Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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Efficacy and/or safety issues in accordance with GLP principles

Status	Public

QUESTION

If a company is carrying out a clinical study, of course with focus on efficacy and in-use safety, in a GLP laboratory? their philosophy is to apply GLP standards, firstly to avoid introducing another standard into an existing quality system, and secondly to apply the highest possible degree of quality. Now there are certain national authorities, who are refusing to accept efficacy studies under GLP.
Their interpretation of the OECD guideline on GLP is a very strict one: GLP is for SAFETY studies!
This may be very logical and straight forward if we are dealing with medicinal products for human use, where "clinical" means "in humans", and "pre-clinical" means "in animals". But what about veterinary products, where we are always dealing with animals and where the target species can also be kept in laboratories, no matter if we are testing efficacy or safety or both at a time?

ANSWER

Ideally, pre-/clinical studies on the target animal species under laboratory conditions, focusing on efficacy and/or safety issues are performed in accordance with GLP principles.
Although this is no legal requirement, it is recommended in the respective European and VICH guidelines that these studies should be carried out according to GLP, if possible. For more information, please see Directive 2009/9/EC, amending 2001/82/EC, annex I, title I, part 4, and Eudralex, volume 7a, guidelines.
However, it has to be pointed out that laboratory studies alone are not sufficient for the demonstration of efficacy and target animal safety of a veterinary pharmaceutical. The efficacy and target animal safety of a proposed product needs to be confirmed in clinical field studies, i.e. in a larger target population under the proposed conditions of use. These studies are to be carried out according to Good Clinical Practice (GCP) (VICH GL 9 on GCP).