GRADUATE CERTIFICATE IN HEALTH PRODUCTS REGULATION
GMS5005: Regulation of Advanced Therapies

21 March 2022 – 25 March 2022

Venue: Zoom

WORKSHOP PROGRAMME

Learning outcomes

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

Graduate Certificate in Pharmaceutical Regulation

GMS5005: Regulation of Advanced Therapies

21 – 25 March 2022

Day 1 – 21 March, Mon

	Topic	Speaker/ Organisation
8.00am	**Zoom Briefing**	**Mr Osman Bin Mohamad** Senior Associate Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
Session 1: Introduction to Advance Therapy Medicinal Products (ATMPs)		
8.15am	**Welcome Graduate Certificate Students**	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
8.40am	**Workshop Briefing**	**Dr Uttara Soumyanarayanan** Senior Education Associate, CoRE
8.50am	**Overview of ATMPs (EU)** • Definition and scope of ATMPs • Examples of approved products • Gene therapy and CAR-T cell therapy	**Dr Patrick Celis** Scientific Administrator (CAT Secretariat) European Medicines Agency (EMA)
Session 2: Regulatory Frameworks for Advance Therapy Medicinal Products (ATMPs)		
9.30am	**US Regulatory Frameworks of Regenerative Medicine Therapies** • US legal framework • Expedited pathway for RMTs	**Ms Judith Arcidiacono** International Regulatory Expert and Standards Development Liaison Office of Cellular Tissue and Gene Therapy U.S. Food and Drug Administration (US FDA)
10.30am	**Refreshment Break**	
11.00am	**TGA Regulatory Framework for ATMPs** • Biologics framework for ATMPs • MA Pathways for ATMPs	**Dr Mathew Adams** Departmental Officer, Biological Science Section, Scientific Evaluation Branch Therapeutic Goods Administration, Australia
11.45pm	**Lunch**	
1.15am	**Overview of HSA's CTGTP Regulatory Framework** • Scope of regulation • Class 1 and Class 2 products • Regulatory Controls	**Dr Kellathur Srinivasan** Director, Advanced Therapy Products Branch Health Sciences Authority (HSA), Singapore
2.00pm	**PMDA Regulatory Framework for Regenerative Medicine** • PMDA legal framework • Considerations for expedited pathways • Examples of approved products	**Dr Shinichi Noda** Deputy Review Director Office of Cellular and Tissue-based Pharmaceuticals and Medical Devices Agency (PMDA), Japan
2.30pm	**Refreshment Break**	
3.00pm	**EU Regulatory Framework for ATMPs** • EU Legal framework • ATMP marketing authorisation procedures • Post-authorisation requirements	**Dr Patrick Celis** EMA
4.00pm	**Practicum I:** • Classification and Categorisation of ATMPs	**Dr Patrick Celis** EMA
5.30pm	**End**	

Day 2 – 22 March, Tue

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment I**	
Session 3: CMC Considerations in ATMP Manufacturing		
9.30am	**Management of Raw Materials for ATMPs** • Starting materials vs raw materials: comparison across RAs • Risk-based approach • Role of pharmacopoeial standards in regulatory requirements	**Dr Fouad Atouf** Vice President Science—Global Biologics The United States Pharmacopeial Convention (USP)
10.30am	**Refreshment Break**	
11.00am	**Cell and Gene Therapy Manufacturing** • Overview of manufacturing • Ensuring scalability • Challenges in ATMP manufacturing	**Dr Lucas Chan** Co-founder CSO CellVec
12.00pm	**Lunch**	
1.30pm	**Manufacturing of CTGTP** • Overview of CART • Manufacturing facility and process • Singapore's cell therapy ecosystem	**Dr Sudipto Bari** Senior Research Fellow, National Cancer Centre Singapore
2.30pm	**CTGTP Manufacturing Facility and GMP Inspections** • Key GMP Audit Areas • Examples of scenarios with non-compliance	**Dr. Elaine Tang** Senior Regulatory Specialist (GMP) Audit & Licensing Division, HPRG Health Sciences Authority (HSA), Singapore
3.15pm	**Introduction to HSA Cell Therapy Facilities** • Overview of layout, processes & products • Future plans	**Dr Marieta Chan** Laboratory Director & Consultant Scientist Health Sciences Authority (HSA), Singapore
3.30 pm	**Refreshment Break**	
4.00pm	**Evaluation of CMC Dossier** • Quality attributes and requirements • Stability requirements • Challenges and considerations	**Dr Lee Lee Ong** Regulatory Consultant Advanced Therapy Products Branch Health Products Regulation Group Health Sciences Authority (HSA), Singapore
5.15pm	**End**	

Day 3 – 23 March, Wed

	Topic	Speaker/ Organisation
8.30am	**Individual and Group assessment II**	
9.30am	**Practicum II** • Case studies: Raw Materials • Handling out of specifications (OOS) products	**Expert Faculty:** Dr Fouad Atouf, USP Dr Ong Lee Lee, HSA
10.30am	**Refreshment Break**	
11.00am	**Practicum II continued**	
12.15pm	**Lunch**	
1.30pm	**Nonclinical Evaluation of ATMPs** • Characteristics of ATMPs • Challenges of nonclinical assessment for ATMPs • Pharmacology and toxicology assessment • Additional data assessment	**Dr Xiaofeng WU** Regulatory Consultant Innovation Office and Clinical Trials Branch Health Sciences Authority (HSA), Singapore
2.30pm	**Case Discussion: Non-Clinical Assessment**	**Expert Faculty:** Dr Xiaofeng WU
Session 4: Clinical Development of ATMPs		
3.15pm	**Clinical Development of ATMPs** • Engagement with US FDA during planning • Design of early phase trials • Execution of trials	**Dr Steve Winitsky** Vice President - Technical, Paraxel Consulting
3.45pm	**Refreshment Break**	
4.15pm	**Review of Clinical Trial Application** • Regulatory requirements for nonclinical and clinical trials • Components of IND submission • Challenges specific to RMTs	**Ms Judith Arcidiacono** US FDA
5.00pm	**End**	

Day 4 – 24 March, Thurs

	Topic	Speaker/ Organisation
8.30am	**Individual and Group Assessment III**	
9.30am	**Practicum III: Clinical Development and Evaluation** • Clinical development studies • Benefit risk evaluation	**Expert Faculty:** Dr Kellathur Srinivasan, HSA
10.30am	**Refreshment Break**	
11.00am	**Practicum III continued**	**Expert Faculty:** Dr Kellathur Srinivasan, HSA
12.00pm	**Lunch**	
1.00pm	**Patient Case Study: Treatment with CAR-T cells** • Clinical utility of CAR-T cell therapies and challenges with treatment	**Dr Francesca Lorraine Lim** Senior Consultant Hematologist Singapore General Hospital (SGH) Assistant Medical Director at the Cell Therapy Facility, Health Science Authority (HSA)
1:45pm	**Practical Aspects of CAR-T cell therapies** • Concerns & challenges: monitoring, access, recruiting pediatric populations • Barriers and enablers impacting uptake	**Dr Bernice Oh** Consultant, Division of Paediatric Haematology and Oncology, National University Hospital
2.30pm	**Challenges with clinical efficacy assessments** • Benefit-risk assessment on limited database • Post-authorisation measures	**Dr Martina Schüssler-Lenz** Chair, EMA Committee for Advanced Therapies, Paul-Ehrlich-Institut (PEI), Federal Institute for Vaccines and Biomedicines, Germany
Session 5: Pharmacovigilance of ATMPs		
3.15pm	**Refreshment Break**	
3.30pm	**Pharmacovigilance and Risk Management of ATMPs** • Safety and efficacy concerns with ATMPs • Routine and additional PV activities • Long-term follow up studies	**Ms Phua Chwee Ping** Regional Head of Patient Safety, Asia-Pacific, Novartis
4.30pm	**Pre-panel Polling Activity** • **Topic:** Preparing the healthcare system for Advanced Therapies	CoRE Staff
5.00pm	**End**	

Day 5 – 25 March, Fri

	Topic	Speaker/ Organisation
Session 6: Challenges and Opportunities in ATMPs		
8.30am	**Challenges in the Development and Translation of ATMPs** • Common development challenges • Regulatory opportunities to expedite development of ATMPs	**Ms Katherine Tsokas** Vice President Regulatory, Quality Risk Management & Drug Safety Janssen, Canada
9.10am	**CMC Challenges in Cell and Gene Therapy** • Challenges with diversified regulatory guidelines	**Dr Lawrence Starke** Global Unit Head, Regulatory Affairs (CMC), Cell & Gene Therapy Novartis, New Jersey
9.50am	**Challenges in Practice: A Clinician's Perspective** • Clinical site: setting up cell therapy facility • Essentials and implementation of Quality Management System (QMS)	**Dr Tan Lip Kun** Senior Consultant and Medical Director Tissue Engineering & Cell Therapy Laboratory, National University Hospital (NUH), Singapore
10.30am	**Panel Session** **"Preparing the healthcare system for Advanced Therapies"**	**Moderator:** **Dr Kellathur Srinivasan** HSA **Panelists:** **Dr Tan Lip Kun** NUH Singapore **Ms Katherine Tsokas** Janssen **Dr Lawrence Starke** Novartis
11.15am	**Refreshment Break**	
11.30am	**End of the Module Assessment**	
12.30pm	**Lunch**	
1.30pm	**Clarifications in EOM Assessment**	CoRE Team
2.15pm	**Progress in ASEAN Frameworks for ATMPs** • NPRA Malaysia	**Dr Azizah Abd Ghani** Head of Biologic Section NPRA, Malaysia
2.45pm	**Refreshment Break**	
3.15pm	**Regulatory Harmonization and Convergence Initiatives**	**Dr Kellathur Srinivasan** HSA
4.00pm	**Graduate Certificate Workshop Conclusion**	**A/Prof Silke Vogel** Deputy Director, CoRE Senior Associate Dean Graduate Studies Duke-NUS Medical School
5.00pm	**End**	