**File no. QA/RI/NRA/Compliance report/63/14**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**Office of Drugs Controller General (India)**
**(QA division)**

**FDA Bhawan, Kotla Road,**
**New Delhi**
**Dated-06/08/2014**

**To**
**All State Drugs Controllers**
**India**

**Subject: - Procedures of Regulatory Inspection.**

Sir,

Consequent upon the discussion held on 47th DCC meeting regarding adoption of uniform procedures in regulatory inspection for issuance of COPP and other GMP inspections, the following points have been summarized for ensuring uniform implementation by both States and CDSCO:

1. All GMP inspections including that of COPP will be focusing mainly on the requirements of Schedule M of Drugs and Cosmetic Rules 1945 with respect to establishing shelf life, conducting validation studies and ensuring prompt and effective recall besides WHO GMP requirements.
2. It has to be ensured that inspections are conducted for 2-5 days depending on the size of the manufacturing unit, the number of products handled, complexity of products and procedures.
3. Inspection team shall prepare inspection plan, conduct opening meeting and exit meeting on the final day to summarize and discuss the observations with the manufacturers.
4. In case of critical observations which have direct impact on the quality, safety and efficacy of the products and where regulatory action has to be initiated immediately, reports are to be finalized at the end of inspection without delay.
5. The final report of inspection may be finalized within one week, critically reviewed by Zonal officers and forwarded to State Licensing Authority for necessary action along with copy to CDSCO (HQ) and manufacturers for compliance, if any.
6. The State Drugs Control Authorities shall also initiate the process to qualify inspectors for inspection of vaccines and pharmaceutical manufacturing facilities based on experience and training and ensure that each inspector carries out minimum five GMP inspections in one year to sustain the performance.
7. The inspections of medicines and Biologicals should be conducted using risk-based approach and should specifically focus on product development, product quality attributes, stability study conducted to establish shelf life in Indian climatic conditions, process validation, complaint/recalls, handling of out of specification, deviations, change control procedures, aseptic processing, sterilization etc.

In view of ensuring uniform implementation of regulatory inspection procedure, it is desired that the above points are complied in GMP inspections.

Yours faithfully

**(Dr. G.N. Singh)**
**Drugs Controller General (India)**

**Copy to:**

1. Joint Drugs Controller (India), CDSCO (HQ)
2. All Deputy Drugs Controllers (India), CDSCO (HQ)
3. All Zonal/Sub-Zonal officers of CDSCO
4. CDSCO website