

---

# **ENHANCEMENT OF GMP INSPECTIONS IN INDIA**

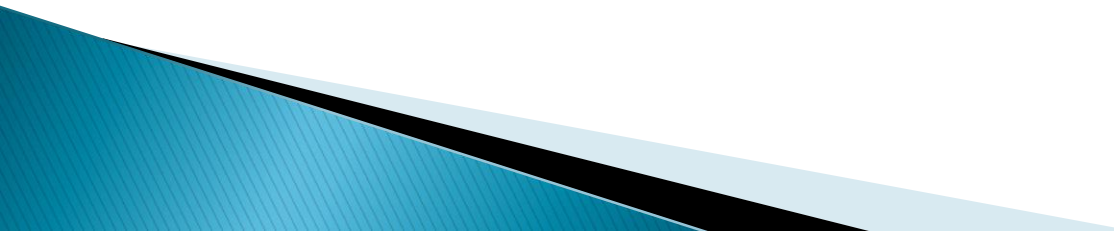
**3<sup>rd</sup> JAPAN- INDIA MEDICAL PRODUCTS REGULATION SYMPOSIUM  
27<sup>th</sup> August 2018**

**Dr. K. Bangarurajan  
Joint Drugs Controller (I)  
CDSCO (HQ)**

# 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

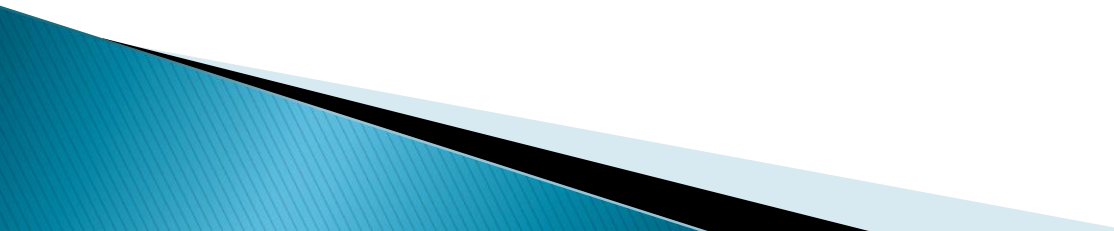
- Identifying high risk facilities based on predefined criteria.
- Training of Inspectors of Central and State Governments including experts from Govt. testing laboratories.
- Common checklist and benchmark is laid down for uniformity.
- Inspection teams were constituted facility wise.
- Pre-notification 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 respect to the post approval for certain period of time

**Thank You !**

