

GSK PhD Graduate Researcher Program

Job Description



Job Title	GSK PhD Graduate Researcher Program – Regulatory Affairs	Dept	Regulatory Affairs
Project description	This project has been designed to support the implementation of an early medicine pipeline regulatory strategy framework		
Job Purpose*			
<p>The GSK PhD Graduate Researcher Program is a government-funded, industry-hosted initiative developed to help bridge the gap between industry and research.</p> <p>The 12-month work placement program is available to PhD graduates or postdoc researchers. The aim of the program is to provide interns with a diverse range of development opportunities, experiences and exposure with view to improving Australia’s success in terms of translation and commercialisation of health and medical research; and expanding the capacity and capability.</p> <p>Background: Our mission at GlaxoSmithKline is to improve the quality of lives by enabling people to do more, feel better and live longer. Our goal is to be one of the world’s most innovative, best performing and trusted healthcare companies. We believe that we all bring something unique to GSK and when we combine our knowledge, experiences and styles together, the impact is incredible.</p> <p>GSK has an extensive pipeline of innovative medicines currently in different stages of development, including in the oncology, rheumatology and cardiovascular areas. The Regularly Affairs Department are at the forefront of the assessment of these medicines for Australian and New Zealand patients and the regulatory strategy taken will direct the access pathway of these medicines in both countries.</p>			
Project Overview and milestones			
Describe the key deliverables to be achieved by the PhD graduate and the ongoing responsibilities of the role			
<p>The candidate will take a leading role in a key Australian regulatory compliance project (Consumer Medicine Information (CMI) reformatting) as well as continue the implementation of an early pipeline regulatory strategy framework.</p> <p>Project milestones/deliverables:</p> <ul style="list-style-type: none"> • Develop and implement a transition plan for the reformatting of GSK’s Australian CMI documents to ensure compliance with new regulatory requirements • Research and report on international regulatory strategies, clinical data considerations, potential regulatory strategies for specified pipeline medicines (Q2/Q3 2022) • Work with Regulatory Submission Lead and cross functional teams to determine the optimal regulatory strategy for Australia and New Zealand (Q3/Q4 2022) • Provide assistance to the broader GSK regulatory team with other regulatory priorities as required 			
Project Objectives			
<p>The successful candidate will:</p> <ul style="list-style-type: none"> • Develop a deeper understanding of international and local regulatory legislation and guidelines • Develop a deeper understanding of the pharmaceutical industry, and how different parts of the business (regulatory affairs, health economics, marketing, sales, government affairs, community affairs) support the delivery of new medicines to patients 			

- Develop a greater understanding of the regulatory framework in which the pharmaceutical industry operates (Medicines Australia, Local SOP/Policies)
- Develop understanding of oncology, HIV clinical area and the current HIV treatment landscape
- Develop business acumen

Required Skills

Describe the key skills and level of proficiency required for this role

- Initiative and an eagerness to learn
- Ability to manage and prioritise multiple ongoing tasks
- Problem solving skills
- Excellent written and oral communication skills
- Ability to work well independently and in a team
- Ability to build and maintain relationships

Education

Preferred area of study 1	PhD or post doc with a focus on any of the following areas: immunology, virology, genetics, pharmacy, chemistry, medicine.
Preferred area of study 2	

Values

Expectations

Patient focus

Transparency

Respect

Integrity

Courage: Decisive, Ambition, Speaking Up, Pace, Challenge status quo when appropriate

Accountability: Results, Clarity, Prioritisation, Ownership, Compliance focussed

Development: Skills, Learning, Adaptable, Curiosity

Teamwork: Aligned, Connected, Inspiring, Contribute to a positive and inclusive work culture.