
## Online learning course outline

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| Topics | Learning objectives | Competency standards addressed* |
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| **Preventing Disaster** | • Describe learnings from previous compounding disasters<br>• Identify risks to mitigate to prevent disaster | 4.7.7 |
| **Understanding the regulations of non-aseptic and aseptic compounding** | • Describe the differences between legislation and standards relating to non-aseptic and aseptic compounding<br>• Outline the regulations for non-aseptic compounding<br>• Outline the regulations for aseptic compounding | 1.3.1, 3.4.2 |

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| **Understanding the regulations of advanced therapeutics preparation** | • Identify types of advanced therapeutic preparations<br>• Explain the regulations for gene therapy preparation<br>• Explain the regulations for CAR T-cell preparation<br>• Explain the regulations for bacteriophage preparation | 1.3.1, 3.4.2 |
| **Quality assurance and Quality Control** | • Explain the importance of quality assurance and quality control in compounding Describe an ongoing stability program<br>• Describe the environmental monitoring system required for compounding | 1.3.1, 4.5.2, 4.7.1 |
| **How to apply a beyond use date?** | • Describe factors considered when applying a beyond use date<br>• Explain factors considered when extending a beyond use date | 3.4.7 |
| **Case study: Product risk assessment** | • Explain the importance of a risk assessment in medicines production<br>• Identify risk assessment requirements in medicines production<br>• Explain risk assessment requirements for investigational medical products<br>• Describe how to identify reputable formulas | 3.4.3, 4.7.1, 4.7.7 |
| **Who is responsible? Including the role of the DTC** | • Describe the responsibilities of the Director of Pharmacy in the production of medicines<br>• Identify what can and cannot be delegated<br>• Describe the responsibilities for gene therapy<br>• Describe the responsibilities for CAR T-cell therapy<br>• Describe the responsibilities for bacteriophage therapy | 3.4.3, 4.6.3, 4.7.1, 4.2.3 |

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| **Infrastructure requirements and compliance to standards** | • Explain how to complete the Production facilities compliance to standards form<br>• Describe the infrastructure and equipment requirements for non-aseptic compounding<br>• Describe the infrastructure and equipment requirements for hazardous non-aseptic compounding<br>• Describe the infrastructure and equipment requirements for aseptic compounding<br>• Describe the infrastructure and equipment requirements for hazardous aseptic compounding<br>• Describe the infrastructure and equipment requirements for biohazard aseptic compounding | 4.4.3, 4.5.2 |
| **Occupational exposure and risk assessment** | • Explain how to assess products for occupational risk<br>• Identify complex calculations undertaken in risk assessments<br>• Define experienced staff in the context of the production of medicines | 3.4.2, 4.7.7 |
| **Case study: Occupational exposure flow chart** | • Describe how to apply the occupational exposure flow chart in practice | 3.4.2, 4.7.7 |
| **Staffing requirements** | • Outline how to introduce a staff risk assessment<br>• Identify requirements for staff entering a cleanroom environment<br>• Identify the staff training needs for compounding and production areas | 4.6.2, 5.1.1 |
| **Third party supplier agreements and outsourcing** | • Differentiate between TGA licenced manufacturing, TGA GMP compliance and PIC/S compliance<br>• Describe the evidence required to approve outsourcing | 3.4.1, 3.4.2 |
| **Documentation in compounding and preparation** | • Describe the types of records required for a compounding pharmacy | 3.4.7 |

**National Competency Standards Framework for Pharmacists in Australia, 2016*