MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

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WORKSHOP BETWEEN THE PDA, PIC/S, MCC, INDUSTRY and INTERESTED PARTIES on the GMP FOR API MANUFACTURERS

To all API Manufacturers and National Medicines Regulatory Authorities, Africa

Following the global trend for an increase in regulatory oversight over the manufacturing of Active Pharmaceutical Ingredients (API's) and the requirements from national medicines regulatory authorities to pronounce on the Good Manufacturing Practice compliance of API sites with acceptable standards of GMP, the Parenteral Drug Association (PDA) Europe, together with the Pharmaceutical Inspections Cooperation Scheme (PIC/S) in co-operation with the Medicines Control Council (MCC) is planning to host a workshop in South Africa on the GMP requirements for API sites. All Manufacturers and national medicines regulatory authorities involved with and overseeing the GMP for API sites in Africa is invited to attend the planned two day workshop.

The workshop is scheduled as follows:

Date: Tuesday – Wednesday, 18 – 19 March 2014
Time: 09h00 – 17h00
Venue: Radisson Blu Hotel, Gautrain Hotel, Sandton, Johannesburg
Phone: +27 (11) 286 1000
General topics for discussion:

(i) International Regulations on API´s and requirements for API import
(ii) Regulatory view on API - Manufacturing Sites
(iii) Link to the ICH Quality Paradigm
(iv) GMP Principals for API manufacturing sites
(v) Facilities, Material management, Equipment, Personnel
(vi) Laboratory, Quality Management System, Validation
(vii) Agents, Brokers, Traders, Distributors, Repackers and Relabellers

Your participation as stakeholders is hereby invited.

Please register for your participation on line at the following website: https://europe.pda.org/GMP2014

Yours faithfully

MS M HELA
REGISTRAR OF MEDICINES