



DEPARTMENT OF PHARMACEUTICALS,
MINISTRY OF CHEMICALS AND FERTILIZERS,
GOVERNMENT OF INDIA



INDIAN DRUG MANUFACTURERS'
ASSOCIATION

PRESENTS

GMP WORKSHOP FOR SMES SCHEDULE M & BEYOND

FOR GLOBAL QUALITY AND COMPLIANCE

Schedule M was introduced as a requirement for GMP compliance in our **Drugs & Cosmetics Act 1940** three decades ago for ensuring that medicines of high Quality & Safety are manufactured consistently.

Many Small and Medium size Enterprises (SMEs) working in the domestic market were immensely benefited in improving the quality standards of the products manufactured by complying with **Schedule M** requirements.

As a part of its commitment to help the SMEs to update their GMP standards with current global trends and to help them to export their products, IDMA, through its Regulatory Committee, is engaged in designing and providing education programmes.

This workshop is designed to provide a basic guidance and practical help for technical, supervisory and supporting Quality Assurance personnel of small scale industries to ensure compliance with these regulations including manufacturing, packaging, holding, distribution and the laboratory requirements.

It will provide guidance for application of the cGMP at the operating, supervisory and management level to successfully discharge their responsibility for implementing the GMP requirements of Schedule M, going beyond to WHO GMP requirements and PIC/S, and firm's Quality Management System.

The expert speakers will provide pragmatic guidance in interpretation and implementation of Schedule M and principles of GMP along with an insight into evolving global regulatory requirements.

Benefits include:

- Guidance on the interpretation and application of Good Manufacturing Practice and Implementation of Schedule M
- Awareness and sharing of evolving regulatory requirements and roadmap for achieving global quality compliance
- Access to an experienced panel of speakers

Workshop Agenda

Morning Sessions

- Registration (9.00 AM to 9.30 AM)
 - Inaugural Session (9.30 AM to 10.15 AM)
1. **Designing a GMP Compliant-Facility** (*Includes premises, facility and equipment, Sanitisation and Hygiene shop floor supervision of GMP practices including Manufacturing and Packaging control*) (10.15 AM to 11.00 AM)
Tea Break (11.00 AM to 11.15 AM)
 2. **Qualification & Validation** (*Includes Facility and Equipment Qualification, Qualification of Critical utilities i.e. HVAC, water system, Equipment, Process validation and cleaning validation*) (11.15 AM to 12.00 PM)

3. **Good Quality Control Practices Including Stability Testing** (covers sampling, testing, specifications & Analytical Method Validation, laboratory electronic data management & Integrity) (12.00 PM to 12.45 PM)

Lunch (12.45 PM to 01.30 PM)

Post Lunch Sessions

4. **Training of Personnel & Internal Audit** (Includes different types of Training, Training for Trainers & Internal Auditors, Required qualities of Trainers and Internal Auditors, performing the Internal audit in line with GMP & ISO) (01.30 PM to 02.15 PM)

5. **Introduction to Product Licensing and Dossier Requirements** (Includes dossier requirements to ASEAN, COPPs and licensing requirements, SMF and VMP preparation) (02.15PM to 03.00 PM)

6. **Introduction to Quality Management System (QMS)** (Includes management strategy, governance, management review and key quality system elements change control and deviation management, complaint management, risk management, self-inspection and quality audits and CAPA system) (03.00PM to 03.45 PM)

Tea Break (03.45 PM to 04.00 PM)

7. **Journey towards PIC/S** (04.00 PM to 04.45 PM)

Q&A Session (04.45 PM to 05.30 PM)

This workshop is designed for:

- Small Scale and Mid-Size Company's Technical Heads, Managerial and Supervisory staff especially in Production / QC / QA, Regulatory and Engineering

Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India will be sharing part of the workshop cost. The balance will be met through a Registration fee from Participants or Sponsors.

Indian Drug Manufacturers' Association

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