



## The New Regulatory Framework for Cellular Therapies in Australia

Sponsored by  **mesoblast**  
the regenerative medicine company

Held in association with University of Western Australia 4<sup>th</sup> Margaret River Region Forum;  
Pathways Towards Molecular and Cellular Therapy  
Quay West Resort, Bunker Bay, West Australia

**Friday 30<sup>th</sup> 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	<b>Lunch</b>

## **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"
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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**

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.

3:30pm-4:00pm	<b>Afternoon Tea</b>
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## **Session 4: Round Table Discussion**

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