OPERATIONS DEVELOPMENT ENGINEER (BRAIN MACHINE INTERFACES)

DEPARTMENT/UNIT	Electrical and Computer Systems Engineering
FACULTY/DIVISION	Faculty of Engineering
CLASSIFICATION	HEW Level 9
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 **Faculty of Engineering** is one of the largest in Australia, renowned worldwide for the quality and calibre of our teaching, research and graduates. We offer a comprehensive range of undergraduate, graduate, postgraduate and higher degree by research programs in a wide range of engineering disciplines. Our research activities provide a platform for establishing a thriving educational enterprise and our staff are committed to creating a dynamic learning environment. The research activities range from fundamental studies to research with a strong applications orientation. To learn more about the Faculty of Engineering, please visit our website: www.eng.monash.edu.au/.

Monash Vision Group (MVG) has been developing technologies to stimulate the visual cortex that have received research approval. The MVG team has also been working on a cortical recording device. The stimulator and recorder work together for a bidirectional brain interface. MVG is part of the Department of Electrical and Computer Systems Engineering (ECSE), in the Faculty of Engineering, Clayton. The group is directed by Professor Arthur Lowery.

Monash Vision Group is in the process of developing plans to commercialise its technologies, and has embarked on a rigorous planning process with the aim of developing Business Plans for two commercial companies that will use its Brain Machine Interface technology. The planning process is expected to take one year, during which external funding will be sought. The planning will involve: market research with clinicians and patients, competitive analysis, building relationships with health-care providers and government technology auditing, supply chain planning, regulatory and legal issues, manufacturing planning and certification and partner development.

POSITION PURPOSE

The Operations Development Engineer (Brain Machine Interfaces) supports the Project Lead (Brain-Machine Interfaces) in the delivery of the Medical Research Future Fund (MRFF) Cortical Frontiers Project operations. It is

critical in identifying the operational requirements for the companies and developing plans that are ready to execute and operationalise when phase 2 funding is obtained.

This focus includes planning the manufacturing supply chains for advanced implantable medical devices, and ensuring that the manufacturing processes will meet regulatory requirements for Class III medical devices. The supply chain will include external suppliers, within Australia and overseas; though the aim is to create a manufacturing base for the devices within Australia. The role will create ready-to-go contracts with suppliers and the organisational structures for the manufacturing sides of the two companies, including draft position descriptions for key roles, and a plans for ramp-up with key milestones.

The position will contribute to defining what is required to form commercial companies from an operations perspective, and to develop deep (and contractual) relationships with technology and research suppliers and manufacturing partners. Together with consultants, this role shall ensure that documentation and manufacturing processes are in a position to satisfy regulatory requirements for commercialisation.

Reporting Line: The position reports to Project Lead (Brain-Machine Interfaces) under broad direction, working with a considerable degree of autonomy

Supervisory Responsibilities: Not applicable

Financial Delegation: Not applicable

Budgetary Responsibilities: Not applicable

KEY RESPONSIBILITIES

1. Drive the operational planning for commercialisation, with the goal of having ready-to-go plans for two new companies in the brain-machine interface space
2. Provide dedicated support and strategic advice to the Project Lead, to support the establishment and ongoing operations of the companies
3. Lead and manage all aspects of the administrative operations of the companies, including but not limited to, project support, research performance, finance, marketing, contract negotiation, IT, compliance and the coordination and management of aligned contractors
4. Create detailed plans for viable manufacturing supply chains for implantable medical devices, including for external hardware
5. Work with regulatory consultants to ensure that the design and manufacturing processes will meet regulatory requirements, such as Therapeutic Goods Administration (TGA) and Food and Drug Administration (FDA)
6. Work collaboratively with the Monash Vision Group team to identify the most opportune applications of Brain Machine Interfaces within the capabilities of an Australian-based manufacturing industry
7. Contribute to the authoring and preparation of an outstanding grant application for Stage 2 funding
8. Plan, initiate and coordinate a broad range of outreach activities to support the objectives of the companies and create significant engagement across relevant external stakeholder groups
9. Initiate and lead continuous improvement activities, including establishing procedures and documenting them accordingly and driving and developing relevant key stakeholders to build on capability

KEY SELECTION CRITERIA

Education/Qualifications

1. The appointee will have:
    - Postgraduate qualifications in engineering and extensive process development experience and medical device expertise; or

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

Knowledge and Skills

2. Demonstrated extensive knowledge of manufacturing and regulatory requirements for implantable medical devices

3. Highly developed analytical and conceptual skills including demonstrated ability to quickly assimilate new concepts and information to support the creation of viable plans for manufacturing including regulatory approval

4. Outstanding planning and organisational skills, with experience establishing priorities, defining and allocating resources, and meeting deadlines whilst working under pressure in a large, complex organisation

5. Excellent communication skills, including the ability to liaise with senior management and stakeholders, develop communication on complex issues in a clear, succinct manner and deliver oral, written, and graphical communication on technical subject matter to a broad variety of audiences

6. Demonstrated excellent written skills and the proven ability to prepare detailed plans, process documentation, role descriptions and grant application subsections

7. Proven ability to solve highly complex problems, including through the application/use of sophisticated analytical and diagnostic skills, judgement, discretion, initiative, innovation and specialised expertise

8. Ability to negotiate supplier agreements, including identifying appropriate suppliers and calibrating their quality processes

9. Superior interpersonal and communication skills with the ability to build successful relationships with current and future suppliers, partners, managers and team-members

OTHER JOB RELATED INFORMATION

- Travel to other locations, including interstate and overseas, will 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

You are required to ensure that 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.