

Pharmaceutical and advanced therapeutic products governance education package

Online learning course outline

This content is presented by **Kerry Watts**, Senior Project and Policy Officer, Advanced Therapeutics, Office for Health and Medical Research, NSW Ministry of Health

Topics	Learning objectives	Competency standards addressed*
Preventing Disaster	<ul style="list-style-type: none"> Describe learnings from previous compounding disasters Identify risks to mitigate to prevent disaster 	4.7.7
Understanding the regulations of non-aseptic and aseptic compounding	<ul style="list-style-type: none"> Describe the differences between legislation and standards relating to non-aseptic and aseptic compounding Outline the regulations for non-aseptic compounding Outline the regulations for aseptic compounding 	1.3.1, 3.4.2
Understanding the regulations of advanced therapeutics preparation	<ul style="list-style-type: none"> Identify types of advanced therapeutic preparations Explain the regulations for gene therapy preparation Explain the regulations for CAR T-cell preparation Explain the regulations for bacteriophage preparation 	1.3.1, 3.4.2
Quality assurance and Quality Control	<ul style="list-style-type: none"> Explain the importance of quality assurance and quality control in compounding Describe an ongoing stability program Describe the environmental monitoring system required for compounding 	1.3.1, 4.5.2, 4.7.1
How to apply a beyond use date?	<ul style="list-style-type: none"> Describe factors considered when applying a beyond use date Explain factors considered when extending a beyond use date 	3.4.7
Case study: Product risk assessment	<ul style="list-style-type: none"> Explain the importance of a risk assessment in medicines production Identify risk assessment requirements in medicines production Explain risk assessment requirements for investigational medical products Describe how to identify reputable formulas 	3.4.3, 4.7.1, 4.7.7
Who is responsible? Including the role of the DTC	<ul style="list-style-type: none"> Describe the responsibilities of the Director of Pharmacy in the production of medicines Identify what can and cannot be delegated Describe the responsibilities for gene therapy Describe the responsibilities for CAR T-cell therapy Describe the responsibilities for bacteriophage therapy 	3.4.3, 4.6.3, 4.7.1, 4.2.3

<p>Infrastructure requirements and compliance to standards</p>	<ul style="list-style-type: none"> • Explain how to complete the Production facilities compliance to standards form • Describe the infrastructure and equipment requirements for non-aseptic compounding • Describe the infrastructure and equipment requirements for hazardous non-aseptic compounding • Describe the infrastructure and equipment requirements for aseptic compounding • Describe the infrastructure and equipment requirements for hazardous aseptic compounding • Describe the infrastructure and equipment requirements for biohazard aseptic compounding 	<p>4.4.3, 4.5.2</p>
<p>Occupational exposure and risk assessment</p>	<ul style="list-style-type: none"> • Explain how to assess products for occupational risk • Identify complex calculations undertaken in risk assessments • Define experienced staff in the context of the production of medicines 	<p>3.4.2, 4.7.7</p>
<p>Case study: Occupational exposure flow chart</p>	<ul style="list-style-type: none"> • Describe how to apply the occupational exposure flow chart in practice 	<p>3.4.2, 4.7.7</p>
<p>Staffing requirements</p>	<ul style="list-style-type: none"> • Outline how to introduce a staff risk assessment • Identify requirements for staff entering a cleanroom environment • Identify the staff training needs for compounding and production areas 	<p>4.6.2, 5.1.1</p>
<p>Third party supplier agreements and outsourcing</p>	<ul style="list-style-type: none"> • Differentiate between TGA licenced manufacturing, TGA GMP compliance and PIC/S compliance • Describe the evidence required to approve outsourcing 	<p>3.4.1, 3.4.2</p>
<p>Documentation in compounding and preparation</p>	<ul style="list-style-type: none"> • Describe the types of records required for a compounding pharmacy 	<p>3.4.7</p>

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