The New Regulatory Framework for Cellular Therapies in Australia

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

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

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"

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 2:00pm – 3:30pm Moderator: Dr Dominic Wall, Centre for Blood Cell Therapies, Melbourne

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.

3:30pm-4:00pm Afternoon Tea

Session 4: Round Table Discussion

4:00pm -5:00pm Moderator: John Rasko, RPAH, Sydney

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