GMP TRAINING PROGRAM FOR TURKISH INSPECTORS

AGENDA

20-21 October 2009

MINISTRY OF HEALTH

ANKARA

Tutors: Bernd Bodecker, Germany (**BB**)
David Cockburn, EMEA (**DC**)
Martin Melzer, Germany (**MM**)
Lesley Graham, UK **(LG)**
Fiona Routley, UK **(FR)**

1 st Day (20 October):

09.00-09.15 Welcome and Introductions

09.15-10.00 Introduction to EU Regulatory system and GMP (Good Manufacturing Practice) Inspection system **(DC)**:

- Overview of the EU regulatory system
- Marketing authorisation procedures, manufacturing authorisations, GMP legislation and guidance
- GMP inspection system.
- Mutual Recognition Agreements (MRA)
- Compilation of Community Procedures
- Qualified Person

10.00-11.00 EU GMP Requirements (1) **(BB)**:

- Quality Management System, Quality Risk Management, Product Quality Review, Change control, Ongoing stability monitoring
- Deviation handling, Failure investigation, Corrective Action and Preventative Action (CAPA), Complaints

11.00-11.30 Break

11.30-12.15 EU GMP Requirements (2) **(MM):**

- Sterile medicinal products
- Biological medicinal products for human use

12.15-13.00 Quality Control **(LG):**

- GMP in the QC laboratory
- Certificates of Analysis
- Dealing with out of specification results
- Parametric Release and Real Time Release Testing

13.00-14.15 Lunch

14.15-15.00 Validation **(BB)**:

- Process validation
- Facility validation/qualification, dedicated facilities, utilities (e.g. water, ventilation)
- Computer system validation
- Supplier qualification and outsourcing

15.00-15.30 Break

15.30-16.15 Good Distribution Practice (GDP) **(MM):**

- GDP legislation and guidance
- GDP Inspections
- Counterfeits

16.15-16.45 Panel Discussion

2 nd Day (21 October):

09.00-09.45 Investigational Medicinal Products **(BB):**

09.45-10.30 Suspected Quality Defects and Product Recall **(DC)**:

- The roles of industry and the regulators
- Defect reporting
- Rapid alerts and recalls

10.30-11.00 Break

11.00-11.30 Inspections from a company perspective **(FR)**

11.30-12.00 Panel Discussion