



香港品質學會

Workshop
on
Quality Management System in Cell Banks

13, 20 January 2024
(2 Saturdays – 4 hours per day)



2024 Intake

Organized by
Hong Kong Society for Quality

Web site: www.hksq.org

Email: hksq1986@gmail.com

Objectives of the Workshop

This Workshop is designed to introduce the principles and practices of PIC/S GMP, AABB and FACT requirements applied in cell banks.

On completion of this Workshop, participants will be more familiar with the knowledge and skills of adoption requirements of GMP, AABB and FACT in a cell and tissue manufacturing environment, as well as donor management and product release for clinical use.

Outline of the Workshop

1. Overview of QMS in Cell Banks

- Introduction to principles of quality management in cell banks, considerations on quality assurance
- Introduction of measures to address risks such as contamination, mix-up, traceability and confidentiality
- Introduction of governance and compliance in cell banks

2. Donor Management

- Introduction of donor education, development of informed consent, screening of donor health, and determination of donor eligibility

3. Cell & Tissue Procurement

- Introduction of procurement process and control
- Review of recording and delivery of collected cells and tissue

4. Cell Processing & Banking

- Introduction to ISBT 128 labeling system
- Review of process for qualifying the collected cells and tissue
- Discussion on processing, testing, cryo-storage of cellular therapy products

5. Product Release

- Discussion on product listing, search and reservation of a cellular therapy product
- Review of product release and distribution
- Review of clinical outcomes

6. Interactions with Collection Sites & Transplantation Center

- Introduction of agreements and medical notifications
- Review of collaboration in collection of cells and tissue, and assisting in transplantation
- Review of handling of adverse events
- Discussion on complaints and recalls

7. Critical Components for Quality Assurance

- Introduction to documentation and quality manual
- Discussion on control of deviation and non-conformity
- Review of controls on equipment and supply
- Brief the considerations for stability program
- Outline of the validation activities for both manufacturing and transportation of cells

4. Discussions on Transplantation Cases & Industrial Incidents

Who should attend

This short course is recommended for those interested in cellular therapy industry, especially in production, quality assurance, quality control, engineering, warehousing, and research and development areas.

Trainer

Ms. Minda Chiang



Certified Pharmaceutical GMP Professional (ASQ CPGP), with over 20 years in the capacity of Head of Quality Assurance in pharmaceutical and cell banking industries. Minda had established and maintained quality system for the first GMP facility for biological drug manufacturing in Hong Kong from scratch to approval by the Hong Kong Department of Health. She is the seasoned quality professional to lead the cell banks to comply with cell therapy standards including AABB and FACT.

Venue

TQM office:

11/F, Lockhart Centre, 301 Lockhart Road, Wanchai, Hong Kong

Date & Time

13 & 20 January 2024

Total 2 Saturdays

13:00 - 17:00

Workshop Fee

- HK\$3,800 for HKSQ members
- HK\$4,000 for ASQ members
- HK\$4,500 for others

Language

Cantonese
(supplemented with English Terms)

How to apply for Enrollment

1. Complete the registration form online at
<https://forms.gle/TZMdke38JF7Sz3r58>

and prepare a crossed cheque for the appropriate registration fees payable to “The Hong Kong Society for Quality Ltd.” Fees paid are not refundable.

2. Send the cheque to the following address:

Hong Kong Society for Quality
P.O. Box 84375
Hung Hom Bay Post Office
Kowloon, Hong Kong

3. Registration form should reach us **on or before 5 January 2024.**

10 seats will be allocated on a first-come-first-served basis (**Priority will be given to HKSQ and ASQ members**).

HKSQ reserves the right to cancellation (in such case, the paid fees will be refunded) and re-arrangement of the workshop details when necessary.

Award

Certificate of Attendance will be issued by Hong Kong Society for Quality to participant who completed the workshop with full attendance.

If you have questions

Please send Ms. Minda Chiang email to
mmpchiang@yahoo.com.hk.