AIFA – UNICRI – FDA

TRAINING COURSE

on

GCP Inspectorates and GCP Inspections

Civil Service Training Centre (CSTC)

P.O.Box M49, Cantonments, Accra,

Ghana

7-11 July 2014

AGENDA

Monday 7 July 2014	
8.30 – 9.00	Registration of participants
Morning session	
Chairpersons: Representatives of Ghana and AIFA	
9.00-10.00	**Opening Session** Welcome remarks and opening by Hudu Mogtari, Chief Executive Officer, Food and Drugs Authority, Ghana Angela Del Vecchio, Head of the GCP and Pharmacovigilance Inspectorate, Agenzia Italiana del Farmaco, (AIFA), Italy Jonathan Lucas, Director, United Nations Interregional Crime and Justice Research Institute, (UNICRI)
10.00-10.35	Aims of GCP Inspections: local legislation and organization (Ghana Representative)
10.35-10.45	Discussion
10.45 - 11.15	*Coffee break*
Chairperson: Representative of UNICRI	
11.15 – 12.15	Promoting social justice through the development of ethical and legal frameworks, Alessandra Liquori O'Neil, Programme Officer, (UNICRI)
12.15 – 13.00	Good Clinical Practice (GCP): aims, principles, ethical aspects, general aspects, Umberto Filibeck, (UNICRI)
13.00-14.30	*Working Lunch*
Afternoon session	
14.30-14.50	Responsibilities of the sponsor/CRO and discussion, Fabrizio Galliccia, (AIFA)
14.50-15.00	Discussion
15.00 – 15.45	GCP: Responsibilities of the monitor; the monitoring plan and the monitoring report, Anna Maria Lepore, (University of Ferrara and Rome)
15:45 -17:00	Practice Session (3 Groups): evaluating a monitoring plan and/or a monitoring report, Anna Maria Lepore, (University of Ferrara and Rome)
17.00-17.10	Learning Questionnaire

Tuesday 8 July 2014	
Morning session	
Chairperson: Representative of Ghana	
9.00-9.15	Stanley Diamenu – Immunization Advisor – WHO, Country Office for Ghana
9.15 -9.40	Responsibilities of the investigator, Angela Del Vecchio, (AIFA)
9.40-9.50	Discussion
9.50 -10.30	Possible legislation for the Respect of Ethics in the CTs authorization procedures: the European Union approach, Umberto Filibeck, (UNICRI)
10.30-11.00	*Coffee break*
Chairpersons: Representatives of AIFA and UNICRI	
11.00 – 11.45	Training program of GCP Inspectors and SOPs of a GCP Inspectorate, Angela Del Vecchio, (AIFA)
11.45 – 12.15	Italian law about CRO requirements, Anna Maria Lepore, (University of Ferrara and Rome)
12.15 – 12.50	Inspections Program: different approaches (criteria for selection of inspections: risk based, other triggers), Fabrizio Galliccia, (AIFA)
12.50-13.00	Discussion
13.00-14.30	*Working Lunch*
Afternoon session	
14.30-15.00	GCP: Protocol and CRF**,** Anna Maria Lepore, (University of Ferrara and Rome)
15.00 – 17.00	Practice session (3 Groups): Protocol and CRF and discussion**,** Angela Del Vecchio, (AIFA)
17.00-17.10	Learning Questionnaire

Wednesday 9 July 2014	
Morning session	
Chairperson: Representative of Ghana	
9.00 - 9.35	EMA reflection Paper on ethical and GCP aspects of CTs conducted outside EU/EEA and submitted for MAA to the EU Regulatory Authorities, Umberto Filibeck, (UNICRI)
9.35-9.45	Discussion
9.45 -10.45	GCP: Basic GCP documentation of a clinical trial according to chapter 8 of GCP ICH and to WHO-GCP (Trial Master File and Investigator's file), Angela Del Vecchio, (AIFA)
10.45-11.15	*Coffee break*
Chairpersons: Representative of AIFA	
11.15 – 11.45	Triggers for GCP inspections**,** Fabrizio Galliccia, (AIFA)
11.45 – 12.20	GCP: informed consent, Anna Maria Lepore, (University of Ferrara and Rome)
12.20-12.30	Discussion
12.30 – 13.00	A European GCP Inspection experience in developing settings, Umberto Filibeck, (UNICRI)
13.00-14.30	*Working Lunch*
Afternoon session	
14.30-15.45	Practice Session (3 Groups): evaluation and drafting an informed consent, Anna Maria Lepore, (University of Ferrara and Rome)
15.45 – 17.00	Practice Session (3 Groups): investigator's file, Fabrizio Galliccia, (AIFA)
17.00-17.10	Learning Questionnaire

Thursday 10 July 2014	
Morning session	
Chairpersons: Representative of UNICRI	
9.00-9.45	Inspections at different types of CTs: in support of a marketing authorization or on-going CTs of different phases. Preparation of a GCP inspection (putting together a plan; information to be requested; evaluation of documentation before the inspection), Angela Del Vecchio, (AIFA)
9.45 -10.30	Review of data listing, Fabrizio Galliccia, (AIFA)
10.30-11.00	*Coffee break*
Chairperson: Representative of Ghana	
11.00 – 11.45	Inspection at investigator site, Angela Del Vecchio, (AIFA)
11.45 – 12.30	Inspection at ethics Committee, Umberto Filibeck, (UNICRI)
12.30-13.00	Inspection/audit at hospital pharmacy, Anna Maria Lepore, (University of Ferrara and Rome)
13.00-14.30	*Working Lunch*
Afternoon session	
14.30-15.15	Inspection at sponsor/CRO site, Fabrizio Galliccia, (AIFA)
15.15 – 17.00	Practice Session (3 Groups): inspection simulation at investigator site, Anna Maria Lepore, (University of Ferrara and Rome)

Friday 11 July 2014	
Morning session	
Chairperson: Representative of Ghana	
9.00-9.45	Inspection at laboratory, WHO Good Clinical Laboratory Practice and EMA procedure, Anna Maria Lepore, (University of Ferrara and Rome)
9.45 – 10.15	Reporting (findings and grading) and decisions, Angela Del Vecchio, (AIFA)
10.15 – 11.00	Common findings and follow up, Fabrizio Galliccia, (AIFA)
11.00-11.30	*Coffee break*
Chairperson: Representative of UNICRI	
11.30 – 12.15	CTs Pharmacovigilance, Angela Del Vecchio, (AIFA)
12.15 – 13.00	Ghana GCP inspections experience and common findings (Representative of Ghana)
13.00-14.30	*Working Lunch*
Afternoon session	
14.30-16.00	Practice Session (3 Groups): trial site inspections: finding evaluation and grading, Fabrizio Galliccia, (AIFA)
16:00-17:00	Closing remarks. Collection of learning questionnaires and evaluation forms. Distribution of Certificate of Attendance.