National Workshop on Medical Device Regulations In India

Date: June 11th - 12th 2010
Venue : FICCI, New Delhi

Federation of Indian Chambers of Commerce and Industry

Federation of Indian Chambers of Commerce & Industry (FICCI) in collaboration with Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India is organizing a two day National Workshop on Medical Device Regulations on June 11th -12th ,2010 with participation from regulators from European Commission and USFDA

With the current double digit growth rate, the Indian Medical Devices, In vitro Diagnostic Devices and Medical Equipment industry is projected to grow close to 4.5 billion US dollars by 2015. With this rapid expansion, regulations are essential for access to devices and ensuring Patient safety. The Indian Government has been working towards harmonizing the evolving regulations for Medical Devices , IVDs and Innovative Products in line with the international standards and practices. With the vision to frame stand alone and comprehensive regulatory guidelines for Medical Devices, this workshop will offer a platform for all stakeholders , including importers and manufacturers, to discuss and deliberate on regulations for Medical Devices, IVD's and Innovative Products and the way forward.

This workshop aims to create awareness of existing regulations as well as proposed modifications being planned for a comprehensive regulatory regime in India. This workshop is also expected to create an awareness of the best practices to make Indian Industry globally competitive

Speakers

Invited
- **Government Regulators**
- **Industry**
- **Academicians/Institutes.**
- **International Speakers from USFDA, European Commission & Industry**

Who Should Attend

- **Manufacturers**
- **Entrepreneurs**
- **Regulatory professionals**
- **Notified bodies**
- **Product designers and developers**
- **Business Consultants/ Regulatory Advisors**
- **Academics**
- **Hospital Administrators**
- **Government & Regulatory Authority**

Inaugural Session

Role of Stakeholders in ensuring robust regulations for a thriving Industry

Plenary Session

Proposed Comprehensive Regulatory framework for Medical Devices

Great Debate

Suitable regulations for India:
Towards Harmonization V/s Law of the Land

Workshop Topics

I. Medical Devices & IVD- Definition & Risk Based Classification
II. Design, Development, Clinical Evaluation and Risk Analysis
III. Bio-compatibility
IV. Quality Audits
V. Vigilance Reporting

Registration

Admission only through prior registration. Limited seating on first-cum-first serve basis

Registration Fees	**Industry** – INR 1000/- per delegate **Government** – No registration fee
Payment Mode	Demand draft/cheque in favor of Federation of Indian Chambers of Commerce & Industry, payable at New Delhi
Postal Address	Ms. Ekta Sharma Medical Devices Division Federation of Indian Chambers of Commerce & Industry (FICCI) Tansen Marg, New Delhi – 110001
Email / Phone	mdf@ficci.com or at 91-11-32618333 (D), 23738760-70 (Ext 305)

For more Information please contact- Gaurav Mendiratta. Executive, FICCI; Email :gaurav.mendiratta@ficci.com