

SSBIO09 Cleanroom Production Technician – Biomaterials and Implantable Textile Materials

1. Job role

TCF sub-sector	Biomedical Textiles
Functional area	Manufacturing –Biomaterials and Implantable Textile Products
Job role	SSBIO09 Cleanroom Production Technician – Biomaterials and Implantable Textile Materials
Job role description	Performs controlled-environment manufacturing of biomaterials and implantable textile products, ensuring sterility, material integrity, precision construction and compliance with strict clinical and regulatory requirements. In the Australian biomedical textiles sector, this role is critical in the production of high-risk products such as implantable meshes, scaffolds, advanced wound care biomaterials and specialised clinical textiles. These products must be manufactured in cleanroom environments to prevent contamination and ensure patient safety. The role involves operating within classified cleanroom environments (e.g. ISO Class environments), handling sensitive biomaterials, performing precision fabrication or assembly processes and maintaining strict contamination control protocols. The technician must comply with ISO 13485, TGA requirements and validated manufacturing procedures. The position works closely with quality assurance teams, process engineers, sterilisation specialists and research and development personnel to ensure that products meet clinical specifications, sterility requirements and performance standards suitable for implantation or advanced clinical use.
Performance expectations	- Producing biomaterials and implantable textile products to exact clinical specifications - Maintaining strict contamination control within cleanroom environments - Ensuring product integrity, sterility readiness and traceability - Minimising defects, contamination events and process deviations - Following validated manufacturing and cleanroom protocols

	• Maintaining accurate documentation and batch records • Supporting compliance with ISO and regulatory standards • Contributing to continuous improvement and process reliability
Specialisation	Cleanroom manufacturing, implantable textiles, biomaterials processing, contamination control, sterile production systems
Application in other TCF sectors	• Medical device manufacturing • Pharmaceutical cleanroom production • Biotechnology and biomaterials processing • Advanced materials manufacturing • Defence and high-specification manufacturing environments

2. Key tasks and critical work functions

Key tasks	• Preparing and maintaining cleanroom work environments • Donning and doffing appropriate cleanroom garments (PPE) • Handling biomaterials and implantable textile components • Operating specialised equipment for fabrication or assembly • Performing precision manufacturing or assembly tasks • Monitoring environmental and process parameters • Recording production and batch data • Cleaning and maintaining equipment and workstations • Collaborating with quality and technical teams
Critical work functions	• Ensuring sterility and contamination control in all production activities • Maintaining integrity of biomaterials and implantable products • Ensuring compliance with cleanroom standards and protocols • Preventing product defects that could impact patient safety • Maintaining full traceability of materials and processes • Supporting audit readiness and regulatory compliance • Enabling safe and reliable production of implantable and clinical products • Maintaining consistency and repeatability in controlled processes

3. Technical skills

Cleanroom operation	Working within classified cleanroom environments
Contamination control	Applying aseptic techniques and particulate control
Biomaterial handling	Managing sensitive and implantable materials
Precision fabrication	Performing high-accuracy manufacturing or assembly
Process monitoring	Observing environmental and process parameters
Equipment operation	Using specialised cleanroom-compatible equipment
Documentation and traceability	Maintaining compliant production records
Quality compliance	Applying ISO 13485 and regulatory standards

4. Generic Skills

Attention to detail	Ensuring precision and contamination control
Communication	Working with technical and quality teams
Problem solving	Identifying and resolving process issues
Teamwork	Supporting integrated cleanroom operations
Time management	Meeting production and process timelines
Discipline	Adhering strictly to cleanroom protocols
Professionalism	Maintaining compliance and high standards

5. Emerging skills

Emerging skills	• Advanced biomaterials and tissue engineering textiles • Automation and robotics in cleanroom production • Real-time environmental monitoring systems • Digital batch records and traceability systems • Nanotechnology and smart biomaterials • Sustainable and bio-based implantable materials
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6. VET Qualifications and Skill Sets

Entry-level preparation	FBP30822 Certificate III in Pharmaceutical Manufacturing or equivalent in Manufacturing, Process Operations or Laboratory Skills
Advanced development	FBP40518 Certificate IV in Pharmaceutical Manufacturing or equivalent at Certificate IV or Diploma in Biotechnology, Manufacturing, Biomedical Engineering or Quality Assurance

7. Job progression

Possible job progression	Cleanroom Operator → Cleanroom Production Technician → Senior Technician → Process or Quality Specialist → Production or Technical Manager
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8. Classification

Australian Qualifications Framework	Level 3-5
Australian Bureau of Statistics (ABS) Skill Levels	Skill Level 2-3
Open Source Classification of Occupations for Australia (OSCA)	Cleanroom Production Technician – Biomedical Textiles / Biomaterials

MSA30107 Certificate III in Process Manufacturing or equivalent
MSM40116 Certificate IV in Process Manufacturing or equivalent



Skills Insight is a Jobs and Skills Council funded by the Australian Government Department of Employment and Workplace Relations.