Guidance on Application for Registration as Authorized Person

Introduction

Under Regulation 30A of the Pharmacy and Poisons Regulations (Cap. 138A), a licensed manufacturer must ensure that at least one Authorized Person ("AP") is employed to be responsible for ensuring and certifying that each batch of the pharmaceutical products has been manufactured and checked in accordance with the Good Manufacturing Practice ("GMP") Guide issued by the Pharmacy and Poisons Board of Hong Kong, and that the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products.

2. For the purpose of making an application for registration as an AP, applicants need to provide evidence to the satisfaction of the Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee") that they possess the required qualifications and experience, and that they are fit and proper persons to be registered as APs. The Committee will assess the supporting evidence with the assistance of the Drug Office of the Department of Health.

Qualification and Experience Requirements

Authorized Person for Pharmaceutical Manufacturers

3. An applicant applying for registration as an AP for pharmaceutical manufacturers is required to satisfy either one of the following qualification requirements:

(a) be a registered pharmacist in Hong Kong; or
(b) hold a qualification awarded on completion of a course recognized by the Committee.

In addition to possessing the above qualifications, the applicant should have:

(c) at least 3 years of relevant practical experience in GMP pharmaceutical manufacturing and/or quality control (at managerial or supervisory level) in one or more pharmaceutical manufacturers.

4. The relevant experience must have been acquired in Hong Kong or in a country or region whose regulatory authority is a Participating Authority of the Pharmaceutical Inspection Cooperation Scheme ("PIC/S").

5. The 3 years of experience should include at least 1 year preparatory period (which is preceded by at least 2 years of the relevant experience) during which the person is under the supervision and professional guidance of a practising AP in Hong Kong and should assist in exercising the duties of an AP. The applicant should provide evidence that he or she has gained such an experience.

6. For an applicant who has already been practising as an AP or equivalent positions in countries or regions whose regulatory authority is a PIC/S Participating Authority, the applicant should provide evidence that his or her qualification and experience are comparable to the requirements stated in paragraph 3.

Authorized Person for Manufacturers of Advanced Therapy Products

7. An applicant applying for registration as an AP for advanced therapy product[1] ("ATP") manufacturers should, subjected to conditions that the Committee thinks fit to impose, be:

(a) a holder of a bachelor's degree in a discipline such as biotechnology, biomedical engineering, medical laboratory science or other similar disciplines with at least 3 years of working experience at managerial or supervisory level in GMP manufacturing or quality control of ATPs;
(b) a holder of a postgraduate degree of science relevant to cell therapy, gene therapy, regenerative medicines or tissue engineering, or other related sciences with at least 2 years of working experience at managerial or supervisory level in GMP manufacturing or quality control of ATPs;
(c) a holder of a degree of doctor of philosophy (PhD) of science relevant to cell therapy, gene therapy, regenerative medicines or tissue engineering, or other related sciences with at least 1 year of working experience at managerial or supervisory level in GMP manufacturing or quality control of ATPs;
(d) a person who has already been practicing as an AP or equivalent positions for ATP manufacturers in a country or region where the regulatory authority is a PIC/S Participating Authority; or
(e) a holder of a degree of PhD of science relevant to cell therapy, gene therapy, regenerative medicines or tissue engineering, or other related sciences with at least 2 years of post-doctoral working experience in the processing or quality control of cells, genes and tissue engineered products and with evidence of theoretical and practical training in GMP principles related to ATP manufacturing[2].

8. The applicant should also provide evidence that he or she has comprehensive knowledge on the pharmaceutical law and administration in Hong Kong as stated in section 1 of Annex A of the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong".

[1] The definition of advanced therapy product is set out in section 2 of the Pharmacy and Poisons Ordinance (Cap. 138).
[2] Registration of AP by the qualification and experience listed in 7(e) is subjected to additional requirement stipulated in section 5.6 of the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong."

Authorized Person for Pharmaceutical Manufacturers of Medical Gases

9. An applicant applying for registration as an AP for Medical Gas Manufacturers is required to satisfy the following qualification and experience requirements stipulated in 9(a) and 9(b), or the requirements in 9(c).

Qualification and Experience Requirements

(a) a holder of a bachelor's degree in a relevant science or engineering discipline with at least 3 years of relevant experience at managerial or supervisory level in the manufacturing or quality control in one or more manufacturers of medical gases;
(b) provide evidence on theoretical training in GMP principles related to the manufacture of medical gases and on the pharmaceutical law and administration in Hong Kong as stated in section 1 of Annex A of the "Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong".

Remarks: The relevant working experience must have been gained in Hong Kong or in a country or region where the regulatory authority is a PIC/S Participating Authority.

Alternative Qualification and Experience Requirements

(c) a person who has already been practicing as an AP or at an equivalent position in a country or region where the regulatory authority is a PIC/S Participating Authority with evidence to demonstrate to the satisfaction of the Committee that his or her qualification and experience are comparable to the requirements as stated in 9(a) and 9(b) respectively.

Authorized Person for Secondary Packaging Manufacturers

10. An applicant applying for registration as an AP solely for certification of the release of pharmaceutical products that have undergone secondary packaging operations is required to satisfy either one of the following qualification and experience requirements:

(a) post-secondary qualification with:

- 1 year of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products; or

- 6 months of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products, together with a certified GMP training.

(b) secondary qualification with:

– 2 years of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products; or

– 1 year of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products, together with a certified GMP training.

11. Secondary qualification means having:

(a) Level 2 or equivalent or above in five subjects (including Chinese Language and English Language) in the Hong Kong Diploma of Secondary Education Examination ("HKDSEE"), or equivalent;
(b) Level 2 / Grade E# or above in five subjects (including Chinese Language and English Language) in the Hong Kong Certificate of Education Examination ("HKCEE"), or equivalent; or
(c) local accredited higher diploma, associate degree, diploma of foundation studies, diploma Yi Jin, or equivalent.

"Grade E" in Chinese Language and English Language (Syllabus B) in the HKCEE before 2007 are accepted administratively as comparable to "Level 2" in Chinese Language and English Language in the 2007 HKCEE and henceforth.

For qualifications awarded by granting bodies outside Hong Kong, the Hong Kong Council for Accreditation of Academic and Vocational Qualifications ("HKCAAVQ") provides assessment services for the general public, organisations, and government bureaux or departments. The HKCAAVQ offers a professional opinion on whether the totality of the educational qualifications (i.e. the integrated learning outcomes of the highest and terminal educational qualification) of an individual meets the standard of a particular level of qualification in Hong Kong (www.hkcaavq.edu.hk).

12. In granting a Certificate of Registration as AP, the Committee must take into consideration but are not limited to the following:

(a) previous drug-related conviction(s), in particular those having significant impact to public interest, of the applicant; and
(b) previous disciplinary action(s) against the applicant.

Application procedure

13. Application form for registration as an AP can be obtained, free of charge, by downloading from the website (www.drugoffice.gov.hk) or in person during the following hours:

Department of Health, Drug Office, Licensing and Compliance Division, Manufacturers Regulatory Unit Room 3817, 38/F, Revenue Tower, 5 Gloucester Road, Wan Chai, Hong Kong Tel.: 2594 7647 Fax: 3904 1225	Monday to Friday 9:00 a.m. to 1:00 p.m. 2:00 p.m. to 5:45 p.m. (up to 6:00 p.m. on Monday) (Closed on Saturdays, Sundays & Public Holidays)

14. The completed application form together with the relevant supporting documents should be submitted by post or in person to the above address.

15. In applying for registration, applicants have to produce the original (with photocopies) or notarised copies of the following supporting documents, together with the completed application form:

(a) certificate(s) of the academic qualification and relevant training;
(b) certificate(s) of the professional qualification (if applicable);
(c) certification(s) of experience in pharmaceutical manufacturing, quality control or secondary packaging (e.g. testimonial(s) from employers);
(d) certification of the preparatory period under the supervision and guidance of a practising AP (e.g. a letter signed by the AP providing guidance certifying that the applicant had gained such experience); and
(e) proofs of identity (Hong Kong identity card or passport).

16. After vetting by the Drug Office, the application will be considered by the Committee. The Committee may impose such conditions relating to the registration as it may think fit.

17. Any applicant aggrieved by a decision made in respect of the applicant may, in the prescribed manner, appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

18. Any enquiries on matters related to the application should be sent to the Manufacturers Regulatory Unit at the above address.

Certificate of registration

19. An applicant who is accepted for registration is required to pay a prescribed fee of $1,420 for a Certificate of Registration which will be issued when his or her name is added to the Register

of Authorized Persons. The certificate issued is valid until the end of the year and has to be renewed every year at a prescribed fee of $1,420.

20. The Committee may cancel or suspend the registration of an AP, or vary the registration condition(s) if, in its opinion, the AP is no longer a fit and proper person, has contravened a condition of the registration, any provision of the Pharmacy and Poisons Regulation or a Code of Practice applicable to AP, or has been convicted of a drug-related offence.

Notes

21. These notes are only a general guide and must not be treated as a complete or authoritative statement of the law on any particular case.

22. Copies of the Pharmacy and Poisons Ordinance and its subsidiary legislation may be purchased by calling the Publications Sales Unit of Information Services Department at 2537 1910 or by email at puborder@isd.gov.hk. Contents of the relevant legislation may also be found at the Hong Kong e-Legislation website (www.elegislation.gov.hk)

Statement of Purposes

Purpose of Collection

This personal data are provided by applicants for the purposes of application for registration as Authorized Person under the Pharmacy and Poisons Ordinance. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to process your application.

Classes of Transferees

2. The personal data you provide are mainly for use within the Department of Health and the Pharmacy and Poisons Board. Moreover, according to the Pharmacy and Poisons Ordinance, part of the information provided, such as names of Authorized Person and addresses, will be entered into a Register for public inspection. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

3. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

4. Enquiries concerning the personal data provided, including the making of access and corrections, should be addressed to:

Senior Pharmacist
Licensing and Compliance Division
Drug Office, Department of Health
Room 3817, 38/F, Revenue Tower,
5 Gloucester Road, Wan Chai, Hong Kong.
Tel: 2961 8028