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Uniform procedures for regulatory inspection:DCGI

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Uniform procedures for regulatory inspection

The drugs controller general of India (DCGI) has issued new rules in order to ensure uniform implementation of regulatory inspection procedures for issuance of CoPP and other GMP certificates by both the state drug authorities and the CDSCO.

According to the new procedures, all GMP inspections including that of CoPP will be focussing mainly on the requirements of Schedule M of Drugs and Cosmetics Rules, 1945 with respect to establishing shelf life, conducting validation studies, and ensuring prompt and effective recall besides WHO GMP requirements.

Also, it has to be ensured that inspections are conducted for two-five days depending on the size of the manufacturing unit, the number of products handled, complexity of products, and procedures. The Inspection team shall prepare an inspection plan, conduct opening meetings and exit meetings on the final day to summarize and discuss the observations with the manufacturers.

In case of critical observations which have a direct impact on the quality, safety, and efficacy of the product and where regulatory action has to be initiated immediately, reports have to be finalized at the end of the inspection without delay. The final report of inspection may be finalized within a week, critically reviewed by zonal officers and forwarded to the respective state licensing authorities for necessary action, along with a copy to CDSCO (HQ) and manufacturers for compliance, if any.

Similarly, the state drug control authorities shall also initiate the process that qualifies inspectors for inspection of vaccines and pharmaceutical manufacturing facilities based on experience and training.They will ensure that each inspector carries out a minimum of five GMP inspections in one year to sustain the performance.

The inspection of medicines and biologicals should be conducted using risk-based approach and should specifically focus on

product development, product quality attributes and stability studies conducted to establish the shelf life in Indian climatic conditions, process validation, complaints/recalls, handling of out of specifications deviations, change control procedures, aseptic processing and sterilization.