Inspection of Clinical Trials of Medical Devices

Wysłane przez marpie w Pią, 15/04/2016 - 14:25

Clinical trial for medical devices inspection

Inspection of clinical trials for medical devices:

Official actions undertaken by the inspectors from the Department of Medicinal Products Inspections. Inspectors conduct inspections according to the President's of the Office authorization and hold official identity cards.

Inspection process

Which documents must be prepared before a inspection?

Information requested by inspectors in the inspection announcement should be submitted by e-mail or send on CD, DVD, 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:

- whether the President of the Office granted approval for conducting the clinical trial and,
- whether all conditions in the application for granting the approval for conducting the clinical trial and in the application for granting approval for implementing amendments in the clinical trial are met,
- whether the clinical trial is conducted in accordance with applicable regulations,
- whether all study participants provided a signed and dated informed consent form,
- the condition of equipment and facilities used during the trial,
- whether the clinical trial is conducted according to the protocol and approved protocol amendments,
- the methods of record-keeping and data storage.

Inspection report

60 days after the final day of inspection, all authorized persons (sponsor, investigator etc.) receive the inspection report in paper format. The report can be also send by email in PDF format, secured by a password. The report describes in detail any non-compliances/non-conformities 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

What are the types of inspections?

Routine inspection – is carried out after an 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 clinical trial participants might be at risk. This type of inspection is carried out without prior notice given to the entity conducting the clinical trial or the clinical investigator nor the sponsor.