

# SSBIO12 Sterilisation and Validation Technician – Biomaterials and Implantable Textile Materials

## 1. Job role

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| TCF sub-sector           | Biomedical Textiles                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Functional area          | Manufacturing – Biomaterials and Implantable Textile Materials                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Job role                 | SSBIO12 Sterilisation and Validation Technician – Biomaterials and Implantable Textile Materials                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Job role description     | <p>Performs validation, verification and monitoring of sterilisation processes for biomaterials and implantable textile products, ensuring sterility assurance, product integrity and compliance with stringent clinical and regulatory standards.</p> <p>In the Australian biomedical textiles sector, this role is critical in ensuring that high-risk products such as implantable meshes, scaffolds, advanced wound care materials and sterile textile systems are effectively sterilised and safe for clinical use. The Sterilisation and Validation Technician ensures that sterilisation processes (such as steam, ethylene oxide (EO), gamma irradiation or other validated methods) are correctly designed, validated, monitored and controlled.</p> <p>The role involves conducting validation protocols, monitoring sterilisation parameters, analysing data, verifying sterility assurance levels (SAL), and maintaining detailed documentation. The technician must comply with ISO 13485, ISO 11135/11137 (as applicable), TGA requirements and validated internal procedures.</p> <p>The position works closely with quality assurance teams, process engineers, cleanroom production staff and external sterilisation service providers to ensure that all sterilisation processes are effective, repeatable and compliant, and that products maintain their performance and biocompatibility after sterilisation.</p> |
| Performance expectations | <ul style="list-style-type: none"> <li>Validating sterilisation processes to meet required sterility assurance levels</li> <li>Monitoring and verifying sterilisation cycle parameters and performance</li> <li>Ensuring compliance with ISO, TGA and regulatory standards</li> <li>Maintaining integrity and performance of biomaterials post-sterilisation</li> <li>Managing and documenting validation and verification activities</li> <li>Identifying and addressing deviations and non-conformances</li> <li>Maintaining full traceability of sterilisation batches and loads</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

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|                                  | <ul style="list-style-type: none"> <li>Supporting audit readiness and regulatory inspections</li> <li>Minimising risks associated with sterilisation failure or variability</li> </ul>                                                                                                                                                       |
| Specialisation                   | Sterilisation validation, process verification, sterility assurance, regulatory compliance, biomaterials sterilisation                                                                                                                                                                                                                       |
| Application in other TCF sectors | <ul style="list-style-type: none"> <li>Medical device sterilisation and validation</li> <li>Pharmaceutical sterilisation and quality systems</li> <li>Biotechnology and laboratory environments</li> <li>Defence and high-specification manufacturing</li> <li>Advanced manufacturing requiring validated sterilisation processes</li> </ul> |

## 2. Key tasks and critical work functions

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| Key tasks               | <ul style="list-style-type: none"> <li>Developing and executing sterilisation validation protocols (IQ/OQ/PQ)</li> <li>Monitoring sterilisation processes and recording critical parameters</li> <li>Analysing data from sterilisation cycles and validation studies</li> <li>Verifying sterility assurance levels and process effectiveness</li> <li>Managing biological indicators, chemical indicators and dosimetry (as applicable)</li> <li>Investigating deviations and implementing corrective actions</li> <li>Maintaining validation and batch documentation</li> <li>Coordinating with external sterilisation providers if applicable</li> <li>Supporting audits and regulatory submissions</li> </ul> |
| Critical work functions | <ul style="list-style-type: none"> <li>Ensuring all products meet required sterility assurance levels (SAL)</li> <li>Maintaining validated and controlled sterilisation processes</li> <li>Preventing release of non-sterile or compromised products</li> <li>Ensuring compliance with regulatory and quality frameworks</li> <li>Maintaining traceability and documentation integrity</li> <li>Supporting patient safety through effective sterilisation</li> <li>Enabling repeatable and reliable sterilisation outcomes</li> <li>Supporting continuous improvement of sterilisation processes</li> </ul>                                                                                                      |

## 3. Technical skills

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|--------------------------------|--------------------------------------------------------------------------------|
| Sterilisation methods          | Understanding and applying steam, EO, gamma and other sterilisation techniques |
| Validation protocols           | Conducting IQ/OQ/PQ and revalidation activities                                |
| Process monitoring             | Tracking temperature, pressure, gas concentration, time and dose parameters    |
| Indicator systems              | Using biological and chemical indicators and dosimetry tools                   |
| Data analysis                  | Interpreting validation and process performance data                           |
| Regulatory compliance          | Applying ISO 13485, ISO 11135/11137 and TGA requirements                       |
| Documentation and traceability | Maintaining compliant validation records and batch documentation               |
| Risk management                | Identifying and mitigating sterilisation risks and failures                    |

#### 4. Generic Skills

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|---------------------|------------------------------------------------------------|
| Attention to detail | Ensuring precision in validation and monitoring activities |
| Analytical thinking | Interpreting complex data and identifying trends           |
| Communication       | Working with QA, engineering and production teams          |
| Problem solving     | Investigating and resolving deviations                     |
| Teamwork            | Supporting integrated compliance systems                   |
| Time management     | Managing validation schedules and deadlines                |
| Professionalism     | Maintaining compliance and documentation standards         |

#### 5. Emerging skills

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| Emerging skills | <ul style="list-style-type: none"> <li>Advanced sterilisation technologies (low-temperature, plasma, novel methods)</li> <li>Real-time process monitoring and digital validation systems</li> <li>Data analytics and predictive quality systems</li> <li>Integration with Industry 4.0 manufacturing environments</li> <li>Sustainable and low-impact sterilisation processes</li> <li>Advanced biomaterial compatibility assessment post-sterilisation</li> </ul> |
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#### 6. VET Qualifications and Skill Sets

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| Entry-level preparation | HLT47015 Certificate IV in Sterilisation Services or equivalent in Manufacturing, Laboratory Skills, or Quality Assurance                                     |
| Advanced development    | MSL50122 Diploma of Laboratory Technology or Bachelor's Degree in Biomedical Engineering, Quality Assurance, Microbiology, Materials Science or related field |

#### 7. Job progression

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| Possible job progression | Validation Assistant → Sterilisation and Validation Technician → Senior Validation Specialist → Quality/Validation Engineer → Quality or Regulatory Manager |
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#### 8. Classification

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| 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) | Sterilisation and Validation Technician - Biomedical Textiles / Biomaterials |



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