FULL-DAY WORKSHOP

# CELL & GENE THERAPY

International Society ISCT Cell & Gene Therapy®

AUSTRALIA AND NEW ZEALAND REGION

## Regulatory & Commercialisation

From Bench to Bedside

**MODULE 1**
**Preclinical Development**
Supporting TGA CTN / CTA

**MODULE 2**
**Clinical Trial Applications**
TGA CTN / CTA pathways

**MODULE 3**
**Phase I & II GMP Manufacturing**
TGA GMP licence applications

**MODULE 4**
**TGA Approval, HTA & Market**
PBAC / MSAC
PBS / MBS access

**23 July 2026**
Thursday, 08:00 – 17:00

**Bio21 Institute**
Melbourne, Victoria
30 Flemingington Road, Parkville

**SUITABLE FOR**

Researchers | Clinicians | Regulatory Affairs | Industry | HTA Specialists

Sponsored by

ThermoFisher SCIENTIFIC

Register

REGISTRATION LINK:https://www.trybooking.com/DLXGI

# The Workshop

OVERVIEW & OBJECTIVES

An intensive, full-day journey across the translational continuum for Cell and Gene Therapies (CGT). From early preclinical studies through to post-market lifecycle management with a sharp focus on the Australian regulatory framework and the pathway to reimbursement.

The Program is curated by Associate Professor Zlatibor Veličković, Director of Cell and Tissue Therapies WA (CTTWA) and sponsored by Thermo Fisher Scientific as part of the Australia & New Zealand chapter of the International Society for Cell and Gene Therapy (ISCT) regional annual meeting satellite activity. It brings together leading Australian and international experts in CGT science, regulation, manufacturing, and market access. Participants will gain practical, end-to-end knowledge of the development, regulation, manufacture, and commercialisation of CGT products in Australia. The program is aimed at researchers, clinicians, industry professionals, regulatory staff, and health-system decision-makers involved in advanced therapies.

## LEARNING OBJECTIVES

1. Understand preclinical requirements and studies required to support Clinical Trial Approval (CTA) for CGT products
2. Identify the key preclinical data package elements needed for Therapeutic Goods Administration (TGA) CTA
3. Navigate the TGA CTA frameworks for biologicals
4. Identify GMP manufacturing requirements for Phase I/II CGT clinical trials, including TGA GMP licence applications
5. Understand the pathway to TGA marketing approval (registration) for CGT
6. Develop knowledge of the health technology assessment (HTA) process for CGT reimbursement in Australia

## WHO SHOULD ATTEND

Researchers · Clinicians · Regulatory Affairs · GMP & Manufacturing · Industry & Biotech · HTA & Reimbursement · Health-System Decision-Makers

Registration link: https://www.trybooking.com/DLXGI

Registration QR code:

# Program

MORNING · MODULES 1 & 2

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| **08:00-08:15** | **Welcome**<br>Housekeeping and introductions | **Zlatibor Veličković**<br>CTTWA, Perth, WA |

## 1 MODULE ONE
## Preclinical Development of CGT

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| **08:15 -08:45** | **Preclinical Development Strategy for CGT Products**<br>PoC, mechanistic & PK/PD studies · in vitro / in vivo model selection · biodistribution, persistence & off-target analysis for the TGA dossier | **Helen Wray**<br>S2N, Sydney, NSW |
| **08:45 -09:15** | **Translating Preclinical Development into Compliant, Clinically Ready Manufacturing for CTA**<br>Assessment of manufacturing processes and translation from laboratory protocols to facility · applicable TGOs and compliance · scale-up, evaluation of materials · suitability for clinical application · implementation of closed, automated systems. | **Liesel Stassen**<br>Q-Gen, Brisbane, QLD |
| **09:15 -09:45** | **Panel Discussion & Q&A**<br>Preclinical-to-clinical transition in the Australian context | **All Speakers + Iga Policinska & Dennis Dowhan**<br>TGA, Canberra, ACT |

**Morning Tea** · 09:45 – 10:05 · Sponsored by Thermo Fisher Scientific

## 2 MODULE TWO
## Clinical Trial Approval for CGT

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| **10:05-10:25** | **The Australian Clinical Trials Framework for CGT**<br>CTN & CTA schemes · SAS and Authorised Prescriber pathways · biologicals regulatory framework for CGT | **Iga Policinska**<br>TGA, Canberra, ACT |
| **10:25-10:45** | **Preparing a TGA CTA Dossier for a CGT Product**<br>Investigational product requirements · characterisation, potency, sterility & release testing · sponsor responsibilities & authorised-person oversight | **Jennie Postma**<br>CTTWA, Perth, WA |
| **10:45-11:15** | **Case Study: First-in-Human CAR T-cell Trial — Australian CTA Experience**<br>A real Australian Phase I CAR T-cell CTA · lessons from regulatory dialogue · the CTA / clinical production interface | **Jessica Li**<br>CoE CIT, PeterMac, Melbourne, VIC |
| **11:15-11:45** | **Panel Discussion & Q&A** | **All Session Speakers** |

**Lunch Break** · 11:45 – 13:15 · Sponsored by Thermo Fisher Scientific

# Program



## 3 MODULE THREE
## Phase I & II GMP Manufacturing

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| **13:15-13:45** | **GMP Requirements for Clinical-Grade CGT Manufacturing in Australia**<br>PIC/S GMP for ATMPs · facility design, cleanrooms, HVAC & personnel flow · process development, scale-up & comparability · quality systems & process control | **Colin McLean**<br>Cell Therapies Pty Ltd. Melbourne, VIC |
| **13:45-14:15** | **TGA GMP Licence Applications for Clinical Trial Manufacturing**<br>The licence application · scope of manufacture · pre-licence inspections, QMS & site master file · variations, renewals & corrective actions | **Alyce Maksoud**<br>TGA, Canberra, ACT |
| **14:15-14:45** | **Panel: Manufacturing Challenges for Phase I/II CGT Trials**<br>Autologous vs allogeneic · chain of custody, cryopreservation & cold-chain · cost of goods & resource planning | **All Speakers + Matt Hewitt**<br>CRL, USA |

**Afternoon Tea** · 14:45 – 15:05 · Sponsored by Thermo Fisher Scientific

## 4 MODULE FOUR
## TGA Marketing Approval & Health Technology Assessment

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| **15:05-15:45** | **Pathway to TGA Marketing Approval for CGT Products**<br>Biologicals registration · full registration dossier · rolling, priority & provisional approval · post-market obligations · an Australian registration example | **Dennis Dowhan**<br>TGA, Canberra, ACT<br>**Alison Carleton**<br>Orthocell, Perth, WA |
| **15:45-16:30** | **Health Technology Assessment for CGT Reimbursement in Australia**<br>Australian HTA frameworks & timelines · real-world evidence & long-term outcomes · outcome-based & risk-sharing models · single-arm & surrogate-endpoint challenges | **Penny Shakespeare**<br>Australian Dept. of Health, Disability and Ageing, Canberra, ACT<br>**Gretchen Poortinga**<br>CoE CIT, PeterMac, Melbourne, VIC<br>**Emily Blyth**<br>Westmead Hospital, Sydney, NSW |
| **16:30-17:00** | **Equity of Access for CGT**<br>Affordable, available & deliverable CGTs · extending infrastructure to more patients · a global vision of access | **Boro Dropulić**<br>Caring Cross, USA<br>**Zlatibor Veličković**<br>CTTWA, Perth, WA |
| **17:00-17:30** | **Panel: Marketing Approval, Reimbursement & Access**<br>Where TGA registration & HTA pathways align and diverge · evidence-generation challenges | **All Session Speakers** |
| **17:30-17:35** | **Closing Remarks** | **Zlatibor Veličković**<br>CTTWA, Perth, WA |

# Speakers



A distinguished faculty drawn from Australia's leading manufacturing facilities, the TGA, government, academia, and international industry.

## Zlatibor Veličković

**Director of Cell & Tissue Therapies Western Australia (CTTWA) and Centre for Advanced Therapies (CAT), Royal Perth Hospital**

Associate Professor Zlatibor Veličković is the Director of CTTWA and CAT at Royal Perth Hospital, a position he has held since January 2022. In this role, he oversees Western Australia's only public hospital TGA-licensed facility for manufacturing cellular therapies for clinical use, including CAR T-cells, TILs, MSCs, and emerging programs in bacteriophage therapy and other advanced therapeutics.

Prior to his current appointment, Zlatibor served as Production Manager at the Department of Cell & Molecular Therapies at Royal Prince Alfred Hospital in Sydney, where he played a pivotal role in establishing CAR T-cell programs. Earlier in his career, he spent a decade as a Senior Scientist in molecular genetics at the Australian Red Cross Blood Service.

Zlatibor holds a PhD in Immunogenetics from the University of Otago, New Zealand, and a Bachelor of Science with First Class Honours in Molecular Biology and Physiology from the University of Belgrade, Serbia. He is an Adjunct Associate Professor at the University of Western Australia, where he teaches advanced therapies and regenerative medicine.

An active contributor to the global cell and gene therapy community, Zlatibor holds numerous leadership and advisory roles. He is a current member of the TGA Advisory Committee on Biologicals, member of the OGTR GTTAC, co-chair of the ISCT ANZ Workforce Development Subcommittee, member of the ISCT APAC Industry committee, member of the Foundation for the Accreditation of Cellular Therapy (FACT) Education Committee, and serves on the National Bacteriophage Therapy Regulation Working Group and institutional biosafety and ethics committees. He is a past Vice President of ISCT ANZ (2022-24).

## Dr Liesel Stassen

**Head of Manufacturing Operations at Q-Gen Cell Therapeutics, QIMR Berghofer**

Dr Stassen holds a PhD in Cell and Molecular Biology and is passionate about advancing cell and gene therapies from bench to bedside. With seven years' experience at Q-Gen and eight years' experience in clinical translation research, Dr Stassen completed five years of postdoctoral research in the fields of infection and immunity before a career move into advanced therapy manufacturing. Liesel has extensive expertise in the manufacture of cell therapies for early-phase clinical trials (Phase I and II). She provides strategic and operational leadership across manufacturing activities, overseeing the production of cell-based therapies to ensure safe, compliant products that consistently meet rigorous quality standards. Her experience strengthens Q-Gen's capacity to support the translation of innovative therapies into clinical application. She supports the vision of Q-Gen to continue to support translational research and early-phase clinical trials with a particular focus on technology transfer and process development.

## Helen Wray

**Skin2Neuron Pty Ltd Board Member**

Helen is an experienced life sciences professional having had a career in the development & commercialisation of novel leading-edge medical technologies spanning more than 25 years. Working predominantly in the translation of cell-based regenerative medicine technologies, she has held leadership and executive roles within both multi-national and Australian life science companies, taking technologies from the lab through effective technology transfer and scale-up, as well as supporting product approvals and commercial launches.

Helen has worked on significant projects for public and private companies including ReCell® and CellSpray® for Clinical Cell Culture (now Avita Medical), AlphaCor® an implantable artificial cornea for Argus Biomedical Pty Ltd (acquired by Cooper Vision) and tissue based cardiovascular technologies for Admedus Ltd (now Anteris). For more than 10 years, she held an executive director role at Capra Commercialisation Partners consulting to Universities, Start-ups and ASX listed companies.

Helen is currently an independent Investor, Director and Advisor, providing strategic planning and translational support to public and private sector teams seeking to progress their technologies towards GMP and the clinic. She currently sits on the Board of Skin2Neuron Pty Ltd and advises on projects in industry and academia.

Helen has a Bachelor of Science (Hons Path) and Master of Business Administration (Adv), from the University of Western Australia, a Master of IP Law from the University of Melbourne and is a Graduate of the Australian Institute of Company Directors

## Iga Policinska

**Director, Pharmacovigilance Compliance and Clinical Trials Section, Therapeutic Goods Administration**

Dr Iga Policinska is the Director of the Pharmacovigilance Compliance and Clinical Trials Section situated in the Pharmacovigilance Branch of the Therapeutic Goods Administration (TGA). She holds a Medical Degree and a Master of Public Health. She has previously worked internationally in a clinical setting and since joining the TGA, in 2015, she has worked across the entire regulatory life cycle of medicines. Dr Policinska holds extensive regulatory and technical knowledge ranging from clinical trials through to pre-market and post-market. She has also represents the TGA internationally through aid programs.

## Jennifer Postma

**Regulatory Affairs Manager at Cell & Tissue Therapies WA (CTTWA), Royal Perth Hospital**

Jennifer Postma is the Regulatory Affairs Manager for Cell & Tissue Therapies WA at Royal Perth Hospital, where she leads regulatory strategy and compliance for advanced cellular therapy programs supporting clinical transplantation and research.

With over 20 years of experience in cell and gene therapies, she has deep expertise in navigating complex regulatory frameworks, including TGA Biologicals, cGMP, and international requirements for advanced therapies.

Jennifer serves as the primary regulatory liaison for cellular therapies, overseeing regulatory submissions and compliance across the product lifecycle from development through clinical application.

She holds a Graduate Certificate in Regulatory Science and brings extensive experience in clinical trial support, biovigilance, and regulatory strategy for emerging therapies.

## Jessica Li

**Manufacturing and Development Manager at Centre of Excellence in Cellular Immunotherapy, Peter MacCallum Cancer Centre**

Dr Jessica Li is the Manufacturing and Development Manager at the Centre of Excellence in Cellular Immunotherapy (CoE CIT) at the Peter MacCallum Cancer Centre. After completing a BSc (Hons) and PhD at the University of Melbourne, Jessica undertook postdoctoral training at the Peter MacCallum Cancer Centre where her research focused on harnessing the immune system to develop novel immunotherapeutic treatments in collaboration with biotech industry partners.

To further her goal of developing cutting-edge research into tangible therapies for patients, Jessica gained hands-on experience in clinical and commercial GMP manufacturing of cell-based therapies at a CDMO before transitioning to her current role at the CoE CIT, a centre established to accelerate novel cell and gene therapy discoveries to the clinic. Jessica oversees the manufacturing process development, scale-up and transfer to GMP-ready clinical production for all cell therapy programs at the CoE CIT. As part of her role, Jessica also serves as the technical lead for the preparation of preclinical, quality and manufacturing data packages for regulatory submissions. This work has led to two in-house developed CAR-T cell products receiving TGA approval for first-in-human clinical trials.

## Colin McLean

**Chief Operating Officer at Cell Therapies Pty Ltd**

Colin McLean is Chief Operating Officer at Cell Therapies Pty Ltd, a TGA-licensed CDMO specialising in cell and gene therapies. With over 14 years of experience in GMP-regulated environments, Colin has led Manufacturing, Quality Control and Quality Assurance operations, cross-functional teams, and regulatory compliance efforts to support clinical and commercial programs.

He currently oversees manufacturing, supply chain, validation, and project delivery, and leads the Asia Pacific Alliance Model to improve access to advanced therapies across the region.

Colin holds a Master's in Transfusion, Transplantation and Tissue Banking from the University of Edinburgh. His background includes regulatory audits, assay validation, tech transfer, and GMP consultancy across a wide range of ATMPs. He is committed to building strong, reliable operations that enable high-quality therapy delivery and long-term partnerships globally.

## Alyce Maksoud

**Senior GMP Inspector Team Leader – Inspection Section, Therapeutic Goods Administration**

Alyce Maksoud is a Senior GMP Inspector and Team Leader in the Inspection Section of the Medical Devices & Product Quality, Manufacturing Quality Branch, where she provides leadership in regulatory oversight and inspection activities. Since joining the Therapeutic Goods Administration (TGA) in 2005, she has built extensive experience across complex manufacturing and compliance environments.

Her specialist expertise encompasses the manufacture and regulation of human blood and blood components, plasma fractionation, human tissues, haematopoietic progenitor cells (HPCs), and cellular and gene therapy products. She brings deep knowledge of processing operations, quality management systems, quality assurance, quality control, infectious disease testing, and the oversight of finished products and clinical trial biologicals. In addition to the regulatory work, Alyce chairs the PIC/s working group on Human Tissues and Cells.

## Matthew Hewitt

**Vice President, CTO Manufacturing Business Division at Charles River Laboratories**

Matthew Hewitt, PhD, currently serves as Vice President, CTO Manufacturing Business Division at Charles River Laboratories (CRL). In this role, Matt leads one of Charles River's CGT CDMO sites in helping partners move assets to clinic and commercial. Matt is also responsible for leading conversations on CRL's cell and gene therapy strategic approach.

Before joining the company, Matt was Head of Clinical Development for Lonza's Personalized Medicine Business Unit where he was responsible for the Cocoon Platform, a closed, automated, scalable cell therapy manufacturing solution that relieves many cell therapy manufacturing difficulties. He played a key role in accelerating clinical development timelines all while overseeing numerous academic and industry collaborations. These collaborations included a lead program in Israel, that culminated in dosing the first patient with a cell therapy manufactured in the Cocoon. He led the R&D Innovation group, which included launching the Personalized Medicine Scientific Advisory Board. This board is responsible for directing current and future personalized medicine activities. In addition, Matt managed a personalized medicine analytics initiative to better understand cell therapy products, enhance clinical efficacy, and manufacturing process robustness.

Prior to Lonza, Matt led the Tumor Immunology and Microenvironment program at Bellicum Pharmaceuticals, which focused on improving cell therapy efficacy in solid tumors. He also led the Immunology group at the University of Pennsylvania's Gene Therapy Program under Dr. James Wilson, leading numerous AAV gene therapy programs.Matt received his PhD in Biophysics and Physiology from the University of Alabama at Birmingham and completed his post-doctoral fellowship at Johns Hopkins University.

## Dennis Dowhan

**A/g Unit Head, Blood Biologicals and Infectious Disease Unit, Biological Sciences Section, Scientific Evaluation Branch, Therapeutic Goods Administration**

Dennis did his Bsc (Hons) at Griffith University and his PhD in Biochemistry at University of Queensland (UQ). He did his post-doctoral work at Baylor College of Medicine USA. Career research interests focused on the role of steroid/nuclear receptors, transcriptional cofactors and epigenetics in regulating transcription and alternative splicing in the context of hormone-dependent cancers. Dennis has worked as a Scientific Evaluator at OGTR and the National Industrial Chemicals Notification and Assessment Scheme, and since 2018 as a Senior Evaluator in Toxicology and the Blood Biologicals and Infectious Disease Unit (BBIDU) at the TGA.

## Dr. Alison Carleton

**Orthocell Ltd**

Dr Alison Carleton is an experienced regulatory affairs professional specialising in medical device and biological regulatory frameworks. Alison is a Senior Regulatory Affairs Associate at Orthocell Ltd, a regenerative medicine company who manufacture collagen medical devices and autologous cell therapies. Alison's regulatory experience encompasses both pre-and post-market phases, including regulatory strategy, clinical evaluation and regulatory submissions and post-market surveillance reporting. Her achievements include the successful applications for TGA ARTG listing, FDA 510(k) premarket clearance, and European Medical Device Regulation (MDR) approval. Alison has also prepared and consulted on reimbursement applications for medical devices and biologics.

Prior to joining Orthocell, Alison established Decode Communications, providing specialized medical and science writing services. Her consultancy work involves structural review of research grants, editing manuscripts for peer-reviewed journals, authoring technical documents for clinical trials and patient-focussed brochures and website content.

Dr. Carleton's career is supported by a strong academic foundation, including a PhD in Medical Biology from the University of Melbourne (Walter and Eliza Hall Institute) and post-graduate qualifications in Professional Writing and Editing.

## Penny Shakespeare

**Deputy Secretary of the Health Resourcing Group, Australian Government Department of Health, Disability and Ageing**

Penny Shakespeare is Deputy Secretary of the Health Resourcing Group within the Australian Government Department of Health, Disability and Ageing. Bringing her deep policy expertise, Penny oversees a broad spectrum of health policy. This includes Medicare and Pharmaceutical Benefits Scheme policies and integrity, programs to support a well-trained and distributed health and care workforce, advancing digital health solutions, harnessing the potential of genomics, immunisation, health emergency management and resilience.

## Gretchen Poortinga, Ph.D.

**Program Operations Director, Centre of Excellence in Cellular Immunotherapy, Peter MacCallum Cancer Centre**

Dr. Gretchen Poortinga was part of the team that established the Centre of Excellence in Cellular Immunotherapy (CoECIT) at Peter MacCallum Cancer Centre. The CoE CIT was established to collaboratively and rapidly identify, develop and deliver globally competitive CAR T and other cell-based immunotherapy breakthroughs for the treatment of cancer. As Program Operations Director, Gretchen works with clinicians, scientists, and other experts to synergise activities across the multifaceted program. Gretchen integrates the CoE CIT with its manufacturing partner Cell Therapies Pty Ltd and liaises with government and industry partners to coordinate key initiatives in the cell and gene sector. Through these efforts, Gretchen helps drive the translation and acceleration of innovative cell-based technologies into the clinic, maximising the Centre's outputs for Australian patients and researchers.

Prior to her role with the CoE CIT, Gretchen was a Senior Research Fellow at the Peter MacCallum and an Honorary Fellow in the Sir Peter MacCallum Department of Oncology, University of Melbourne, conducting highly translational research, including that which formed the basis of a first-in-class phase 1 clinical trial in haematologic malignancies.

## Emily Blyth

**University of Sydney and Westmead Hospital**

Associate Professor Emily Blyth is a clinician–scientist at the University of Sydney and Westmead Hospital, where she leads a clinically embedded program in cellular immunotherapy. Her work spans the full lifecycle of cell and gene therapies, from discovery and early clinical trials through to manufacturing, real-world outcomes and system-level implementation, with a strong focus on ensuring therapies can be delivered safely, equitably and at scale within the public health system. She is a founding member and NSW State Lead of the Collaborative Centres Program for Advanced Therapies (CCPAT) and holds senior leadership roles nationally and internationally, including within ISCT as the ANZ Regional Vice President 2024-26.

## Boro Dropulić

**Caring Cross, USA**

Boro received his PhD from the University of Western Australia and his MBA from the Johns Hopkins University (JHU). He has been in the gene therapy field since the late 1980s. After a Fogarty Fellowship at the NIH, he joined the faculty at JHU where he worked on developing Lentiviral vectors as delivery systems for gene therapy. After 4 years in academia, he founded his first company ViRxSys and led the team that first demonstrated the safety of Lentiviral vectors in humans with his UPenn colleagues. Later he founded Lentigen, which first developed the Lentiviral vector used to produce Kymriah®, the first FDA-approved gene therapy product.

Later, Boro saw an opportunity to integrate Lentiviral vector technology with closed-system automated cell processing devices to enable distributive place-of-care manufacturing at hospitals, potentially improving the

affordability and accessibility of gene therapy products like CAR-T cells. He therefore spearheaded the acquisition of Lentigen by Miltenyi Biotec in 2014 and led the development of a global place-of-care network of clinical centers that were able to successfully manufacture CAR-T cell products and demonstrate their therapeutic benefits in clinical trials.

Seeing a need for improved business models to support the affordability and accessibility of gene therapy products, Boro co-founded Caring Cross a 501 (c)(3) non-profit and serves as the Executive Director. He also is the CEO of Vector BioMed, a public benefit corporation that was spun-out of Caring Cross to provide affordable GMP Lentiviral vector manufacturing services to the gene therapy scientific community.

# Sponsor