

## THE USE OF ANIMAL MODELS IN PRECLINICAL RESEARCH AND GLP

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Scientific questions and extensive regulations (laws and decrees; scientific, health-authority and ethical requirements and guidelines) govern the planning, approval and performance of an animal experiment. The use of animals in research involves responsibility for the animals. Well-trained research staff reduce animal pain and distress because they can perform the techniques with proficiency, resulting in the generation of better quality data. Animals that are under pain and/or distress have difficulty adapting to changes in their environment or physiological condition, displaying unpredictable maladaptive or abnormal responses, which is an uncontrolled experimental variable. For these reasons, it is critical that individuals working with animals are knowledgeable in the appropriate handling and use for the animals that are utilized.

In Europe, the care and wellbeing of animals used in biomedical experimentation is governed by Directive 86/609/CEE, actually in revision after a period of public consultation, which has been incorporated into the Italian legislation in 1992, with the Law Decree 116/1992, constituting the first step towards establishing bioethically-grounded laws for protecting the psychological and physical welfare of laboratory animals

The principles of Good Laboratory Practice (GLP) define a set of rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical safety studies are planned, performed, monitored, recorded, archived and reported. The principles of GLP, developed in the framework of the Organisation for Economic Co-operation and Development (OECD) were introduced in European Directive 88/320/CEE e 90/18/CEE implemented in Italy by the Law Decree 120/1992 and the Ministry of Health Decree 10 August 1997 establishing the GLP Unit Monitoring Authority.

In relationship to the animal welfare Law, the GLP Law requires the development of standard operating protocols for efforts that are repeated. The GLP protocols should be documents that can be cited as references in research planning.

A general overview of the rules of good practice in caring for laboratory animals and links with GLP quality rules will be discussed, focussing on housing conditions, the proper means of handling animals, the Standard Operation Procedures (SPO) that must be in place for animal care.