

SSBIO14 Regulatory Affairs Specialist

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	SSBIO14 Regulatory Affairs Specialist
Job role description	Manages regulatory compliance, product registration and lifecycle documentation for biotextile products ensuring all products meet national and international regulatory requirements prior to and during market use. In the Australian biotextile sector, this role is critical in ensuring that products such as surgical textiles, implantable materials, wound care systems and advanced clinical fabrics comply with Therapeutic Goods Administration (TGA) requirements, ISO standards (including ISO 13485) and applicable international frameworks. The Regulatory Affairs Specialist ensures that products are appropriately classified, documented, assessed and approved for clinical use. The role involves preparing and maintaining technical files, managing regulatory submissions, supporting audits and inspections, monitoring regulatory changes and ensuring ongoing compliance throughout the product lifecycle. It requires close collaboration with product development, quality assurance, manufacturing, sterilisation and clinical teams. The position ensures that all biotextile products entering or remaining in the market are safe, effective and compliant with all relevant regulatory and quality requirements, supporting both patient safety and organisational risk management.
Performance expectations	- Ensuring all products meet TGA and international regulatory requirements - Preparing accurate and complete regulatory submissions and technical documentation - Maintaining compliance across the full product lifecycle

	- Monitoring regulatory changes and updating internal systems accordingly - Supporting audits, inspections and regulatory reviews - Ensuring traceability and documentation integrity - Minimising regulatory risk and non-compliance issues - Supporting timely product approvals and market access - Maintaining alignment between regulatory, quality and manufacturing systems
Specialisation	Regulatory submissions, medical textile compliance, TGA processes, ISO 13485 systems, product lifecycle regulation
Application in other TCF sectors	- Medical device regulatory affairs - Pharmaceutical regulatory compliance - Biotechnology and biomaterials sectors - Advanced manufacturing and quality systems - Defence and high-specification regulated industries

2. Key tasks and critical work functions

Key tasks	- Preparing and submitting regulatory applications and product registrations - Compiling and maintaining technical documentation and design dossiers - Classifying products according to regulatory frameworks - Monitoring regulatory changes and updating compliance strategies - Supporting internal and external audits and inspections - Liaising with regulatory bodies and notified bodies - Maintaining product lifecycle compliance documentation - Supporting risk management and post-market surveillance - Collaborating with QA, R&D and production teams
Critical work functions	- Ensuring products meet all regulatory and safety requirements - Maintaining compliance across all stages of the product lifecycle - Preventing regulatory non-compliance and associated risks - Supporting safe market entry and continued product approval - Maintaining integrity and traceability of regulatory documentation - Enabling successful audits and regulatory reviews - Supporting patient safety through compliant product systems - Aligning regulatory requirements with manufacturing and quality processes

3. Technical skills

Regulatory frameworks	Understanding TGA, ISO 13485 and international regulations
Technical documentation	Preparing technical files, dossiers and submissions
Product classification	Assigning correct regulatory classifications
Audit support	Preparing for and supporting regulatory audits
Risk management	Applying risk assessment and mitigation strategies

Post-market surveillance	Monitoring product performance and compliance after release
Documentation systems	Managing controlled regulatory documentation
Compliance analysis	Interpreting and applying regulatory requirements

4. Generic Skills

Attention to detail	Ensuring accuracy in regulatory documentation
Analytical thinking	Interpreting complex regulatory frameworks
Communication	Liaising with regulators and internal teams
Problem solving	Resolving compliance issues
Teamwork	Working across cross-functional teams
Time management	Managing submissions and deadlines
Professionalism	Maintaining ethical and compliance standards

5. Emerging skills

Emerging skills	• Digital regulatory submission systems and eCTD platforms • Global regulatory harmonisation and international market access • Data analytics for post-market surveillance • Integration with digital quality management systems (eQMS) • AI-assisted regulatory compliance tools • Advanced risk-based regulatory frameworks
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6. VET Qualifications and Skill Sets

Entry-level preparation	No qualification
Advanced development	Degree in Biomedical Engineering, Regulatory Affairs, Science, Law or related field

7. Job progression

Possible job progression	Regulatory Assistant → Regulatory Affairs Specialist → Senior Specialist → Regulatory Manager → Director of Regulatory Affairs
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8. Classification

Australian Qualifications Framework	Level 5-7
Australian Bureau of Statistics (ABS) Skill Levels	Skill Level 1
Open Source Classification of Occupations for Australia (OSCA)	111632 Regulatory Affairs Manager



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