ADPHA CPD

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Pharmaceutical and advanced therapeutic products governance education package

ONLINE COURSE

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Online learning course outline

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Topics	Learning objectives	Competency standards addressed*
Preventing Disaster	• 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	• 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	• 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	• 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?	• 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	• 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	• 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
Infrastructure requirements and compliance to standards	• 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	4.4.3, 4.5.2
Occupational exposure and risk assessment	• 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	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 • Identify requirements for staff entering a cleanroom environment • 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 • 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