



CYCLOTEK

a concept to care company

Manufacturing Services



***Making
Radiopharmaceuticals
Accessible***

Innovate

Underpinned by our innovative approach, our product development and manufacturing service offering can be tailored to meet your development needs, enabling the cost effective, phase appropriate translation of your product.

Adapt

Cyclotek has the people, the systems and infrastructure to validate novel radiopharmaceuticals for supply into clinical trials, and through the TGA's Special Access Scheme, or Authorised Prescriber pathways.

Deliver

Cyclotek have well established logistic management for the transport of radioactive products via an extensive road & air network. We are leading the way in the development of advanced freight mobility.

Contract Development and Manufacturing

19

Products Validated

17

*Radiopharmaceuticals
Routinely Manufactured*

142

*Clinical Trials Supplied
(Pharma and Investigator)*

2,560

*Batches Manufactured in
Support of Clinical Trials*

46

*PET/CT Clinical Trial
Imaging Sites Supplied*

6,470

Clinical Trial Doses Supplied

Cyclotek has a proud history of collaborating with both local and international partners to develop, manufacture and supply novel radiopharmaceuticals. We undertake these activities to support the translation of radiopharmaceutical products through pre-clinical and phase 0-III clinical trials.

Cyclotek's phase appropriate, GMP compliant infrastructure is designed to enable rapid technology transfer and validation of your radiopharmaceuticals into clinical trials. This infrastructure is complemented by our highly skilled personnel and extensive logistics network.

Cyclotek has established a world class CDMO capability. Together with key strategic partnerships and engagements across academia and industry, Cyclotek will be your CDMO of choice as you bring your radiopharmaceutical product to market in the ASEAN and Pacific region.

To hear more about our CDMO capability,
please contact Sam Graf

Samuel.Graf@cyclotek.com



Cyclotek Reach

Our established manufacturing network includes five facilities across the Australian states of Victoria, New South Wales, Queensland, and Wellington, New Zealand, with a total group footprint of 28,600 ft.²

Cyclotek is excited to announce a substantial expansion of our manufacturing capacity, with additional facilities underway in Queensland, New South Wales and New Zealand. Together with new research facilities at The University of Melbourne and 40 Clements Avenue, Cyclotek will offer a full CDMO service across the phases of discovery, translation and commercialisation.

Upon completion, this expansion will take our footprint to 57,750 ft.²

<p>MELBOURNE - BUNDOORA 38 Clements Avenue, Bundoora, VIC, 3083.</p>	<p>MELBOURNE - BUNDOORA 40 Clements Avenue, Bundoora, VIC, 3083.</p>	<p>MELBOURNE - PARKVILLE Victorian Comprehensive Cancer Centre Level 2B, 305 Grattan Street Melbourne, VIC, 3000.</p>
<p>THE UNIVERISTY OF MELBOURNE Ground Floor, David Caro Building, The University of Melbourne, Parkville, VIC, 3000.</p>	<p>MELBOURNE - PARKVILLE Bio21 Molecular Science and Biotechnology Institute 30 Flemington Road, Parkville, VIC, 3052.</p>	<p>SYDNEY - LUCAS HEIGHTS Building 79, Business & Technology Park, New Illawarra Road, Lucas Heights, NSW, 2234.</p>
<p>SYDNEY - MACQUARIE UNIVERSITY Macquarie Hospital, 3 Technology Place, Macquarie University, NSW, 2109.</p>	<p>BRISBANE - WOOLLOONGABBA Princess Alexandra Hospital, Gate 1, Bdg 39, Cornwall Street, Woolloongabba, QLD, 4102.</p>	<p>BRISBANE - MANSFIELD 14 Dividend Street, Mansfield, Brisbane, QLD, 4122.</p>
<p>WELLINGTON - NEW ZEALAND 145 Stewart Duff Drive, Rongotai, Wellington, 6022.</p>		<p>AUCKLAND - NEW ZEALAND 20 Fisher Crescent, Mt Wellington, Auckland, 1060.</p>

Product Development Leadership



Greg Santamaria is the Co-Founder, Director and CEO of Cyclotek. With extensive experience in business development and operations, Greg holds several board positions within the fields of healthcare, manufacturing, wholesale and finance.



Dr Rob Ware is the Co-Founder, Director and Chief Medical Officer of Cyclotek. Dr Ware is a nuclear medicine physician specializing in cancer imaging and PET, currently overseeing Cyclotek's tracer development and clinical trial programs.



Jon Evans is the CEO of Cyclotek International. For over 20 years, Jon has held strategy leadership positions across the private and public healthcare sector, assisting health corporations to successfully access international markets.



Dr Mark Frazzetto is the Director of Quality And Research at Cyclotek. He leads the quality team, ensuring GMP compliance and product quality. With over 20 years in the biopharmaceutical industry, he specializes in developing novel therapies for various diseases.



Joshua Seale is Cyclotek's Director of Facilities and Operations. Having led the radiopharmaceutical manufacturing, engineering and logistics teams for multiple years, Josh specialises in the management of radiopharmaceutical manufacturing and infrastructure.



Dr Cheryl Falzon is Cyclotek's Product Onboarding Manager. With over 14 years of experience, Dr. Falzon specializes in the validation of equipment and methods for the GMP compliant manufacture of radiopharmaceuticals, for clinical trials and commercial use.



Mat Heald is Cyclotek's Product Development and Implementation Manager. With over 15 years experience in radiopharmaceutical development, he specialises in the translation of automated radiopharmaceutical manufacturing techniques.



Sam Graf is Head of Innovation and Partnerships at Cyclotek. Following completion of his Master of Science at the University of Melbourne, Sam joined the Cyclotek team to manage external communications, research collaborations and industry partnerships.



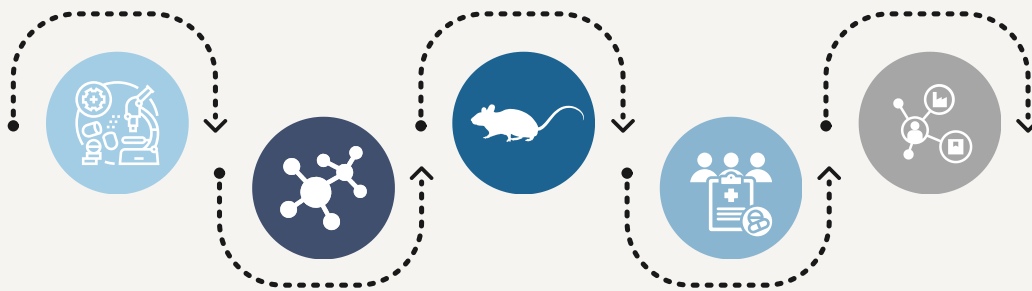
Our Services

Cyclotek offers a full CDMO service across the entire radiopharmaceutical research and commercialisation pathway. We enable innovative companies to deliver the highest quality product into the Australian, New Zealand and ASEAN markets, on time, every time.

Research and Development

Through a strategic Partnership with the University of Melbourne's Faculty of Science, our state-of-the-art radiopharmaceutical research and development laboratories are fully equipped to support the pre-clinical evaluation of your product.

Through this partnership, Cyclotek offers multiple radiopharmaceutical research services including Screening & Discovery, Candidate Characterisation, Radiolabelling and Quality Control Method Development.



Product Implementation

Cyclotek's Product Development and Implementation (PDI) team specialises in cGMP manufacturing tailored to the development phase of your product, accommodating for pre-clinical, phase 0/I and phase II-III requirements.

Our dedicated PDI team has extensive experience in the disciplines of radiopharmaceutical production, quality control, quality assurance, engineering and regulatory. From small molecules to antibodies, manual production to automated synthesis, we have the expertise to support the translation and validation of your product and methods onto our automated platforms.

Our technology transfer process begins with a feasibility and gap analysis to align the product owner and Cyclotek's existing resources, followed by scale up and automation of your methods. Throughout the validation process, your materials, equipment and manufacturing methods are qualified following rigorous validation protocols, enabling the hand over of validation reports and manufacturing batch records to the product owner.

Our Services

Manufacturing

Cyclotek's manufacturing facilities are licenced to utilise multiple diagnostic and therapeutic radioisotopes. Active engagement with the regulatory body enables our team to rapidly bring on new radioisotopes.

Our production cleanrooms contain multiple shielded manufacturing cells, automated synthesisers and dispensing cells. With an unmatched logistics network and bespoke ordering platform, we reliably manufacture and supply across all stages of the product lifecycle:

- Pre-clinical
- First in Human
- Phase I
- Phase II-III
- Commercial Supply



Quality Control and Assurance

Each facility is home to a dedicated quality control laboratory, containing a suite analytical equipment.

Coupled with our centralised microbiological testing facility, located within our manufacturing headquarters in Bundoora, Victoria, Cyclotek is proud to offer a full suite of manufacturing and quality control testing services, including, but not limited to:

- Radionuclidic Identity
- Radiochemical Purity
- Sterility
radioactive and decayed samples
- Endotoxin
- Solvent analysis



Radioisotopes access

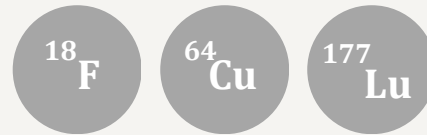
MELBOURNE - PARKVILLE



MELBOURNE - BUNDOORA



MELBOURNE - VCCC



SYDNEY - LUCAS HEIGHTS



CNSW-MU

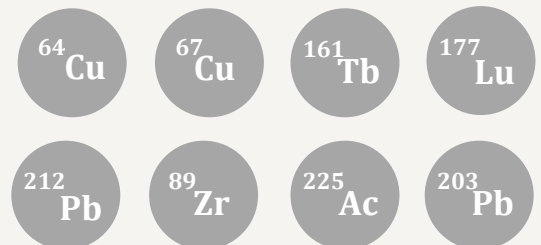


BRISBANE - WOOLLOONGABBA



Future Facilities

MELBOURNE - BUNDOORA



BRISBANE - MANSFIELD

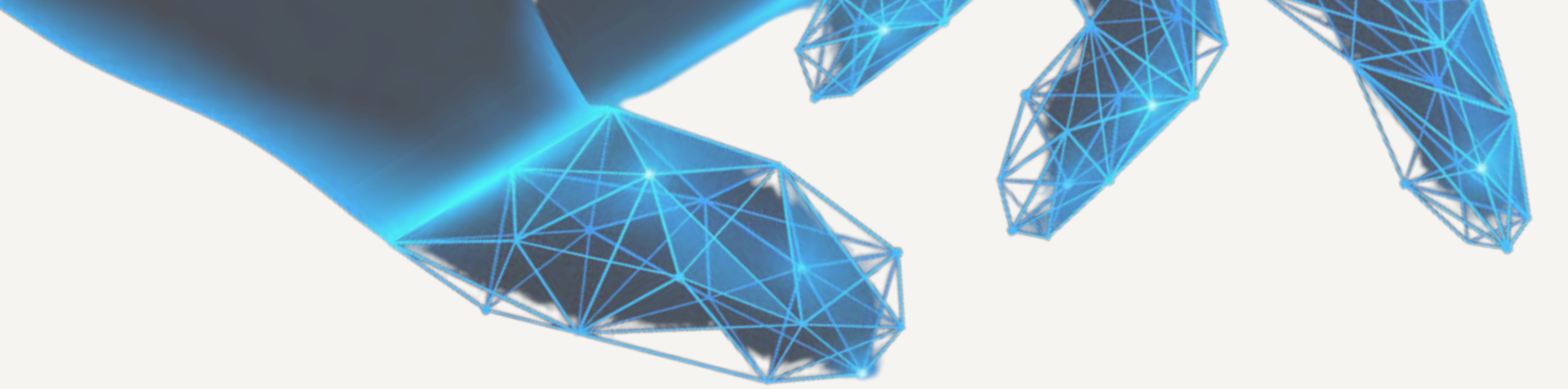


AUCKLAND - NEW ZEALAND



THE UNIVERSITY OF MELBOURNE







a concept to care company

"making radiopharmaceuticals accessible"

Ideal Results:

Those that are attained over the long term without compromise to staff or environment, are gained by leadership that understands human behaviour, harnesses strategies, communicates effectively, embeds creativity, inspires and listens.