Pharmexcil Conference on

"Recent Advancements in Regulatory Landscape of India & Regulated Markets"

Dt: 25th Feb 2020, Goa

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Pharmexcil has initiated pan India training program with the support of Ministry of Commerce & Industry 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 organized one day conference on **"Recent Advancements in Regulatory landscape of India & Regulated Markets"** on 25th Feb 2020 at Hotel Fidalgo, panjim, Goa with a view to empower Goa based manufacturing units on the recent developments happening in the Indian Drug regulations as well as with regulatory guidelines of product registrations in the overseas markets and regulatory preparedness for USFDA audits.

We sought the cooperation of Food & Drugs Administration, Goa and Central Drugs Standard Control Organization (CDSCO), West Zone to mobilize the participation of the members. The Director, FDA-Goa and Deputy Drugs Controller (I), CDSCO-West Zone, Mumbai 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 Culture Transformation, Data Integrity & Audit trails, Regulatory Preparedness for USFDA audits & Containment practices & Handling of Aseptic procedures etc.

Participants- 140 members

About 140 professionals from Industry, Regulatory Agencies & Acdemia have attended the conference. Various sectors of industries like Pharmaceuticals (API, Formulations, Nutraceuticals), Clinical Research Organizations and professionals working in various departments like Quality Assurance, Quality Control, Production, Regulatory Affairs and Business Development have actively engaed in the conference.

Regulators from Food & Drugs Administration, Goa and from Central Drugs Standard control organization (CDSCO), sub Zone-Goa and teaching faculty and students from colleges have actively participated in the conference.

Inauguration of the Conference:

Chief Guest: **Mrs.Nila Mohanan,**
Secretary, Health, Education & Industries & Skill Development, Govt of Goa

Guest of Honour: **Mrs. Jyothi Sardesai,** Director, FDA
Dr.Rubina Bose, *Deputy Drugs Controller (I), CDSCO, West Zone, Mumbai*

Mr.Ravi Uday Bhaskar, Director General, Pharmexcil & Ms.Lakshmi Prasanna, Sr. Regulatory Affairs Officer, Pharmexcil have participated in the inaugural ceremony with Light lamping.

Mr.Udaya Bhaskar, *Director General, 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 industries in international market place.

Mrs.Jyothi Sardesai, Director, Food & Drugs Administration, *Goa* deliberated about the activities of FDA and their proactive approach in organizing periodical educational programs both for the industry as well as for regulators, recent initiatives adopted by the department for faster clearance of applications like e-governance portal and fixed timelines etc.

Dr.Rubina Bose, *DDC(I), CDSCO West 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.

Mrs.Nila Mohanan, Secretary, Health, Education & Industries & Skill Development, Govt of Goa has appreciate the efforts of Pharmexcil in organizing training programs for industry and stated that the Pharmaceutical industry is the one which is boosting the Indian economy even in tough situations and global economic crisis. She called the industries to collaborate with academic institutions in bridging the gap between the Couse curriculum and industry practices.

RECENT ADVANCEMENTS IN REGULATORY LANDSCAPE OF INDIA & REGULATED MARKETS

Organized by Pharmexcil in collaboration with FDA, Goa & CDSCO, WZ

25th Feb 2020, Venue: Hotel Fidalgo, Panaji, Goa

TIME	PROGRAMME	
09.30 to 10.00 am	REGISTRATION	
INAUGURAL SESSION		
10:00 to 10:30 am	Inaugural Ceremony (10.00am-10.10am) Address by • **Mr.Ravi Udaya Bhaskar**, DG, Pharmexcil • **Dr..Rubina Bose**, DDC(I), West Zone, Mumbai • **Dr.PBN Prasad**, DDC(I), West Zone, Mumbai • **Mrs. Jyothi Sardesai**, Director, FDA, Goa **Chief Guest: Mrs.Nila Mohanan,** *Secretary, Health, Education & Industies 7 Skill Development, Govt of Goa*	
TECHNICAL SESSION		
10.30 to 11.15 am	**Experience of Transformation of Culture with respect to Quality**	**Mr. Sunil Kumar** Director & Global Head , Culture Transformation & Operational Excellence, Cipla
11.15 to 11.30 am	Tea Break	
11.30 to 12.15 pm	**Recent Advancements in Indian drug Regulations & draft amendment of schedule M.**	**Dr.Rubina Bose,** DDC(I), CDSCO **&** **Dr.PBN Prasad,** DDC(I), CDSCO
12.15 to 01.00 pm	**Regulatory preparedness for USFDA Audits -** Key gaps between Requirements & practices with observations made (483) and warning letters	**Dr Vinay Gopal Nayak,** Independent Director, Aarti Industries Ltd & Director at Surge Chemicals (India) Pvt. Ltd
01.00 to 02.00 pm	Lunch break	
02.00 to 3.00 pm	**Data Integrity with special emphasis on Audit Trails**.	**Mr. Manu Grover,** Country Pharma Business Development Manager, Agilent Technologies Inc
03.00 to 03.15 pm	Tea Break	
03.15 to 04.00 pm	**Containment Practices & Handling of Aseptic Procedures- Expectations & Constraints**	**Mr.Swain Pradipta** Vice President -Operations Sun Pharma
04.00 to 04.30 pm	Panel Discussion / Q&A	
04.30 to 5.00 pm	Post conference Evaluation followed by Closing ceremony	

Deliberations of the Conference

(1) Quality Culture Transformation

Presented by: **Mr. Sunil Kumar,** *Director & Global Head*
Culture Transformation & Operational Excellence, CIPLA Ltd.

Mr.Sunil Kumar is a Certified Lean Six Sigma Master Black Belt with multi continents international experience at different sites and corporate levels for about 16 yrs of project execution, operations and people management experience.

He has given a detailed presentation on Importance of Quality Culture Transformation with special deliberation on importance Right behavior & right mind set, for the efficient management of pharma industry as per the regulated procedures. Importance of Collective ownership of Quality across functions, Open environment in lab and on shop floor to freely raise suggestions, Quality prioritized as much as delivery and cost, Essential capabilities (e.g. problem solving / 5 why habit) developed and internalized at scale are explained. While talking about Working days, it was mentioned that adequate recognition for quality related achievements, Aligned integrative review mechanism and Active role modelling of quality related behaviors are to be adopted by the institutions. Regarding Quality Operating systems, Organization wide awareness of Quality metrics, Continuous improvement process deployed for quality, Simplified and automated systems / processes are much needed.

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

Presented by: **Dr. Rubina Bose,** *Deputy Drugs Controller (I), CDSCO, West Zone, Mumabi*

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 CDSCO initiatives such as 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, Draft Cosmetic Rules etc.

(3) Regulatory preparedness for USFDA Audits

Presented by: **Dr Vinay Gopal Nayak,** Independent Director, Aarti Industries Ltd

Dr.VG Naik guided the participants on the Key gaps between Requirements & practices with observations made (483) and warning letters and thus on how to prepare well for regulatory audits.

He explained about Pre-Approval inspection program and its importance & necessity, procedures, Role of CDER & District Offices of FDA, key aspects of PAI, Organization readiness, constitution of audit team & theirs qualification & skills, Documentation review procedures & Audit cycle. Stresses on preparation for audit with detailed discussion on role of Host, Scribes, Runners & Frontiers/spokespersons, Backroom staff, Senior Management etc. He further deliberated on Audit report, compliance deficiencies, and strategy for effective audit along with development data for different dosage forms viz solid dosage, sterile dosage etc. He further elaborated on things to keep in mind during technology transfer & Scale up, about Stability programs, Manufacturing controls, production issues, packaging & labelling issues, sampling programs, Material flow, Laboratory control, test data, Analytical methods, handling of OOS & OOT, Microbial labs. He further detailed about system based audits, utilities such as Water system, HVAC & Compressed air etc along with Training related to PAI.

(4) Data Integrity & Audit Trails

Presented by: **Mr. Manu Grover,**
Country Pharma Business Development Manager, Agilent Technologies Inc

Mr. Manu Grover, post Graduate in pharmacy has more than 16yrs of industrial and instrumentation experience in multinational pharmaceutical companies.

In his presentation on "Data Integrity (DI) & Audit Trials" he explained about the concepts of Data Integrity and importance of electronic data, common causes of data integrity vulnerability, ALCOA principles, DI trends etc. He exemplified the USFDA Data integrity warning letters trends with examples and deliberated about the technical documents specifying the data integrity and their evolution and current documents of each of regulatory agency and their key points to remember.
He further guided the delegates on expectations of regulatory auditors & best practices etc.

(5) Containment Practices & Handling of Aseptic Procedures

Presented by: **Mr. Pradipta Kumar Swain,** Vice President -Operations Sun Pharma

Mr. Pradipta Swain is a post graduate in Pharmaceutical operation and Management having 23 years' experience in pharma formulations, specialist in sterile dosage forms.

In his presentation on "Containment Practices & Handling of Aseptic Procedures", he has appraised about contamination, Containment types & practices, Technologies available for containment and Aseptic procedures – Expectation and constraints etc. He detailed about the contamination & cross contamination, examples of contaminants and their sizes, sources of contamination, clean room concepts & technologies such as Barrier and Isolator Technology, Barrier systems-

Open & Closed Restricted Access Barrier Systems, Active & Passive O-RABS Isolators, Closed Restricted Access Barrier systems (c-RABS), Advantages & constraints of o-RABS, c-RABS & isolators, Points to Consider for Traditional Cleanrooms, RABS, and Isolator Designs etc. Further explained about Use of robot for autoclave loading and unloading – without human touch of product, Stopper Treatment- aseptically stopper transfer without human touch, VHP pass box, Sterilization technology – E-Beam, Single Use/Disposable containment Technology, Aseptic Techniques & constraints.

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 Global requirements and key concepts of aseptic techniques. Most of the participants have given positive feedback and requested for repeated workshops in Goa.