



**PHARMACEUTICAL INSPECTION CONVENTION  
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

PS/INF 18/2024 (Rev. 1)  
22 April 2024

**27<sup>th</sup> PIC/S EXPERT CIRCLE MEETING ON HUMAN BLOOD, TISSUES, CELLS,  
AND ADVANCED THERAPY MEDICINAL PRODUCTS (ATMPs)  
KUALA LUMPUR, MALAYSIA  
20 - 22 August 2024  
“Human Blood, Tissues, Cells and ATMPs:  
Inspection Approach, Current Trends and Experience Sharing”**

**Second Announcement**

The PIC/S Expert Circle on Human Blood, Tissue, Cells, and ATMPs is pleased to invite GMP inspectors to a meeting to be held in Kuala Lumpur, Malaysia from 20 to 22 August 2024. In addition, the Coordinating Committee will meet on 19 and 23 August 2024.

The meeting will be hosted by the National Pharmaceutical Regulatory Agency (NPRA), Malaysia.

**1. OBJECTIVES OF THE MEETING**

- i. Update on the progress of the working group on revision of the PIC/S guidelines on Blood Establishments, on the PIC/S Aide-Memoire on Inspections to Tissues and Cells Establishments, and on the PIC/S Aide-Memoire on Inspections to ATMPs.
- ii. Update on the progress of the preparation of PIC/S curricula for inspectors to Blood Establishments, Tissues, and Cells Establishments, and ATMPs manufacturing site.
- iii. Discussion on contemporary issues in the field of blood components, plasma derivatives, cells, and tissues with particular focus on ATMPs.
- iv. Sharing knowledge on research, development, and production of ATMPs.
- v. Sharing experiences between inspectors to improve consistency among inspectors in the field of Blood Establishments, Tissues, and Cells Establishments, and ATMPs inspections.

## 2. SCHEDULE

Day	Date	Time	Event
Tuesday	20 August 2024	08:00 - 09:00	Registration of participants
		09:00 - 10:15	Opening session
		10:15 - 10:45	Photo session
		10:45 - 13:00	Presentations: Regulatory Session Update on the activity of the PIC/S Expert Circle on Human Blood, Tissues, Cells and ATMPs, presentations on the new Regulatory Framework of Substances of Human Origin and on WHO Nonproprietary Names Programme and Classification of ATMPs active substances
		13:00 - 14:00	Lunch
		14:00 - 17:30	Presentations: Human blood session
			Presentations: Tissues & cells session
Wednesday	21 August 2024	08.30 - 13:00	Workshops (rotating)
		13:00 - 14:00	Lunch
		14:00 - 16:00	Workshops (rotating) <u>Workshop 1</u> Tissues and cells <u>Workshop 2</u> Case studies in ATMPs <u>Workshop 3</u> Inspection on blood establishments (case studies)
		16:00 - 17:00	Presentations: ATMPs in the hosting country
		19:00 - 21:00	Networking dinner (NPRA invitation)

Day	Date	Time	Event
Thursday	22 August 2024	09:00 - 13:00	Presentations: Industry/Academia Session <ul style="list-style-type: none"> <li>● Presentations on CCS in ATMPs, rapid microbiological methods and endotoxins tests in ATMPs</li> <li>● Key Contamination Control Blindspots in ATMP Facilities and Operations (case studies)</li> <li>● ATMPs facility design for ATMPs</li> <li>● Challenges to Cells and Genes Therapy Development in Malaysia</li> </ul>
		13:00 - 14:00	Lunch
		14:00 - 14:30	Presentations: Industry/Academia Session Wharton's Jelly Mesenchymal Stem Cells in Biotherapeutics Development: Insight into Quality Control as part of GMP
		14:30 - 16:40	Presentations: ATMPs session Including presentations for IATMPs, ATMPs manufacture in hospitals. Insights and Experiences on ATMPs in Indonesia
		16:40 - 18:00	Summarizing of workshops and closing remarks
<b><u>NB:</u> for Coordinating Committee Members only:</b>			
Monday	19 August 2024	15:00 - 18:00	Coordinating Committee Pre-Meeting
Friday	23 August 2024	09:00 - 12:00	Coordinating Committee Post-Meeting

A more detailed program will be sent later, and more information about this Expert Circle can also be found at the event website: <http://picshubcelta2024.com>.

Please note that to minimize the environmental footprint of the meeting, documents will not be printed out. Presentation materials will be provided via PDF copies.

### **3. EXPERT CIRCLE MEETING ORGANIZER**

NPRA Secretariat

Email: [hbtcatraining@npra.gov.my](mailto:hbtcatraining@npra.gov.my)

#### 4. ATTENDANCE

The meeting is addressed to inspectors of PIC/S Participating Authorities, PIC/S Applicants, and Pre-Applicants, PIC/S Partners, and other interested non-PIC/S Regulatory Authorities in the field of human blood, tissues, and cells (including ATMPs).

#### 5. LANGUAGE & DRESS CODE

The working language of the meeting is English and dress code is casual.

#### 6. VENUE AND ACCOMMODATION

##### Venue

The meeting will be held in **M Resort & Hotel, Kuala Lumpur**, Jalan Damansara, Bukit Kiara, 60000 Kuala Lumpur, Malaysia.

##### Accommodation

There are many options available for hotels located close to the venue. Listed below are some of the options available:

- I. M Resort & Hotel, Kuala Lumpur
  - Website: <https://mresort-hotel.com.my/>
  - Price starting from MYR 427.00 per night (approx. 84 Euro)
- II. Eastin Hotel Kuala Lumpur
  - Website: <https://kualalumpur.eastin.com/>
  - Price starting from MYR 355.60 per night (approx. 70 Euro)
- III. Sheraton Petaling Jaya Hotel
  - Website: <https://www.marriott.com/en-us/hotels/szbsi-sheraton-petaling-jaya-hotel/overview/>
  - Price starting from MYR 530.00 per night (approx. 104 Euro)
- IV. Hilton Petaling Jaya
  - Website: <https://www.hilton.com/en/hotels/pethitw-hilton-petaling-jaya/>
  - Price starting from MYR 346.00 per night (approx. 68 Euro)

#### 7. REGISTRATION

A registration fee of **MYR 2,000.00** (approx. 390 Euro), will be charged for this event. Lunch and refreshments will be provided each day. The number of participants is restricted to 100 in total. Registrations will be granted on a first-come, first-served basis. Travel and accommodation expenses will be the responsibility of the participants.

The registration link with the payment details will be forwarded to the applicants after NPRA Secretariat has received the pre-registration. Please take note that this event is only for regulatory authorities. **The pre-registration deadline is 19 July 2024.**

## 8. TRAVEL INFORMATION

### Visa Requirement

For more information regarding visa, travelers may refer to the website of Malaysian Immigration Department <https://www.imi.gov.my/>.

### Airport

Flights to Kuala Lumpur can be booked via several airlines (e.g. Malaysia Airlines, Emirates, Etihad Airways, Singapore Airlines, etc.). The nearest airport to the venue is Kuala Lumpur International Airport (KLIA) (Airport Code: KUL). International flights will be arriving at Terminal 1 or Terminal 2, KLIA. For more information, please visit <https://airports.malaysiaairports.com.my/>.

### Public Transportation to the Venue

#### a. KLIA Express / MRT

The fastest way to get from KLIA to the city center is by taking the KLIA ekspres. This is a non-stop service to the KL City Air Terminal (KL CAT) located in KL Sentral which will take 28 minutes. There is also a transit train service with 3 stops along the journey at Bandar Tasik Selatan, Putrajaya/Cyberjaya and Salak Tinggi. The transit train service will take 35 minutes. The trains are equipped with comfortable seats, digital entertainment, wheelchair seat restraint, wheelchair-friendly washroom, and luggage racks.

Travelers can visit the KLIA ekspres website at [www.kliaekspres.com](http://www.kliaekspres.com) for the full fares and schedule.

From KL Sentral, it is a 10-minute walk to Muzium Negara MRT Station. Take the MRT towards Kwasa Damansara, heading to Phileo Damansara MRT Station. The hotel is 1 km away from the station. Travelers may take any taxi/e-hailing service to the hotel.

#### b. Airport Taxi

Airport taxis operate through a coupon system that can be purchased at the respective counters. The airport taxi service provider has a variety of vehicle types in their fleet ranging from family sedans to luxury vehicles. The charges start from MYR 90.00 (approx. 18 Euro) and are fixed based on the desired destinations.

Coupons can be purchased from counters at:

- Terminal 1 - Domestic Arrival, Level 3, Main Terminal Building
- Terminal 2 - Transport Hub, Level 1, Gateway shopping mall

#### c. E-hailing (GrabCar, etc.)

The Grab App can be installed via Google Play Store or Apple App Store upon arrival. E-hailing pickup location from the airport will be at:

- Terminal 1 - Gate 3 & 4, Level 1, Main Terminal Building
- Terminal 2 - Transport Hub, Level 1, Gateway shopping mall

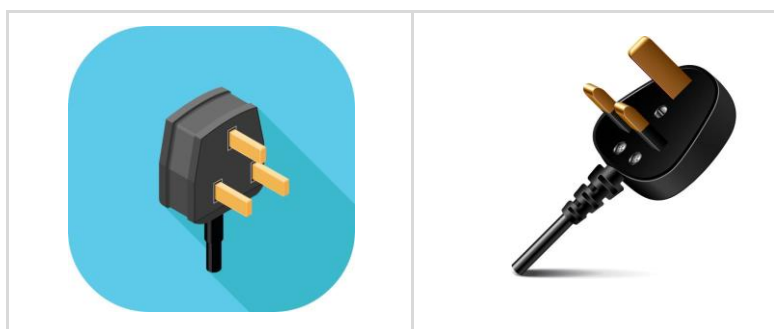
### Currency

Malaysia's currency is the Malaysian Ringgit (MYR). Travelers can change their currency at the Kuala Lumpur International Airport (KLIA) upon arrival, and money changers also available in the shopping malls. All major credit cards (Visa, MasterCard, etc.) are

accepted at most stores in Kuala Lumpur. Exchange rates (as of 19 January 2024): 1 US Dollar (\$) = 4.7140 Malaysian Ringgit (MYR) and 1 Euro (€) = 5.1331 Malaysian Ringgit (MYR). Please refer to <https://www.bnm.gov.my/latest-rates> for more information.

### Electricity

Electricity in Malaysia is 240 volts AC and 50Hz power cycle. Standard outlets are plugs with three rectangular pins (UK-plug).



## **9. NETWORKING DINNER**

The National Pharmaceutical Regulatory Agency (NPRA), Malaysia, cordially invites all participants to join the networking dinner on the evening of Wednesday, **21 August 2024**.

## **10. HEALTH**

All travelers are allowed to enter Malaysia regardless of their COVID-19 vaccination status and do not require a pre-departure or on-arrival COVID-19 test. There are no quarantine orders related to COVID-19 enforced by the Malaysian Government upon arrival being imposed. Please ensure that you bring along all your regular prescription medicine, as well as a copy of your prescription from your physician. The nearest hospital from M Hotel & Resort is Columbia Asia Hospital - Petaling Jaya, Lot 69, Jalan 13/6, Seksyen 13, 46200 Petaling Jaya, Selangor; Telephone: +603 7949 9999.

## **11. TOURIST ATTRACTIONS & GO CASHLESS WITH E-WALLET**

Discover the captivating beauty of Malaysia's diversity. For further details, visit <https://www.malaysia.travel/explore>.

Embrace the convenience of going cashless throughout Malaysia, whether dining in restaurants, shopping at malls, using public transport, or accessing over-the-counter services. E-wallet options include Grabpay, Touch 'n Go eWallet, Boost, ShopeePay, Lazada Wallet, and more.

## **12. EMERGENCY TELEPHONE NUMBER**

Police, Emergency Call Center, Search and Rescue (SAR), Emergency Medical Aid (Ambulance) – Dial 999