

From:
Sent: 21 September 2015 10:59
To: SANTE-D6-GL-GMP-IMP
Subject: Answers on public consultation questions- dreg on gmp for imp-

Dear Sirs/Mrs,

Please find enclosed comments on the consultations on Guidance document "Principles and guidelines on good manufacturing practice and detailed arrangement for inspection for ensuring the quality of investigational medicinal products".

See consultation document http://ec.europa.eu/health/human-use/clinical-trials/developments/pc_gmp_1/public_consultation_dreg_on_gmp_for_imp_2015_rev_180815.pdf

Q1A: Yes.

Q1B Yes for those projects and products I have handled as a QA auditor and QA manager. Even if the process and manufacturing procedure is not set (can be changed during development phase) a broad specification on procedures used should be available.

Q2: a_ yes. If many batches are produced during development phase I think the archiving can be overwhelming for some manufacturers. Otherwise 25 years as for clinical trials with the full responsibility of archiving with the sponsor should be applied.

Q3: I think that for the handling and courier it seems reasonable in order to estimate risk and take precautions in the handling of such investigational drugs. However, some manufacturers will argue that the full certificate of analysis gives too much details and could be a confidentiality risk to the manufacturer in early development phase. I would argue that shipment and handling will be under CDA and agreements and that patient safety comes first. A full certificate of analysis is needed to be able to estimate GMP and patient safety (and courier safety).

Q4a: retention samples. Yes, I think for safety reasons and to have the possibilities to re-analyse samples they should be retained. But a time limit should probably be included.

Q4b: Photographs could be of use if no retention samples are saved. However, I feel retention samples are of great importance and should be retained.

Q5. We have no figures, need to be found at medical Products Agency in Sweden.

Best regards,