CDSCO

Activity Report

Four Days Integrated Workshop for Drug Regulators on Medical Devices Regulations (March 03rd - 06th, 2014) At FDA Building, Bambolim, Goa

Organized by:

Central Drugs Standard Control Organization (C.D.S.C.O)
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India

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The objectives of the workshop are as under:

- To plug loop-hole in the knowledge regarding present regulations and proposed regulations on Medical Devices.
- To develop knowledge and skills in inspecting Medical device manufacturing units
- To understand and interpret, effectively and uniformly, new regulations on Medical devices by the regulators
- To upgrade the changing regulatory environment ; as per ISO, EU and USFDA regulations

included in the Workshop:

1. Medical Device Regulation in India: Current & Proposed
2. Drugs Vs. Device: Symbols & Terminology Used
3. Design & Development of Medical Devices
4. Classification of Medical Devices
5. Biocompatibility: Safety Assessment of Medical Devices
6. Clinical Investigation and Clinical Evaluation of Medical Devices
7. Quality System for Medical Device : ISO 13485 & Non-compliances observed during Audits
8. Methods of Sterilization of Medical Devices
9. Standards of Medical Devices
10. PMS, Complaints Handling, Product Recall & AEs Reporting
11. Evaluation of In Vitro Diagnostics
12. Risk Management
13. Import & Export Regulations
14. Model Demonstration on the following:

i. Cardiac Angioplasty

ii. Orthopaedic implants

The idea of having such workshop on Medical device regulations was welcomed by all participants. They felt that regulations of devices are very grey area in which they need to develop expertise in understanding the proposed Schedule M III requirements for Medical device regulations which are on par with the international requirements.

All participants had appreciated the efforts made by the resource persons in making detailed presentations and explaining concepts of device regulation, classification of devices, role of notified bodies, clinical trails on devices etc.

Participants also expressed their views that this workshop has provided them lot of information on the proposed medical device regulations, various international guidelines (ISO), and demonstration/video films on usage of medical devices.

Participants also emphasized on the need of more such training workshops in order to have better understating and in depth knowledge and development of necessary skills required for regulatory inspections. It was also suggested by participants to have more workshops mainly on Quality System Managements, Quality audits, Role of Notified bodies, Regulatory requirements for specific class of medical devices, Medical device Reports(PMS) and Visit to Medical Device Industries.

Tentative Programme Schedule for "Four Days Integrated Workshop for Drug Regulators on Medical Device Regulation"

VENUE: FDA Building , Bambolim, Goa
Date: 3rd to 6th March, 2014

Date	Time		
	09:00 am-09:30 am	***Registration***	
Day 1 03.03.2014 (Monday)			
	09:30 am-10:15 am	***Inauguration***	
	10:15am-10:45am	***Tea Break***	
	10:45am-11:00am	***Pre Training Assessment***	
	TECHNICAL SESSION		
		Topic	***Name of the Speakers (S)***
	11:00am-1:00pm	Medical Device Regulation in India: Current & Proposed	Dr. S. Eswara Reddy, Deputy Drugs Controller(I), Ahmedabad
	1:00pm-2:00pm	***Lunch Break***	
	2:00pm-3:00pm	Drugs Vs. Device Symbols & Terminology Used.	Mrs. Sumati Randeo, Associate Director, Strategic Regulatory Affairs, Asia Pacific, Abbott Laboratories.
	3:00pm-3:20pm	***Tea Break***	
	3.20 pm-4:00pm	Model Demonstration for Cardiac Angioplasty, Abbott Laboratories	
	4:00pm-5:30pm	Design & Development of Medical Devices	Dr. Pankaj Bhatia, Boston Scientific
	5:30pm-6:00pm	Open House Discussion	
Day 2 04.03.2014 (Tuesday)	09:30am-11:00am	Classification of Medical Devices	Mr. Sudhakar Mairpadi M/s. Philips India Limited
	11:00am-11:20am	***Tea Break***	
	11:20am-11:30am	***Group Activity***	
	11:30am-1:00pm	Biocompatibility: Safety Assessment of Medical Devices	Mr. Muraleedharan CV, Scientist G & Associate Head, Shri Chitra Institute Trivendrum.
	1:00pm-2.00pm	***Lunch Break***	
	2:00pm-3:30pm	Clinical Investigation and Clinical Evaluation of Medical Devices	Dr. Bina Nayak, Vibgyor

		Tea Break	
		Group Activity	
	4:00pm-5:30pm	Quality System for Medical Device : ISO 13485 & Non-compliances observed during Audits	Mr. Madan Gopal, CE Manager, Product Specialist-Active Medical Device Health Care, BSi India
	5:30pm-6:00pm	Open House Discussion	
Day 3 05.03.2014 (Wednesday)	09:30am-11:00am	Methods of Sterilization of Medical Devices	Ms. Alzira Martins, Johnson and Johnson
	11:00am-11:20am	***Tea Break***	
	11:20am-11:30am	***Group Activity***	
	11:30am-1:00pm	Standards of Medical Devices	Mr. William (Bill) H. Duffell, Jr. PhD, Senior Regulatory Advocacy Executive, Global Regulatory Affairs, Medtronic Inc. USA
	1:00pm-2:00pm	***Lunch Break***	
	2:00pm-3:30pm	PMS, Complaints Handling, Product Recall & AEs Reporting	Mr. David Cannistraci, Vice President Regulatory Affairs and Quality Assurance, Covidien
	3:30pm-3:50pm	***Tea Break***	
	3:50pm- 4:00 pm	***Group Activity***	
	4:00pm-5:30pm	Evaluation of In Vitro Diagnostics	Ms. Ajita Kondalkar, M/s. Johnson and Johnson
	5:30pm-6:00pm	Open House Discussion	
Day 4 06.03.2014 (Thursday)	09:30am-11:00am	Risk Management	Mr. G. Kalyan Varma, TUV
	11:00am-11:20am	***Tea Break***	
	11:20am-11.30am	***Group Activity***	
	11:30am-1:00pm	Model Demonstration for Orthopaedics	Dr. Bandekar , M/s. Johnson and Johnson
	1:00pm-2:00pm	***Lunch Break***	
	2:00pm-3:15pm	Import & Export Regulations	Dr. Eswara Reddy, Deputy Drugs Controller(I), / Dr. Ravi Kant Sharma, ADC(I)
	3:15pm – 3:30 pm	***Post Training Assessment***	
	3:30pm Onwards	***Valedictory Function***	
	5:00pm-5:30pm	***Tea Break***	

List of Resource Persons:

1. Dr. S. Eswara Reddy, Deputy Drugs Controller (I), CDSCO-Ahmedabad
2. Mrs. Sumati Randeo, Associate Director, Strategic Regulatory Affairs, Asia Pacific, Abbott Laboratories.
3. Dr. Pankaj Bhatia, Boston Scientific
4. Mr. Sudhakar Mairpadi, Philips India Limited
5. Mr. Muraleedharan CV, Scientist G & Associate Head, Shri Chitra Institute Trivendrum
6. Dr. Bina Nayak, Vibgyor
7. Mr. Madan Gopal, CE Manager, Product Specialist-Active Medical Device Health Care, BSi India
8. Ms. Alzira Martins, Johnson and Johnson
9. Mr. William (Bill) H. Duffell, Jr. PhD, Senior Regulatory Advocacy Executive, Global Regulatory Affairs, Medtronic Inc. USA
10. Mr. David Cannistraci, Vice President Regulatory Affairs and Quality Assurance, Covidien
11. Ms. Ajita Kondalkar, M/s. Johnson and Johnson
12. Mr. G. Kalyan Varma, TUV
13. Dr. Bandekar , M/s. Johnson and Johnson
14. Dr. Ravi Kant Sharma, ADC (I)

1. Sh. Y.K. Shelar, DI, CDSCO (HQ), New Delhi
2. Sh. Mukesh Kumar, DI, CDSCO (HQ), New Delhi
3. Sh. Vinod Kumar,DI, CDSCO (HQ), New Delhi
4. Mrs. Shraddha Srivastava, DI, CDSCO (HQ), New Delhi
5. Sh. Sushant Sarkar, DI, CDSCO (HQ), New Delhi
6. Sh. Rajesh K. Verma, DI, CDSCO (HQ), New Delhi
7. Sh. Manvillavan C, DI, CDSCO (HQ), New Delhi
8. Sh. Arunachalam C.,DI, CDSCO (HQ), New Delhi
9. Sh. J.G. Selvaraj, DI, CDSCO (HQ), New Delhi
10. Sh. Suresh Kumar Kalwania, DI, CDSCO (HQ), New Delhi
11. Sh. Sanjay Kumar Agarwal, DI, CDSCO (HQ), New Delhi
12. Sh. Ashish Kumar Rai, DI, CDSCO (HQ), New Delhi
13. Ms. Nisha Kaushik, DI, CDSCO (HQ), New Delhi
14. Sh. V. Sooraj, DI, CDSCO (HQ), New Delhi
15. Sh. Hari Babu, DI, CDSCO (HQ), New Delhi
16. Sh. Mohan, DI, CDSCO (HQ), New Delhi
17. Sh. Sourabh Jain, DI, CDSCO (HQ), New Delhi
18. Sh. Sidharth Sahai Malhotra, DI, CDSCO (HQ), New Delhi
19. Sh. V. Rajappan, DI, North Zone, Ghaziabad
20. Sh. S.P.N. Singh,DI, North Zone, Ghaziabad
21. Sh. Deepak Kumar,DI, West Zone, Mumbai
22. Sh. Navneeet Pratap Singh, DI,West Zone, Mumbai
23. Sh. D. K. Sable, DI, West Zone, Mumbai
24. Sh. P.B. Gautam, DI, West Zone, Mumbai
25. Sh. Desh Raj Singh, DI, West Zone, Mumbai
26. Sh. Nitin M. Jadhav, DI, West Zone, Mumbai
27. Mrs. Reka, DI, South Zone, Chennai
28. Mrs. P. Priyadharsini, DI, South Zone, Chennai
29. Sh. V. S. Parbhakar, DI, South Zone, Chennai
30. Sh. Rajeshekhar, DI, South Zone, Chennai
31. Sh. Sushant Sharma, DI, Sub Zonal, Chandigarh
32. Sh. M. N. Anjinappa, DI, Sub Zonal, Bangalore

o Zonal, Bangalore

Hyderabad

35. Sh. Mahesh N.A, DI, Sub-Zone, Bangalore
36. Sh. Narender Kumar Ahooja, ADC, Haryana
37. Dr. Manoj Kumar Tripathi, ADC Rajasthan
38. Ms. M.M.Pawar, Asst. Commissioner, Mumbai
39. Sh. Shobit, FDA Madhya Pradesh
40. Sh. Sanganna S. Sheeli, ADC, FDA Karnataka
41. Sh. T.P Annamalai, DC, Vellore Tamilnadu
42. Sh. H. Mahapatra, DC-Orrisa
43. Sh. M.R. Pradeep, Kerala
44. Sh. K. Avnesh, DI, Hyderabad
45. Ms. Jyoti J Sardessai, Dy. Director, Goa
46. Sh. Rajender Naik, Asst. Drug Controller, Goa
47. Sh. RatnaKumar Arlekar, Asst. Drugs Controller, Goa
48. Ms. Medha Desai, Asst. Drugs Controller, Goa
49. Ms. Swati Laad, DI, Goa
50. Ms. Kavita Borkar, DI, Goa

WORKSHOP ON MEDICAL DEVICES REGULATIONS

3rd - 6th MARCH 2014 AT FDA GOA.