SENIOR REGULATORY AFFAIRS OFFICER

DEPARTMENT/UNIT	Institute of Vector-Borne Disease
FACULTY/DIVISION	Provost and Senior Vice-President
CLASSIFICATION	HEW Level 7
WORK LOCATION	Clayton campus

ORGANISATIONAL CONTEXT

Monash is a university of transformation, progress and optimism. Our people are our most valued asset, with our academics among the best in the world and our professional staff revolutionising the way we operate as an organisation. For more information about our University and our exciting future, please visit www.monash.edu.

The **Provost and Senior Vice-President** is the Chief Academic Officer of the University and is responsible for: setting the University's academic strategy and priorities with a view to improving the education and research performance of the University; oversight of faculties, academic related portfolios and University-wide centres and institutes, oversight of academic staffing including recruitment, development, reward and recognition, policies and procedures; strategic leadership for the delivery of academic programs; identifying and cultivating interdisciplinary areas of excellence and collaboration.

The **Institute of Vector-Borne Disease** (IVBD) falls within the Office of the Provost and Senior Vice-President. The primary purpose of the Institute is to spearhead the University's research efforts in eliminating diseases such as dengue fever and Zika. The Institute is home to dedicated laboratory facilities, including a large BSL2 and BSL3 insectary. The Institute houses the World Mosquito Program (WMP) within Monash University, an international collaborative research program designed to prevent the transmission of arboviral diseases threatening the health of people living in tropical and subtropical regions and aims to improve global health whilst significantly reducing the financial burden on local health systems in these regions.

The **World Mosquito Program** (WMP) is an international collaborative research program designed to prevent the transmission of arboviral diseases threatening the health of people living in tropical and subtropical regions and aims to improve global health whilst significantly reducing the financial burden on local health systems in these regions. The WMP uses safe and natural bacteria called Wolbachia to reduce the ability of mosquitoes to transmit mosquito-borne diseases including dengue, Zika and chikungunya. Following many years of laboratory research and field trials with promising results, the WMP is now expanding its activities worldwide and has widespread support from communities, governments and regulators. The WMP currently operates in 12 countries and is expanding.

POSITION PURPOSE

The Senior Regulatory Affairs Officer provides specialist support to the World Mosquito Program (WMP)'s business development and project implementation teams. The Senior Regulatory Affairs Officer is a key liaison point between the WMP, and internal and external client groups and partners, and is the point of contact with an Independent Safety Advisory Committee to ensure availability of relevant data and alignment with WMP's strategy.

The Senior Regulatory Affairs Officer will support the WMP's current activities and future growth by overseeing a portfolio of data and documentation relating to the safety and efficacy of the Wolbachia method. The Senior Regulatory Affairs Officer will develop clear and concise documentation to support regulatory submissions and approvals, and will provide specialist advice on the regulatory landscape relevant to the advancement of WMP's objectives.

Reporting Line: The position reports to and has broad direction from the Director, Business Development Manager, and with day-to-day direction from the Manager, Epidemiology

Supervisory Responsibilities: Not applicable

Financial Delegation: Not applicable

Budget Responsibilities: Not applicable

KEY RESPONSIBILITIES

1. Co-ordinate the collation and ongoing maintenance of a central portfolio (investigators' brochure) of data and documentation related to WMP's Wolbachia method, including laboratory, environmental, field, and epidemiological data
2. Identify gaps in this portfolio, particularly related to the demonstration of safety and quality, and work with subject matter experts within WMP to determine how these can be addressed through research or other activity
3. Act as the WMP focal point for interaction with the Independent Safety Advisory Committee, to collate and analyse relevant data from various internal and external sources, prepare reports to the committee, and disseminate their advice and recommendations
4. Provide advice and guidance in the area of regulatory affairs, including analysing national regulatory agency requirements in advance of new applications
5. Provide support in preparing clear and comprehensible, user-friendly documentation and proposals for national regulatory agencies and other key stakeholders such as the World Health Organisation (WHO), and key funders
6. Scrutinise the regulatory landscape and processes that are relevant to competing technologies and analyse how these benefit or harm prospects for WMP's method
7. Build and sustain effective relationships with a network of colleagues, clients and key stakeholders to ensure that the regulatory, safety and quality aspects of WMP's activities are managed efficiently and to a high standard

KEY SELECTION CRITERIA

Education/Qualifications

1. The appointee will have:
    - A degree qualification in life sciences, pharmacy, health, environmental science or other relevant field, with work experience in a regulatory environment related to healthcare, public health or environmental health; or

- an equivalent combination of relevant experience and/or education/training

Knowledge and Skills

2. Demonstrated experience in the preparation and submission of documentation to regulatory agencies;

3. High-level skills in scientific and technical writing, including synthesising information from multiple sources, conducting literature reviews, and writing investigators' brochures, regulatory submissions and/or technical reports

4. Demonstrated ability to collate, manipulate and evaluate scientific data, including laboratory, environmental, clinical, and epidemiological data

5. Familiarity with national and international regulatory requirements and legislation related to human health and/or environmental health products

6. Highly developed planning and organisational skills, with the ability to establish priorities, implement improvements and meet deadlines

7. Demonstrated relationship management and consulting skills, including the ability to interact with, negotiate with and gain co-operation from internal and external stakeholders

8. Demonstrated analytical, research and problem solving skills and the ability to identify and recommend solutions to challenging issues

9. Highly developed interpersonal and communication skills with the ability to prepare professional documentation for various audiences and provide expert advice in areas of specialised or functional knowledge

10. Advanced computer literacy, particularly with current business management software packages and their various applications

OTHER JOB RELATED INFORMATION

- Travel to international WMP offices and project sites may be required
- There may be a requirement to work additional hours from time to time
- There may be peak periods of work during which taking of leave may be restricted

LEGAL COMPLIANCE

Ensure you are aware of and adhere to legislation and University policy relevant to the duties undertaken, including: Equal Employment Opportunity, supporting equity and fairness; Occupational Health and Safety, supporting a safe workplace; Conflict of Interest (including Conflict of Interest in Research); Paid Outside Work; Privacy; Research Conduct; and Staff/Student Relationships.