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ANNEX V
TO PROCEDURE FOR CONDUCTING GCP INSPECTIONS
REQUESTED BY THE EMEA:
PHASE I UNITS

GCP Inspectors Working Group

Applies to: EMEA, EU/EEA Inspectorates	
Summary of scope: This guidance compiles the main aspects that are to be verified at phase I units during a GCP inspection requested by the EMEA	
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1 PURPOSE

The scope of this document is to provide guidance for the preparation of GCP inspections conducted in Phase I Units. The points to consider in this document are specific to these types of units and other guidance documents should be referred to for consideration of those areas common to other types of inspections, e.g. computer systems, archiving and quality systems.

2 RESPONSIBILITIES

Not Applicable

3 DEFINITIONS

Abbreviations used in the document:

GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction

4 DESCRIPTION OF PROCEDURE/REQUIREMENTS, INCLUDING RESPONSIBILITIES

4.1 ETHICS AND REGULATORY APPROVAL

Points to consider:

- Independence of the Ethics Committee
- What documents does the Committee review. Approval of a generic screening consent forms.
- Approval of advertising.
- Documentation of approvals
- Process for submission for Ethics Committee approvals, updating and maintenance of ethics committee documentation
- ICH GCP compliance statement of the Ethics Committee
- List of members of the Ethics Committee
- Process for for submission regulatory approval l, updating and maintenance of regulatory documentation
- Annual reporting to the Ethics Committee.

4.2. QUALITY ASSURANCE AND SOPs

Points to Consider

- Written procedures for every aspect of the study process (SOPs)
- Organisation of the QA group
- Training on SOPs, GCP and also specific protocols
- Audits on vendors and suppliers

4.3. INVESTIGATOR MASTER FILE

Points to Consider

- Source documents
- Storage of medical records
- Long-term archive arrangements.
- Documentation of meetings

- Delegation log in place and signed
- Use of Direct Electronic Data Capture methods

4.4. PERSONNEL

Points to Consider

- Relationship of the Investigator with the Sponsor company
- Adequate staff resources.
- Basic life support and advanced life support training
- Qualifications of the Investigators
- Qualification of Bank/Agency staff
- Management of Agency/Bank staff

4.5. FACILITIES

Points to Consider

4.5.1 Emergency Procedures and Equipment

- Availability and maintenance of emergency medicines and equipment
- Emergency contact numbers provided to the volunteers
- Procedures in case of an emergency
- Agreement with the local hospital(s) for any services provided
- Fire evacuation procedures

4.5.2 General Facilities

- Security of the facility with respect to unauthorised or limited access.
- Back-up power supply
- Storage of samples. Monitoring of the fridges and freezers
- Maintenance, service and calibration of instruments/equipment
- Facilities for archiving, laboratory and pharmacy.

4.5.3 Volunteer Care

- Procedures for testing for use of illegal drugs (drugs of abuse)
- Measures in place to ensure compliance of the volunteers with the protocol.
- Monitoring of subjects
- Facilities for meals. Documentation of meals.
- Leisure facilities for lengthy stays/overnight stays
- Identification of subjects during their stay

4.6. SAMPLING

Points to consider

- Processing of samples within the unit prior to shipment to the laboratory.
- Facilities equipped and resourced to handle the capacity of samples.
- Procedures for collection of urine samples.
- Procedures for sample management e.g. collection, processing, consideration for missed and late samples, aliquoting, labelling, storage and shipment
 - Clocks –easily visible and synchronised.

4.7. INVESTIGATIONAL MEDICINAL PRODUCT

Points to Consider

- Authorisation/Licence(s)

- Blinding, if applicable
- Storage
- Packaging and labeling
- IMP administration

4.8. RECRUITMENT AND CONSENT

Points to Consider

- Recruitment strategies
- Volunteer database
- Collection and verification of volunteer histories.
- Contact with the subject's primary physician/family doctor
- Procedures to prevent 'over-volunteering.
- Routine screening procedure
- Subject records
- Procedures taken to verify the identity of the volunteers
- Procedures for payment
- Procedures for taking consent.
- Training of the recruitment staff.
- Recruitment of staff from the facility/institution

4.9. CONTRACTS

Points to Consider

- Contracts in place prior to study start.
- Management and documentation of collaborations with other departments/organisations

4.10. INSURANCE AND INDEMNITY

Points to Consider

- Provisions in place for insurance and indemnity
- Indemnification of the investigator
- Professional indemnity insurance for nurses, if applicable

4.11. CONFIDENTIALITY

Points to Consider

- Confidentiality agreements for Agency staff, consultants etc

4.12. ADVERSE EVENTS

Points to Consider

- Follow- up and counselling
- SUSAR reporting to Ethics Committee/Regulatory Authorities
- SUSARs information provided to investigator(s)

5 FORMS NEEDED FOR THIS PROCEDURE

Not Applicable

6 REFERENCES AND RELATED DOCUMENTS

- Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Directive 2005/28/EC laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such product
- CPMP/ICH/135/95: “Note for Guidance on Good Clinical Practice”.
- Annex 13 to the EU Guide to Good Manufacturing Practice (Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002).
- ABPI Guidelines for Medical Experiments in Non-Patient Human Volunteers, 1988.