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BIRAC – CDSA REGULATORY WORKSHOP ON

Current Regulation on Medical Devices & in vitro Diagnostic Kits

FOURTH WORKSHOP OF THE SERIES

Demystifying Indian Drug Regulations for Product Approvals

16 OCTOBER 2014 INDIA HABITAT CENTRE, NEW DELHI

Current Regulation on Medical Devices and *in vitro* Diagnostic Kits

Program Agenda

Date: 16 Oct, 2014 **Venue: IHC, New Delhi**

08:30–09:00	**Registration**	**Ms Neha Mishra** Training Coordinator, CDSA
09:00–09:15	Introduction of CDSA	**Dr. Sudhakar Bangera** Program Director, CDSA
09:15–09:45	Inaugural Address & Program Objective	**Dr. Renu Swarup**, MD, BIRAC & Sr. Advisor DBT
Session I : Current Regulatory Regime		
09:45–10:30	**Introduction to CDSCO, its structure with respect to Medical Devices. Regulations for import, manufacture & sale of Medical Devices** (Details of the CDSCO, Structure, Detailed procedures for applications for import, local manufacture, sale of Medical Devices and responsibilities)	**Sh. Aseem Sahu** DDC(I), CDSCO, HQ / **Sh. Somnath Basu** ADC(I) , CDSCO, HQ
10:30–11:00	Regulations for *in vitro* diagnostics (IVD) Kits & Role of NIB in Testing	**Dr. Reba Chhabra** Head, Diagnostic Division, NIB
11:00–11:15	**Tea/Coffee Break**	
Session II : Medical Device Sector Specific Requirements		
11:15–11:45	**Classifications of Medical Devices – Comparative Analysis** (Definition of medical devices in Indian law compared to other countries, classification system & their usefulness, notification of Medical Devices etc.)	**Sh. Malay Mitra**, Former DDC(I), CDSCO HQ
11:45–12:15	**Design and development of Medical Devices** (Encompass the thought process behind design & development of Medical Devices and their proving for human use)	**Sh. Sameer D Saral** Director Operations, Trivitron Healthcare
12:15–12:45	**Testing requirements of medical devices, parametric release** (Important issues in testing of Medical Devices as these are not drugs and same yardstick cannot be applied to all types and designs of Medical Devices)	**Ms. Divya Ganapathy,** Tech. Consultant, UL Life & Health Services, Mumbai.

12:45–13:30	**Lunch Break**	
Session III: Proposed Regulatory Bill		
13:30–14:00	**Overview of current /draft Bill of Medical Devices** (Mainly comparisons with Indian Proposed Medical Device Bill and International Regulatory norms)	**Sh. Shailendra Kumar**, Director (Drugs), MoHFW
14:00–14:15	Industry Perspective	**Dr. Sumati Randeo**, Associate Director, Abbott Quality & Regulatory, Asia Pacific, Abbott
Panel Discussion	**Impression of new Medical Device Bill and probabilities of developing Indian CE marking system**	
14:15–17:00	**Moderator** : Sh. Ajay Pitre, MD, Pitre Business Ventures Identify the gaps in the present regulations and how to improve upon it, at least the way we think till such time the regulations change Sharing Industry Experiences	**Sh. Shailendra Kumar**, Director (Drugs), MoHFW **Dr. Surinder Singh**, Director, NIB **Dr. C. Sokhey**, Former Dy. Director, NIB **Dr. Sumati Randeo** **Sh. Arun Ramteke**, Consultant, Regulatory Affairs, CDSA **Dr. Sashi Kumar**, MD, Phoenix Medical System
17:00–17:15	**Tea/Coffee Break**	
17:15–17:30	Concluding Session & Closure of the Workshop	CDSA