Module 22: Regulatory Requirements for Cell Tissue and Gene Therapies

Date: 1-3 July 2025

Module Leader(s): Daniel Rabbie

Day 1: 1 July 2025

Time	Activity	Leader
	Registration	
	Welcome & Overview of Module 22	Daniel Rabbie, Achilles Therapeutics
	Lecture 1: Cell, Gene, and Tissue Therapy Regulation – Helicopter View	Daniel Rabbie, Achilles Therapeutics
	Lunch	
	Lecture 2: Product Classification and Procedures	Daniel Rabbie, Achilles Therapeutics
	15 minute break	
	Lecture 3: National Considerations - Medicines as Genetically Modified Organisms (GMOs)	Sabine Ruehle, Boyd Consultants
	Afternoon Break	
	Lecture 4: National Considerations – Regulation of Tissues & Cells and other relevant legislation	Daniel Rabbie, Achilles Therapeutics

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Day 2: 2 July 2025

Time	Activity	Leader
	Lecture 5: Quality, safety and efficacy of Cell, Gene and Tissue Therapies – Helicopter View	Florence Salmon, Hookipa Pharma
	Morning Break	
	Lecture 6: Manufacturing and Control (Part I)	Florence Salmon, Hookipa Pharma
	Lunch	
	Lecture 7: Manufacturing and Control (Part II)	Florence Salmon, Hookipa Pharma
	Afternoon Break	
	Lecture 8: Translation - Non-clinical and Clinical Development	Sean Russell, PrimeRA Pharma Partners
	Day 2 Recap Overview - Q&A Workshop & Case Study	

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Day 3: 3 July 2025

Time	Activity	Leader
	Lecture 9: Product Development for Cell, Gene and Tissue Therapies – Helicopter View	Sean Russell, PrimeRA Pharma Partners
	Morning Break	
	Lecture 10: Global Regulatory Pathways for Expedited Product Development	Sean Russell, PrimeRA Pharma Partners
	Lunch	
	Lecture 11: Strategic ATMP Development	Sean Russell, PrimeRA Pharma Partners
	Afternoon Break	
	Case Study – ATMP Development Programme	
	Q&A Workshop with Speakers & Delegates	
	Close of Module	