



**Southern African Development Community International Conference on
Harmonisation Quality guidelines No 7 (ICH Q7) training
Venue, Arusha, United Republic of Tanzania**

Date: 27th June 2011 to 30th June 2011

PROGRAMME

26th June 2011 : Arrival of delegates

27th June 2011 :

07:30 – 09:00	Registration
09:00 – 09:15	Remarks from Secretariat
09:15 – 09:30	Official Opening
09:30 – 10:00	Objectives of the Training
10:00 – 10:30	Tea/Coffee Break
10:30 – 11:30	Common Technical Document (CTD) Format (excipients, reference standards, packaging, etc) Presenters: Annika Ridell & Parviz Nasiri
11:30 – 12:30	Active Pharmaceutical Ingredient (API) (Manufactures, Starting Materials, Intermediates, Process validation (sterile drug substance), Characterisation, Impurities/How to control, Setting Specifications, Stability). Presenters: Annika Ridell & Parviz Nasiri

12:30 – 13:00	Plenary discussion
13:00 – 14:00	Lunch Break
14:00 – 15:00	Workshop 1: Requirement for starting material Presenters: Annika Ridell & Parviz Nasiri
15:00 to 15:30	Tea/Coffee Break
15:30 – 16:30	Workshop 2: Stability studies and justification of Specification (this concerns impurities, residual solvents, particle size). Presenters: Annika Ridell & Parviz Nasiri
16:30 – 17.00	Plenary and close of close of day 1

28TH June 2011

08:30 – 09:00	Recap of DAY 1
09:00 – 10:00	Drug Product: Pharmaceutical Development, Formulation development, Antioxidant and anti-microbial preservatives, Compatibility, Dissolution, Manufacture/Critical Parameters setting Specifications, Stability / shelf-life. Sterile drug substance and drug product Presenters: Annika Ridell & Parviz Nasiri
10:00 – 1030	Tea/Coffee Break
10:30 – 11:30	Regulatory Aspects: Status of ICH Q7 guideline dossier submission versus Good Manufacturing Practice (GMP); role of inspector versus role of assessor, GMP certificates. Presenter: Knud Ryhl
11:30 – 12:30	Buildings, Facilities and Equipment (Qualification, Maintenance and calibration, Cleaning and cleaning,

	validation). Presenter: Knud Ryhl
12:30 – 13:00	Plenary Discussion
13:00 – 14:00	Lunch Break
14:00 – 15:00	Quality Control (QC) Laboratories (Documentation, Validation of Analytical methods, Handling of out of specification results, Ongoing stability monitoring). Presenter: Knud Ryhl
15:00 – 15:30	Tea/Coffee Break
15:30 – 16:30	Production (Documentation, Process deviations, Process validation, In-Process checks, Packaging and labelling, Reprocessing reworking and recovery). Presenter: Knud Ryhl
16:30 – 17:00	Plenary and close of day two

29th June 2011

08:30 – 09:00	Recap of DAY 2
09:00 – 09:45	Quality Management System: Training and Responsibilities, Documentation, Change management, Complaints and recalls, Outsourcing and supplies, Data Integrity. Presenter: Knud Ryhl
09:45 – 10:30	Storage and Distribution: Traceability, Brokers and Traders, Repackaging and Relabeling, Returns. Presenter: Knud Ryhl
10:30 – 11:00	Tea/Coffee Break
11:00 – 11:45	General Questions & Answers including evaluation.
11:45 – 12:30	Presentation of Certificates of completion.
12:30 – 13:00	Closure words from host to delegates.

13:00 – 14:00	Lunch Break
14:00 – 18:00	Excursion Tour to Ngorongoro Crater.

30th June 2011

09:30 – 10:30	Regulators Forum Meeting.
10:30 – 10:45	Tea/Coffee Break.
10:45 – 12:30	Development of two year training plan.
12:30 – 13:30	General Discussion.
13:30 – 14:30	Lunch Break
14:30 – 15:30	END OF EVENT and DEPARTURES