



The New Regulatory Framework for Cellular Therapies in Australia

Sponsored by  **mesoblast**
the regenerative medicine company

Held in association with University of Western Australia 4th Margaret River Region Forum;
 Pathways Towards Molecular and Cellular Therapy
Quay West Resort, Bunker Bay, West Australia
Friday 30th April

All sessions will be held in the Marquee

Thursday, 29 April Dress Code: Informal

7:00pm BBQ

Friday, 30 April Dress Code: Informal

7:30am-8:00am Registration Marquee

The New Regulatory Framework for Cellular Therapies in Australia

Co-Convenors – Professor John Rasko, Professor Minghao Zheng

Ms Pam Dyson
 Dr Ian Lewis
 Dr Janet Macpherson
 Mr Rick Tocchetti
 Dr Dominic Wall
 Mr Craig Wright

8.00am-8:05am **Welcome**

Prof. John Rasko, Regional Vice President of ISCT

Session 1: The New Biologicals Framework for Cellular Therapies - Regulatory Update from the Therapeutic Goods Administration

Chairs: Dr Stewart Hay RISS Ltd & Mr Craig Wright, RPAH, Sydney

8:05am-9:05am Dr Glenn Smith, Blood & Tissues Unit, Office of Devices, Blood & Tissues, TGA

9:05am-10:05am Ms Jeanette Ripper, Blood, Tissues and Cellular Therapies Audit Team, Office of Manufacturing Quality, TGA

10:05am-10:30am **Morning Tea**

Session 2: Microcontamination in Cellular Therapy Products

*Chairs: Ms Pamela Dyson, SA Pathology &
Dr Marian Sturm, Cell and Tissue Therapies W.A*

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| 10:30am-11:00am | Dr Glenn Smith, Blood & Tissues Unit, Office of Devices, Blood & Tissues, TGA - New Infectious Diseases Standard |
| 11:00am-11:25am | Prof David Speers, PathWest Laboratory Medicine – Viral screening |
| 11:25am-11:50am | A/Prof Tuckweng Kok , SA Pathology - Mycoplasma as adventitious agents |
| 11:50am-12:15pm | Prof Ming Hao Zheng, Centre for Orthopaedic Research, UWA - Prevalence of viral infections in tissue donors |
| 12:15pm-1:30pm | Discussion |
| 12:30pm-1:30pm | Lunch |

Session 3

Keynote

Chair: Prof Richard Herrmann, Cell and Tissue Therapies W.A

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| 1:15pm-2:00pm | Prof Derek Hart, Transplantation and Immunotherapy, University of Sydney - "The human CD141 and CD1c dendritic cell subsets as candidates for immune therapies" |
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Derek Hart discovered the interstitial dendritic cell (DC), defined the human DC and its subsets and several DC surface molecules and his research now leads the translation of DC biology into diagnostic and clinical haematological practice.

Case Studies

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| 2:00pm – 3:30pm | <i>Moderator: Dr Dominic Wall, Centre for Blood Cell Therapies, Melbourne</i> |
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Panellists:

Regulatory representatives Glenn Smith, TGA, Allison Wyndham and Jeanette Ripper, TGA.

Industry representatives Mr Craig Wright, RPAH, Sydney, Ms Pam Dyson, SA Pathology, Paul Anderson, Orthocell.

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| 3:30pm-4:00pm | Afternoon Tea |
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Session 4: Round Table Discussion

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| 4:00pm -5:00pm | <i>Moderator: John Rasko, RPAH, Sydney</i> |
| 4:00pm-4:15pm | Dr Kilian Kelly, Mesoblast - "Pathways to Approval for New Cell Therapies" |
| 4:15pm-5:00pm | Q&A Panelists selected from invited speakers & audience |

5:00pm

ISCT Meeting Close

Join with Third Australia-China-Japan Symposium on Bioengineering, Biotherapeutics and Health Sciences for conference dinner

6:00pm

Bus transfer to Wise Winery

6:20pm-7:00pm

Wine tasting

7:00pm-11:00pm

Conference dinner at the Wise Winery

Dress Code: Informal

11:00pm

Bus transfer to Bunker Bay Resort

Saturday, 01 May

8:30am

Bus transfer to airport

2:00pm

Bus transfer to airport