All Sector-based Function Guide – Biomedical Engineering

Functions of Biomedical Engineers, Technologists and Associates across sectors

Contents

Healthcare

Health & Disability

Rehabilitation Engineer & Rehabilitation Engineering Technician

1. Pressure, posture and mobility
    - Wheelchair services
    - Design, modification and optimisation of specialised and custom seating and mobility systems
    - Postural management
    - Pressure management and custom pressure care AT
    - Manipulation and mobility aids
2. Electronic Assistive Technologies
    - Specialist controls for powered mobility and alternative access to the computer and other technology
    - Brain computer interfaces
    - Creating integrated technology solutions (e.g. wheelchairs with complex seating, respiratory support and computer control)
    - Control by nerve or brain sensing systems
    - Functional Electrical Stimulation (FES)
3. Assistive Technologies for Activities of Daily Living (ADL)
    - Customisation, modification and integration of existing AT
    - Design and fabrication of custom ADL AT
    - AT to support children with life, learning and play
    - Equipment and supports relating to transferring (into and out of wheelchairs, commodes, beds and other equipment)
    - AT for persons with severe visual, auditory or tactile impairments
    - Speciality equipment, including for recreation
4. Augmentative and Alternative Communication (AAC) and Environmental Controls (EC)
    - Electronic communicators (such as speech synthesisers)
    - Adapted or specially programmed computers, telephones or other ICT (including sensory systems)
5. Clinical Movement Analysis
    - Advanced kinematics
    - Analysis of human performance (incl. quantitative and qualitative tools)
    - Biomechanics of movement
    - Gait analysis

6. Prostheses and Orthoses
    - Design and development of physical prostheses and orthoses
    - Design and development of sensory prostheses
    - Modification and optimisation of existing prostheses and orthoses

Medical device design and manufacture (personalised medical devices)

- Medical Specialist consultation and support
- Design of personalised medical devices
- Documentation of design and manufacture
- Manufacture and management of traditional manufacturing of medical devices
- Advise clinical staff (Medical, Nursing and Allied Health) on Engineering issues
- Manage and oversee risk analysis and regulatory compliance
- Develop and maintain quality management systems
- Develop novel Medical Devices in response to Clinical need

Clinical Engineering

Clinical Engineer and Biomedical Engineering Technician

1. Clinical Support
    - Education, incident investigation and collaboration with clinical specialists and partners
    - Home patients and associated technology (selection, installation, use education, troubleshooting)
    - Specialist clinical services support (i.e. bypass, pacemaker, ventilation and balloon pumps)
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2. Health Technology & Infrastructure Asset Management
    - Life cycle management of medical devices and systems (i.e. general medical and dental equipment, hospital in home devices, simulation centres, research facilities, wearable devices, pathology equipment, medical imaging systems and radiation therapy treatment systems)
    - Specialist clinical technology support (i.e. bypass, pacemaker, ventilation and balloon pumps)
    - Management of health technology infrastructure including medical gas and electrical safety
    - Hospital redevelopment and service development project support
    - Service contract management and associated vendor performance in delivering service.
    - Support in the National Safety and Quality Health Service (NSQHS) Standards and other compliance audit activities.
    - Support of Radiation Safety (including laser / non-ionising)
3. Standards and Compliance
    - Maintain regulatory and standards compliance applicable to medical devices and systems
    - Development of policies and procedures
    - Post-market regulatory support (recall management, adverse event reporting)
    - Assessment, documentation and implementation of non-OEM part use
    - Assessment, documentation and implementation of maintenance programs deviating from manufacturer's recommendations
4. Health Technology R&D
    - Collaborate with universities, clinicians and industry partners in R&D projects
5. Medical Systems and Cybersecurity
    - Support Internet of Medical Things (IoMT) and Tele-health products, systems and services
    - Medical device/information technology integration and support
    - Medical systems design, documentation, connection and testing
    - Cybersecurity assessment, documentation and connection

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Medical Technology Design and Manufacturing

(including personalised medical devices)

Research Engineer

- Literature review
- Clinical consultation
- Needs analysis
- Concept generation and prototyping
- Proof-of-concept assessments
- Preparation and handover of documentation to inform product development

Product Development Engineer

- Product development Project Management/Implementation
- Design of medical devices within an ISO 13485 certified quality management framework
    - design controls (design inputs, design outputs, verification and validation, manufacturing transfer)
    - risk management (ISO 14971)
- Design History File and Device Master File creation
- Supply chain procurement
- Design for manufacture at scale
- Compliance with relevant Australian and International Standards
- Design of medical devices in compliance with relevant Australian and International standards
- Collaboration and communication with various disciplines (e.g. Quality Assurance, Regulatory Affairs, Production and Sales & Marketing Representatives)

Quality Assurance Engineer

- Establishing or maintaining a compliant Quality Management System (I.e. ISO 13485, MDSAP, 21 CFR 820)
- Product development project team member (compliance with the QMS and relevant domestic and international regulatory frameworks)
- Oversight of engineering change management
- Corrective and preventive action oversight, root cause analysis, solution development and implementation
- Complaint and non-conformance investigation including management of risk for non-conformance in releasing products

- Collaboration and communication with various departments/disciplines including regulatory affairs, product development, production and procurement

Regulatory Affairs Engineer

- Product development project team member (relevance to regulatory requirements I.e. for design testing)
- Regulatory submission documentation development and ongoing management
- Post-market activities (e.g. vigilance monitoring, regulatory reporting, recall management, registration renewal, surveillance)

Production/Process Engineer

- Product development project team member (design for manufacture)
- Process qualification (IQ/OQ/PQ)
- Design/manufacturing transfer
- Risk management activities related to medical device/system process
- Design and manufacture of custom production tools and equipment appropriate to GMP
- Good manufacturing practice for maintaining quality during production
- Procedure and process efficiency development, monitoring and maintenance

Research & Education

Research (PhD, Post-doc, Academic)

- Develop and investigate new theories in clinical, biological and anatomical domains using engineering principles
- Perform detailed literature reviews
- Identify new opportunities for innovation and development of new ideas
- Generation of new theoretical perspectives to solve unmet clinical and societal needs
- Design and conduct rigorous scientific experiments
- Operation and development of advanced laboratory and technical equipment that enhance research outcomes
- Perform proof of concept testing
- Document applications for funding and ethics approvals
- Record and analyse data/information using relevant techniques
- Document scientific theory, process and outcomes in the form of a research paper for peer review
- Conduct contract research for industry and document reports
- Contribute to the public and elevate public awareness of educational and scientific developments
- Promote critical enquiry and public debate in public discourse within the community where appropriate
- Present research to scientific community, industry, government
- Collaborate with scientific community, industry, government

Curriculum development

- Liaise with peers, relevant industry representatives and relevant professional organisations
- Design of graduate programs relevant to available career pathways within Biomedical Engineering
- Design of course/subject outlines ensuring overall content meets the expectations of accrediting bodies and future employers of Biomedical Engineers

Teaching

- Contextual delivery of biomedical engineering content
- Demonstrate practical examples of content implementation
- Support student learning
- Oversee assessment of content
- Mentoring students in the undergraduate and post graduate degrees and providing career guidance

Sport

Sports Equipment (Disability & Elite Athlete solutions)

(seeking confirmation and input from the Biomedical Community practicing in this area)

Regulatory (TGA, FDA, Certified Bodies)

Reviewers

- Technical experts reviewing medical technology submission files
- Assess compliance of submitted medical technology relevant to associated target market(s)
- Liase with clients and internal experts

Auditors

- Review client information demonstrating compliance with requirements (I.e. compliance systems, technical files)
- Attend client premises
- Interview stakeholders

Post Market Vigilance Monitoring and Investigation

- Research into clinical/technical area relevant to issue raised
- Investigation of issue raised (I.e. stakeholder consultation, root cause analysis)
- Reporting of outcomes

Regulatory development/reform

- Preparation of consultation papers
- Identification of stakeholders for consultation
- Collaboration with stakeholder advisory groups
- Policy development

Regulatory (NDIS)

(seking confirmation and input from the Biomedical Community practicing in this area)

Medical Device Supply Chain – Service Provider

Contract Medical Technology Manufacturing

- See Production Engineer
- See Quality Assurance Engineer
- See Regulatory Affairs Engineer

Packaging and Sterilisation

- Production Engineer
- Quality Engineer

Industrial Design/Biomedical Designer

- This role does not hold an engineering qualification, but is a stakeholder in product development team

Private Industry - Other

Rehabilitation Engineering Services

- See Rehabilitation Engineer

Biomedical Consultant

- As advertised by the consultancy in the context of the sectors and roles outlined in this document

Medical Technology Supplier – Biomedical Engineer

- Installation, maintenance (corrective & preventive)

Examples of role titles

Healthcare

Biomedical Engineering Function	Examples of Role Titles in Use
Rehabilitation Engineer	Rehabilitation Engineer Senior Rehabilitation Engineer (>3 years' experience expected) Principal Rehabilitation Engineer (>5 years' experience expected) Consultant Rehabilitation Engineer
Rehabilitation Engineering Technician	Rehabilitation Engineering Technician
Clinical Engineer	Clinical Engineer Biomedical Engineer
Biomedical Technician (Clinical Engineering)	Biomedical Technician
Clinical Engineer - Medical Systems and Cybersecurity	Biomedical Engineer
Clinical Engineer - Medical device design and manufacture – personalised medical devices	Biomedical Engineer Product Development Engineer

Health Technology Design and Manufacturing

Biomedical Engineering Function	Examples of Role Titles in Use
Research	Research & Development Engineer (Research combined with product development)
Product Development	Research & Development Engineer (Research combined with product development) Design Engineer
Quality Assurance	Quality Assurance Engineer

Production	Production Engineer
Asset Management	Engineer

Research & Education

Biomedical Engineering Function	Examples of Role Titles in Use
Research	Lecturer Senior Lecturer (assistant professor) Associate Professor Professor Dean
Curriculum development	Lecturer Senior Lecturer (assistant professor) Associate Professor Professor Dean
Teaching	Tutor Lab Demonstrator Lecturer Senior Lecturer (assistant professor) Associate Professor Professor Dean

Regulatory (TGA, NDIS, Certified Bodies)

Biomedical Engineering Function	Examples of Role Titles in Use
Reviewers	
Auditors	
Post-market Vigilance Monitoring and Investigation	

Regulatory Development/Reform	

Medical Device Supply Chain & Private Industry

Biomedical Engineering Function	**Examples of Role Titles in Use**
Service Engineer	
Service Technician	
Biomedical Consultant	