

Cases CT & QP responsibilities
Clinical Supplies Forum
06 November 2015, Astellas Leiden

CONSULTANCY

PROJECTS

INTERIM MANAGEMENT

AUDITING & TRAINING



Questions I

ANNEX VI of the CTR states what should be on the IMP labels. What should you do when you will not include all standard requirements on the label:

- A: justify it in the protocol
- B: justify it in a note to file
- C: both A and B
- D: nothing

Question II

Are you allowed to use unauthorised auxiliary medicinal product in a clinical trial?

A: YES

B: NO

Question III

Unauthorized Auxiliary medicinal products should have the same particulars on the label as an unauthorized IMP?

A: YES

B: NO

Question IV

The retest date can be omitted from the primary label if the following is true:

- A: if the information is available via another system (e.g. IRT system)
- B: If the clinical trial occurs in the US only
- C: If the retest date is available on the secondary label

Question V

What does not need to appear on the label of an authorized IMP?

- A: Clinical trial reference code
- B: Name of the main contact
- C: subject identification/treatment number
- D: All of the above should be on the label

Case I: labeling syringe in sealed box

Blinded clinical trial: ClinSF012

Product A: ClinSF 10 mg

Product B: Benelux 20 mg

Retest date: JUL 2016, will need to be extended during study to JUL 2017

Label space on syringe is limited, syringe is intended to stay within secondary sealed pack. One syringe is packed per blister. One blister is entered in one box.

Administration: intramuscular

The product will be administered in the hospital, dosing occurs once per week during 4 weeks.

Assignment

Design the primary and secondary label with the minimum requirements only.

Thanks for your attention!