

CE Mark Workshop for Medical Devices

Toronto, Montreal and Vancouver

September 8, 10 and 13

OVERVIEW	SCHEDULE	
<p>This workshop is designed to provide medical device companies with an overview of the European Union (EU) regulatory system. Manuela Ahlers, an expert with TÜV NORD CERT GmbH, has been invited to give you the know-how to systematically seek regulatory approval for your medical devices.</p> <p>This workshop will prepare you for exporting your product to the EU market.</p> <p>This will be an interactive full day workshop.</p>	<p>8:00 - 8:30 8:30 - 9:00 9:00 - 9:45 9:45 - 10:00 10:00 - 12:00 12:00 - 1:00pm 1:00 - 2:00 pm 2:00 - 2:30 pm 2:30 - 2:45 pm 2:45 - 3:15 pm 3:15 - 4:15 pm 4:15 - 5:00 pm</p>	<p>Registration and continental breakfast Welcoming remarks Overall description of the “European Global Approach” – Legal framework and basic Requirements Coffee break Description of the different conformity assessment procedures (Modular System) – Classification system – Certification process Lunch Special requirements of Medical Devices Directive – Labelling – Instructions for use – Clinical evaluation – Technical documentation – Special issues Changes in Medical Devices Directive due to directive 2007/47/EC which is implemented in MDD and came into force in March 2010 Break Outsourcing of Processes – Subcontracting, OEM/Private labelling Case studies / Workshop – Practical exercises on real medical devices (classification and certification). Workshop conclusion – One-on-One sessions</p>

Locations:

Toronto

Ontario Investment and Trade Centre, 35th Floor
250 Young Street, M5B 2L7

Montreal

MAECI, Place Bonaventure, 800 rue de La Gauchetière Ouest
Suite 8750, H5A 1K6

Vancouver

Morris J. Wosk Centre for Dialogue
580 West Hastings St., V6B 1L6