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

INDIAN DRUG MANUFACTURERS' ASSOCIATION
WEST BENGAL STATE BOARD

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 it's 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

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 AND FERTILIZERS,
GOVERNMENT OF INDIA

INDIAN DRUG MANUFACTURERS' ASSOCIATION
WEST BENGAL STATE BOARD

PRESENTS

GMP WORKSHOP FOR SMEs SCHEDULE M & BEYOND

FOR GLOBAL QUALITY AND COMPLIANCE

On Saturday, 8th August 2015 at Banquet Room, (Victoria 1 & 2) At Hotel Park Plaza, 17 Garcha 1st Lane, Ballygunge, Kolkata – 700 019

AGENDA

MORNING SESSIONS:

Registration (9.00 AM to 9.30 AM)
Inaugural Session (9.30 AM to 10.00 AM)

1. **Designing a GMP Compliant-Facility** *(includes premises, facility and equipment, sanitations & hygiene, including Manufacturing and Packaging Control, in process controls, batch reconciliation, packing operations, Barcoding and batch release* (10.00 AM to 11.00 AM)
   Prof. (Dr.) Jayanta Chattopadhyay

Tea Break (11.00 AM to 11.15 AM)

2. **Qualification and Validation** *(includes facility and Equipment Qualification, Qualification of Critical utilities i.e. HVAC, Water System; Process Validation and Cleaning Validation*) (11.15 AM to 12.15 PM)
   Speaker – **Mr Narendra Kumar**, *Head QA, M/s. Orchid Healthcare, Chennai.*
3. **Good Quality Control Practices Including Stability Testing** *(includes Sampling, Testing, Specifications and Analytical Method Validation, Laboratory electronic Data Management*
   (12.15 PM to 01.00 PM) Speaker – **Mr J L Sipahimalani**, *Chairman-APA and Quality Management &Technical Subcommittee, IDMA.*

Lunch (01.00 PM to 01.45 PM)

POST LUNCH SESSIONS:

4. **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)*
   (01.45 PM to 02.45 PM) Speaker **: Mr S M Mudda,** *Director – Global Strategy (Technical), Micro Labs Ltd.*
5. **Training of Personnel & Internal Audit** *(Includes different types of Training, Training for Trainers & Internal Auditors, Required qualities of Trainers & Internal Auditors, Performing the Internal Audit in line with GMP & ISO)*
   (02.45 PM to 03.30 PM). Speaker :**R. Raghunandanan***, Former Vice-President – Quality (South Asia), GSK and Pharma Consultant, Mumbai.*

Tea Break (03.30 PM to 03.45 PM)

6. **Journey towards PIC/S** (03.45 PM to 04.15 PM) Speaker: **Mr Kapil Bhargava**, *Retired Deputy Drug Controller (India), CDSCO.* Q & A Session (04.15 PM to 05.00 PM)

For further details, please contact: Ardhendu Banerjee,
IDMA, West Bengal State Board, C/o. Strassenburg Pharmaceuticals Ltd.,
Phone : 033 2284 7177 / 8013 / 9106, Mobile : +919830531473, Email : ardhendu@strassenburgpharma.com

REGISTRATION FORM

To,
Indian Drug Manufacturers' Association
West Bengal State Board
C/o Strassenburg Pharmaceuticals Ltd
P-6, C.I.T. Road, (4th Floor), Kolkata – 700 014
Phone : 22847177/8103; Fax:22451198; E-mail: ardhendu@strassenburgpharma.com; info@strassenburgpharma.com

Date : _____

Dear Sir,

IDMA WBSB presents

"GMP workshop for SMEs – Schedule M & Beyond",
on Saturday, 8th August 2015 from 9.00 am to 5.00 pm at the
Banquet Room (Victoria 1 & 2)**at Hotel Park Plaza,**17, Garcha 1st Lane, Ballygunge, Kolkata 700019.

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

Kindly register the name/s of the following person/s from our company to participate in the above programme :-

SR. NO.	NAME	DESIGNATION
1.		
2.		
3.		
4.		
5.		

Our Cheque/DD* no._____ dated _____ for

Rs. _____ is enclosed.

Thanking you,

(Name & Designation)

Name of the Company : _____

Address : _____

_____

Tel No. : _____ Email : _____ _____

Registration Fee : Rs. 1000/- per person

Note *:Participation fee is neither refundable nor adjustable against future programmes. However, changes in nominations are accepted. Kindly use photocopies of this form for additional registrations. The cheque/DD to be drawn on* ***"Indian Drug Manufacturers' Association West Bengal State Board".***
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~