Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines

Qualification and Experience Requirements for Key Personnel (Guidelines for the Trade)

Under section 133 of the Chinese Medicine Ordinance ("CMO"), manufacturers holding a manufacturer licence in proprietary Chinese medicines ("pCms") may apply to the Chinese Medicines Board ("CMB") under the Chinese Medicine Council of Hong Kong for a Certificate for Manufacturer ("pCm GMP Certificate") to certify that they follow the requirements for good practices in manufacture and quality control of pCms.

2. In 2003, the CMB developed the Hong Kong Good Manufacturing Practice Guidelines for Proprietary Chinese Medicines ("Guidelines") on the standards of manufacture and quality control of pCms with a view to promoting standardisation of the pCm manufacturing industry and ensuring quality and safety of pCms, thereby protecting public health and enhancing public confidence in using pCms.

3. Chapter 2 of the Guidelines sets out the requirements in respect of "Personnel" that a manufacturer should have an adequate number of competent personnel with practical experience to carry out relevant duties. The Guidelines also require that **the head of manufacturing department, the head of quality control department and the authorised person responsible for the release of every batch of finished products for sale should be included as the key personnel of the pCm manufacturer**, whose duties must comply with the Guidelines. Moreover, the key posts should be occupied by full-time personnel who are able to exercise independent judgement basing on the application of scientific principles and the understanding of the practical problems encountered in the manufacture and quality control of pCms.

4. To ensure that the key personnel involved in the Good Manufacturing Practice for pCms ("pCm GMP") are competent and comply with the requirements of the Guidelines, and to assist the trade to identify suitable key personnel to support its implementation of pCm GMP, as well as to encourage people with expertise to enter the Chinese medicines trade thus facilitating the long-term development of pCm GMP, the CMB has formulated a set of minimum requirements on the qualifications and experience of such key personnel so as to provide reference criteria for assessing their suitability in application for pCm GMP Certificate.

5. As regards the reference criteria, there are 4 and 5 options with respect to minimum requirements on qualification and experience for "Authorised person" and "Head of the manufacturing or quality control department" respectively. They are as follows:

Key Personnel	Option	Qualifications	Experience
A. Authorised Person	(1)	Holder of a bachelor's degree in Chinese medicines awarded by a university in Hong Kong; or, in the opinion of the CMB, an equivalent qualification.	• 2 years practical experience in a supervisory or managerial role relevant to pCms manufacture / quality control; or • 1 year practical experience under Good Manufacturing Practice ("GMP") in a supervisory or managerial role relevant to pCms manufacture / quality control^. Experience shall include at least 6 months of relevant practical experience obtained in Hong Kong.
	(2)	Pharmacist registered under the Pharmacy and Poisons Ordinance (Chapter 138, Laws of Hong Kong).	-Same as above-
	(3)	Authorised person of a pCm manufacturer which has been awarded a GMP certificate by a member of the Pharmaceutical Inspection Co-operation Scheme (hereinafter called "PIC/S").	-Same as above-
	(4)	Holder of a bachelor's degree in a relevant science subject*****.	• 3 years practical experience in a supervisory or managerial role relevant to pCms manufacture / quality control; or • 18 months practical experience under GMP in a supervisory or managerial role relevant to pCms manufacture / quality control^. Experience shall include at least 6 months of relevant practical experience obtained in Hong Kong.

Key Personnel	Option	Qualifications	Experience
B. Head of Manufacturing or Quality Control Department	(1)	Holder of a bachelor's degree in Chinese medicines awarded by a university in Hong Kong; or, in the opinion of the CMB, an equivalent qualification.	• 2 years practical experience relevant to pCms manufacture / quality control; or • 1 year practical experience under GMP relevant to pCms manufacture / quality control^. Experience shall include at least 6 months of relevant practical experience obtained in Hong Kong.
	(2)	Pharmacist registered under the Pharmacy and Poisons Ordinance.	-Same as above-
	(3)	Head of the manufacturing or quality control department of a pCm manufacturer which has been awarded a GMP certificate by a member of the PIC/S.	-Same as above-
	(4)	Holder of a bachelor's degree in a relevant science subject*****;	• 3 years practical experience relevant to pCms manufacture / quality control; or • 18 months practical experience under GMP relevant to pCms manufacture / quality control^. Experience shall include at least 6 months of relevant practical experience obtained in Hong Kong.
	(5)	Holder of a diploma in Chinese medicines awarded by a university in Hong Kong or the Vocational Training Council; or, in the opinion of the CMB, an equivalent qualification.	• 4 years practical experience relevant to pCms manufacture / quality control; or • 2 years practical experience under GMP relevant to pCms manufacture / quality control^. Experience shall include at least 1 year of relevant practical experience obtained in Hong Kong.

Remarks:

^ Without prejudice to the generality of the requirements of criteria, duration of practical experience obtained under GMP relevant to pCms manufacture / quality control should generally be equivalent to double of that obtained not under GMP.

***** "A bachelor's degree in a relevant science subject" generally includes a major subject in the following areas: (Analytical or Organic) Chemistry or Biochemistry, Chemical Engineering, Microbiology, Pharmacy, Pharmaceutical Science / Technology, Pharmacology, Toxicology, Pharmacognosy, Physiology, Medicine or other science subjects accepted by the CMB.

6. Apart from referring to the above minimum requirements on qualification and experience, the manufacturers of pCms planning to implement pCm GMP shall consider whether the key personnel being recruited are adequately qualified and experienced to cater for their individual needs.

7. Manufacturers of pCms, in applying for pCm GMP Certificates, should submit adequate supporting documents in respect of the qualifications and experience of the relevant key personnel for approval.

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This document has been translated into English. If there is any inconsistency or ambiguity between the English version and the Chinese version, the Chinese version shall prevail.