Inspection of Veterinary Medicinal Products Clinical Trials

Wysłane przez marpie w Pią, 15/04/2016 - 14:26

Clinical trial inspection of veterinary medicinal products

GCP inspection of a veterinary medicinal product clinical trial: Official procedures undertaken by the inspectors from the Department of Medicinal Products which hold official identity cards, according to the President's of the Office authorization. The main goal of their tasks is to verify how a clinical trial of veterinary medicinal product is conducted.

Inspection process

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Information requested by inspectors in the inspection announcement should be submitted by e-mail or send on a CD, DVD or other device to the lead inspector at the following address: *Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych, Al. Jerozolimskie 181C, 02-222 Warsaw.* Taking into account effective communication between involved parties, the documentation files should be prepared in a transparent manner, allowing for easy navigation between folders. PDF Adobe 5.0 and newer or XLS format (Excel 2003 or 2007) is preferred.

What is the scope of an inspection?

Inspectors verify amongst others:

- whether the President of the Office granted approval for conducting the clinical trial and whether all conditions of the approval are met,
- whether the clinical trial is conducted in accordance with VICH Good Clinical Practice,
- whether the clinical trial is conducted according to the protocol and approved protocol amendments,
- the condition of equipment and facilities used during the trial,
- the methods of record-keeping and data storage,
- whether the owner of participating animals provided a signed and dated informed consent form.

Inspection report

30 days after the final day of inspection, all authorized persons (sponsor, investigator, etc.) receive an inspection report in paper format. The report can also be send by e-mail in PDF format, secured by a password. The report describes in detail any findings with references to the corresponding legislative acts, which were breached, and grades the findings accordingly (Critical, Major, Minor or Comment – which is not a non-compliance, but is meant to help in conducting the clinical trial).

Grading of findings

Types of Inspection

Routine inspection – is carried out after an inspection announcement is send to the entity

conducting the clinical trial and to the sponsor, 30 days before the planned inspection/.

Unannounced inspection – is carried when there is suspicion that the life or health of people or animals may be at risk. This type of control is carried out without prior notice given to the entity conducting the clinical trial or the clinical investigator nor the sponsor.