GRADUATE CERTIFICATE IN PHARMACEUTICAL REGULATION

GMS5103: Regulation of Cell, Tissue and Gene Therapies

22nd June – 26th June 2020

Duke-NUS Medical School

DRAFT WORKSHOP PROGRAMME

Learning outcomes

- Define and categorize the scope of different ATMPs and distinguish them from conventional pharmaceutical products.
- Describe the critical components in the production and administration of ATMPs including manufacturing, nonclinical/clinical development
- Become familiar with the regulatory requirements across ATMP product lifecycle.
- Distinguish between the established ATMP regulatory frameworks across the globe and the various initiatives to promote regulatory harmonization in ASEAN region.

This programme is accurate as of 7 Feb 2020 and may be subjected to further refinement if necessary before the actual event.

Time	Topics to be covered	Suggested Pre-reads	Potential Speaker/ Facilitator
Day 1 (22 June)			
Session I: Introduction to Advance Therapy Medicinal Products (ATMPs)			
09:00	**Welcome Address**		**Prof John Lim** Executive Director Centre of Regulatory Excellence Duke-NUS Medical School
09:15	**Workshop Briefing**		
09:30	**Overview of ATMPs** • Definition and scope of ATMPs • Product Lifecycle of ATMPs • CART versus TCR		
10:30	**Tea Break**		
Session II: Regulatory frameworks for Advance Therapy Medicinal Products (ATMPs)			
11:00	Comparison of regulatory frameworks: US, EMA and Japan		
12:00	Commercial Manufacturing of ATMPs • Regulatory requirements		
12:30	**Tea Break**		
1:30	Overview of CGTP Regulatory Framework		
2:30	**Practicum I** • Categorisation of products as cell, gene therapy or combination device		
End of Day 1			

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Day 2 (23 June)			
Session III: CMC Considerations in ATMP Manufacturing			
8:30	IRA and GRA		
09:30	**Cell and Gene Therapy Manufacturing** • Viral vector production • Ensuring scalability • Cell counting and viability		
10:30	**Tea Break**		
11:00	**Manufacturing facility and GMP inspections** • Logistical aspects: administration, handling human samples (GMP) • Manufacturing and supply chain operations		
12:00	**Lunch**		
13:00	**Management of Raw Materials for ATMPs** • Risk-based approach • Case Example		
14:00	**Site visit** *(To be confirmed)*		
15:30	**Tea Break**		
End of Day 2			

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Day 3 (24 June)			
Session IV: Nonclinical development to Post-authorisation activities			
08:30	**IRA/GRA exercise**		
09:30	**Nonclinical Development of ATMPs** • Early phase testing • Choosing relevant animal models • Regulatory requirements • Environmental risk assessment of viral vectors		
10:15	**Tea Break**		
10:45	Clinical Development • Autologous versus allogenic • Design of clinical trials • Execution of trials		
12:00	**Lunch**		
13:00	Post-authorisation surveillance		
13:50 with Tea Break	Practicum II		
End of Day 3			

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Day 4: APEC RHSC ATP Workshop (25 June)			
09:00	**Welcome Address**		**A/Prof Silke Vogel** Deputy Director Centre of Regulatory Excellence Duke-NUS Medical School
09:15	Overview of ATMP regulation by different regulatory authorities		
10:15	**Tea Break**		
10:15	Utility of pharmacopoeias		
11:10	Evaluation of CMC dossier		
12:00	**Lunch**		
13:00	Review of Clinical Trial Application		
13:45	Handling out-of-spec products		
14:45	**Tea Break**		
15:15	**Team-based exercise**		
End of Day 4			

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Day 5: APEC RHSC ATP Workshop (13 March)			
08:30	**End of the course MCQ**		
09:30	Challenges with diversified regulatory guidelines and requirements		
10:30	**Tea Break**		
11:00	Regulatory harmonization and convergence initiatives		
12:00	**Lunch**		
13:00	**Patient Access** • Pricing and access of Advance Therapies		
13:45	Case study		
14:30	Gallery walk of different NRA frameworks		
15:30	**Tea Break**		
16:00	Upcoming trends in ATMPs		
16:45	Closing GC workshop		**A/Prof Silke Vogel** Deputy Director Centre of Regulatory Excellence Duke-NUS Medical School
End of Day 5			

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