



**Biomedical
Division**
The Global Voice of Quality™

Canadian Medical Device Regulations and CMDCAS Educational Course

Location: Embassy Suites Mandalay Bay Resort
2101 Mandalay Bay Road
Oxnard, California
805-760-9044

Date: October 30 & 31, 2012

Program Details:

This 2 day class will provide an in-depth look at and summarize the key aspects of the Canadian Medical Device Regulations and the CMDCAS (Canadian Medical Device Conformity Assessment System). It will be of value to anyone working in the Medical Device community and anyone marketing or planning to market medical devices in Canada.

This course will be taught by **Deborah Iampietro** (Lead Medical Device CMDCAS auditor) and **Egan Cobbold** (Medical Devices Bureau Health Canada). The course will be presented in 7 modules over 2 days. Each participant will receive a certificate of completion.

- Module 1 - Overview of CMDCAS – Canadian regulatory framework
- Module 2 - CMDR overview and where to find information
- Module 3 - Licensing activities (device and establishments)
- Module 4 - QMS Implementation: Relationship between the Applicable CMDR requirements and ISO 13485:2003.
- Module 5 - Auditing Activities to CMDR
- Module 6 – GD 211: Learn how the new guidance will impact your company
- Module 7 - Hot Topics presentation by Health Canada including the Voluntary Audit Program and new guidance regarding 'sharing' of audits.

Cost:

2 Day course: Early Bird registration until September 16th for ASQ members is \$850.00. Non ASQ members \$950.00.

Cost includes: full breakfast, lunch, breaks and managers reception each day and course materials.

Registration is limited so please register early.

Course registration deadline is October 10, 2012. Early bird price discount by September 16, 2012 Register by going to <http://www.acteva.com/booking.cfm?bevoid=232117>

For hotel reservations use the following link for the **Embassy Suites Mandalay Bay** and receive the special room rate of \$145.00/night resort view or \$179.00 ocean view. The room block will fill up quickly, so please reserve soon.

<http://embassysuites.hilton.com/en/es/groups/personalized/O/OXNCAES-ASQ-20121029/index.jhtml>

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