

## **Core Curriculum of GCP inspection in MRCT/GCP inspection Priority Work Area (PWA)**

Target trainees: Experienced GCP inspectors

### **Basics of GCP**

- 1) Declaration of Helsinki
- 2) Introduction of ICH E6(R2) Guideline (Mainly focus on the integrated addendum)
- 3) Difference between global standard and local (domestic) standard

Suggested formats: Presentations, Q&A, Experience sharing

### **Planning of GCP inspections**

- 1) Selection of clinical trials for inspection
- 2) Selection of medical institutions for inspection
- 3) Establishing an inspection team and arranging inspection schedules

Suggested formats: Presentations, Q&A, Experience sharing, Case study exercise

### **Preparation of GCP inspections**

- 1) Prior check of related documents
- 2) Identification of high risk factors such as endpoint measures and differences in clinical practice across participating economies
- 3) Tools to avoid omission of the points to be inspected

Suggested formats: Presentations, Q&A, Case study exercise

### **Conducting GCP inspections**

- 1) To trial sites
  - Points to be inspected (e.g., responsibilities of investigator, IRB and head of the institution, subject selection, informed consent, medical records and CRFs, investigational products storage, document archiving, contract with the sponsor, SOP)

Suggested formats: Presentations, Q&A, Case study exercise

- 2) To sponsors
  - Points to be inspected (e.g., organization/structure, selection of medical institutions and principal investigator, protocol preparation and management, contract with medical institutions, control of investigational products, monitoring, SAE reporting procedure, audit, record keeping, SOP)

- Points to consider in case of using Contract Research Organization (CRO)

Suggested formats: Presentations, Q&A, Case study exercise

### **Evaluation of Inspection findings and Decision for Regulatory actions**

- 1) Root Cause Analysis (RCA)
- 2) Corrective action and preventive action (CAPA)
- 3) Grading of deviations

Critical/Not critical, Major/Minor...

- 4) Decision for regulatory actions

Official action indicated? Voluntary action indicated? No action indicated?

Suggested formats: Presentations, Q&A, Experience sharing, Case study exercise

### **Documentation/Reporting of Inspection results**

- 1) Points to be included in the report of inspection results
- 2) How and when the result is informed to sponsors and medical institutions

Suggested formats: Presentations, Q&A, Experience sharing, Case study exercise

### **GCP international collaboration**

- 1) Possibility of work sharing to exchange information of GCP inspection