Pharmexcil Conference on

"Recent Advancements in Regulatory landscape of India & Emerging Markets"

15th Feb 2020

Hotel Le Royal Meridian, Chennai

Conference on
"Recent Advancements In Regulatory Landscape of India & Emerging Markets"
Dt:15th Feb 2020, Chennai

In our endeavors to educate the industry about the market & regulatory developments happening across the world and to make them aware of the export opportunities available, Pharmexcil has initiated pan India training program with the support of Ministry of Commerce & Industry.

Pharmexcil has organized one day conference on **"Recent Advancements in Regulatory landscape of India Emerging Markets"** on 15th Feb 2020 at Hotel Le Royal Meridian, Chennai with a view to empower the medium and small scale units on the recent developments happening in the Indian Drug regulations as well as with international market requirements and regulatory guidelines of product registrations in the emerging markets.

The one day conference is focused on Regulatory Affairs developments in INDIA and Emerging markets like CIS, ASEAN & AFRICA regions. We sought the cooperation of Indian Drug Manufacturers Association, Tamilnadu Puduchery, Kerala Branch (IDMA TNPKSB) to mobilize the participation of their members.

The Drug Regulatory agencies- Central Drugs Standard Control Organization (CDSCO) South Zone, Chennai and Drugs Control Administration of Tamilnadu have graced the conference and talked about the recent developments happening in Indian Drugs Regulations.

Experts from the industry have deliberated on the important aspects of Quality Management System and GXPs, Data Integrity & Audit trails and Regulatory Strategy for Emerging Markets and Opportunities & Challenges for MSME in emerging markets along with handholding measures of the Govt of India for encouraging the exports.

Participants- 185 members

Industry professionals working in various departments like Quality Assurance, Quality Control, Production, Regulatory Affairs and Business Development, Regulators from State Drugs Control Administration, TN and from Central Drugs Standard control organization (CDSCO), BCG vaccine Laboratory, Guindy Pastuer Institute, Coonoor etc have actively participated in the conference.

Various sectors of industries like Pharmaceuticals (API, Formulations, Neutraceuticals), Clinical Research Organizations participated in the workshop.

About 185 members are participated in the workshop, of which about 165 members (from 55 companies)located Chennai/ Tamilnadu, Puducherry, Bangalore, Hyderabad, and Mumbai etc and 20 members from CDSCO, DCA, TN and other Govt institutions.

Conference on "Recent Advancements in Regulatory landscape of India & Emerging Markets"

Hotel Le Royal Meridian, Chennai

15th February, 2020

Agenda

TIME	PROGRAMME	
09.30 to 10.00 am	REGISTRATION	
INAUGURAL SESSION		
10:00 to 10:30 am	Inaugural Ceremony - Address by • **Shri. J.Jayaseelan**, Chairman, IDMA, TNPKSB • **Shri. Ravi Udaya Bhaskar**, DG, Pharmexcil • **Mrs.Shanthy Gunasekaran**, DDC(I), South Zone, Chennai • **Shri. K. Sivabalan**, Director, Tamil Nadu Drugs Control Department	
TECHNICAL SESSION		
10.30 to 11.15 am	Overview of Global GXPs and Quality Management System- Key gaps in GXP w.r.t to Regulatory expectations and Practical implementation aspects	**Dr.Hari Vayas Bansal,** Director- VCAB Pharma Trainers & Chief Mentor- GxP Pharma Trainee
11.15 to 11.30 am	**Tea Break**	
11.30 to 12.15 pm	Data Integrity with special emphasis on Audit Trials	**Mr. Anand Iyer**, Business Head – South Asia, UL India Pvt Ltd
12.15 to 01.00 pm	Recent advancements in Indian regulations with special focus on Draft amendment of Schedule-M	**Mrs. Shanthy Gunasekaran,** DDC (I), South Zone, CDSCO, Chennai.
01.00 to 02.00 pm	**Lunch break**	
02.00 to 2.45 pm	Regulatory Strategy for Emerging Markets	**Mr. Sadiq Basha,** Vice President Regulatory Affairs Strides Pharma Science Limited
02.45 to 03.30 pm	Opportunities & Challenges for MSME in Emerging markets	**Mr.Sumantha Choudhury,** Consultant
03.30 to 03.45 pm	**Tea Break**	
03.45 to 04.15 pm	Indian Pharma Exports Unlocking the Potential for MSMEs	**Ms.Lakshmi Prasanna,** Regulatory Affairs Officer, Pharmexcil
04.15 to 04.45 pm	**Panel Discussion / Q&A**	
04.45 to 05.00 pm	Concluding Remarks & Vote of Thanks	Mr. S. Sivanandhan, Hon. Secretary, IDMA, TNPKSB

Inauguration of the Conference:

Guest of Honor: Mrs.Shanthy Gunasekaran, *Deputy Drugs Controller (I), CDSCO, South Zone, Chennai*

Mr.K.Sivabalan, *Director, Drugs Control Administration*

Other Guests: **Mr.Jayaseelan,** *Chairman, IDMA-TNPKSB*

Mr.Sivanandhan, *Secretary, IDMA-TNPKSB*

Mrs.Shanthy Gunasekaran, Mr.K.Sivabalan, Mr.Jayasellan, Ms.Lakshmi Prasanna, Sr. Regulatory Affairs Officer, Pharmexcil have participated in the inaugural ceremony with Light lamping.

Ms.Lakshmi Prasanna, *Sr. Regulatory Affairs Officer*, *Pharmexcil* Has welcomed all the dignitaries and briefed about the role and activities of Pharmexcil, export performance of Indian pharmaceuticals, exports in FY 19 & FY 202, the incentives being offered by Ministry of Commerce under MAI scheme etc. Also detailed about the measured taken by Pharmexcil for strengthening the technical capabilities of MSMEs.

Mr.Jayaseelan, *Chairman, IDMA-TNPKSB* has briefed about the organization and activities and details of their members. He also touched upon relevant issues currently concerning the Indian Pharma Industry and urged Pharmexcil to organize more such workshops or training programs in Chennai.

Mr.K.Sivabalan, *Drugs Controller*, *Government of Tamilanadu* deliberated about the activities of Drugs Control Department, recent initiatives adopted by the department for faster clearance of applications like e-governance portal and fixed timelines etc.

Mrs.Shnthy Gunasekaran, *DDC(I), CDSCO South Zone* praised Pharmexcil for organizing the technical conferences at the right time of dynamic regulatory environment in the country. She has briefed about the recent initiatives of CDSCO in making the national regulations on par with WHO Guidelines, New Drug & Clinical Trails Rules & Medical Devices Rules, e-Governance initiatives viz SUGAM portal.

Deliberations of the Conference

(1) Overview of Quality Management System in Global GxP and Regulatory Environment

Presented by: **Mr. Hari Vayas Bansal,**
Chief Mentor-GxP Pharma Traine

Mr.Hari vaysa Bansal is a Quality & compliance management professional having 23 yrs. experience with demonstrated accomplishments in building commercial quality organizations and implementing compliance and quality improvements.

He has given a detailed presentation on Quality aspects of the Pharmaceutical industry and QMS guidelines directed by the various regulatory agencies and the importance of QMS principles for an industry to succeed in compliance with regulatory audits. Further deliberated upon the Global GXP practices such as GMP, GLP, GDP & GCP etc. and role of Quality in various operations of Pharmaceutical Development, Technology Transfer, Commercial manufacturing and Post Marketing Surveillance etc. Further stressed upon the manor five elements of GxP i.e People, Procedure, Products, Premises & Equipment and Processes.

He further elaborated the regulatory Guidelines for cGMP and major pitfalls, recent trends in Inspections & Key areas of observations & most general observations / mistakes committed by the industry etc and emphasized the collective response of management, quality professionals, and shop floor persons for the success of regulatory audit.

(2) Data Integrity- Importance of Audit Trials

Presented by: **Mr. Anand Iyer,**
Business Head, South Asia at UL PURE Learning

Mr. Anand Iyer, at his role as Business Head responsible for creating business development strategies, new market & solutions development, consulting and advisory services to life science companies in South Asia. Anand has been helping life science companies improve Quality & Regulatory compliance, increase competency and performance through continuous improvement.

In his presentation on Data Integrity & Importance of Audit Trails, he emphasized about ALCOA principle (attributable, legible, contemporaneous, original, and accurate) for maintaining complete data integrity. For these some key elements are paramount. These are organizational behavior, its culture and taking over ownership of systems and data. There is also a need to create a right environment to enable data governance practices. He said that Pharma companies must engage in continuous trail from capture to archive, look at stability of values with attribution, protection against loss or destruction, and allow ease of review for data quality and validation of systems. Delving into data integrity and audit trail, he said the latter means a secure, computer-generated, time-stamped electronic record that allows for reconstruction of the course of events relating to the creation, modification, or deletion of an electronic record.

(3) Recent advancements in Indian regulations - Draft amendment of Schedule-M

Presented by: **Ms Shanthy Gunasekaran,**
Deputy Drugs Controller(I), CDSCO, Chennaii

She briefed about the vision, Mission of CDSCO, evolution of Indian drug regulations especially GMP (Schedule M), About Indian Drug regulatory system, and functions of various bodies, recent series of drug regulations implemented by the government. She has stressed upon the draft Schedule-M (Good Manufacturing Practices) to make it on par with WHO standards. She 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. She further stressed about the recent inclusions in GMP and the corresponding sections and major differences/comparison between current GMP and proposed amendments

She further explained about the GMP requirements for sterile products, Small volume & Large Volume parenteral and Opthalmic products etc. Also specified about the special requirements for Hazardous materials, Biological products and topical products etc. Also explained about initiatives of CDSCO for e-governance viz digitalization and SUGAM portal, the recent advancements in Indian Regulations like New Drugs & Clinical Trial Rules, 2019, Prohibition of Irrational FDCs, GCP guidelines, Regulation of Cosmetics and Blood banks etc.

(4) Regulatory Strategy for Emerging Markets

Presented by: **Mr. Sadiq Basha,**
Vice President -Regulatory Affairs, Strides Pharma Sciences Limited

Mr. Sadiq Basha, post Graduate in pharmacy has core experience in global regulatory affairs function for a period of 17 years. His prime responsibility is to maintain the Organization Regulatory strategy aligned with Global business strategy. Also ensures to provide technical regulatory support and guidance to deliver product filings and approvals targets globally.

His presentation on "Regulatory Strategy for Emerging markets" has given the insights to the participants on "Understanding the Emerging Markets as a whole" and "Strategy considerations of different regions emerging markets".

Understanding the Emerging Markets–
Factors effecting these markets, considerations for entering into these regions and their market share in global pharmaceuticals, Leading therapeutic areas/specialty areas in the regions, Challenges for growth etc

Strategy considerations of different regions –
A detailed deliberation of Market overview and regulatory requirements of various emerging regions like Latin America, Africa & Middle East, Russia& CIS & Asia Pacific regions. He emphasized much on the dossier format, Registration fee, Labelling & document requirements, Plant inspection requirements and special provisions such as Mutual Recognition among the Regulatory authorities.
He has guided the participants on Product development strategy for emerging markets with special focus on Commercial considerations, Submission strategy, Life cycle management and Clinical, quality requirements etc along with WHO prequalification process and its necessity to capture emerging markets.

(5) Opportunities & Challenges for MSME in Emerging Markets

Presented by: **Mr. Sumantha Choudhury,** Marketing & Strategic Consultant

Mr. Sumantha Choudhury is a Pharmacy graduate having 50 years' experience in pharma industry at top managerial positions. He is Course coordinator, International Trade (Africa), Center for African Studies, University of Mumbai.

In his presentation on "Opportunities & Challenges for MSME in Emerging Markets", he has appraised about the Indian pharmaceuticals performance (domestic & export) over last decade and todays scenario. His talk was focused on Middle East, Africa & Asean region and briefed about current exports of Indian pharmaceuticals to these regions in particular. He further explained about the changing scenario in each of these regions, fact sheets of each region, opportunities for small & medium scale companies in these regions either for establishing the manufacturing activity or to export from India and potential opportunities available for Indian companies. He further detailed about the harmonization of regulations/Mutual Recognition in African region for faster clearance of approvals to facilitate easy access of medicines, WALCO (West Africa Logistics Corridor) Role & its advantages for Indian companies.

(6) Indian Pharma Exports- Unlocking the Potential for MSMEs

Presented by: **Ms.Lakshmi Prasanna,** Sr. Regulatory Affairs Officer, Pharmexcil

Ms.Lakshmi Prasanna in has explained about the role and activities of Pharmaceuticals Export Promoting Council (Pharmexcil), its membership (RCMC) procedural formalities, advantages of having membership and initiatives of Pharmexcil such as Pan India training programs as per the needs of industry, International delegations, Consultative meetings with Regulatory agencies, Pharmexcil representations in policy matters related to exports etc.

In her presentation on “Exports of Indian Pharmaceuticals-Unlocking the Potential for SMEs” explained about the details of Indian Pharma Market and its contribution, Journey of Indian pharma Industry in the global market, credentials of Indian industries, export performance-region wise. Further elaborated about role of SMEs, challenges faced by SMEs in exports and potential opportunities in export market.

She explained the various incentives/handholding measures of 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 vatrious components of MAIs and application requirements, timeliness for processing. Also explained about various schemes offered by Dept of Pharmaceuticals such as Pharmaceuticals Technology Up gradation Assistance (PTUS) Scheme, Assistance to Bulk Drug Industry for Common Facility Centre, Assistance for Cluster Development & Pharmaceutical Promotion Development Scheme etc.

Feedback:

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 along with the overview about the requirements of ASEAN and AFRICA both in terms of regulatory submissions and understanding market requirements. Most of the participants have given positive feedback and requested for repeated workshops in Chennai region.