

POSITION DESCRIPTION – Alfred Health/The Alfred/Caulfield Hospital/Sandringham Hospital

Date revised: December 2017

POSITION:	Lead Pharmacist, Clinical Trials Services
AWARD/AGREEMENT:	HSU 4
CLASSIFICATION TITLE:	Hospital Pharmacist TA20-TA22
DEPARTMENT/UNIT:	Pharmacy
DIVISION:	Medical Services
ACCOUNTABLE TO:	Deputy Director Operations

ALFRED HEALTH

Alfred Health is the main provider of health services to people living in the inner southeast suburbs of Melbourne and is also a major provider of specialist services to people across Victoria. The health service operates three outstanding facilities, The Alfred, Caulfield, and Sandringham.

Further information about Alfred Health is available at www.alfredhealth.org.au

OUR VALUES

Our staff are expected to demonstrate and uphold our values of:

Integrity, Accountability, Collaboration and Knowledge.

Our values provide the platform for the way we work and the decisions we make. Through this approach, our Vision and Mission are achieved.

DEPARTMENT

The Pharmacy services operate over 4 sites within Alfred Health and involve in training interns, undergraduate and overseas research students. Pharmacists are essential members of all clinical teams and have a critical role in patient management. Their understanding of Pharmaceutics, Pharmacology and Medicine Management ensures Alfred Health patients receive the best pharmacy care possible. The service has 3 key priorities:

- Medication Safety
- Cost effective use of medicines
- Delivery of specialist pharmacy expertise at critical points in the patient care pathway

Services have been aligned with the Alfred Health clinical programme structure

Further information is available at www.alfredhealth.org.au/Department.aspx?ID=180

TEAM SPECIFIC INFORMATION – CLINICAL TRIALS

The Alfred Health Clinical Trials Pharmacy Service provides quality, efficient and cost-effective investigational drug services across all four of our campuses. The department is based at the Alfred but oversees the quality and governance and financial management of over 250 trials both commercial and local investigator led.

The service plays a key specialist role within the Pharmacy Operational Services.

The service is managed at The Alfred by GCP trained pharmacists and technical staff to ensure the studies are conducted according to international and local standards of good clinical research practice. The purpose built Clinical Trials Pharmacy facility includes restricted access, temperature monitored storage, and access to a sterile preparation suite.

The services are provided seven days a week, and range from first-in-human phase 1 to phase 4 studies.

The Clinical Trials Pharmacy plays a key role in the whole clinical trials process from ethics submission through to audits from international regulatory bodies.

POSITION SUMMARY

- Leading, coordinating and managing the Clinical Trial Pharmacy Service
- Ensure that the relevant legislative requirements, hospital guidelines and accreditation and professional standards are met
- Quality assurance and quality improvement of clinical trials pharmacy service
- Acting as the Pharmacy representative in the Alfred Research and Ethics Committee
- Supervision and training of relevant pharmacy staff in the performance of their day to day responsibilities.
- Ensuring relevant pharmacy staff comply with pharmacy and hospital procedures
- Mentoring and performance management of relevant pharmacy staff and post and undergraduate pharmacists.
- Ensuring relevant budgets are monitored and managed and information provided to advise the Pharmacy Executive on clinical trial activity and its associated revenue
- Ensure accurate and timely provision of Clinical Trial medications to patients and staff

DIRECT REPORTS:

- All staff working within the Clinical Trials service
- All students whilst working within the clinical trials service

KEY RESPONSIBILITIES

Service Provision

- Coordinate and develop the activities of the clinical trials pharmacy service.
- Act as the lead and point of contact for clinical trials.
- Responsible for the supervision and management of all clinical trials financial data and accounts including invoicing, enquiries and reports.
- Review trial protocols for Ethics submissions and attend the monthly Ethics Review Committee.
- Lead the provision of consistent, quality, efficient and cost effective clinical trial pharmacy services within the available resources.
- Liaise with outside agencies where necessary.

- Coordinate and prepare monthly key performance indicator summaries for all areas of responsibility and report to Deputy Director Operations.
- Oversee the monthly financial analysis and annual budget plan for the clinical trials service.
- Participate in multidisciplinary team meetings.
- Oversee the answering of queries relating to trials in response to patients, carers and all healthcare staff within the organisation.
- Develop, implement and report measures and benchmarks for the clinical trials pharmacy service.
- Lead the development of clinical trials policies and procedures.
- Identify and develop clinical trials pharmacy risk management processes.
- Support AlfredHealth in controlling risks associated with clinical trials pharmacy services.

Policies and Procedures

- Update and maintain current policies relating to the clinical trials pharmacy service including documentation within ISO9001:2000.
- Update and maintain developmental plans specific to the clinical trials pharmacy service in the departmental developmental and governance business plan.
- Ensure there is ongoing review of all local procedures to ensure that these are appropriate, effective and followed by staff.
- Ensure pharmacy staff compliance with pharmacy and hospital procedures relating to their responsibilities including but not limited to Drug Formulary, Drug Guidelines and medication chart, prescription and activity documentation.

Staff Management and supervision

- Update and maintain pharmacist orientation programs to clinical trials pharmacy services.
- Provide clinical trial staff with appropriate supervision, training and instruction in accordance with Alfred Health policies.
- Ensure all clinical trials staff are appropriately trained and credentialed against clear procedures and competency standards.
- Conduct performance development reviews of all staff within area of responsibility.
- Identification of training and educational requirements and priorities in conjunction with the Lead Pharmacist for Education.
- Oversee supervision of all pharmacists, trainees and students working within area of responsibility.
- Ensure the organisation of at least weekly team meetings.
- Coordinate ADO and annual leave of relevant staff with the Deputy Director Workforce.
- Assist in the various university undergraduate and postgraduate experiential placement programs.

Research and Audit

- Develop and contribute to a practice based research program relevant to the clinical trials service.
- Present advances in practice at appropriate pharmacy and medication forums
- Publish advances in practice in appropriate peer reviewed journals

Service Development and Strategy

- Implement of a succession plan for clinical trials pharmacy positions
- Identify and introduce new clinical trials practices that can result in improved service provision.
- Contribute to the strategic plan for pharmacy services which addresses Hospital priorities, emerging pharmaceutical trends, technological change, and patient care objectives.
- Lead the preparation of pharmacy ethics submissions and programs, and to advise on pharmaceutical issues.
- Represent Pharmacy in the Hospital Ethics Committee including monthly attendance of Ethics Research Review Committee and protocol amendments review.
- Provide information and advice on drug usage and costs to where appropriate.

- Provide accurate and timely information for management purposes to ensure that the systematic provision of services is achieved.
- Lead the provision of the day-to-day service including drug accountability, dispensing, stock receipt and liaison with internal and external customers.
- Supervise trial stock control procedures including re-ordering, drug returns, and appropriate storage conditions etc.
- Lead all clinical trials monitor visits and be responsible for follow up of all findings and recommendations.
- Be responsible for all regulatory inspections and audits, and assist on the follow up of outstanding findings and recommendations.
- Oversee the setting up of clinical trials procedures for new trials.
- Review and update clinical trial pharmacy charges annually.
- Be the responsible point of contact for trial investigators and/or sponsor in the setting up of new trials.
- Be responsible for the preparation of clinical trial costings for investigators' protocol Ethics submission.
- Be responsible for trial pre-study site-selection and auditor visits.
- Be responsible for trial initiation meetings and close-out monitor visits.
- Provide pharmacy consultancy service to trial customers in study design, randomisation, sourcing drug supply, manufacturing and regulatory requirements.
- Contribute to the strategic plan for pharmacy services which addresses Hospital priorities, emerging pharmaceutical trends, technological change, and patient care objectives.

General

- Assist with general administrative responsibilities when requested.
- Represent the Pharmacy Department at external and internal meetings.
- Participate in the extended working hours services when required.
- Participate in weekend, public holiday and on-call services when required.
- Actively participate in the AlfredHealth Performance Review and Development Program.
- Maintain and document ongoing CPD at a level applicable to the post and in line with registration requirements.
- Practice within the Code of Ethics of the Society of Hospital Pharmacists of Australia.
- Attend and actively contribute to the pharmacy department meetings and educational forums.
- Ensure that the relevant legislative requirements, hospital guidelines and accreditation and professional standards are met
- Practice according to policies and procedures.
- Participate in the pharmacy department and AlfredHealth quality management programs.
- This post is one of continual development. The job description is intended as a guide to the principal duties and responsibilities of the post and complements individual objectives set in line with the department's annual business objectives. Responsibilities will be reviewed periodically in line with service priorities and duties may change or new duties be introduced after consultation with the post holder.

In this position you must comply with the actions set out in the relevant section(s) of the OHS Roles and Responsibilities Guideline.

QUALITY, SAFETY, RISK and IMPROVEMENT

- Maintain an understanding of individual responsibility for patient safety, quality & risk and contribute to organisational quality and safety initiatives.
- Follow organisational safety, quality & risk policies and guidelines.
- Maintain a safe working environment for yourself, your colleagues and members of the public.
- Escalate concerns regarding safety, quality & risk to appropriate staff member, if unable to rectify yourself.
- Promote and participate in the evaluation and continuous improvement processes.
- Comply with principles of Patient Centred Care.
- Comply with Alfred Health mandatory continuing professional development requirements.

- Comply with requirement of National Safety & Quality Health Service Standards and other relevant regulatory requirements.

OTHER REQUIREMENTS FOR ALL ALFRED HEALTH STAFF:

- Provide staff working in area of responsibility with appropriate supervision, education, training and instruction in accordance with Alfred Health policies.
- Ensure compliance with relevant Alfred Health clinical and administrative policies and guidelines.
- Comply with relevant privacy legislation.
- Protect confidential information from unauthorised disclosure and not use, disclose or copy confidential information except for the purpose of and to the extent necessary to perform your employment duties at Alfred Health.
- Comply with Alfred Health medication management and medication safety policies and guidelines.
- In this position you must comply with the actions set out in the relevant section(s) of the OHS Roles and Responsibilities Guideline.
- Research activities will be undertaken commensurate with the role.

KEY CAPABILITIES AND VALUES:

Capabilities

Skills:

- Demonstrated leadership and decision making skills
- Demonstrated ability in clinical trial management
- Communicates regularly with pharmacists outside the organisation through active participation in the affairs of pharmacy professional organisations.
- Ability to search and analyse medical and paramedical literature
- Advanced presentation and writing skills
- Ability to liaise with clinical trial personnel within Bayside and external trial sponsors
- Advanced computer skills

Core attributes:

- Leadership and commitment to service development
- Commitment to patient care and the ethical conduct of clinical trial
- Customer focused
- Trustworthy, courteous, reliable and thorough
- Motivated, enthusiastic, initiative and dedicated
- Commitment to continuing education and professional development
- Attention to detail and accuracy

Values

Values consistent with those of Alfred Health which are integrity, accountability, collaboration and knowledge.

QUALIFICATIONS/EXPERIENCE REQUIRED

- Registered pharmacist with AHPRA
- Relevant post-graduate qualification such as Masters in Clinical Pharmacy Practice, MBA or equivalent
- Completion of a specialist qualification, or completion or progression towards a PhD highly desirable

Experience:

- Experience in the provision of an advanced clinical trials pharmacy services
- Superior administrative and organisational skills, and exhibit the ability to work and communicate effectively with pharmacy staff and other health professionals
- Demonstrated experience in distribution, clinical and aseptic preparation services
- Ability to work and communicate effectively with external trial sponsors
- Extensive hospital pharmacy experience with a demonstrated understanding of contemporary practice in hospital pharmacy services, QuM and therapeutics.
- Extensive experience in the critical evaluation of medical literature and demonstrated ability to translate into clinical practice
- Extensive experience in supervision, mentoring and development of staff

Position Description authorised by: Deputy Director of Pharmacy

Date: December 2017