



AusMedtech2009 PROGRAM*

Day 1 - Monday 15 June

TIME	PROGRAM DETAILS
8:00am – 6:00pm	Delegate Registration commences
8:00am – 9:30am	AusMedtech National Advisory Committee meeting (<i>venue to be confirmed</i>)
10:00am – 12:30pm	<p><u>Workshop 1: How to complete a 510(k) submission</u></p> <p>To get a medical device to market in the U.S. requires the clearance of a 510(k) submission or the approval of a Premarket Approval Application, or PMA, by the U.S. Food and Drug Administration (FDA). During this session, you will learn how the FDA classifies medical devices and which types of devices qualify for the submission of a 510(k). The session will cover how the 510(k) process varies from the PMA approval process. You will also learn what is required to be provided in a 510(k) submission, as well as when 510(k)s are required for device modifications. This session also will cover certain FDA postmarket regulatory requirements that apply once FDA has cleared your 510(k). Topics to be covered include:</p> <ul style="list-style-type: none"> • How the U.S. FDA classifies medical devices • The various pathways to enter the U.S. market and the differences between them • The 510(k) process • 510(k) submission requirements • Postmarket regulatory requirements • Q&A <p><i>Sponsored by Hogan & Hartson LLP, Washington DC, United States</i></p> <p>Speaker:</p> <ul style="list-style-type: none"> • Mike Heyl, Associate, Hogan and Hartson LLP, Washington DC, United States

* Program current as at 14 April – subject to change

	<p><u>Workshop 2: Design for Manufacture</u> Design for manufacture is a much talked about term. Many manufacturers fill niche product areas where the value of the product is high but the volume per annum is low, 50 to 500 per year. Come and learn about issues that need to be considered in the development of low volume high value products and some of the techniques that can be applied during this process to get the best outcome when the product enters manufacture. The workshop will use real life corporate examples to illustrate a number of the principles that will be presented. <i>Sponsored by Arrk Australia and New Zealand Pty Ltd</i></p> <p>Speakers:</p> <ul style="list-style-type: none"> • Travis Hardy, Business Manager – Tooling & Production, ARRK Australia and New Zealand Pty Ltd • David James, Director Manufacturing Innovation Group, Invetech • Nanosonics, representative to be confirmed 	
12:30pm – 1:30pm	LUNCH (including networking with exhibitors)	
1:30pm – 3:30pm	<p><u>Workshop 3: Design from the Human Perspective</u> In this workshop IDEO, a global innovation consultancy that creates impact through Design Thinking, will lead participants in a series of exercises that demonstrate IDEO's human centered design process. In just two hours, participants will identify novel and actionable product and service ideas that leverage new technology channels to help combat the growing epidemic of teen obesity. The most favoured ideas will be selected for presentation to the entire AusMedtech audience.</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Arna Ionescu, Co-Leader, Connected Health, IDEO, California, United States • Peter Coughlan, Partner, IDEO, California, United States <p><u>Workshop 4: Putting a value on your Company – Hypothetical</u> How do you know how much of the company to give away for how many investment dollars. One of the major issues confronting founders and owners when trying to source equity investment. This workshop will investigate this matter and provide insight into processes so that by the end of the workshop you will be able to put a realistic value on your Company.</p> <p>Speaker:</p> <ul style="list-style-type: none"> • Hamish Hawthorn, Chief Executive Officer, ATP Innovations Pty Ltd 	
3:30pm – 4:00pm	AFTERNOON TEA (including networking with exhibitors) <i>Sponsored by Baker & McKenzie</i>	
4:00pm – 5:15pm	<p><u>Managing the Business</u></p> <ul style="list-style-type: none"> • Business Planning • Managing Cash Flow • Other tips for running small to medium sized business. <p>Chair: Elisabeth Coffey, Partner, Baker & McKenzie</p> <p>Speakers:</p> <ul style="list-style-type: none"> • John McKay, Director, TFG International • Fiona Pak-Poy, General Partner, Innovation Capital 	<p><u>In Vitro Diagnostics</u></p> <ul style="list-style-type: none"> • The future of IVD regulations in Australia • Is the real value of IVDs in health economics truly recognized? • Taking IVDs to the market • Product development for IVDs <p>Speakers:</p> <ul style="list-style-type: none"> • Dr Rob Danby, Manager IVD, Biomedical Instruments & Devices Group, Invetech

* Program current as at 14 April – subject to change

	<ul style="list-style-type: none"> David Wilson, Asset Strategist, The David Wilson Alliance Mary Saywell, Senior Associate, Baker & McKenzie <p><i>Sponsored by Baker & McKenzie</i></p>	<ul style="list-style-type: none"> Dr Jenny Harry, Managing Director, Tyrian Diagnostics Dr Andrew Campitelli, Manager Diagnostics, MiniFAB
6:30pm – 7:00pm	PRE DINNER DRINKS	
7:00pm – 10:00pm	CONFERENCE NETWORKING DINNER Speaker: <ul style="list-style-type: none"> Philip Merryweather, Managing Director, Vericap Finance Pty Ltd <p><i>Sponsored by Brandwood Biomedical</i></p>	

Day 2 – Tuesday 16 June

TIME	PROGRAM DETAILS	
7:30am – 8:30 am	Medica 2009/Arab Health Briefing Breakfast <i>For interested parties wishing to attend Medica 09 in Germany</i> Speaker: <ul style="list-style-type: none"> Kevin Grundy, Managing Director, Kevin Grundy International Business Development (re Arab Health meeting) 	
7:30am	Conference Registration Commences	
8:45am – 9:00am	Conference Welcome Dr Anna Lavelle, Chief Executive Officer, AusBiotech Limited	
9:00am – 9:15am	Conference Opening Address The Hon Jodi McKay MP, Minister for Science and Medical Research, Government of New South Wales	
9:15am – 9:45am	Key Note Speaker “A Roadmap for Global Success” Mr Donal O’Dwyer, Chairman, Atcor Medical Holdings Ltd Director, Cochlear Ltd, Sunshine Heart Inc and Mesoblast Ltd	
9:45am – 10:15am	MORNING TEA (including networking with exhibitors)	
10:15am – 11:30am	<u>Attracting Capital in Troubled times</u> There is more to Medical Technology Companies than the market need/technology, what are some of the key attributes to a successful business and how do you get them in your	<u>Mapping the Commercialisation Roadway</u> The Commercialisation Roadmap will give small technically based medical device companies guidance into different areas of commercialisation which will be critical to their success and growth.

* Program current as at 14 April – subject to change

	<p>business?</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Paul Cheever, Consultant, Access Capital Advisers • Mike Quinn, Chief Executive Officer, Innovation Capital • Andrew Sneddon, former partner, PricewaterhouseCoopers, Non-Executive Director, TGR Biosciences Pty Ltd 	<p>Chair: Nadia Odorico, Principal, Griffith Hack</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Nairy Baghdikian, Director, Cognetum • Professor Karen Reynolds, Medical Device Partnering Program • Joe Seisedos, Senior Associate, Griffith Hack <p><i>Sponsored by Griffith Hack</i></p>
11:30am – 11:45am	SESSION CHANGE OVER	
11:45am - 1:00pm	<p><u>Global Partnering</u></p> <p>Australian manufacturers are interested in the Global Market; few if any develop products for sale in the Australian market alone. Come and hear from industry executives about various options for accessing the global marketplace. Whether it is establishing your own network, partnering with a large group or other this session will attempt to discuss some of these issues.</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Kevin Grundy, Managing Director, Kevin Grundy International Business Development • Jairo Kerr Azevedo, Chief Executive Officer, Opto Global Holdings Pty Ltd • Rob Douglas, Chief Operating Officer, ResMed Ltd • Cochlear representative to be confirmed 	<p><u>Update on Global Regulation</u></p> <p>Chair: Dr Arthur Brandwood, Chief Executive Officer, Brandwood Biomedical Pty Ltd</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Dr Peter Havel, TUV SUD Japan Ltd • Dr Jonathan Sackier, President, Paradigm Shift Healthcare Consulting, United Kingdom • Dr Martin Devitt, Medical Director, Perficio Clinical & Regulatory Pty Ltd <p><i>Sponsored by Brandwood Biomedical</i></p>
1:00pm – 2:15pm	LUNCH (including networking with exhibitors)	
2:15pm – 3:30pm	<p><u>Future Technologies</u></p> <p>Bionics aren't just bionics – come and hear about the applications and challenges, both technical and commercial in some ground breaking work.</p> <p>Chair: Shane Coombe, Senior Manager Manufacturing (Biomedical), Department of State and Regional Development, NSW Government</p> <p>Speakers:</p> <ul style="list-style-type: none"> • Professor Nigel Lovell, Graduate School of Biomedical Engineering, The University of New South Wales • Professor Rob Shepherd, Director, Bionic Ear Institute • Dr Colin Sutton, Director, Mission Pty Limited <p><i>Sponsored by NSW Government</i></p>	
3:30pm – 4:15pm	AFTERNOON TEA (including networking with exhibitors)	

* Program current as at 14 April – subject to change

4:15pm – 5:45pm	<p><u>War Stories</u> Come and listen to some of the interesting stories from a selection of our local industry. Each will present a particular perspective on a problem that confronted their business and their strategy to address the issue and its success. Questions are welcome!</p> <p>Chair: Davies Collison Cave representative to be confirmed Speakers:</p> <ul style="list-style-type: none"> • David Radford, Executive Director and Chief Executive Officer, Nanosonics • David Barda, Chief Technology Officer, Simavita Pty Ltd • Davies Collison Cave representative to be confirmed • Neil Anderson, CathRX to be confirmed <p><i>Sponsored by Davies Collison Cave</i></p>
5:45pm – 6:45pm	<p>CONFERENCE CLOSING AND NETWORK RECEPTION FOR AUSMEDTECH2009 DELEGATES <i>Sponsored by Invetech</i></p>