

Training in Good Manufacturing Practices (GMP) by the World Health Organization (WHO), to inspectors from the State Drug Administration (SFDA), Food and Drug Administration of the Jiangsu Province and Zhejiang Province, Peoples Republic of China

A two week GMP training workshop was presented by the WHO, to inspectors from the Chinese Drug Regulatory Authority (State, Provincial and local).

The programme focused on presentations and "mock inspections". Inspectors were given presentations on different types of inspections, how to prepare for inspections, and how to perform an inspection. This was followed by the "mock inspections". The "mock inspections" were performed at various manufacturing sites, for different dosage forms. Emphasis was placed on how to do an inspection, what are the key questions to be asked, and how to identify risk areas to be inspected for each. Inspections were followed by discussion sessions where observations, questions, and GMP related aspects were discussed and clarified.

The first week: Jiangsu Province (16 to 20 May).

The programme was as follows:

16 May	Presentations: Types of Inspections How to prepare for an inspection How to do an inspection
17 May	"Mock Inspection" at a manufacturer of Active Pharmaceutical Ingredients (APIs): (Manufacturing, packaging, cleaning) Discussion
18 May	"Mock Inspection" at a manufacturer of Active Pharmaceutical Ingredients (APIs): Receiving, storage, sampling, release "Mock Inspection" at a manufacturer of sterile products (small volume injections - terminal sterilization (moist heat). Discussion
19 May	"Mock Inspection" at a manufacturer of oral solid dosage forms (tablets and capsules): Weighing, granulation, mixing, blending, compression. Presentation and practical aspects of GMP recommendations for HVAC systems (WHO, ISO, ISPE), and dust extraction systems

	Discussion
20 May	"Mock Inspection" at a manufacturer of freeze-dried products. GMP recommendations for purified water systems. Qualification and validation (systems, equipment, processes). Batch manufacturing record review. Discussion Summary and close

The presentations used, were those from the WHO Basic training material, GMP text and supplementary guidelines (Water systems) and Draft guidelines (HVAC), including ISO 14644-1.

The second week: Zhejiang Province (23 to 26 May 2005).

The programme was as follows:

23 May	Presentations: Types of Inspections How to prepare for an inspection How to do an inspection "Mock Inspection" at a manufacturer of Active Pharmaceutical Ingredients (APIs) Discussion
24 May	"Mock Inspection" at a manufacturer of Oral Solid Dosage forms. Discussion
25 May	Presentations: Types of Inspections How to prepare for an inspection How to do an inspection
26 May	"Mock Inspection" at a manufacturer of Oral Solid Dosage Forms: Soft Gelatine Capsules Quality Control Laboratories Discussion

	Summary and close
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Presenter:

Dr AJ van Zyl

Participants: 22