Pharmexcil's Workshop on

"Recent advancements in Indian Drug Regulations with reference to Draft Schedule –M (GMP)"

10th Aug 2019

Hotel Hindustan International,
Kolkata

Pharmexcil has organized one day Workshop on "Recent advancements in Indian Drug Regulations with reference to Draft Schedule –M (GMP)" on 10th Aug 2019 at Hotel Hindustan International, 235, 1, Acharya Jagadish Chandra Bose Rd, Sreepally, Elgin, Kolkata, West Bengal.

An overview of the amendments in the Draft Schedule-M (GMP) with new perspectives from the experts would help strengthen our concepts as well as validate our ideas on the changes in the current practices and the various issues concerning its implementation. This workshop has been specially designed for the MSMEs to build their capabilities to match the current global trends which would ultimately provide export opportunities.

We sought the cooperation of Central Drugs Standard Control Organization (CDESCO-East Zone) and Indian Drugs Manufacturers Association (IDMA) to mobilize the participation of their members.

Participants:

Participants includes Industry professionals, regulators from state Drugs Control Administration and from Central Drugs Standard control organization (CDSCO). Various sectors of industries like Pharmaceuticals (API & Formulations), clinical research organizations participated in the workshop.

About 200 members are participated in the workshop, of which about 150 members are from Industries located in West Bengal (Approximately 100 companies) and about 50 members are from Drugs Control Department, Govt of West Bengal and CDSCO-East Zone.

Program details:

01	Overview of Draft Schedule-M(GMP) 2018 & Difference between existing Schedule – M 2001 & Draft Schedule – M 2018	**Dr. A. Ramkishan**, Deputy Drugs Controller (I), CDSCO-EZ-Kolkata
02	HVAC System & its Validation	**Mr. Puneet Randeo**, Program Manager–HVAC&Lighting, UL India Pvt Ltd
03	Water System & its Validation	**Dr.Hari Vayas Bansal,** Director-VCAB Pharma Trainers & Chief Mentor-GxP Pharma Trainee
04	Good Laboratory Practices and Basics of Data Integrity	**Mr. Manu Grover** Country Pharma Business Development Manager Laboratory Solution Services Agilent Technologies Inc.
06	Opportunities for MSME in Exports	**Ms.Lakshmi Prasanna,** Sr.Regulatory Affairs Officer, Pharmexcil

Inauguration of the workshop:

Dr.V.Ravichandiran, Director,-NIPER-Kolkata, **Dr. A. Ramkishan**, Deputy Drugs Controller (I), CDSCO-EZ-Kolkata, **Mr.Deepnath Roy Chowdhury**, National President, IDMA, **Mr.Udaya Bhaskar**, Director General-Pharmexcil are participated in the inaugural ceremony with Light lamping.

Dr.V.Ravichandiran, Director-NIPER-Kolkata has given introductory remarks with the objective of the workshop and called for the collaboration of Industry bodies, Regulatory agencies and Academic and Research institution in making the country self-reliant in manufacture of essential medicines.

Mr.Udaya Bhaskar, Director General-Pharmexcil has briefed about the export performance of Indian Pharmaceutical Industry, role and activities of Pharmexcil in promotion of pharma exports and the initiatives of Ministry of Industry and Commerce in encouraging the SMEs to enter the export market.

Mr.Deepnath Roy Chowdhury, National President, IDMA welcomed all the speakers, guests, participants and also congratulated the State Board Committee for successfully organizing the workshop. He also touched upon relevant issues currently concerning the Indian Pharma Industry. He thanked Pharmexcil for organizing training programs for SMEs.

Deliberations during the Workshop:

- **Dr. A. Ramkishan,** *Deputy Drugs Controller, Central Drugs Standard Control Organization (CDSCO)* has given presentation on "Recent advancements in Indian regulations with special focus on Draft amendment of Schedule-M". He briefed about the vision, Mission of CDSCO, About Indian Drug regulatory system, and functions of various bodies, Has given detailed presentation about Draft amendment of Schedule M-2018. He emphasized about the principles of Pharmaceutical Quality System, Quality Risk Management, Qualification and Validation, Product Recall, Change Controls, handling of Complaints, Quality Audits, Sanitation & hygiene, Training,

Reference Standards, Waste Materials, Documentation, computerized system etc. Dr.Ramkishan further stressed about the recent inclusions in GMP and the corresponding sections.
Also explained about the recent advancements in Indian Regulations like Clinical Trial Rules, 2019 Medical Devices Rules, 2017, Prohibition of Irrational FDCs, Oxytocin Prohibition, GCP guidelines, Regulation of Cosmetics and Blood banks, Trace and Track system for top 300 brands, Public Relation Office (PRO), Intelligence office etc.

- **Mr. Puneet Randeo,** Program Manager–HVAC & Lighting, UL India Pvt Ltd has given presentation on "HVAC System & its Validation". He briefed about Pharmaceuticals new drug life cycle, HVAC system - purpose, Functions and Uses. He deliberated in detail about the Chillers assessment- Principle, Concerns & Approach. Methodologies, Key parameters influencing performance of chillers, Analysis and reporting. He further explained about the HVAC validation concept, testing procedures and parameters in pharmaceutical industry.

- **Dr.Hari Vayas Bansal,** Director- VCAB Pharma Trainers & Chief Mentor-GxP Pharma Trainee has given presentation on "Water System & its Validation". He briefed about Importance of Water in Pharmaceuticals manufacturing, Grades of Pharmaceutical Water- Potable water, Purified water, Water for injection(WFI), Sterile water for injection, inhalation, irrigation, Bacteriostatic water for injections, Production Methods Overview, Storage & Distribution Considerations, Qualification / Validation, Sampling, Testing Requirements, Acceptance Criteria, Trending, Investigation & Revalidation & Change control. He elaborated the Water Purification Systems and Design, Typical Water System Design, Supply Water Pre-Treatment, Treatment Process for Different Types of Waters, Methods for Preparation of Pharmaceutical Water, Methods for Preparation of Pharmaceutical Water, Storage System Considerations, Distribution & Storage System Design Attributes, Sanitization of Purified Water and Water for Injection Distribution & Storage Systems, Qualification/Validation of a Water System, IQ/OQ/PQ, Sampling Basics, Monitoring and testing methods, data evaluation, Microbilogical specifications, Trending, OOT & OOS handling and Revalidation & Change Control etc.

- **Mr. Manu Grover,** Country Pharma Business Development Manager Laboratory Solution Services, Agilent Technologies Inc has given presentation on **"Good Laboratory Practices and Basics of Data Integrity"**. He briefed about history, Mission, Objectives of GLP, concepts, Standard Operating Procedures (SOP), Instrumentation Validation, Analyst & Laboratory Certification, Specimen/Sample Tracking, Documentation and Maintenance of Records and OECD guidelines. He also detailed about the principles of Data Integrity, management of Electronic Data, Common Causes,Various guidelines related to GLP, ALCOA for Data Integrity, Records Protection, Review of audit trails etc.

- **Ms.Lakshmi Prasanna,** Sr.Regulatory Affairs Officer, Pharmexcil has given presentation on **"Exports of Indian Pharmaceuticals-Unlocking the Potential for SMEs"**. She explained about the details of Indian Pharma Market and its contribution, Journey of Indian pharma Industry in the global market. Further elaborated about role of SMEs, challenges faced by SMEs in exports and potential opportunities in export market. She explained the various incentives offered by the Government of India (Ministry of Commerce & industry) and Department of Pharmaceuticals to Industry members to encourage the exports. She detailed about the Market Access Initiative (MAI) scheme of Ministry of Commerce and various schemes offered by DOP.

- **Panel Discussion and Q&A Session**: The above expert panelists responded to all questions raised by the participants. This session was well moderated by Dr. A. Ramkishan, Deputy Drugs Controller (I), CDSCO-EZ; he additionally provided valuable inputs to the various queries. The delegates present participated enthusiastically and were greatly benefited through the various clarifications provided by the eminent speakers.

- **<u>Feedback:</u>**

  The participants expressed that the contents of the workshop are well chosen with a view of creating awareness on the recent advancements happened in Indian regulations. Most of the participants have given positive feedback and are looking forward for such kind of programs.