Pharmexcil Workshop on

"Recent Advancements in Regulatory landscape of Emerging Markets"

24th May 2019

The Capitol Hotel, Bangalore

Pharmexcil has organized one day Workshop on ""Recent Advancements in Regulatory landscape of Emerging Markets" on 24th May 2019 at The Capitol Hotel, No:03, Raj Bhavan Road, Bangalore with a view to empower the medium and small scale units on the market requirements and regulatory guidelines of emerging markets.

The one day workshop is focused on Regulatory Affairs developments in INDIA, ASEAN & AFRICA regions. We sought the cooperation of Karnataka Drugs and Pharmaceuticals Manufacturers Association (KDPMA) to mobilize the participation of their members.

Speakers:

We invited Dr.Ramkishan, DDC (I), CDSCO, East Zone to guide the participants on latest amendments in Drugs & Cosmetics Act. We also invited senior Regulatory affairs officials from industries like GSK Consumer Healthcare and Mylan laboratories Ltd. Business developments exprts from UL India Pure Learning and Nuwill Research & Innovations Pvt Ltd were invited as speakers for the workshop.

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 140 members are participated in the workshop, of which about 110 members are from Industries located in located in Bangalore, Hyderabad, Chennai and Mumbai (Approximately 35 companies) and about 30 members are from Drugs Control Department, Govt of Karnataka.

Program details:

01	Living Quality- Measuring Pulse!: Focus on Behavior and Culture	**Mr.Arun Mishra,** *EVP-RA, (India Sub Continent), GSK Consumer Healthcare*
02	Recent advancements in Indian regulations with special focus on Draft amendment of Schedule-M	**Dr.Ramkishan,** *DDC(I), CDSCO, East Zone*
03	Data Integrity with special emphasis on Audit Trials	**Mr. Anand Iyer,** *Business Head, South Asia at UL PURE Learning*
04	Market & Regulatory requirements of ASEAN Region	**Mr.Mallikarjuna GK,** *Head - Quality and Regulatory Affairs, Nuwill Research and Innovations Pvt. Ltd*
06	Market & Regulatory requirements of AFRICA Region	**Mrs. Seemeen Chandrantooty** *AGM, Regulatory Affairs, Mylan laboratories*

Inauguration of the workshop:

Mr.Amaresh Tumbagi, Drugs Controller, Government of Karnataka was invited as Guest of Honor for inauguration of the workshop. Mr.Raghuveer Kini, Executive Director, Pharmexcil & Mr.Sunil Attavar, President, KDPMA and all the distinguished speakers are participated in the inaugural ceremony with Light lamping.

Deliberations during the Workshop:

- **Mr.Raghuveer Kini**, *Executive Director, Pharmexcil* has briefed about the role and activities of Pharmexcil, brief outline about India's exports FY 2018-19. And explained about the incentives being offered by Ministry of Commerce under MAI scheme etc.

- **Mr.Sunil Attavar**, *President, KDPMA* has given an overview of the KDPMA organization and the details of their member companies. He stated that the state of Karnataka accounts for 3 per cent of the total pharma units in the country but chips in 6 per cent of earnings in exports. There are 12 US FDA plants and 82 WHO-GMP audited units. The state is also home to over 100 pharma colleges and the access to trained personnel is at arm's length. He urged Pharmexcil to organize more such workshops or training programs in Bangalore. Further requested Pharmexcil to conduct iPHEX 2021 in Bengaluru.

- **Mr.Amaresh Tumbagi**, *Drugs Controller, Government of Karnataka* 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. He stated that the Karnataka drugs control department is now aggressively working to ensure that 12 of the 15 Sakala services related to pharmaceutical certifications will now be able to take the online route from June 1st 2019. Further stated that Karnataka is known for its high quality production plants and research centers serving the international customers. In addition, it is hub for medical devices and biotech kits and several products are being exported from here.

- **Mr. Arun Mishra**, *Executive vice president, Regulatory Affairs (Indian Sub-Continent), GSK Consumer Healthcare* has given presentation on 'Living Quality- Measuring Pulse: Focus on Behavior and Culture' and pointed out that India has made a mark in the global markets and there are many countries looking at making it big. Our industry has inspired many countries in Asia, Africa and Latin America to get into this business by building both capability and capacity. In terms of the former, our scientific strength, skills sets and technical expertise is not seen anywhere in the world. Similarly in terms of production plants, India is home to the large base of globally approved units. Now taking a cue from Indian talent in pharma, many countries are changing their curriculum. So we should be heedful that our academic program are globally relevant. Stating that there was a paradigm shift in healthcare on understanding the disease and prescribing targeted therapy, Mishra said that India too need to realize that there is decentralization of information and decision making is changing. Even in drug manufacturing, quality and increasing number of regulations coming in called for Indian pharma to continuously ensure enhancing its standards, transparency and accountability.

- **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, Abour Indian Drug regulatory system, and functions of various bodies, , recent series of drug regulations implemented by the government like notification of Mundra port in Gujarat and Kamarajar port in in Chennai under Rule 43A of Drugs and Cosmetics Rules and implementation of 24X7 service for import/export of drugs at airport/seaport offices of CDSCO with effect from May 11, 2019. 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. Anand Iyer,** *Business Head, South Asia at UL PURE Learning* has given presentation on "Data Integrity with special emphasis on Audit Trials". There are concerns in data integrity, as more often the issue is that companies do not save electronic or hard copies of the data to be submitted. Efforts may not even be made not to record the data. There are also moves to back date the submitted data, fabricate the information, copy existing records as new information. Further, discarding data, deleting information when they realise that the product has failed, said Iyer. 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, 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.

- **Mr.Mallikarjuna GK,** *Head - Quality and Regulatory Affairs, Nuwill Research and Innovations Pvt. Ltd* has given presentation on "Market & Regulatory requirements of ASEAN Region". He briefed about overview of ASEAN region, demographics, Objectives of ASEAN integration, its Pharmaceutical Product Working Group (PPWG), their objectives and activities. Presented the market potentials of the region, list of regulatory agencies in the region, Dossier requirements, Drugs Registration approval process, ACTD format, its contents and modules, difference between ACTD and ICH CTD modules, Approval timelines, special requirements of stability studies as per ICH Zone IVb by Singapore and Indonesia, Product Labelling requirements. Also briefed about Post approval changes etc.

- **Mrs. Seemeen Chandrantooty** *AGM, Regulatory Affairs, Mylan laboratories* has given presentation on "Market & Regulatory requirements of AFRICA Region". She briefed about SUB -SAHARAN AFRICA 46 Countries, African pharmaceutical market scenario, Market Opportunities, factors that demand Drug Product, Market challenges and Solution to Overcome the challenges. Detailed about the Regulatory Landscape, Dossier Registration and Regulatory Requirements, CMC documents and structure of CTD modules etc. She has presented Regulatory Snapshot-South Africa, Regulatory Requirements-French West Africa, ZAZIBONA Collaborative Medicines Registration, East African Community, North Africa and Submission Route through Collaborative Procedure between the WHO Prequalification of Medicines Programme and National Medicines Regulatory Authorities.Further, explained the Labeling details for French West Africa, ZAZIBONA, Kenya and Specific labelling requirements-ZAZIBONA etc.

Feedback:

The participants expressed that the contents of the workshop are well chosen with a view of creating awareness on the recent advcnements happened in indian regulationas along with the overview about the requirements of ASEAN and AFRICA. Most of the participants have given positive feedback and are looking forward for such kind of programs.