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

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| 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  |
| 09:45–10:30   | **Session I: Current Regulatory Regime**  
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                                                        |                                                                           |
| 11:15–11:45   | **Session II: Medical Device Sector Specific Requirements**  
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. |
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<td>12:45–13:30</td>
<td>Lunch Break</td>
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| 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                                                                   |