香港品質學會

Workshop

on

Pharmaceutical Good Manufacturing Practices

8 July – 26 August 2017

(8 Saturdays – 4 hours per day)

2017 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 GMP applied in different regions, requirements of PIC/S GMP, Eudra GMP, US GMP, Heath Canada Guidelines, WHO GMP be considered.

On completion of this Workshop, participants will be more familiar with the knowledge and skills of adoption GMP requirements in a factory environment.

Outline of the Workshop

1. Principles of GMP

- Introduction to GMP requirements, quality structure, management review and common non-conformities in GMP
- Introduction of measures to avoid cross-contamination

2. Documentation System

- Introduction to documentation system, including quality manual, site master file (SMF), specifications, batch instructions, document control, and good recording practices

3. Hygiene Requirements in GMP Plant

- Introduction to classification of clean areas, good personal hygiene practices, clothing requirements and working behaviour in clean areas

4. Supply & Materials Control

- Introduction to supply management, materials control, including control of labels, critical components, materials in production line, returned/ rejected/ recalled materials and disposition, and good distribution practices (GDP)

5. Qualification & Validation

- Introduction to validation documentation including validation master plan (VMP), URS, FS and DS, validation protocol, critical attributes and parameters (CQA, CPP, CMA), types of qualification and validation, stages of qualification (DQ, IQ, OQ and PQ) particularly for water system, process validation, test method validation, cleaning validation, control of deviation and non-conformity, and change control

6. Inspection & Self-inspection

- Introduction to principles, skills and limitation of inspection, type of inspection including self-inspection, regulatory inspection, supplier audit, unannounced inspection, inspection process based on ISO 19011

7. Complaint & Product Recall

- Introduction to complaint procedures and records, customer complaint management based on ISO 10002
- Introduction to recall strategy, health hazard evaluation, classification of urgency for product recalls, recall action plan, recall notification, recall monitoring and termination, recall effectiveness check, and responsibilities of involved parties

8. Pharmaceutical Development & Technology Transfer

- Introduction to lifecycle of pharmaceutical products
- Introduction to stages of pharmaceutical development, including pre-clinical and clinical studies, based on ICH Q8 pharmaceutical development and ICH Q10 pharmaceutical quality system
- Introduction to technology transfer based on WHO guidelines on transfer of technology in pharmaceutical manufacturing
- Introduction to GMP requirements for investigational pharmaceutical products

Who should attend

This short course is recommended for those interested in pharmaceutical (including both western drugs and Chinese medicines), cellular therapy, food, cosmetic and medical devices 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 more than 15 years in the capacity of Quality Assurance Manager in GMP pharmaceutical manufacturing companies, with scopes including chemical drugs, sterile drugs, biological drugs, and with experience in the quality management systems for laboratory, manufacturing of Traditional Chinese Medicine and medical devices.

Venue

Medication Management Centre,
Wah Lok Industrial Centre, 31-35 Shan Mei Street, Fo Tan, N.T. (Detail address to be included in confirmation email)

Date & Time

8, 15, 22, 29 July 2017,
5, 12, 19, 26 August 2017

Total 8 Saturdays

09:00 - 13:00

Workshop Fee

- HK$4,800 for HKSQ members
- HK$5,000 for ASQ members
- HK$5,200 for others

Language

Cantonese
(supplemented with English Terms)

How to apply for Enrollment

1. Complete the registration form online at https://docs.google.com/forms/d/e/1FAIpQLSd6h3lfADPWkYv3t9jE9BN1mTpIGvUxVvYsJiF45P6Wjtihdw/viewform?usp=sf_link

   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:

   Mr. C.P. Chow
   Hong Kong Society for Quality
   P.O. Box 84375
   Hunghom Bay Post Office
   Kowloon, Hong Kong

   (Fax: 3522 4128)

3. Registration form should reach us **before 28 June 2017**.

10 seats will be allocated on a first-come-first-served basis.

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

Award

Certificate of Achievement will be issued by Hong Kong Society for Quality to participant who completed the workshop with satisfactory attendance and passed the written assessment.

If you have questions

Please call Ms. Minda Chiang at 9774 3811 by phone, or send fax to 3522 4128, or send email to hksq1986@gmail.com.