ENHANCEMENT OF GMP INSPECTIONS IN INDIA

3rd JAPAN- INDIA MEDICAL PRODUTS REGULATION SYMPOSIUM

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Outline

- Drugs Regulation
- Indian Pharmaceutical Industry
- GMP Certification
- Recent amendments
- Risk Based Inspections
- Role as Observers
- Capacity Building
- Way forward

Drugs Regulation

- Drugs fall under the **Concurrent List** of the Constitution of India

- Drugs & Cosmetics Act is a **Central Act** enforced by both Central and State Government

Indian Pharmaceutical Industry – A Brief Profile

Type of Manufacturing Unit	Number of Units (Approx)
Formulations	4900
Active Pharmaceutical Ingredients	1500
Vaccines	30
Medical Devices	350
Miscellaneous (Surgical dressings, Blood banks, Disinfectants etc)	2850

Cont…

Type of Manufacturing Unit	Number of Units (Approx)
Others	
Cosmetics	2300
Ayurveda, Unani	4800
Homeopathy	1000
Whole sale and Retails	800,000

GMP Certification

- GMP Certification for Statuary Licence to manufacture drugs in the country :-
  - Compliance to GMP requirement as specified in Drugs & Cosmetics Act and Rules is verified.
  - Inspection conducted jointly by Central Licensing Approving Authority (CLAA) and State Licence Authority. (SLA)
- GMP Certification for issuance of Certification of Pharmaceutical Products
  - Compliance to GMP requirement as specified in WHO TRS published from time to time are verified.
  - Inspection conducted jointly by Central Licensing Approving Authority (CLAA) and State Licence Authority. (SLA)

Recent Advancements in Drugs and Cosmetics Act 1940 and Rules 1945 for GMP

- Joint GMP inspection by Central and State Drugs Regulators mandated since October 2017 vide GSR 1337 (E)
- Proposal to upgrade Schedule M in line with WHO GMP standards and PIC/S submitted to Ministry of Health and Family Welfare

Risk Based Inspections

- Identifying high risk facilities based on predefined criteria.
- Training of Inspectors of Central and State Governments including experts from Govt. testing laboratories.
- Common checklist and benchmark is laid down for uniformity.
- Inspection teams were constituted facility wise.
- Pre-notification of inspection dates to manufacturers.
- Inspection report with observations were shared with manufactures to be compliant.

Role as Observers

- CDSCO Drugs Inspectors involve in GMP inspections conducted in India by WHO and Regulatory Authorities of other countries like USFDA, PMDA, Russia, etc

Capacity Building

- CDSCO provides trainings to Drugs Inspectors
- CDSCO Drugs Inspectors participated in trainings conducted by regulatory authorities like WHO, EU, USFDA, etc
- PMDA – ATC helped in capacity building of CDSCO GMP inspectors

Way forward

- Post Marketing Drug evaluation
- Extensive monitoring with respective to the post approval for certain period of time

Thank You !