FICCI
Federation of Indian Chambers of Commerce and Industry

Quality Management System
2nd Workshop on USFDA & CDRH Regulations for Medical Devices
August 5th – 6th , 2010, FICCI, New Delhi

As the Indian medical devices industry progresses towards high quality innovative products and services, the opportunity of exports is bound to increase. India today offers not just cost advantage but innovative solutions in many technology sectors. The medical devices & equipments sector in India has a huge opportunity arising from the focus on affordable healthcare in different countries of the world.

This workshop is the second in series, being organized by FICCI including USFDA participation, provides an overview of the Quality Management System Regulation requirements, as mandated by USFDA. The industry will not only gain a better understanding of the requirements for exports to the developed countries, but will be able to adapt best practices in their day – to- day activity thereby ensuring availability of quality products for better outcome and patient safety

Experts

Trainers

Ms. Erin Keith, USFDA Assistant Director (India), Medical Devices

Mr. Dipesh Shah, USFDA Assistant Director (India), Medical Devices

Who Should Attend

- **Manufactures**
- **Entrepreneurs**
- **Regulatory Professional**
- **Notified Bodies**
- **Product designers and developers**
- **Business Consultant/ Regulatory Advisor**
- **Academics**
- **Government & Regulatory Authority**

Registration

Program

Day I

900 – 930 Hrs	**Registration**
930 – 1000 Hrs	Introduction
1000- 1115 Hrs	***Management Control*** ▪Management Responsibility ▪Training & Audit
1115 – 1130 Hrs	*Tea Break*
1130 – 1230 Hrs	***Design Controls (Part I)***
1230 - 1330 Hrs	*Lunch Break*
1330 – 1500 Hrs	***Design Control (Part II)***
1500 – 1600 Hrs	***Documents/ Record Control (Part I)***
1600 – 1615 Hrs	*Tea Break*
1615 – 1645 Hrs	***Documents/ Record Control (Part II)***
1645 – 1730 Hrs	**Q & A**

Day II

900 – 930 Hrs	**Questions**
930 – 1030 Hrs	***Production & Process Control*** ▪ Process Controls ▪Process Validation
1030 – 1130 Hrs	***Material Control (Part I)*** ▪Purchasing Control
1130 – 1145 Hrs	*Tea Break*
1145 – 1215 Hrs	***Material Control (Part II)*** ▪Acceptance Control
1215 – 1315 Hrs	***Corrective and Preventive Action (Part I)***
1315 – 1415 Hrs	*Lunch Break*
1415 – 1545 Hrs	***Corrective and Preventive Action (Part II)***
1545 – 1600 Hrs	*Tea Break*
1600 – 1645 Hrs	**Q & A**

Fee **Industry INR 5000/- (Five Thousand Rupees Only) per Delegates**
Limited Seating: Paid seats - 40 (first- cum- first serve basis)
Government/ Regulator: No Registration Fee

Payment Mode Demand Draft/ Cheque in favor of Federation of Indian Chambers of Commerce & Industry, payable at New Delhi

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