

# RECENT ADVANCEMENTS IN REGULATORY LANDSCAPE OF INDIA & REGULATED MARKETS

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

**25<sup>th</sup> Feb 2020, Venue: Hotel Fidalgo, Panaji, Goa**

(Tentative Agenda)

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 <ul style="list-style-type: none"><li>Mr.Ravi Udaya Bhaskar, DG, Pharmexcil</li><li>Dr..Rubina Bose, DDC(I), West Zone, Mumbai</li><li>Dr.PBN Prasad, DDC(I), West Zone, Mumbai</li><li>Mrs. Jyothi Sardesai, Director, FDA, Goa</li></ul>	
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 Nayak 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 (TBC)
04.00 to 04.30 pm	Panel Discussion / Q&A	
04.30 to 5.00 pm	Post conference Evaluation followed by Closing ceremony	

