three Rs stand for “Replace, Reduce, Refine”.

3 Code of Conduct

Through its Code of Conduct and other Valneva policies, Valneva has established rules and procedures to ensure lawful and ethical business behaviour. This policy applies the requirements laid out in the Code of Conduct and other Valneva policies and in no way contradicts those.

4 Responsibilities

All Valneva personnel involved in proposing, commissioning, planning, or conducting scientific work using laboratory animals are required to comply with the ethical and welfare standards established in this policy. This includes ensuring adherence to international regulations, national law, EU directives, and the principles of the 3Rs (Replacement, Reduction, and Refinement).

Senior Management (Level I): Managing Directors (of the Valneva Austria GmbH entity) and senior leadership of departments like Regulatory Affairs, R&D, and Quality Control, are responsible for making strategic decisions that align with Valneva’s ethical standards. This includes the selection and oversight of internal and external animal testing, ensuring both legal and ethical compliance.

Planning and Design (Level II): Managers, scientists, and technicians involved in the planning and design of animal studies must ensure that these studies comply with applicable laws and ethical guidelines. They translate strategic objectives into practical, compliant study designs.

Operational Personnel (Level III): Those directly conducting animal experiments (e.g. Animal Technicians, Research Associates), including the Project Licence Holder, Designated Veterinarian, Animal Welfare Officer, Head of the Laboratory Animal Facility, and the Animal-Welfare Body, are responsible for implementing protocols and adhering to welfare standards. This level also involves maintaining continuous education and training to stay updated on best practices in animal welfare.

General Responsibilities (All Levels): All personnel are required to uphold the ethical principles and welfare standards outlined in this policy, ensure transparency by reporting any concerns or incidents of non-compliance, and actively participate in a culture of care, emphasizing open communication and continuous improvement in animal welfare practices.

These roles collectively ensure a structured, transparent, and ethical approach to animal welfare across Valneva’s operations. For more detailed descriptions of responsibilities, refer to the Detailed Operational Requirement (DOR): “*Valneva’s Animal Welfare Framework: A Culture of Care Approach*”.

5 Procedure

Valneva is committed to implementing comprehensive procedures that ensure the ethical treatment of animals across all research, development and commercial manufacturing activities. Our processes are designed to ensure full compliance with applicable regulations and are guided by the principles of the 3Rs (Replacement, Reduction, Refinement). These procedures apply to all animal studies conducted both internally and through external

partners, ensuring that the highest standards of animal welfare are maintained at every stage of the research process.

For a more detailed description of our processes and operational requirements, please refer to the Animal Welfare DOR. This document outlines the specific protocols, responsibilities, and compliance measures that govern all aspects of animal care and research at Valneva.

The following subsections summarize Valneva's procedures for conducting, overseeing, and reviewing animal research, both within our facilities and in collaboration with external organizations.

5.1 Monitoring, Oversight, and Audits of Animal Welfare

Valneva ensures strict adherence to animal welfare standards through comprehensive monitoring, audits, and oversight mechanisms. Regular internal and external audits, including unannounced inspections by local authorities, and audits by national and international agencies, verify compliance with both regulatory and ethical standards. Internally, the Quality Assurance (QA) Department conducts annual audits to ensure GxP compliance in the laboratory animal facility.

The Animal-welfare Body plays a central role in overseeing all aspects of animal welfare within Valneva's laboratory animal facility. This multidisciplinary Body, legally mandated by national law, includes veterinarians, technicians, scientists, and optional members such as the Head of the Laboratory Animal Facility. Chaired by the Animal Welfare Officer, the Animal-welfare Body provides oversight and guidance on animal acquisition, housing, daily management, and experimental procedures involving animals.

The Animal-welfare Body is responsible for reviewing all applications for project authorizations, as well as overseeing external animal testing commissioned by Valneva. This ensures that all external tests adhere to Valneva's ethical standards and align with internal animal welfare practices before being commissioned. The Body convenes quarterly to evaluate applications, monitor ongoing projects, and provide recommendations to enhance compliance and ethical practices in line with Valneva's commitment to animal welfare.

In addition to project oversight, the Animal-welfare Body actively reviews and updates Valneva's Standard Operating Procedures (SOPs) and Working Instructions (WIs) to integrate the latest advancements in animal welfare, rigorously applying the 3Rs principles (Replacement, Reduction, and Refinement). The body also monitors the implementation of its recommendations and ensures the continued appropriateness of animal care practices.

Valneva further employs a comprehensive tracking system, managed by the Laboratory Animal Facility department, to track all animal testing conducted both internally and externally. This database ensures full transparency, accountability, and alignment with regulatory frameworks, providing essential data for regulatory authorities and supporting Valneva's commitment to ethical testing and continuous improvement.

5.1.1 Communication and Oversight Mechanisms

Valneva ensures regular upward and downward communication flows regarding animal welfare matters to maintain alignment across all levels of the organization. These mechanisms are designed to facilitate effective monitoring, reporting, and continuous improvement in animal welfare practices.

Upward Flow: The Animal-welfare Body provides quarterly reports to senior management (Level I), summarizing key outcomes from meetings, compliance reviews, significant findings, and the status of risk assessments and deviation systems within GxP processes. These reports are escalated to the EC when strategic input or action is required. Additionally, any deviations related to animal welfare identified through Valneva's GMP deviation system are analyzed and included in these reports, ensuring that critical issues are addressed at the highest level.

Downward Flow: Strategic directives, policy updates, or goals specifically related to animal welfare, as defined by the EC, are communicated to operational levels via the Animal Welfare Officer and relevant departmental heads. This ensures that all personnel involved in animal care and research receive clear and relevant guidance aligned with Valneva's ethical standards and commitments. For GxP-related processes, these updates also include insights and actions derived from the GMP Risk Assessment and deviation management system, reinforcing a culture of compliance and accountability.

Risk Identification and Monitoring Mechanisms: The GMP Risk Assessment and deviation systems are integral to Valneva's framework for identifying, monitoring, and addressing risks associated with animal welfare within GxP processes. These systems ensure that any deviations from established SOPs, including those with potential implications for animal welfare, are systematically tracked, analyzed, and resolved. By embedding these mechanisms into the broader oversight framework, Valneva proactively mitigates risks of mismanagement, safeguards ethical standards, and ensures compliance with regulatory requirements. Lessons learned from these processes are reviewed by the Animal-welfare Body and used to drive improvements in both GxP and non-GxP practices, fostering a robust risk management culture.

5.2 Approval and Ethical Review of Animal Testing

Valneva conducts both internal and external animal testing, following detailed processes outlined in our Detailed Operational Requirement ("*Valneva's Animal Welfare Framework: A Culture of Care Approach*").

Our laboratory animal facility allows us to uphold the highest standards of welfare and compliance for internal testing, with each "Application for project authorisation" thoroughly reviewed by our Animal Welfare Officer, the Animal-welfare Body, and relevant experts. Each Application must be authorized by the Managing Director or his/her deputy to ensure oversight and adherence to our highest standards.

External testing is conducted only when necessary, such as for regulatory obligations or specific project requirements, and is overseen by the responsible teams in Valneva's Regulatory Affairs Department and R&D Organization, including the Animal-welfare Body, and carried out by qualified Preclinical Contract Research Organizations (CROs) that meet Valneva's ethical and regulatory standards. All testing, internal and external, is rigorously controlled and closely monitored to ensure adherence to strict ethical guidelines and a commitment to animal welfare.

5.3 Training and Competency

Valneva is committed to ensuring that all personnel involved in animal experimentation and care are properly trained in accordance with national and EU regulations. For internal animal testing, staff (e.g., Animal Technicians, Research Associates) are required to complete both theoretical and practical training, with a focus on specialized courses that ensure they are fully qualified for their roles. This training is regularly updated to reflect best practices in animal welfare, ensuring that all personnel have the necessary competencies to perform animal testing responsibly and ethically.

Senior management and decision-makers involved in external animal testing must be trained on the contents of this policy and the Detailed Operational Requirement (“*Valneva’s Animal Welfare Framework: A Culture of Care Approach*”) to ensure alignment with Valneva’s ethical standards and principles.

Line Managers and the Head of the Laboratory Animal Facility are responsible for overseeing that all necessary training is completed and documented.

6 Non – Compliance with this Policy

Valneva employees in scope of this policy shall comply with this policy. Not observing any of the provisions of this policy may cause effects detrimental to Valneva, such as:

- Compliance issues on a local or global level
- Increased legal and commercial risks
- The company’s money is not optimally spent / resources are not properly allocated

Non-compliance with this policy will be reported to the relevant supervisor. Violations may lead to disciplinary actions involving Valneva’s HR Department.

7 Corporate References

Policies:

Valneva Code of Conduct and Ethics

Detailed Operational Requirement (DOR):

Valneva's Animal Welfare Framework: A Culture of Care Approach

8 Monitoring & Review of this Policy

The policy owner is responsible for monitoring the effectiveness and implementation of this policy, which also includes defining the departments and individuals who are in the scope of this policy (see also section 4) and therefore require training.

Any improvements to the policy will be made as soon as possible.

In accordance with the aforementioned terms, the policy owner shall undertake a review of this policy every two years.

9 Stakeholder Engagement and Communication

Valneva is committed to transparency and active engagement with stakeholders on matters of animal welfare. This policy serves as a part of our communication strategy, offering clear insights into our ethical standards and practices in animal care, research, and testing. It is publicly available on Valneva’s website and intranet, ensuring accessibility for employees, clients, end-users, and the wider public. Updates are regularly provided to employees via email to maintain awareness.

Valneva recognizes the importance of addressing the expectations of all stakeholder groups, including our clients and end-users, who rely on our commitment to ethical practices. Their trust in our approach to animal welfare is integral to maintaining Valneva’s reputation for high-quality, ethically developed products. By aligning our practices with the expectations of these stakeholders, we reinforce the integrity and transparency of our operations.

Within Valneva, the Animal-welfare Body plays a pivotal role in overseeing animal welfare practices and ensuring all procedures align with our ethical commitments. The Body's members, including veterinarians, scientists, and technicians, engage in open, collegial discussions and are encouraged to express diverse viewpoints. Decisions are reached through consensus, allowing for transparent decision-making. Any concerns regarding animal welfare practices can be raised without fear of reprisal. Additionally, Valneva's "Compliance & Ethics Helpline" provides an anonymous avenue for reporting concerns, supporting our commitment to an open and secure environment.

Valneva collaborates with regulatory authorities, to ensure compliance with national animal welfare standards. Regular audits by these authorities reinforce our adherence to legal requirements and help us continually improve our practices. To remain informed about advancements in ethical practices, Valneva actively participates in industry seminars and congresses, such as the 3R Society, the annual conference of the German Society for Laboratory Animal Science (GV-SOLAS) and the European FELASA Congress (Federation of European Laboratory Animal Science Associations). These engagements allow Valneva to share insights, learn from peers, and stay at the forefront of best practices in animal welfare.