

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

CONSULTANCY

PROJECTS

INTERIM MANAGEMENT

AUDITING & TRAINING



QP responsibilities I – Adaptive clinical trial

Evaluate treatment by observing participant outcomes on a prescribed schedule, and modifying parameters of the trial protocol in accord with those observations.

Modifications may include changes in:

- dosage
- sample size
- patient selection

Can the QP release product for the clinical trial independent of the clinical evaluations during the study?

Yes/No

QP responsibilities II – IRT

The IRT system manages the expiry date of the IMPs.

Is the QP responsible that the IRT system is meeting the requirements of the clinical trial?

A: YES

B: NO

QP responsibilities III – preparation IMP in the clinical trial

The QP is responsible to ensure the quality of the IMP in order to safeguard:

- The safety of the subject
- Robustness of the clinical data generated in the trial

Is the QP responsible for product handling in the hospital or clinic?

A: YES

B: NO

QP responsibilities IV - Hospital handlings

The QP is responsible for the release of re-labeled and/or re-packaging of IMPs in the hospital or clinica

A: YES

B: NO

Thanks for your attention!