Position Description

Position Title: Grade 2 Pharmacist, Clinical Trials

Classification:	Pharmacist Grade 2, SX2 – SX5
Business unit/department:	Pharmacy Department
Work location:	Austin Hospital ☒ Heidelberg Repatriation Hospital ☒ Royal Talbot Rehabilitation Centre ☐ Other ☐ (please specify)
Agreement:	Victorian Public Health Sector (Medical Scientists, Pharmacists and Psychologists) Single Enterprise Agreement 2021-2025
Employment type:	Fixed-Term Full-Time
Hours per week:	38 hours with ADO
Reports to:	Senior Pharmacist, Clinical Trials Manager
Direct reports:	Nil
Financial management:	
Date:	11JUN2025

Position purpose

This position is to support Pharmacy Clinical Trials Manager in the provision of pharmacy Investigational Drug Service across Austin Health.

Duties and responsibilities include: coordinating, collaborating and providing support of investigational drug service; providing accurate and timely dispensing of trial and trial related drugs; performing administrative responsibilities; providing direct supervision to technician and students; performing education and counselling to participants and their carers, medical and nursing staff and other pharmacists; supporting the Oncology/ Cytotoxic compounding Pharmacist; performing other duties consistent with the job classification, as required. This role will primarily be based at the Austin campus with rotational shifts at the Repat campus.

Key customers are:
Director of Pharmacy, Pharmacy Clinical Trials Manager and Clinical Trial staff, trial co-ordinators, pharmaceutical company trial monitors, trial investigators, pharmacy staff, patients and nursing staff.

About the Directorate/Division/Department

The Pharmacy Department Mission Statement is:

"Working together to provide optimum pharmaceutical care".

Comprehensive pharmacy services are provided at the two main sites of Austin and Repatriation campuses and also to Royal Talbot Rehabilitation Centre. Pharmacy staff participate in a coordinated work team via a roster system, and they work at different sites (as needed) in order to provide an integrated, high quality service to all pharmacy department customers.

Our philosophy is to foster a learning environment and to promote teamwork as the best method to deliver day to day services, for both our customers and the individual staff members. A priority for all pharmacy staff members must be to use every available opportunity to demonstrate the value of the pharmacy services to our customers. This is a conscious effort to develop and effectively market the pharmacy services, and to target the services offered by achieving a better understanding of the needs of each customer group.

Position responsibilities

Pharmacy Clinical Trial Duties

- Be familiar with the standard practice involved in conducting a clinical trial, including the policy and procedures, restrictions, adherence to privacy and confidentiality and adverse event reporting procedures.
- To conduct clinical trials in accordance with the study protocol, legal and hospital requirements, ICH-GCP, NHMRC National Statement on Ethical Conduct in Human Research and SHPA Standards of Practice of Pharmacy Investigation Drugs Service.
- To dispense clinical trials drugs and other medicines related to the trial in a timely manner.
- To receive and store investigational drugs as specified in the protocol.
- To assist in the maintenance of Clinical Trial Standard Operating Procedures (SOPs).
- To assist investigators and sponsors in the development of clinical trial protocols.
- To communicate and educate pharmacy staff, medical and nursing staff on relevant clinical trial information.
- To counsel participants and their carers on clinical trial medications.
- To report adverse events in accordance with the protocol and Austin Health policy and procedures.
- To prepare sterile, non-sterile, cytotoxic, GMO and advanced therapies for clinical trials.
- To develop procedures for the preparation of sterile and non-sterile clinical trial medications in accordance with project specific protocols.

Outcome Measure:

- Up-to-date and in-depth knowledge of current practice in Clinical Trials.
- Competent in all aspects of clinical trials activities.
- Investigational drugs and related medicines dispensed timely in accordance with the protocol.
- Dispensing records accurately completed at the time of dispensing.
- The handling of clinical trials medications is in accordance with protocol, Therapeutic Goods Administration, ICH-GCP, NHMRC National Statement on Ethical Conduct in Human Research and SHPA standards of Practice of Pharmacy Investigation Drugs Service.
- Clinical Trials SOPs are current.
- Adequate inventory levels are maintained.
- Adverse event reported.

Trial Folder Set-up

- To set up pharmacy folder for investigational drug for the clinical trial allocated by the Clinical Trials Manager in accordance with Sponsor or Investigator's protocol and comply with relevant legislative Acts, standards and guidelines.

Outcome Measure:

- Investigational medicine Pharmacy Folders set up within the requested time frame.

Stock Control and Storage

- The Pharmacy Clinical Trials Pharmacist is involved in receiving, returning and sending trial drugs; there are strict procedures for acknowledgement and receipt of trial stock. Many trial drugs also require special handling and electronic temperature logging, both during transit and storage life in the pharmacy.
- To ensure investigational drugs are stored separately from other pharmacy stock.
- To assist with temperature monitoring of investigational drugs.
- To monitor expiry date of investigational drugs.

Outcome Measure:

- Investigational drugs are received, stored, returned and disposed in accordance with the protocol.
- Investigational drugs stored in the clinical trials area of the pharmacy department.
- Investigational drugs are in-date and stored at the correct temperatures and environmental conditions as specified in the protocol, investigator's brochure or approved information and according to the appropriate statutory regulations.
- Storage of investigational drugs complied with the conditions specified by the protocol, clinical trial sponsor or manufacturer, and complied with legislation.
- Investigational drugs for each protocol are clearly segregated and be placed in separate containers or areas and clearly labelled with the Protocol Number.

Manufacturing

- To assist the manufacturing pharmacists in the preparation of trial products including sterile, non-sterile and cytotoxic therapies in accordance with Austin Health guidelines and Standard Operating Procedures.
- To prepare Genetically Modified Organisms (GMO) and advanced trial products as required.

Outcome Measures:

- Successful completion of validation for manufacturing of sterile and cytotoxic products and revalidation every 12 months
- Manufactured products prepared when required according to Standard Operating Procedures

Training

- To assist Clinical Trials Manager in the orientation and training of pharmacists, resident pharmacists, intern pharmacists, students and technicians rotated to the area.

Outcome Measures:

- Clinical trials staff are competent in dispensing trials medicines.
- New pharmacy clinical trials staff are familiar with Clinical Trials Policy and Procedures.

Administrative Duties

- To maintain familiarity with all administrative duties in the Clinical Trials area and to assist the Pharmacy Clinical Trials Manager with administrative duties as requested.
- To assist the billing of clinical trials.
- To assist with archiving of clinical trial records as required.

Outcome Measures:

- Able to perform administrative duties when requested.

- Accurately bill Sponsors and Investigators for clinical trial activities.

Selection criteria

Essential skills and experience:

- Practical knowledge of and experience in conducting clinical trials.
- Previous hospital pharmacy experience, including haematology and oncology rotations.
- Good attention to detail and high level of accuracy.
- Well developed clinical pharmacy knowledge.
- Excellent time management skills. Capacity to perform under pressure, to meet time constraints and determine work priorities.
- Effective and courteous communication skills.
- Proven ability to use initiative, identify and solve problems.
- Proven ability to forward plan, establish and complete targets.
- Customer focus approach to work and service quality.
- Highly developed written and oral communication skills.
- Proficient in computer applications
- A commitment to Austin Health values: Our actions show we care, we bring our best, together we achieve and we shape the future. www.austin.org.au/about-us

Desirable but not essential:

1. Previous experience in compounding.
2. Post-graduate qualifications (pharmacy related).
3. A broad range of experience in hospital pharmacy.

Professional qualifications and registration requirements

Registered as a pharmacist with AHPRA and with no restrictions.

Quality, safety and risk – all roles

All Austin Health employees are required to:

- Maintain a safe working environment for yourself, colleagues and members of the public by following organisational safety, quality and risk policies and guidelines.
- Escalate concerns regarding safety, quality and risk to the appropriate staff member, if unable to rectify yourself.
- Promote and participate in the evaluation and continuous improvement processes.
- Comply with the principles of person-centered care.
- Comply with requirements of National Safety and Quality Health Service Standards and other relevant regulatory requirements.

Other conditions – all roles

All Austin Health employees are required to:

- Adhere to Austin Health's core values: *our actions show we care, we bring our best, together we achieve, and we shape the future.*
- Comply with the Austin Health's Code of Conduct policy, as well as all other policies and procedures (as amended from time to time).
- Comply with all Austin Health mandatory training and continuing professional development requirements.
- Provide proof of immunity to nominated vaccine preventable diseases in accordance with Austin Health's immunisation screening policy.
- Work across multiple sites as per work requirements and/or directed by management.

General information

Cultural safety
Austin Health is committed to cultural safety and health equity for Aboriginal and/or Torres Strait Islander People. We recognise cultural safety as the positive recognition and celebration of cultures. It is more than just the absence of racism or discrimination, and more than cultural awareness and cultural sensitivity. It empowers people and enables them to contribute and feel safe to be themselves.

Equal Opportunity Employer
We celebrate, value, and include people of all backgrounds, genders, identities, cultures, bodies, and abilities. We welcome and support applications from talented people identifying as Aboriginal and/or Torres Strait Islander, people with disability, neurodiverse people, LGBTQIA+ and people of all ages and cultures.

Austin Health is a child safe environment
We are committed to the safety and wellbeing of children and young people. We want children to be safe, happy and empowered. Austin Health has zero tolerance for any form of child abuse and commits to protect children. We take allegations of abuse and neglect seriously and will make every effort to mitigate and respond to risk in line with hospital policy and procedures.