

Module 22: Regulatory Requirements for Cell Tissue and Gene Therapies



Date:

Module Leader(s): Daniel Rabbie

Day 1:

Time	Activity	Leader
11:00 – 11:20	Registration	
11:20 – 11:30	Welcome & Overview of Module 22	Daniel Rabbie, Achilles Therapeutics
11:30 – 12:30	Lecture 1: Cell, Gene, and Tissue Therapy Regulation – Helicopter View	Daniel Rabbie, Achilles Therapeutics
12:30 – 13:00	Lunch	
13.00 – 14.00	Lecture 2: Product Classification and Procedures	Daniel Rabbie, Achilles Therapeutics
15 minute break		
14:00 – 15:00	Lecture 3: National Considerations - Medicines as Genetically Modified Organisms (GMOs)	Sabine Ruehle, Boyd Consultants
15:00 – 15:30	Afternoon Break	
15:30 – 16:30	Lecture 4: National Considerations – Regulation of Tissues & Cells and other relevant legislation	Daniel Rabbie, Achilles Therapeutics

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Date:

Day 2:

Time	Activity	Leader
09:00 – 10:00	Lecture 5: Quality, safety and efficacy of Cell, Gene and Tissue Therapies – Helicopter View	Florence Salmon, Hookipa Pharma
10.00 – 10:30	Morning Break	
10:30 – 12.00	Lecture 6: Manufacturing and Control (Part I)	Florence Salmon, Hookipa Pharma
12.00 – 12.30	Lunch	
12.30 – 13.30	Lecture 7: Manufacturing and Control (Part II)	Florence Salmon, Hookipa Pharma
13.30 – 14.00	Afternoon Break	
14.00 – 15.30	Lecture 8: Translation - Non-clinical and Clinical Development	Sean Russell, PrimeRA Pharma Partners
15:30 – 16.30	Day 2 Recap	
<i>1 hour</i>	Overview - Q&A Workshop & Case Study	

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Day 3:

Time	Activity	Leader
09.00 – 10.00	Lecture 9: Product Development for Cell, Gene and Tissue Therapies – Helicopter View	Sean Russell, PrimeRA Pharma Partners
10.00 – 10.30	Morning Break	
10.30 – 12.00	Lecture 10: Global Regulatory Pathways for Expedited Product Development	Sean Russell, PrimeRA Pharma Partners
12:00 – 12.30	Lunch	
12.30 – 13.45	Lecture 11: Strategic ATMP Development	Sean Russell, PrimeRA Pharma Partners
13.45 – 14.00	Afternoon Break	
14.00 – 15.30	Case Study – ATMP Development Programme	
15.30 – 16:30	Q&A Workshop with Speakers & Delegates	
16:30	Close of Module	