INVITATION

The Government of Alberta, International and Intergovernmental Relations, in cooperation with Alberta Innovates Technology Futures, BioAlberta, the Ward of the 21st Century (W21C) and the Canadian Trade Commissioner Service invite Alberta companies to participate in a

CE CERTIFICATION SEMINAR FOR MEDICAL DEVICES

How to successfully gain access to the EU Market

Wednesday, October 8, 2014

W21C Research and Innovation Centre
University of Calgary – Cumming School of Medicine
TRW Building, GD01, 3280 Hospital Drive NW
Calgary, Alberta T2N 4Z6

A full day seminar, presented by an expert from Germany, with the opportunity for one-on-one meetings

Why Europe?

- The European Union is the world's second largest market for medical devices and holds significant potential for Canadian companies.
- Three of the five largest medical device markets in the world are located in Western Europe; Germany, France and the UK.
- The European Commission recently introduced major changes to the way Notified Bodies audit all manufacturers of medical devices and to the supervision of Notified Bodies which will significantly change the nature of CE-Certification from 2014 onwards. This will also have a direct impact on Canadian Medical Devices exporters.

Opportunity for 1-on-1 meetings

Interested companies have the opportunity for a 1-on-1 meeting with our presenter, **Manuela Ahlers,** Lead & Senior Auditor, TUV NORD after the presentation session.

TENTATIVE AGENDA

8:00 – 8:30	*Registration and Continental Breakfast*
8:30 – 8:35	Welcoming remarks
8:35 – 8:40	Presentation by Partners
8:40 – 8:50	Presentation "**The European Market**" by Ms. Monika de Villiers, Trade Commissioner Life Sciences, Germany, DFATD
8:50 – 9:15	Overall description of the "European Global Approach" – Legal framework and basic requirements
9:15 – 9:45	*NETWORKING coffee break*
9:45 – 11:15	Description of the different conformity assessment procedures (Modular System) –Certification process - Classification system
11:15 –12:15	Special requirements of Medical Devices Directive Labelling, Instructions for use, Technical documentation
12:15 – 1:15	*Buffet Lunch*
1:15 – 2:15	Outsourcing of Processes – Subcontracting, OEM/Private labelling Supplier control
2:15 – 2:45	*NETWORKING coffee break*
2:45 – 4:00	News in European Medical Device regulation system: The New Medical Device Regulation in Europe
4:00 – 4:10	Workshop conclusion
4:10 – 5:30	Opportunity for One-on-One sessions

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Please find attached additional information as follows:

- **Registration form.** The event is free of charge**.**
- **Bios of our speakers: Manuela Ahlers,** Lead & Senior Auditor, TUV NORD and **Monika de Villiers**, Trade Commissioner Life Sciences, Canadian Consulate Düsseldorf, Germany.

For additional information, registration for the workshop and to book a 1-on-1 meeting, please contact:

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- ***Deadline for Registration: September 30, 2014 -***