

A cleanroom manufacturing environment with workers in white protective suits and a robotic arm. The scene is brightly lit with blue and white tones.

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# **CLEANROOM MANUFACTURING**

**20<sup>TH</sup>— 21<sup>ST</sup> APRIL 2026 | STAMFORD PLAZA MELBOURNE, AUSTRALIA**

## EVENT OVERVIEW

Cleanroom manufacturing is fast becoming the backbone of Australia's high-tech economy, fuelling growth across pharmaceuticals, biotechnology, MedTech, and even space exploration. According to Horizon Grand View Research, Australia's cleanroom technology market is forecast to reach US\$181.4 million by 2030, expanding at a 6% CAGR between 2025 and 2030. This steady growth underscores the pivotal role cleanroom facilities play in enabling innovation, ensuring product quality, and meeting stringent regulatory standards across advanced industries.

In Brisbane, the Translational Research Institute (TRI), in collaboration with the Queensland Government, is investing \$100 million in the Translational Manufacturing Facility (TM@TRI). Scheduled to open in early 2026, it will be the nation's first on-demand cGMP cleanroom facility, designed to support high-potential biotech, pharmaceutical, and MedTech companies in accelerating innovation and scaling production. At the same time, Pfizer is advancing its cleanroom capabilities with AU\$150 million (US\$98 million) expansion of its Melbourne site. The project includes the addition of two 40 m<sup>2</sup> freeze-drying fridges (lyophilizers) to increase production of antimicrobial treatments for hospitalized patients with serious infections. Together, these investments highlight Australia's growing commitment to strengthening its cleanroom infrastructure and positioning the nation as a hub for advanced pharmaceutical and biotech manufacturing.

In biotechnology, Cartherics has launched a state-of-the-art cleanroom facility for clinical-scale manufacturing of cell therapy products. With the global cell therapy market expected to surpass \$60 billion by 2032, the company is strategically positioned to leverage cleanroom-enabled manufacturing for the scalable production of off-the-shelf immune stem cell therapies, initially targeting ovarian cancer and endometriosis.

The **Cleanroom Manufacturing** conference by **Trueventus** offers the ultimate platform for professionals driving innovation in cleanroom technology and manufacturing practices. This event convenes industry leaders and experts to share practical insights, case studies, and best practices in contamination control, facility optimization, and regulatory compliance. Attendees will also explore emerging solutions—from modular cleanrooms and advanced air filtration systems to automation technologies—while networking with the key stakeholders shaping the future of sterile and cleanroom manufacturing.

## WHY YOU CANNOT MISS THIS EVENT

- Studying strategies for particle and microbial contamination control
- Analyzing real-time systems for monitoring air quality, particles, and contamination in controlled spaces
- Navigating strategies for recovering from facility shutdowns in sterile and cleanroom manufacturing
- Examining advanced HEPA and ULPA filtration systems for superior air quality in cleanrooms
- Discussing cleanroom robotics for enhanced precision and cleanliness
- Explore business incentives and investment opportunities in Australia's booming controlled environment manufacturing sector

## WHO SHOULD ATTEND?

**This event is targeted but not limited to:**

**CXOs, VPs/ Directors/ Heads/ General Managers/ Managers of:**

- Cleanroom Design and Construction
- Sterile Manufacturing Operations
- Quality Assurance and Quality Control (QA/QC)
- Facilities and Maintenance Management
- HVAC and Environmental Controls
- Contamination Control and Monitoring
- Utilities and Energy Management
- Process Engineering and Technology
- Environmental Health and Safety (EHS)
- Regulatory Compliance and Validation

**From the following industries:**

- Pharmaceutical Manufacturing
- Biotech and Life Sciences
- Medical Device Manufacturing
- Semiconductor and Microelectronics
- Aerospace and Defence (Cleanroom Applications)
- Food and Beverage (Sterile Environments)
- Healthcare Facilities Management

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## EXHIBITOR SPONSOR



ONBoard Solutions is a proudly Australian, ISO 9001 accredited supplier, delivering Cleanroom Products, Advanced Materials, and Production Equipment to the manufacturing industries across Australia and New Zealand. Since our establishment in 2000, we have been committed to supporting critical environments with cutting-edge solutions that ensure safety, compliance, and efficiency.

At ONBoard Solutions, we understand the stringent demands of cleanroom environments. Our extensive range of products is designed to meet Good Manufacturing Practice (GMP) requirements with ease. Whether you need sterile, non-sterile, single-use, or launderable cleanroom supplies, we've got you covered. We partner with global market leaders who uphold the highest manufacturing standards, ensuring that the products we supply are not only reliable but also innovative and compliant with the latest industry regulations.

FOR FURTHER DETAILS, CONTACT

☎ : +63285488255 ✉ : [registrationsph@trueventus.com](mailto:registrationsph@trueventus.com)

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## FEATURING PRESENTATIONS AND CASE STUDIES BY DISTINGUISHED SPEAKERS



**Robyn Hofer**  
Microbiology & Sterility Assurance Manager  
**CBE Pure Solutions**  
Melbourne, Victoria



**Andy Gay**  
Director  
**Sterilizer Validation Australia (SVA)**  
Gold Coast, Queensland



**Charles Fridlender**  
Managing Director  
**Pharmachal Health Group**  
Melbourne, Victoria



**Ashutosh Singh**  
Regulatory & Quality Manager  
**Cryosite Limited**  
Sydney, New South Wales



**Jesus Diaz**  
Cultivation Director  
**Austranna Pty Ltd**  
Ipswich, Queensland



**Yong Jian Lee**  
Senior Technical Services Manager, APAC  
**Charles River Laboratories**  
Australia



**Colin McLean**  
Chief Operating Officer  
**Cell Therapies Pty Ltd**  
Melbourne, Victoria



**Daniel McConville**  
OHS & Food Safety Consultant  
**McConville OHS & Risk Solutions**  
Melbourne, Victoria



**Rahul Bangur**  
Engineering Technology Manager  
**Sabre Medical**  
Sydney, New South Wales



**Richard Peirce**  
Quality Director  
**Patheon**  
Brisbane, Queensland



**Dr. Reza Koochak**  
Director  
**Pharma Tech**  
Sydney, New South Wales



**Marta Sánchez Miranda**  
Client Engagement Facilitator  
**The Australian National Fabrication Facility (ANFF)**  
Sydney, New South Wales



**Allison Myers**  
Chief Quality & Regulatory Affairs Officer  
**PolyNovo Limited**  
Melbourne, Victoria



**Mary Nasopoulos**  
Director, Validation & Sterility Assurance  
**Vaxxas**  
Brisbane, Queensland



**Ligia Touron**  
Head of Quality  
**PPC Moulding Services**  
Sydney, New South Wales



**Robert Caunce**  
Quality Director  
**IDT Australia**  
Melbourne, Victoria

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## Day One: Monday, 20<sup>th</sup> April 2026

0800 Registration & Coffee

0850 Opening Keynote Address

0900 Session One

### Design Principles for ISO-Classified Cleanrooms: Standards and Best Practices for Contamination Control

- IDT an organisation with over 50 years experience
- IDT covers manufacturing of API to Sterile Finished Product
- IDT contamination and containment strategy across the business

**Robert Counce**, Quality Director

**IDT Australia, Melbourne, Victoria**

0945 Session Two

### Rapid Microbiological Methods (RMM) - From Production to Patient

- How rapid sterility testing works and the associated validation requirements
- Why rapid methods are essential for short shelf life products, enabling timely release to patients
- Recent advancements in microbiology methods driving faster, more reliable contamination detection

**Robyn Hofer**, Microbiology & Sterility Assurance Manager

**CBE Pure Solutions, Melbourne, Victoria**

1030 The Speed Networking - The Mad Minutes!

*Fun and fast, this networking activity is a great opportunity to grow your connections.*

1105 Morning Refreshments

1130 Session Three (Topic to be Revised)

### Integrating Plant Hygiene and Microbial Risk Assessment into Pharmaceutical QA/QC Systems

- Risk-based hygiene zoning and microbial risk assessment
- Integration of hygiene programs into QA governance
- Cross-functional ownership and continuous improvement

**Richard Peirce**, Quality Director

**Patheon, Brisbane, Queensland**

1215 Session Four

### Strategies for Particle and Microbial Contamination Control: Identifying and Mitigating Contamination Risks in Critical Environments

- Environmental Monitoring (EM) in EU GMP Annex 1 and the importance of species-level microbial ID in EM
- EMPQ: What microbial identification results can tell you
- The risk of the unknown - the importance of updated and curated libraries

**Yong Jian Lee**, Senior Technical Services Manager, APAC

**Charles River Laboratories, Australia**

1300 Networking Luncheon

1400 Session Five

### Successful operation of a GMP cleanroom within Cell and Gene Therapy manufacturing

- Key operational principles that keep GMP cleanrooms performing at a high and reliable standard within Cell Therapy
- How to build a culture of compliance and technical excellence in Cell and Gene Therapy teams
- Practical lessons from managing advanced therapy manufacturing in a fast growing & changing environment

**Colin McLean**, Chief Operating Officer

**Cell Therapies Pty Ltd, Melbourne, Victoria**

1445 Session Six

### Managing Risk in Cleanroom Manufacturing of Novel Clinical Trial Products

- Vaxxas Technology – Aseptic process – high-density microarray patch (HD-MAP)
- Applying a Risk based approach to the novel -high-density microarray patch (HD-MAP)
- TGA licence to manufacture clinical trial material for - high-density microarray patch (HD-MAP) process

**Mary Nasopoulos**, Director, Validation & Sterility Assurance

**Vaxxas, Brisbane, Queensland**

1530 Afternoon Refreshments

1600 Session Seven

### Minimizing Human Contamination Risks Through Best Practices in Gowning Systems

- Human factor is the biggest contamination risk: Operators shed millions of particles daily, making proper gowning essential for cleanroom integrity.
- Best practices start before gowning: Personal hygiene, dedicated gowning zones, and correct donning sequence reduce contamination dramatically.
- Training and culture matter: Consistent education, competency checks, and reinforcing the “why” behind each step ensure compliance and product safety.

**Ligia Touron**, Head of Quality

**PPC Moulding Services, Sydney, New South Wales**

1645 Session Eight

### Leading through Change: Ensuring performance, as well as compliance in adversity

- Leading through tough times can be extraordinarily difficult, but often these are the most rewarding times in your career. Embrace it.
- How to galvanise a team, large or small, when the worst is happening. How to ensure patient safety and supply continuity, whilst maintaining Quality AND Compliance when times are tough.
- If you look after your team, you are automatically looking after the patient. Focus on what you can influence.

**Allison Myers**, Chief Quality & Regulatory Affairs Officer

**PolyNovo Limited, Melbourne, Victoria**

1730 End of Day One

## Day Two: Tuesday, 21<sup>st</sup> April 2026

0800 Registration & Coffee

0850 Chairperson Welcome Address

0900 Session One

### Preventive Maintenance Strategies of Critical Cleanroom Equipment to Ensure Operational Integrity and Avoid Contamination Risks

- Risk-based maintenance planning for critical assets
- Schedule and execute maintenance activities in accordance with ISO 14644, EU GMP Annex 1, and manufacturer recommendations, with documented work instructions and acceptance criteria
- Apply controlled maintenance practices including gowning, tool control, material cleanliness, and post-maintenance cleaning and sanitisation to prevent introduction of particulates or bioburden

**Charles Fridlender**, Managing Director  
Pharmachal Health Group, Melbourne, Victoria

0945 Session Two

### Inhalation-Grade Medicinal Cannabis: Hygiene, MRA, and Specifications Aligned to TGO100 & Ph. Eur 5.1.8

- Build a PQS-integrated hygiene program for medicinal cannabis that meets TGO100 inhalation limits and aligns with Ph. Eur. 5.1.8 for herbal materials.
- Operationalize controls: zoned grow/post-harvest, PRIVA-driven Water Safety Plan (HPC/indicators), validated drying ( $Aw \leq 0.65$ ), EM across grow & controlled rooms, and verified cleaning/sanitisation rotations.
- Track outcomes with KPIs: lower YM/bioburden and excursions,  $\geq 98\%$  EM compliance,  $\geq 90\%$  first-pass release, and audit-ready evidence tied to Annex 7/GACP.

**Jesus Diaz**, Cultivation Director  
Austranna Pty Ltd, Ipswich, Queensland

1030 Morning Refreshments

1100 Session Three

### A practical approach to hospital based sterile reprocessing environments

- Integrating emerging technologies into proven fundamental basics
- Using evidence-based planning to deliver long-term adaptability in an environment of increasing surgical complexity and constantly emerging technologies
- Delivering resilient design that will continue to deliver excellence well into the future

**Andy Gay**, Director  
Sterilizer Validation Australia (SVA), Gold Coast, Queensland

1145 Session Four

### Key Methodologies for Testing Airflow, Particle Counts, and Microbiological Control to Ensure Compliance

- Conduct airflow velocity measurements and smoke visualisation studies to confirm unidirectional flow, absence of turbulence, and effective contamination control in accordance with ISO 14644 and EU GMP Annex 1.
- Perform airborne particle counting at defined sizes (e.g.  $\geq 0.5 \mu\text{m}$  and  $\geq 5.0 \mu\text{m}$ ) under at-rest and in-operation conditions to verify cleanroom classification and ongoing performance.
- Apply active air sampling, settle plates, contact plates, and surface swabbing to assess viable contamination risks and compliance with alert and action limits.

**Ashutosh Singh**, Regulatory & Quality Manager  
Cryosite Limited, Sydney, New South Wales

1230 Networking Luncheon

1400 Session Five

### Bridging the Gap Between Innovation and GMP: The Role of Agile Cleanroom Manufacturers in Accelerating Australia's MedTech and Biotech Pipeline

- How specialised cleanroom facilities enable rapid, compliant progression from prototype to pre-commercial manufacturing by supporting innovators before they are ready for large cGMP infrastructure.
- Real examples from Sabre Medical on contamination control, sterile barrier packaging, biomaterial handling, and process design that reduce risk and support ISO 13485 and regulatory readiness.
- How flexible cleanroom manufacturing reduces time to clinical trials and time to market, derisks development, and builds national capacity in MedTech and biotech, complementing major investments from State and Federal government for setting up manufacturing capability in Australia

**Rahul Bangur**, Engineering Technology Manager  
Sabre Medical, Sydney, New South Wales

1445 Session Six

### Cleanroom Environments for Ready-to-Eat and High-Care Food Production

- How cleanroom design principles can be applied to high-care and ready-to-eat food environments to reduce contamination risk.
- Key differences between traditional food manufacturing and controlled environment production.
- Practical challenges and system failures when implementing cleanroom-style controls in food operations.

**Daniel McConville**, OHS & Food Safety Consultant  
McConville OHS & Risk Solutions, Melbourne, Victoria

1530 Afternoon Refreshments

1600 Session Seven

### Cold Chain Management for the Storage and Transportation of Sterile Products

- Maintaining Temperature Integrity: Explain how continuous temperature monitoring, proper packaging, and validated equipment ensure sterile products remain within required temperature ranges from manufacturing to patient use.
- Risk Management & Compliance: Discuss risk assessments, deviation handling, validation requirements, and alignment with regulatory standards (TGA, PIC/S, WHO) to prevent contamination, degradation, or product failure.
- Optimised Storage & Transport Systems: Highlight best practices for warehouse design, controlled environments, qualified cold rooms, transport validation, and selecting reliable logistics partners to maintain sterility and product quality throughout the supply chain.

**Dr. Reza Koochak**, Director  
Pharma Tech, Sydney, New South Wales

1645 Session Eight

### An open and shared access model to cleanroom manufacturing and how it supports innovation

- Cleanroom manufacturing requires large capital investment, as well as access to specialized infrastructure and safety measures.
- Small and medium enterprises, and researchers, do not normally have the resources to have their own cleanroom and equipment.
- ANFF has created a national and open-access network that allows everyone to access cleanroom facilities without the need to own their own cleanrooms. This also allows different cleanroom manufacturing specialities in different nodes.

**Marta Sanchez Miranda**, Client Engagement Facilitator  
The Australian National Fabrication Facility (ANFF), Sydney, New South Wales

1730 End of Conference

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20<sup>th</sup> - 21<sup>st</sup> April 2026 | Stamford Plaza Melbourne, Australia



## COMPANY DETAILS

Name	Industry
Address	
Postcode	Country
Tel	Fax

### REGISTER NOW

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## ATTENDEE DETAILS

1	Name	Job Title
	Tel	Email
2	Name	Job Title
	Tel	Email
3	Name	Job Title
	Tel	Email
4	Name	Job Title
	Tel	Email
5	Name	Job Title
	Tel	Email

### TERMS & CONDITIONS

- The course fee is inclusive of the event proceedings, materials, refreshment and lunch.
- Upon receipt of the complete registration form, invoice will be issued. Trueventus request that all payments be made within 5 working days of the invoice being issued. Full payment must be received prior to the event. Only delegates that have made full payment will be admitted to event. Clients are responsible for their own banking fees and banking fees will not be absorbed into the booking price.
- Substitution & cancellations policy. Should the registered delegate is unable to attend, a substitute delegate is welcome at no extra charge. Written notifications of all substitutions is required 5 working days prior to the event. Trueventus contracts carry 100% full liability upon receipt of registration. Non payment does not constitute cancellation. A 100% of cancellation fee will be charged under the terms outlined below: Due to limited event seats, Trueventus agrees to book and confirm the seat for the client upon issuance of invoice. Upon signing of this contract, client agrees that in case of dispute or cancellation of this contract Trueventus will not be for total contract value. If a client does not attend the event without written notification at least 5 working days prior to the event date, he/she will deemed as no show. A no show at the event still constitutes that the client will have to pay the invoice amount that was issued to them. Trueventus does not provide refunds for cancellations. By signing this contract the client also agrees that if they cancel that Trueventus reserves the right to pursue monies owned via the use of local debt collection agency were the client is situated. Furthermore the client will be held liable for any costs incurred in collection of outstanding monies. When any cancellations are notified in writing to Trueventus 5 working days prior to the event, a credit voucher will be issued for use in future Trueventus events.
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- All Trueventus events are held in a classroom or theater format.
- All Trueventus events are held at either 5 or 4 Star Hotels.
- All payment must be directed to Trueventus in full prior to the event. Any company's participating in National training schemes such as HRDC Scheme and are applying grants you must first pay Trueventus and upon you receiving the grant you will be refunded this amount back. Failure to pay prior to the event can result in your company being blocked from joining the conference.
- All transaction charges, withholding taxes, local taxes, or currency exchange issues will be strictly absorbed by sender. Trueventus reserves absolute right to refuse admission of participant/s to the event should invoice amount is not received in full.

## APPROVAL

NB: Signatory must be authorised on behalf of contracting organisation.

Name	Job Title
Email	
Tel	Fax
Authorising Signature	

## REGISTRATION FEES

Corporate	
End of March 2026	AUD 2195 (Per Delegate)
1st April 2026 onwards	AUD 2495 (Per Delegate)

All options inclusive of delegate pack, luncheon and refreshments.

## PAYMENT METHODS

Payment is due in 5 working days. By Signing and returning this form, you are accepting our terms and conditions.

Bank Transfer

Credit Card

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