

Position Title	Clinical Trial Pharmacist
Group/Portfolio	Griffith Health Group – Clinical Trial Unit
Classification	HEW 8
Position Number	00063414
Reports To	Operations Manager
Employment Type	Continuing contingent

1.0 Position Purpose

The position will support commercially funded and investigator-led research projects in the Clinical Trial Unit (CTU) by providing clinical trial pharmacy services. This will include Investigational Medicine Products (IMP) preparation and dispensing, as well as being involved in IMP receipt, storage and destruction.

The Clinical Trial pharmacist works in line with protocol, appropriate quality standards and regulations. Working across a range of clinical trials the role will support the day-to-day operations of the CTU through teamwork, professionalism and accountability. The Clinical Trial Pharmacist will report to the Operations Manager. Flexibility in working hours is a requirement for this role.

2.0 Eligibility Requirements

- The occupant of this position must provide evidence of current registration as a Pharmacist with the Australian Health Practitioner Regulation Agency (AHPRA)
- Practical knowledge of and experience in conducting clinical trials, aseptic techniques and a current GCP certificate is essential for this role.

3.0 Key Responsibilities

- Ensure that all IMP activities are conducted in accordance with protocols, GCP and any other relevant national and international regulations (e.g. TGA, ICH-GCP and NHMRC).
- Prepare IMP using aseptic techniques for a variety of dosage forms (i.e. infusions, vaccines) and products (i.e. Genetically Modified Organisms (GMO) trial products).
- Lead pharmacy specific clinical trial setup, maintain pharmacy and administration, and manage any IMP receipt and dispensing in accordance with the protocol and operational requirements.

- Ensure IMP is received, stored, returned and disposed in accordance with the protocol and applicable regulations, and complete any relevant documentation (e.g. accountability logs).
- Prepare study specific IMP worksheets, labels, logs, manuals and blinding plans and contribute to prescreen of potential clinical trial participants based on eligibility criteria.
- Support CTU management in clinical trial feasibility assessment for future trials, as well as ongoing clinical trial monitoring and auditing of ongoing trials.
- Prepare/Review CTU Standard Operating Procedures (SOPs) and Work Instructions (WI) on pharmacy related tasks e.g. aseptic drug preparation, media fill etc., while also organising and completing aseptic technique certification for the required staff members in preparation of planned trials
- Ensure proactive working relationships and effective communication with all CTU team members, as well as internal and external stakeholders including trial sponsors, academic and clinical investigators, researchers, patients and research participants.
- Ensure and maintain compliance with relevant legislation and University policies and procedures, including equity and health & safety and exhibit good practice in relation to same.
- Be a leading example of the principles and values embodied in the University's Code of Conduct, and behave, act and communicate at all times to reflect fairness, ethics and professionalism.

4.0 Key Capabilities

- Griffith University identifies the attributes of resilience, flexibility, creativity, digital literacy and entrepreneurship as critical to our graduates' success, in the rapidly changing future world of work. We have established a Griffith University Capability Development Framework to provide a common language of some of the non-technical organisation skills that will support our staff to thrive now and into the future. The Capability Development Framework will assist you to understand the current skill level of this position in the non-technical but critical skill domains that are increasingly important in a changing workplace context.
- To read about some of the non-technical organisation skills for this position, please see the Leads Self section of our [Capability Development Framework](#).