

SSBIO11 Process and Quality Technician – Biomaterials and Implantable Textile Materials

1. Job role

TCF sub-sector	Biomedical Textiles
Functional area	Manufacturing – Biomaterials and Implantable Textile Products
Job role	SSBIO11 Process and Quality Technician – Biomaterials and Implantable Textile Materials
Job role description	Monitors, controls and verifies manufacturing processes and product quality for biomaterials and implantable textile products, ensuring compliance with clinical, regulatory and performance requirements. In the Australian biomedical textiles sector, this role is critical in ensuring that high-risk products such as implantable meshes, scaffold materials and advanced wound care textiles meet strict standards for safety, consistency, biocompatibility and traceability. The Process and Quality Technician operates across production environments, cleanrooms and testing interfaces to maintain validated processes and confirm product conformity. The role involves process monitoring, in-line and final product inspection, testing coordination, data analysis and documentation. It requires strict adherence to ISO 13485, TGA requirements and validated quality systems. The technician works closely with production teams, cleanroom operators, engineers and quality assurance personnel to ensure all materials and products meet required specifications and are suitable for clinical and implantable use.
Performance expectations	• Ensuring manufacturing processes operate within validated parameters • Verifying product quality against clinical and technical specifications • Maintaining traceability of materials, batches and production data • Identifying and managing non-conformances and deviations • Supporting continuous improvement of processes and quality systems • Maintaining accurate and compliant documentation • Supporting audit readiness and regulatory compliance • Minimising defects, variability and process inefficiencies

Specialisation	Process control, quality assurance, validation, biomaterials testing, implantable textile compliance
Application in other TCF sectors	• Medical device manufacturing • Pharmaceutical production and QA • Biotechnology and biomaterials processing • Advanced manufacturing quality systems • Defence and high-specification manufacturing

2. Key tasks and critical work functions

Key tasks	• Monitoring production processes and recording critical parameters • Conducting in-line and final product inspections • Verifying compliance with specifications and standards • Managing non-conformance reporting and corrective actions • Supporting validation and qualification activities • Maintaining batch records and traceability documentation • Coordinating testing and inspection activities • Collaborating with production and engineering teams
Critical work functions	• Ensuring product safety and suitability for clinical and implantable use • Maintaining integrity of validated manufacturing processes • Preventing release of non-compliant or defective products • Supporting regulatory compliance and audit readiness • Maintaining full traceability of materials and processes • Enabling continuous improvement in quality and process performance • Supporting consistent and repeatable production outcomes

3. Technical skills

Process monitoring	Tracking and controlling production parameters
Quality inspection	Conducting visual and technical inspections
Testing coordination	Supporting laboratory and validation testing
Data analysis	Interpreting process and quality data
Non-conformance management	Identifying and resolving deviations
Documentation and traceability	Maintaining compliant records and batch tracking
Regulatory compliance	Applying ISO 13485 and TGA requirements
Validation support	Assisting in process validation and verification activities

4. Generic Skills

Attention to detail	Ensuring accuracy in monitoring and inspection
Communication	Working with production, QA and engineering teams
Problem solving	Resolving quality and process issues

Teamwork	Supporting integrated manufacturing systems
Time management	Meeting production and reporting timelines
Analytical thinking	Interpreting data and trends
Professionalism	Maintaining compliance and documentation standards

5. Emerging skills

Emerging skills	• Digital quality systems and electronic batch records • Real-time process monitoring and analytics • Advanced biomaterials testing methods • Automation and AI in quality control • Risk-based quality management systems • Integration with smart manufacturing systems
-----------------	--

6. VET Qualifications and Skill Sets

Entry-level preparation	MSA40108 Certificate IV in Manufacturing Technology or equivalent in Laboratory Skills or Quality Assurance
Advanced development	MSM50316 Diploma of Production Management or diploma or bachelor's degree in Quality Assurance, Biomedical Engineering, Materials Science or Manufacturing

7. Job progression

Possible job progression	Quality Assistant → Process and Quality Technician → Senior Quality Specialist → Quality Engineer → Quality or Compliance Manager
--------------------------	---

8. Classification

Australian Qualifications Framework	Level 4-6
Australian Bureau of Statistics (ABS) Skill Levels	Skill Level 2-3
Open Source Classification of Occupations for Australia (OSCA)	Process and Quality Technician - Biomedical Textiles / Biomaterials



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