

# PROGRAMME REPORT

Asia Pacific Perspective for Healthcare Professionals in  
Advanced Therapy: From Bench to Bedside  
2022-2023

Department of Pharmacology and Pharmacy  
The University of Hong Kong

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## A. Learning Materials

All learning materials including the videos, notes and multiple-choice assessments are reserved only for programme enrollees and login is required to access. Enrollees may log in their account at <https://cpd.hku.hk> to revisit the programme by navigating to “Advanced Therapy Products Training” and “On-demand Materials” under the site menu.

### Module 1: Introduction to Advanced Therapy I

1.1. Introduction to Advanced Therapy Products

<https://cpd.hku.hk/modules/module-1-introduction-to-advanced-therapy-products/5299/>

1.2. The Scientific Principles of Cell and Gene Products – Part 1

<https://cpd.hku.hk/modules/module-1-introduction-to-advanced-therapy-products/5301/>

1.3. Introduction to Cell Therapy – Part 1

<https://cpd.hku.hk/modules/module-1-introduction-to-advanced-therapy-products/5302/>

1.4. Introduction to Gene Therapy – Part 1

<https://cpd.hku.hk/modules/module-1-introduction-to-advanced-therapy-products/5303/>

### Module 2: Introduction to Advanced Therapy II

2.1. Introduction to Cell Therapy – Part 2

<https://cpd.hku.hk/modules/module-2-introduction-to-advanced-therapy-products/5456/>

2.2. Introduction to Gene Therapy – Part 2

<https://cpd.hku.hk/modules/module-2-introduction-to-advanced-therapy-products/5457/>

## Module 3: Overview of Regulatory Framework – A Regional Perspective

3.1. Overview – Regulation of Pharmaceutical Products in Hong Kong

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/5869/>

3.2. Regulation of Medical Device in Hong Kong and Greater Bay Area

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/5871/>

3.3. Regulation of Health Supplements in Hong Kong

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/5873/>

3.4. Great Bay Area Perspectives – Regulation of Pharmaceutical Products in China

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/5875/>

3.5. Great Bay Area Perspectives – Regulation of Pharmaceutical Products in Macau

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/5877/>

3.6. Pharmaceutical Advertisement – Local and Global Perspectives

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/6031/>

3.7. Pharmaceutical Advertisement – Industrial Practice

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/6075/>

3.8. Understanding of Quality-related ICH Guidelines

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/6077/>

### 3.9. Overview of Common Technical Document Dossier

<https://cpd.hku.hk/modules/module-3-overview-of-regulatory-framework-a-regional-perspective/6079/>

## **Module 4: Asia Perspectives for ATP Regulation: Challenges and Opportunities**

### 4.1. Regulations of Advanced Therapy Products in Hong Kong

<https://cpd.hku.hk/modules/module-4-asia-perspectives-for-atp-regulation-challenges-and-opportunities/5954/>

### 4.2. Practical Issues and Experience of ATP Registration in Hong Kong

<https://cpd.hku.hk/modules/module-4-asia-perspectives-for-atp-regulation-challenges-and-opportunities/5956/>

### 4.3. Regulations of Advanced Therapy Products in China

<https://cpd.hku.hk/modules/module-4-asia-perspectives-for-atp-regulation-challenges-and-opportunities/5958/>

### 4.4. Intellectual Properties in ATP: A Case Study on Global Patents in the Field of CAR-T Cell Therapy

<https://cpd.hku.hk/modules/module-4-asia-perspectives-for-atp-regulation-challenges-and-opportunities/6081/>

### 4.5. The Scientific Principles of Cell and Gene Products – Part 2

<https://cpd.hku.hk/modules/module-4-asia-perspectives-for-atp-regulation-challenges-and-opportunities/6085/>

## Module 5: Clinical Trials, Pharmacovigilance and Future Industrial Prospects of Advanced Therapy

5.1. Considerations and Implementation of Clinical Trials on Advanced Therapy: a Local Perspective

<https://cpd.hku.hk/modules/module-5-clinical-trials-pharmacovigilance-and-future-industrial-prospects-of-advanced-therapy/6281/>

5.2. Regulation of Clinical Trials on Advanced Therapy Products in China

<https://cpd.hku.hk/modules/module-5-clinical-trials-pharmacovigilance-and-future-industrial-prospects-of-advanced-therapy/6283/>

5.3. Biosimilars for Advanced Therapy: reality of Just Fantasy

<https://cpd.hku.hk/modules/module-5-clinical-trials-pharmacovigilance-and-future-industrial-prospects-of-advanced-therapy/6285/>

5.4. Post-marketing Pharmacovigilance of Advanced Therapies – The Example of Tisagenlecleucel

<https://cpd.hku.hk/modules/module-5-clinical-trials-pharmacovigilance-and-future-industrial-prospects-of-advanced-therapy/6287/>

## Module 6: Institutional Readiness of ATP Delivery and Services

6.1. CAR-T Therapy in Hong Kong: Pharmacist's Perspectives

<https://cpd.hku.hk/modules/module-6-institutional-readiness-of-atp-delivery-and-services/6437/>

6.2. CAR-T Cell Therapy – Clinical Journey

<https://cpd.hku.hk/modules/module-6-institutional-readiness-of-atp-delivery-and-services/6439/>

6.3. Precautions and Considerations in Delivery of Advanced Therapy Medicinal Products

<https://cpd.hku.hk/modules/module-6-institutional-readiness-of-atp-delivery-and-services/6441/>

## **Module 7: Institutional Readiness and Clinical Application**

7.1. Translation and Commercialisation of Stem-Cell Therapy: a Local Perspective

<https://cpd.hku.hk/modules/module-7-institutional-readiness-and-clinical-application/6532/>

7.2. Governance and Preparation Requirements for ATMPs

<https://cpd.hku.hk/modules/module-7-institutional-readiness-and-clinical-application/6535/>

7.3. Care of CAR-T Patients – The Nursing Perspective

<https://cpd.hku.hk/modules/module-7-institutional-readiness-and-clinical-application/6537/>

7.4. Management of Acute Toxicity and Supportive Care for CAR-T Cell Therapy

<https://cpd.hku.hk/modules/module-7-institutional-readiness-and-clinical-application/6539/>

## **Module 8: Clinical Application of ATP and Patient Care**

8.1. Stem Cell Therapy – Application and Clinical Journey

<https://cpd.hku.hk/modules/module-8-clinical-application-of-atp-and-patient-care/6623/>

8.2. Implementation and Clinical Management of Gene Therapy

<https://cpd.hku.hk/modules/module-8-clinical-application-of-atp-and-patient-care/6625/>

8.3. Set-up of CAR-T Cell Therapy Services

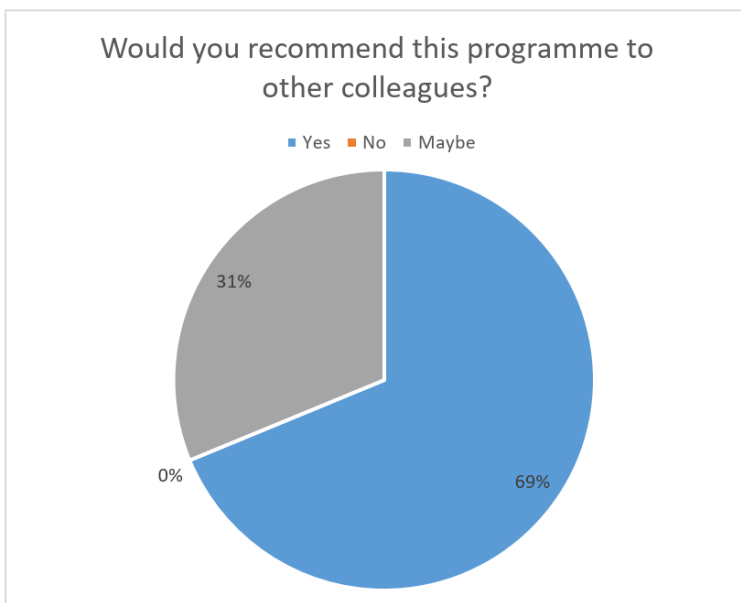
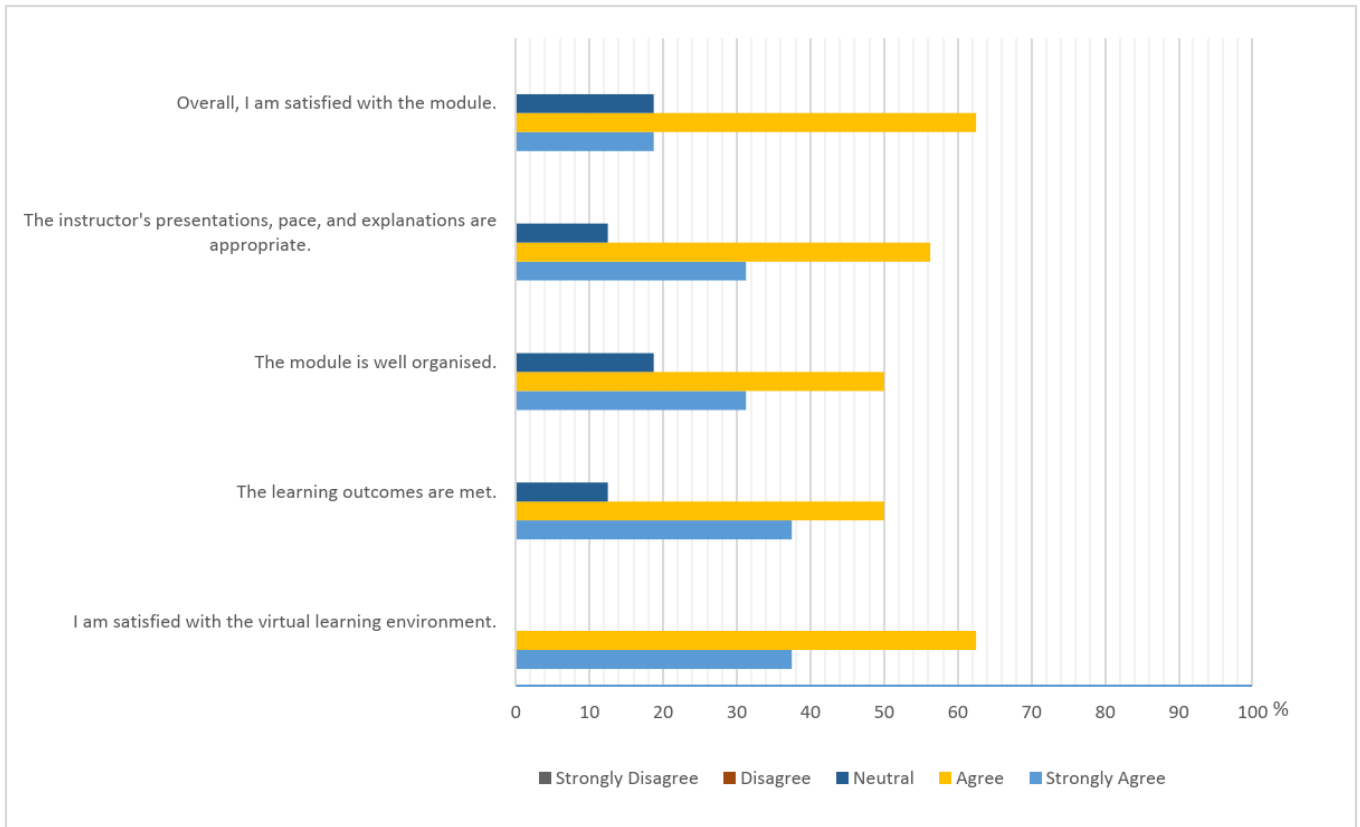
<https://cpd.hku.hk/modules/module-8-clinical-application-of-atp-and-patient-care/6627/>

8.a. The Unusual Case of a Rare Disease: Spinal Muscular Atrophy

<https://cpd.hku.hk/modules/module-8-clinical-application-of-atp-and-patient-care/6676/>

## B. Programme Evaluation & Feedback

### Results



## Comments

- Areas of appreciation
  - “Most updated status of ATP development and regulations.”
  - “Topics on IP and regulations in China are very interesting and insightful. Second session of the module is very practical and useful.” (“Practical Issues and Experience of ATP Registration in Hong Kong” by Dr. Fine Tong from Novartis and Ms. Sharon Fung from Bayer)
  - “Session 8 of module 3.” (“Understanding of Quality-related ICH Guideline” by Dr. Radivoj Arezina of Stridon Clinical Research Ltd.)
  
- Areas of improvement
  - “A bit too condensed in each day. Not enough time for break.”
  - “Technical issue, like stable connection of the presenter; and better time control and break.”
  - “Technical difficulty. Overall very good.”

## C. Acknowledgements & Disclaimer

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