

**INFORMATION SESSION FOR AUSTRALIAN SUPPLIERS/IMPORTERS
OF MEDICAL DEVICES**

Wednesday 26 APRIL 2017 AT 1PM TO 5PM

Ground Floor, 810 Pacific Highway, Gordon NSW 2072

(Parking is available in the Gordon Centre opposite)

(Afternoon tea will be provided)

AGENDA

- Medical devices – definitions, examples
- Regulatory framework in Australia and the TGA
 - Roles and responsibilities
 - Key regulatory requirements
- Medical devices with wireless (Bluetooth) and telecom capabilities
 - TGA Application process
- Practical case study: TGA registration for a blood pressure monitor
- Post TGA registration: ongoing responsibilities for manufacturers and sponsors
 - Changes to TGA registrations
- Post-market vigilance and annual reporting
 - Medical devices recalls
 - Cancellation of TGA registration

A Certificate of Attendance and copy of the presentation will be sent electronically to all participants following the information session

COST \$425 pp plus GST

(\$350 pp plus GST for additional participants from the same company)

RSVP by 31 March 2017

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Prior payment will be required to secure a seat. An invoice will be issued on RSVP.

Company Name:		
	Attendee	Amount
1		\$425.00
2		\$350.00
3		\$350.00