CRF-C
HRB Clinical Research Facility Cork

IMP management in HPRA regulated Clinical Trials

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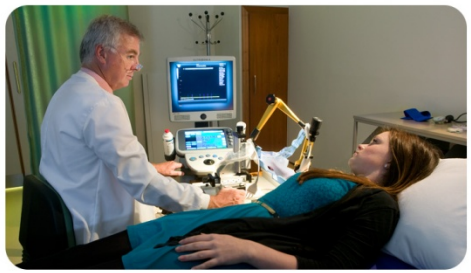
UCC

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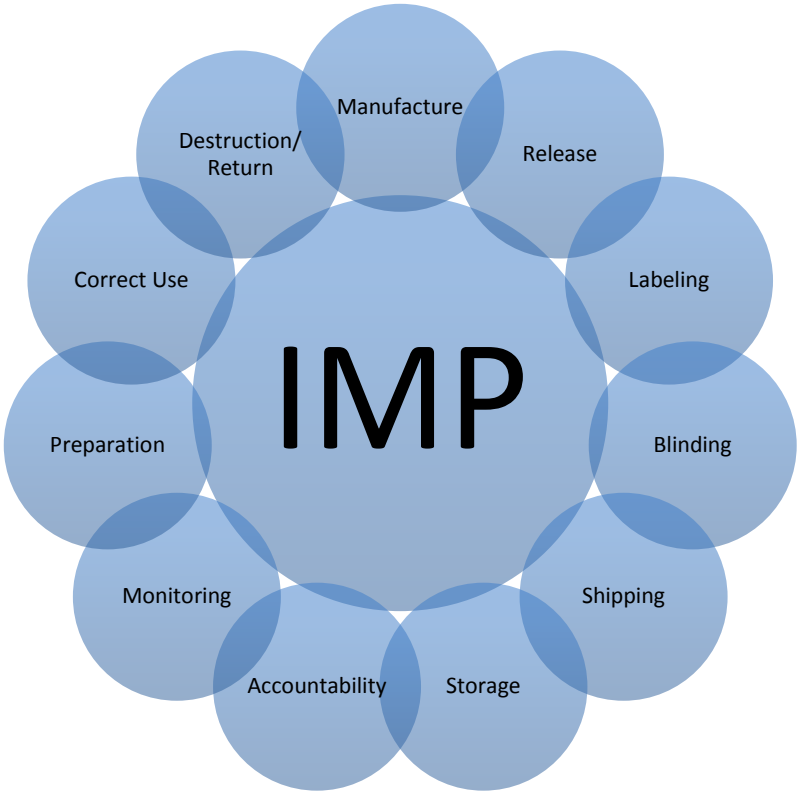
Principles of ICH GCP

12. Investigational products should be manufactured, handled, and stored in accordance with applicable **good manufacturing practise** (GMP)

Manufactured according to GMP …

Need to consider:



4.6.1 "Responsibility for investigational product(s) accountability at the trial site(s) rests with the investigator/institution."

4.6.2 Investigator can delegate some of the duties to a pharmacist or other appropriate individual-

- delegation log
- Responsibility still rests with investigator!
- Investigator responsible for training pharmacist and keeping pharmacy department updated on all amendments

Investigational Products

4.6.3 Maintain records of :

- *the product's delivery*
- *Inventory at site*
- *Use by each subject*
- *Return to sponsor or disposal of unused product*

Records should include:

- *Dates, Quantities, Batch numbers, Expiry dates, Unique code numbers for IP, if applicable, Trial subject codes, if applicable*

- *Monitor -Carry out Drug Reconciliation*

Investigational Products

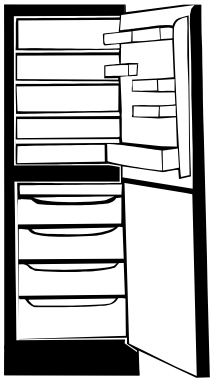
4.6.5 "The investigator should ensure that the IP are used only in accordance with the approved protocol"

4.6.6 Explain the correct use of the IP and check that subject is following the instructions properly

- Investigator responsibility
- Record any deviations – with explanation
- If a long study – check regularly with participant.

Investigational Products

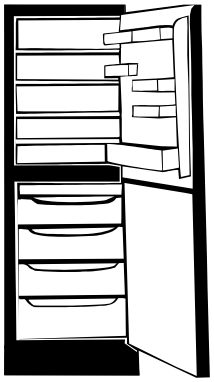
4.6.4 "The investigational medicinal product(s) should be stored as specified by the sponsor and in accordance with applicable regulatory requirements"



- Investigator should ensure they have adequate facilities, sponsor should review storage areas, fridges as part of site selection

IMP at site -Consider:

- security
- storage space
- segregation of drugs
- temperature monitoring
- temperature mapping
- humidity
- calibration of thermometers
- servicing of fridges
- alarm system
- back up systems- out of hours…



IMP in transit:

- Security
- Chain of Custody
- temperature monitoring – data logger
- Arrival at correct place!
- Out of hours arrival
- Temp on arrival –if large quantity loaded into fridge..

Temperature Excursions

- Be aware of temp limits
- Quarantine IMP
- Ensure no patient receives the IMP
- Inform Sponsor
- Await their decision

IMP preparation

Consider:

- Does IMP need to be prepared? Solution, dilution etc
- Who can prepare it? Pharmacist only? Study nurse?
- Do you need specialist facilities – e.g cytotoxic , oncology drugs
- Does IMP need to be overlabelled – e.g commercial stock
- Does pharmacy provide 24 hour cover?

Randomisation & Unblinding

Consider:

- Who can unblind? restrict access
- If code-break envelopes provided – store securely
- Access to codes out-of-hours- phone/ web based?
- Regulatory unblinding for SUSAR
- Unblinding to treat an SAE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