

SSBIO04 - Biomedical Textile Product Development Engineer

Disclaimer

These Occupational Frameworks and Skill Profiles have been developed as workforce planning, occupational mapping and skills reference resources for the Australian textile, clothing and footwear (TCF) industry. They are intended to describe the typical functions, responsibilities, skills and capabilities associated with occupations across the industry.

These documents are not intended to replace or override industrial instruments or employment arrangements, including awards, enterprise agreements, employment contracts, position descriptions, classification structures, licensing or regulatory requirements, or other statutory obligations. Where differences arise, the relevant industrial, legislative or regulatory requirements take precedence. The Skill Profiles should be used as complementary reference documents to support workforce planning, career development, training and skills recognition.

1. Job role

TCF sub-sector	Biomedical Textiles
Functional area	Research and Product Development
Job role	SSBIO05 Biomedical Textile Product Development Engineer
Job role description	Designs, develops, validates and commercialises biomedical textile products for healthcare, medical device, rehabilitation and protective applications. The role leads multidisciplinary product development from concept through design, prototype evaluation, verification, validation, regulatory compliance and transfer to manufacture.
Performance expectations	• Lead product design and development. • Select appropriate materials. • Develop engineering specifications. • Plan verification and validation. • Interpret laboratory and clinical results. • Ensure ISO 13485 and regulatory compliance. • Lead risk management. • Support commercialisation. • Mentor technical staff. • Deliver projects on time and within budget.
Specialisation	Biomedical textile engineering, medical devices, advanced materials, product validation, regulatory compliance, innovation.
Application in other TCF sectors	• Technical textiles. • Defence and protective textiles. • Smart textiles. • Advanced manufacturing. • Medical devices. • Research and development.

2. Key tasks and critical work functions

Key tasks	• Design biomedical textile products. • Prepare engineering specifications. • Select fibres, fabrics and components. • Lead prototype evaluation. • Develop validation protocols. • Analyse technical data. • Manage technical documentation. • Coordinate multidisciplinary teams. • Support production transfer. • Ensure regulatory compliance.
Critical work functions	• Deliver innovative products. • Ensure engineering integrity. • Maintain compliance. • Improve manufacturability. • Manage technical risk. • Drive continuous improvement.

3. Technical skills

Product engineering	Designing biomedical textile products.
Materials engineering	Selecting suitable fibres, fabrics and composites.
Verification and validation	Developing and approving validation programs.
Risk management	Applying medical device risk management principles.
Regulatory compliance	Supporting ISO 13485 and applicable regulatory requirements.
Data analysis	Interpreting laboratory and clinical performance data.
Project management	Managing technical development projects.
Commercialisation	Supporting transfer from development to production.

4. Generic Skills

Leadership	Leading multidisciplinary technical teams.
Communication	Communicating technical information to diverse stakeholders.
Problem solving	Resolving complex engineering issues.
Critical thinking	Evaluating technical alternatives.
Planning	Managing priorities and project schedules.
Collaboration	Working with clinicians, scientists and manufacturers.
Ethical practice	Supporting safe and compliant medical products.

5. Emerging skills

Emerging skills	• Smart and connected textiles. • Digital engineering.
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	• AI-assisted product development. • Sustainable biomaterials. • Additive manufacturing. • Digital quality management.
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6. VET Qualifications and Skill Sets

Entry-level preparation	Bachelor of Engineering (Biomedical, Mechanical, Manufacturing or Materials), Textile Engineering or equivalent.
Advanced development	Postgraduate qualifications in Biomedical Engineering, Materials Engineering, Medical Devices, Regulatory Affairs or Innovation Management.

7. Job progression

Possible job progression	Graduate Product Development Engineer → Biomedical Textile Product Development Engineer → Senior Product Development Engineer → Principal Engineer → Technical Manager → Innovation Manager → R&D Manager
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8. Classification

Australian Qualifications Framework	AQF Level 6+
Australian Bureau of Statistics (ABS) Skill Levels	Skill Level 1
Open Source Classification of Occupations for Australia (OSCA)	243934 Engineering Technologist OSCA Specialisation Biomedical Engineering Technologist



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