Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong

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Pharmacy and Poisons Board of Hong Kong

Contents

1. Background

1.1 The GMP Guides issued by the Pharmacy and Poisons Board ("the Board") for Licensed Manufacturers of pharmaceutical products ("Pharmaceutical Manufacturers") and those carrying out only secondary packaging of pharmaceutical products ("Secondary Packaging Manufacturers") respectively require that batches of pharmaceutical products should only be released for sale or supply after certification by an Authorized Person ("AP").

1.2 In addition, both GMP guides require that personnel must have the necessary qualifications and practical experience to carry out their responsibilities, and manufacturers are responsible for providing training for all personnel whose activities could affect the quality of the product.

1.3 To ensure these requirements are met, the AP and other key personnel must be suitably qualified, experienced and competent for the types of manufacturing operations undertaken by the manufacturers for whom he or she works.

1.4 Moreover, manufacturers and APs must ensure that training programmes as well as continuing professional development ("CPD") is part of the organisation's culture.

1.5 Under the Pharmacy and Poisons Regulations (Cap. 138A), a Licensed Manufacturer must ensure that at least one AP is employed to be responsible for ensuring and certifying that:

a. each batch of the pharmaceutical products has been manufactured and checked in accordance with the GMP Guide; and

b. the registrable particulars of each batch of the pharmaceutical products correspond exactly with the registered particulars of the products.

1.6 The stipulated requirements for registration as an AP are that:

a. the person is a registered pharmacist or holds a qualification awarded on completion of a course recognized by the Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee"); and

b. the person has at least 3 years of relevant experience in Hong Kong or a place outside Hong Kong in manufacturing pharmaceutical products in accordance with the GMP Guide or a document similar or equivalent to that Guide issued or adopted by a competent authority of a place outside Hong Kong; or meets any other criteria that the Committee may specify.

2. Purpose of this Guidance

2.1 This document outlines the requirements relating to the qualifications, experience and training necessary for the APs and other key personnel working for manufacturers of pharmaceutical products in Hong Kong.

3. Scope

3.1 This document applies to:

a. APs, Heads of Production and Heads of Quality Control of Pharmaceutical Manufacturers ;

b. APs, Heads of Production and Heads of Quality Control of Licensed Manufacturers of advanced therapy products[1] ("ATPs");

c. APs, Heads of Production and Heads of Quality Control of Licensed Manufacturers of medical gases; and

d. APs (i.e. Quality Assurance Officers) and Persons-in-charge of Secondary Packaging Manufacturers.

[1] The definition of advanced therapy product is set out in section 2 of the Pharmacy and Poisons Ordinance (Cap.138).

4. Authorized Person for Pharmaceutical Manufacturers

4.1 The scientific education and relevant experience of APs should be such as to enable them to exercise independent professional judgement, on the basis of the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.

Registration as an AP for Pharmaceutical Manufacturers

4.2 An applicant applying for registration as an AP for Pharmaceutical Manufacturers should meet:

a. the qualification and experience requirements stipulated in 4.3 and 4.4 respectively; or

b. the requirements stipulated in 4.7.

Qualification and Experience Requirements

4.3 The applicant should either be:

a. a registered pharmacist; or

b. a holder of a qualification awarded on completion of a course recognized by the Committee—

i. In order for a course to be recognized by the Committee, the admission requirements for the course should require the applicants to have a qualification in pharmacy, medicine, veterinary medicine, pharmaceutical chemistry or technology, biology or other related sciences, awarded on completion of a university course of study or a course considered as equivalent by the Committee.

ii. The curriculum of the course should cover at least the knowledge requirements for APs as stated in sections 1 to 7 of Annex A. If the curriculum of the course did not cover the knowledge requirements stated in section 1 of Annex A, the applicant should provide evidence that he or she has comprehensive knowledge on the pharmaceutical law and administration in Hong Kong as stated in that section. Explanatory notes in Annex B provide elaboration on the criteria for recognition of a course by the Committee.

4.4 The applicant, in addition to 4.3, should possess relevant practical experience—

a. at least 3 years of relevant experience at managerial or supervisory level in GMP pharmaceutical manufacturing in one or more pharmaceutical manufacturers; and/or

b. at least 3 years of relevant experience at managerial or supervisory level in quality control in one or more pharmaceutical manufacturers.

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

4.6 The 3 years of relevant 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.

Alternative Qualification and Experience Requirements

4.7 An applicant who has already been practising as an AP or equivalent positions in countries or regions where the regulatory authority is a PIC/S Participating Authority should provide evidence to demonstrate to the satisfaction of the Committee that his or her qualification and experience are comparable to the requirements as stated in 4.3 and 4.4 respectively.

Additional Requirements for Release of Pharmaceutical Products Requiring Special Attention

4.8 An AP employed for the release of pharmaceutical products requiring special attention should provide evidence of relevant training and/or practical experience, so as to demonstrate to the satisfaction of the Committee that he or she is suitably qualified, experienced and competent for the types of the manufacturing operations undertaken by the Pharmaceutical Manufacturers for whom he or she works.

4.9 Additional requirements for some types of products that require special attention are listed below:

a. For sterile pharmaceutical products, the APs should receive relevant training and/or possess relevant practical experience in sterile manufacturing.

b. For ATPs or medical gases, the APs should receive relevant training and/or possess practical experience relevant to the types of the manufacturing operations undertaken by the manufacturer.

c. For active pharmaceutical ingredients, the APs should possess qualification of training in knowledge requirement as stated in section 8 of Annex A.

d. For investigational medicinal products, the APs should possess qualification of training in knowledge requirement as stated in section 9 of Annex A.

5. Authorized Person for Pharmaceutical Manufacturers of Advanced Therapy Products

5.1 The scientific education and relevant experience of APs of Pharmaceutical Manufacturers of ATPs ("ATP Manufacturers") should be such as to enable them to exercise professional judgement, on the basis of the application of scientific principles and their understanding to the practical problems encountered in GMP manufacturing and quality control of ATPs.

Registration as an AP for ATP Manufacturers

5.2 An applicant applying for registration as an AP for ATP Manufacturers should meet the qualification and experience requirements stipulated in 5.3 and 5.4, and any conditions the Committee thinks fit to impose.

Qualification and Experience Requirements

5.3 The applicant should be:

a. a holder of a bachelor's degree in a discipline such as biotechnology, biomedical engineering, medical laboratory science and 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, who in this case should be registered as the AP with additional requirement stipulated in 5.6.

5.4 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.

Additional Requirements for Release of ATPs

5.5 An AP employed for the release of ATPs should:

a. provide evidence of relevant training and/or practical experience in sterile pharmaceutical products, biological substances and products, active pharmaceutical ingredients, and/or investigational medicinal products, in the case it may apply, so as to demonstrate to the satisfaction of the Committee that he or she is suitably qualified, experienced and competent for the types of the manufacturing operations undertaken by the manufacturer for whom he or she works; and

b. meet any other criteria that the Committee may specify.

5.6 An AP registered with the qualification and experience as stated in 5.3(e) and employed for the release of ATPs, in addition to 5.5, should demonstrate to the Committee—on the basis of application of scientific principles and his or her understanding to the practical problems encountered in GMP manufacturing and quality control of the ATPs—that he or she can exercise the duties as an AP for the types of the manufacturing operations undertaken by the manufacturer of ATPs, with the collaboration of:

a. one or more AP(s) registered for Pharmaceutical Manufacturers or AP(s) for ATP Manufacturers that is registered with qualification and experience other than in 5.3(e); or

b. one or more person(s) who has already been practicing as an AP or equivalent positions in a country or region where the regulatory authority is a PIC/S Participating Authority.

5A. Authorized Person for Pharmaceutical Manufacturers of Medical Gases

5A.1. The scientific education and relevant experience of APs of Pharmaceutical Manufacturers of medical gases ("Medical Gas Manufacturers") should be such as to enable them to exercise professional judgement, on the basis of the application of scientific principles and their understanding to the practical problems encountered in GMP manufacturing and quality control of medical gases.

Registration as an AP for Medical Gas Manufacturers

5A.2. An applicant applying for registration as an AP for Medical Gas Manufacturers should meet the qualification and experience requirements stipulated in 5A.3 and 5A.4, or the requirements in 5A.6.

Qualification and Experience Requirements

5A.3. The applicant should be 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.

5A.4. The applicant should also 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.

5A.5. 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

5A.6. An applicant who has already been practising as an AP or at an equivalent position in a country or region where the regulatory authority is a PIC/S Participating Authority should provide evidence to demonstrate to the satisfaction of the Committee that his or her qualification and experience are comparable to the requirements as stated in 5A.3 and 5A.4 respectively.

6. Authorized Person for Secondary Packaging Manufacturers

6.1 The education and relevant experience of APs for Secondary Packaging Manufacturers (i.e. Quality Assurance Officer) should be such as to enable them to exercise independent professional judgement, on the basis of the application of relevant principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.

Registration as an AP for Secondary Packaging Manufacturers (i.e. Quality Assurance Officer)

6.2 An applicant applying for registration as an AP solely for secondary packaging operations (i.e. Quality Assurance Officer) should meet the qualification and experience requirements stipulated in 6.3.

Qualification and Experience Requirements

6.3 The applicant should possess—

a. post-secondary qualification with 1 year of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products;

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

c. secondary qualification with 2 years of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products; or

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

6.4 The criteria for recognition of a certified GMP training for APs for Secondary Packaging Manufacturers (i.e. Quality Assurance Officers) and Persons-in-charge of Secondary Packaging Manufacturers are set out in Annex D.

6.5 Secondary qualification means an attainment of–

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[2] 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.

6.6 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 (http://www.hkcaavq.edu.hk/).

[2] '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.

7. Other Key Personnel

7.1 The education and relevant experience of Heads of Production and Heads of Quality Control should be such as to enable them to exercise independent professional judgement, on the basis of the application of relevant principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.

Head of Production and Head of Quality Control for Pharmaceutical Manufacturers

Qualification and Experience Requirements

7.2 The Head of Production or Head of Quality Control for Pharmaceutical Manufacturers should be:

a. a holder of a bachelor's degree in pharmacy with at least 2 years relevant working experience in GMP pharmaceutical manufacturing or quality control;

b. a holder of the Higher Diploma in Pharmaceutical Technology or of the Certificate in Dispensing Studies awarded by the Vocational Training Council of Hong Kong ("VTC"), with at least 3 years of relevant working experience in GMP pharmaceutical manufacturing or quality control;

c. a holder of the Higher Diploma in Pharmaceutical Science (Technology and Management) awarded by the VTC with at least 3 years of relevant working experience in GMP pharmaceutical manufacturing or quality control[3]; or

d. a holder of a bachelor's degree in a relevant science discipline with at least 3 years of relevant working experience in GMP pharmaceutical manufacturing or quality control.

Additional Requirements for Those Working for Manufacturers of Pharmaceutical Products Requiring Special Attention

7.3 A Head of Production or a Head of Quality Control for manufacturers of pharmaceutical products that require special attention (e.g. sterile products) should provide evidence of relevant training and/or practical experience, so as to demonstrate to the satisfaction of the Committee that he or she is suitably qualified, experienced and competent for the types of manufacturing and quality control operations undertaken by the manufacturers for whom he or she works.

[3]Graduates of this course in the year 2014 are required to provide an additional "Certificate in Pharmaceutical Science (Pharmaceutical Microbiology Module)" awarded by the VTC.

Head of Production and Head of Quality Control for ATP Manufacturers

7.4 The Head of Production and Head of Quality Control for ATP Manufacturers should meet the qualification and experience requirements stipulated in 7.5 and 7.6.

Qualification and Experience Requirements

7.5 The Head of Production or Head of Quality Control for ATP Manufacturers should be—

a. a holder of a bachelor's degree in a discipline such as biotechnology, biomedical engineering, medical laboratory science and 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 similar 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 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; or

d. 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.

7.6 The Head of Production or Head of Quality Control for ATP Manufacturers should provide evidence that he or she received relevant training and/or possess practical experience in sterile pharmaceutical products, biological substances and products, active pharmaceutical ingredients, and/or investigational medicinal products, in the case it may apply, so as to demonstrate to the satisfaction of the Committee that he or she is suitably qualified, experienced and competent for the types of manufacturing operations undertaken by the manufacturers for whom he or she works.

The Head of Production or the Head of Quality Control Performing the Role of AP

7.7 The same person can perform the role of Head of Quality Control and the AP of ATP Manufacturers. It is also possible for the AP to be responsible for production. However, responsibility of the Head of Production and the Head of Quality Control cannot be assumed by the same person.

7.8 In manufacturers with small organization where personnel are multi-skilled and trained in both production and quality control activities, it may be acceptable that the same person is responsible for

both roles with respect to different batches. For any given batch, the responsibility for production and quality control of the batch must be vested on two different persons. Accordingly, it becomes particularly important that the independency of the quality control activities from the production activities for the same batch is clearly established through appropriate written procedures.

Head of Production and Head of Quality Control for Medical Gas Manufacturers

7.9 The Head of Production and Head of Quality Control for Medical Gas Manufacturers should meet the qualification and experience requirements stipulated in 7.10.

Qualification and Experience Requirements

7.10 The Head of Production or Head of Quality Control for Medical Gas Manufacturers should be a holder of a bachelor's degree in a science or engineering discipline with at least 3 years of working experience at managerial or supervisory level in manufacturing or quality control of medical gases and with evidence on theoretical training in GMP principles related to the manufacture of medical gases.

7.11 The same person can perform the role of Head of Quality Control and the AP of Medical Gas Manufacturers. However, responsibility of the Head of Production and the Head of Quality Control cannot be assumed by the same person.

Person-in-charge of Secondary Packaging

Qualification and Experience Requirements

7.12 The Person-in-charge of Secondary Packaging should possess:

a. post-secondary qualification with 1 year of experience in GMP Pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products;

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

c. secondary qualification with 2 years of experience in GMP Pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products; or

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

7.13 Details of the certified GMP training and meaning of 'secondary qualification' are set out in Annex D and section 6.5 respectively.

8. Continuing Professional Development for Authorized Persons and Other Key Personnel

8.1 The continuing professional development ("CPD") training programme for APs and other key personnel of Licensed Manufacturers is to ensure that they continue to possess up-to-date knowledge and skills with a view to maintain quality professional practice. Under the programme, key personnel should undertake CPD training every year on topics relevant to their role and duties.

CPD Training for APs

8.2 In order to renew his or her registration each year, a registered AP must provide evidence that he or she has undertaken CPD training at courses, seminars, webinars or any other form of training approved by the Committee for—

a. at least 20 hours per year or equivalent for an AP for Pharmaceutical Manufacturers, including APs for ATP and Medical Gas Manufacturers; or

b. at least 7 hours per year or equivalent for an AP solely for Secondary Packaging Manufacturers (i.e. a Quality Assurance Officer).

8.3 A registered AP should fulfill the requirements every year for a period from 1 December of the previous year to 30 November of the current year in order for their registration to be renewed in January annually. For example, to renew the registration in January 2022, registered AP should fulfill and complete the required CPD training within the period from 1 December 2020 to 30 November 2021. Details of requirements are set out in Annex C.

8.4 Examples of CPD training topics relevant to the role and duties of AP for Pharmaceutical Manufacturers include:

a. Role and professional duties of an AP

b. Quality management systems

c. Quality risk management

d. Qualification & validation

e. PIC/S GMP Guide and Annexes

f. Pharmaceutical manufacturing or technology

g. Pharmaceutical packaging

h. Warehousing

i. Pharmaceutical microbiology

j. Sampling, analysis and testing of pharmaceuticals

k. Active pharmaceutical ingredients

l. Mathematics and statistics related to pharmaceuticals

m. Registration of pharmaceutical products

8.5 Examples of CPD training topics relevant to the role and duties of AP for Secondary Packaging Manufacturers (i.e. Quality Assurance Officer) include:

a. Pharmaceutical law and administration in Hong Kong

b. Role and professional duties of an AP

c. Quality management systems

d. Quality risk management

e. PIC/S GMP Guide and Annexes

f. Pharmaceutical packaging

g. Warehousing

h. Registration of pharmaceutical products

CPD Training for Head of Production and Head of Quality Control

8.6 The Head of Production or Quality Control for Pharmaceutical Manufacturers, including heads for ATP and Medical Gas Manufacturers, who does not perform the role of AP should undertake at least 14 hours per year or equivalent of CPD training on topics relevant to his or her role and duties. He or she should maintain records of this training for review by inspectors during GMP inspections. The CPD requirements will be implemented at a later stage as determined by the Committee.

8.7 Examples of CPD training topics relevant to the role and duties of Head of Production or Quality Control include:

a. Quality management systems

b. Quality risk management

c. Qualification & validation

d. PIC/S GMP Guide and Annexes

e. Pharmaceutical manufacturing or technology

f. Pharmaceutical packaging

g. Warehousing

h. Pharmaceutical microbiology

i. Sampling, analysis and testing of pharmaceuticals

CPD Training for Person-in-charge of Secondary Packaging

8.8 The Person-in-charge of Secondary Packaging should undertake at least 7 hours per year or equivalent of CPD training on topics relevant to his or her role and duties. He or she should maintain records of this training for review by inspectors during GMP inspections. The CPD requirements will be implemented at a later stage as determined by the Committee.

8.9 Examples of CPD training topics relevant to the role and duties of Person-in-charge of Secondary Packaging include:

a. Quality management systems

b. Quality risk management

c. PIC/S GMP Guide and Annexes

d. Pharmaceutical packaging

e. Warehousing

Approved CPD Training

8.10 The CPD training activities and their providers should be assessed and approved by the Committee. A list of approved CPD training activities and their providers is available on the websites of the Board and Drug Office. The list will be updated periodically.

8.11 For those CPD training activities organised by other training providers (i.e. activities and/or their providers not recognized by the Committee yet), APs or those training providers should submit application, via the Drug Office, to the Committee for approval. For details, please refer to Annex C.

Annex A: Knowledge Requirements for Authorized Person

1. Pharmaceutical Law and Administration in Hong Kong

1.1 The AP, in particular, must ensure that all legislative obligations are fully satisfied before any product is released for sale or supply.

1.2 An AP must have comprehensive knowledge of all Hong Kong legislation relating to the registration, manufacture, storage and supply of pharmaceutical products and should have a thorough understanding of the following:

a. Registration of pharmaceutical products, manufacturing and wholesaler licensing / approval structure, content, application and approval procedures, and responsibilities;

b. Role, legal status and structure of the relevant pharmacopoeia requirements in Hong Kong;

c. Procedures for dealing with complaints and product recalls, the role of the defect reporting process in Hong Kong; and

d. How to interpret and apply the regulations concerning importation and exportation of pharmaceutical products in Hong Kong.

2. The Role and Professional Duties of an AP

2.1 It is incumbent upon all APs that they discharge their professional duties in accordance with the Code of Practice for Hong Kong Licensed Manufacturers and Registered Authorized Persons.

2.2 It is the responsibility of the AP to certify that a product has been manufactured or packaged in compliance with the requirements of the current GMP guide issued by the Board in respect of pharmaceutical products and the registrable particulars correspond with the registered particulars for the products.

2.3 The AP must be aware of any information, incidents or deviations which may influence their decision to certify whether a batch is suitable for release for sale or supply.

2.4 APs should have a thorough understanding of the following:

a. The routine legal duties of an AP, the level of oversight required; including detailed knowledge on the principles and application of ‘quality risk management’ within the pharmaceutical industry;

b. Batch review and decision making on disposition of batches of pharmaceutical products, i.e. whether to release for sale or supply; or in the case of non-compliant or defective material to decide on its rejection, rework orreprocessing;

c. The key factors, information or metrics that confirm a batch of pharmaceutical product has a suitable pedigree demonstrated throughout the manufacturing supply chain and has been manufactured according to current PIC/S GMP requirements;

d. The principles and practice of current GMP and quality assurance ("QA") as given in the current PIC/S Guide to GMP, including related Hong Kong legislation;

e. The conduct and obligations of holders of a manufacturer licence and registration certificates for pharmaceutical products;

f. The preparation for and management of regulatory GMP inspections;

g. The tools and methods used for risk management and their interface with regulatory requirements; and

h. The requirements for APs when acting as independent contractors or on behalf of third parties.

3. Quality Management Systems

3.1 The manufacture of pharmaceutical products requires the establishment and implementation of an effective 'quality management system' ("QMS"). The basic concepts of QA, GMP, quality control ("QC") and quality risk management, which are inter-related, form the basis of such a system for the manufacture of pharmaceutical products from initial development, through clinical phases to commercial supply.

3.2 APs must have a thorough understanding of the following:

a. The philosophy and basic principles of QA;

b. The design criteria for an effective QMS including but not limited to;

   i. auditing and self-inspections;

   ii. management of quality and GMP at approved vendors and contractors;

   iii. deviations, root cause analysis, corrective and preventive actions;

   iv. change control;

   v. documentation and record keeping;

   vi. quality risk management;

   vii. complaints and recalls; the interpersonal skills (leadership, delegation, communication, etc.) necessary to implement an effective QMS;

c. The interpersonal skills (leadership, delegation, communication, etc.) necessary to implement an effective QMS;

d. The principles of design, selection, qualification and maintenance of premises, equipment, utilities, and services;

e. Calibration, preventative maintenance and training;

f. The principles of purchasing and supplier certification, including knowledge of supply chains and material control including but not limited to:

   i. the roles of brokers, distributors and repackers;

ii. prevention of counterfeiting and illegal activities;

iii. processes to support and verify the supply chain pedigree;

iv. monitoring and control of both product and raw material transport and distribution processes.

g. Production planning, scheduling, and inventory control;

h. Product quality reviews;

i. The interface between QA and the planning, production, quality control, purchasing, pharmaceutical development, regulatory affairs, medical, pharmacovigilance and marketing departments;

j. The skills and competences needed to provide effective Good Pharmaceutical Manufacturing Practice training;

k. Organizational structures and reporting relationships;

l. Technical agreements and auditing in contract giving and acceptance.

4. Pharmaceutical Formulation and Processing

4.1 The formulation and processing conditions employed in the manufacture of pharmaceutical products have a significant effect upon their safety, quality and efficacy. Even subtle changes to the input materials and/or processing conditions can have a profound adverse effect on content uniformity, stability, bioavailability, and other attributes which are not detectable by routine QC testing.

4.2 It is vitally important that the AP understands the principles of formulation and pharmaceutical processing to ensure that informed release decisions are made.

4.3 APs must have a good understanding of the following:

a. The major processing techniques, their limitations and critical control parameters;

b. The factors that could potentially affect purity, content uniformity, stability (chemical, physical and microbiological) and bioavailability in manufacture;

c. The principles of process validation and control;

d. The principles of technology transfer and production scale-up;

e. Pre-formulation studies and product development; and

f. The storage and distribution of materials and finished products.

5. Pharmaceutical Microbiology

5.1 The AP must understand the significance of the presence of bacteria, yeasts, moulds, viruses and toxins in pharmaceutical starting materials, products and production environments. In addition, they must understand how to prevent contamination through good product and facility design, GMP and control over starting materials, intermediates, finished products, production plant and processes, people and the environment.

5.2 APs must have a good understanding of the following:

a. Sources and types of micro-organisms as related to pharmaceutical production;

b. Production of sterile and non-sterile products and associated environmental controls;

c. Bacterial endotoxins and pyrogens, their sources, removal and testing;

d. Microbiology of water, its production and distribution systems; including different grades of water, their use, manufacture and control;

e. Sterilization and disinfection methods;

f. Interpretation of microbiological data;

g. Validation of microbiological test methods;

h. Microbiological specifications;

i. Selection and use of preservatives;

j. Microbiological test methods used in routine manufacture and product development; and

k. Rapid methods of microbiological testing.

6. Analysis and Testing

6.1 The sampling and testing of materials does not by itself assure product quality. It must be seen as one part of a comprehensive QMS, including QA and GMP, which must be correctly implemented and controlled.

6.2 The data generated by laboratory testing of samples must be evaluated before materials are released for sale or supply.

6.3 APs must have a good understanding of the following:

a. Good Control Laboratory Practice;

b. The underlying principles of and interpretation of qualitative and quantitative analytical methods in common use for the analysis of medicinal products;

c. The underlying principles, application and interpretation of biological analytical test methods and validation;

d. The underlying principles, application and interpretation of analytical method selection and validation;

e. The underlying principles, application and interpretation of stability testing (protocols and methods), used during development to determine product shelf life and support ongoing marketing of the product;

f. The significance of degradation, contamination and adulteration of pharmaceutical materials;

g. The underlying principles, methods and types, purpose, significance and management of systems of in-process control;

h. The underlying principles, application and design of sampling regimes;

i. The underlying principles, application and design of analytical method transfers;

j. The International Conference on Harmonisation guidelines for method validation, impurities and stability testing;

k. "Out-of-specification" results and systems or procedures for monitoring and control; and

l. Sample retention and retesting.

7. Pharmaceutical Packaging

7.1 It is a requirement of GMP that holders of manufacturing licences establish procedures for their packaging operations to minimise the risk of cross-contamination, mix-up or substitutions. The AP must understand the importance of controlling packaging components (both primary and printed materials) throughout the supply chain to assure the quality of finished products.

7.2 APs must have a good understanding of the following:

a. Control of packaging components by suppliers and throughout production;

b. The chain of systems which ensure the integrity and accuracy of textual information from originator to routine production, including artwork generation, text approvals and regulatory submission requirements;

c. The testing of packaging materials as part of incoming goods checks, including the application of sampling regimes and vendor assurance programmes;

d. The potential root causes of label and other printed component mix-ups and how they can be identified and eliminated;

e. The optimum layout, organization and control of packaging operations, different types of packaging and labelling processes and equipment, including the consideration of the type of equipment required for high volume or high speed operations and smaller or manual operations;

f. The underlying principles and application of in-process controls conducted during packaging operations, including line clearance, pack integrity testing, challenge testing, reconciliation, bar coding and optical systems;

g. The design and completion of packaging batch records, including full traceability of all products and materials for investigation and recall purposes;

h. Effects of packaging materials on product stability; and

i. The requirements and desirability of tamper-evidence, anti-counterfeiting and general supply chain security.

8. Active Pharmaceutical Ingredients

8.1 The AP working for an active pharmaceutical ingredient ("API") manufacturer, or an ATP Manufacturer or Medical Gas Manufacturer where applicable, must understand the influence of manufacturing pathways and associated physico-chemical and biological attributes, of both active pharmaceutical ingredients and major excipients on the quality of the finished dosage form.

8.2 APs working for API manufacturers must have a good understanding of the following:

a. The steps commonly taken in the manufacture of APIs and excipients including their purpose and limitations;

b. The requirements of Part II of the PIC/S Guide to GMP as applied to the production of APIs;

c. The pathways responsible for the generation of impurities or degradation products, analytical methods for their identification, quantification, and possible strategies for elimination of such impurities;

d. The potential and avoidance of contamination and adulteration of API and verification of the supply chain pedigree;

e. The physico-chemical and biological properties of APIs and excipients, and their effect on the attributes of the final dosage form;

f. The requirements for APIs intended for use in sterile products, ATPs and medical gases;

g. The principles and technical requirements for the manufacture and control of bulk biological, herbal and biotech products; and

h. API audit and certification requirements.

9. Investigational Medicinal Products

9.1 The manufacture, packaging and distribution of investigational medicinal products ("IMPs") must be controlled. There are significant differences between the manufacture and packaging of IMPs and licensed dosage forms. The AP must understand these differences together with the safeguards required to assure the quality of IMPs supply.

9.2 APs involved in the manufacture, packaging and distribution of IMPs must have a good understanding of the following:

a. The application and interpretation of specific GMPs associated with the manufacture of IMPs;

b. The underlying principles and application of the manufacture and control, the expectations around the level of validation required for each phase of development, including those for analytical methods and those processes, equipment and tests essential to assure the safety and quality of the products;

c. The underlying principles and application of the control of packaging operations including blinding and associated controls;

d. The requirements for effective batch documentation, control, sampling, testing and batch release or certification, including the control and release of imported IMPs, comparators from other countries;

e. Change control and material traceability;

f. Controls surrounding the procurement, storage, distribution and control of IMPs, non-IMPs, placebo and licensed and un-licensed comparators;

g. The underlying principles, application and interpretation of Good Clinical Practice;

h. An appreciation of the Declaration of Helsinki;

i. The requirements for the content, management, control and application of the product registration file;

j. The structure and contents of the application of clinical trial certificate;

k. Clinical trial design at all phases (I, II, III and IV), including early stage safety and dose ranging studies through to post marketing studies;

l. The requirements for specific dosage forms and drug types; and

m. Safety management for clinical trials, including pharmacovigilance and associated reporting requirements.

Note: For the definition of IMP, please refer to the Annex 13 of the PIC/S Guide to GMP.

Annex B: Explanatory Notes for Recognition of a Course for Registration as Authorized Person of Pharmaceutical Manufacturers

1. Introduction

1.1 Regulation 30C of the Pharmacy and Poisons Regulations (Chapter 138A) stipulates that an applicant for registration as an AP could be a registered pharmacist or a holder of a qualification awarded on completion of a course which was recognized by the Committee.

1.2 This paper provides additional information for course providers and applicants for registration as AP when submitting applications for recognition of a course for registration as an AP of Pharmaceutical Manufacturers by the Committee. This does not apply to an AP of a manufacturer solely engaged in secondary packaging operations or in the manufacture of ATPs.

2. Course Requirements

2.1 In order for a course to be recognized by the Committee, it must meet established professional qualifications and educational standards. The goals and objectives of the course should embrace the scope of contemporary practice responsibilities of APs in Pharmaceutical Manufacturers as well as the emerging roles that ensure the production, control and release of products complying GMP requirements.

2.2 The course provider should demonstrate that it has the abilities and capacities to effectively manage the quality of the course, and the course meets the required standards to achieve its claimed objectives and deliver the intended learning outcomes. The criteria which the Committee must consider in recognition of the course include but are not limited to the followings:

2.2.1 Course providers

2.2.1.1 The course should be organized by a university that has an academic mission towards research and other scholarly activities.

2.2.2 Student admissions

2.2.2.1 The admission requirements for the course should require the applicant to have a qualification in pharmacy, medicine, veterinary medicine, pharmaceutical chemistry or technology, biology or other related sciences awarded on completion of a university course of study or a course considered as equivalent by the Committee.

2.2.3 Academic program

2.2.3.1 General course design

2.2.3.1.1 The course should, on completion, award an accredited master degree. The duration of the course should be at least one year for a full-time course or two years for a part-time course or in equivalent hours in core theoretical teaching and practical tuition. The mode of teaching can be face-to-face classroom teaching or distance learning.

2.2.3.1.2 Alternatively, the course should have been recognized by a PIC/S Participating Authority as educational requirements for practice as an AP or equivalent positions in that country or region.

2.2.3.2 Course curriculum (knowledge and skills)

2.2.3.2.1 The curriculum of the course should cover at least the following topics for the knowledge requirements for APs:

a. Pharmaceutical law and administration in Hong Kong
b. The role and professional duties of AP
c. Quality management systems
d. Pharmaceutical formulation and processing
e. Pharmaceutical microbiology
f. Analysis and testing
g. Pharmaceutical packaging

(For details, please refer to sections 1-7 in Annex A of the Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong).

2.2.3.3 Course assessment

2.2.3.3.1 To assess the student learning and progression, the assessment instruments of the course should be reliable and valid.

3. Application submission

3.1 There is no prescribed form for the application. The application must be made in writing by the course provider or an applicant applying for registration as AP. The application letter with the course portfolio and the documentary proof which the course fulfils the criteria set above should be submitted to the Drug Office, Department of Health.

Licensing and Compliance Division,
Drug Office, Department of Health
Room 3817,
38/F, Revenue Tower,
5 Gloucester Road,
Wan Chai, Hong Kong

Tel: 2594 7674 Fax.: 3904 1225
Email: gmp@dh.gov.hk

Monday to Friday
9:00 am to 1:00 pm
2:00 pm to 5:45 pm
(up to 6:00 pm on Monday)
(Closed on Saturdays, Sundays and Public Holidays)

Note: A meeting with the course provider may be held. The course provider should present specific information about the course as requested by the Committee.

Annex C: Continuing Professional Development Training Programme for Authorized Persons and Other Key Personnel

1. Introduction

1.1 The objective of the continuing professional development ("CPD") training programme for registered APs and other key personnel of Licensed Manufacturers is to ensure that they continue to possess up-to-date knowledge and skills in pharmaceutical quality management, regulatory aspects and GMP standards, product manufacturing and control technology, and general work practices with a view to maintain quality professional practice.

2. CPD Requirements

2.1 Key Personnel for Pharmaceutical Manufacturers

2.1.1 To renew the registration as an AP for Pharmaceutical Manufacturers including an AP for ATP Manufacturers each year, every AP must provide evidence that he or she has undertaken at least 20 hours per year or equivalent of CPD training at courses, seminars or any other form of training approved by the Committee.

2.1.2 The Heads of Production and Quality Control are encouraged to undertake at least 14 hours per year or equivalent of CPD training on topics relevant to their role and duties on self-regulatory and voluntary basis.

2.2 Key Personnel for Secondary Packaging Manufacturers

2.2.1 To renew the registration as an AP for Secondary Packaging Manufacturers (also known as Quality Assurance Officer) each year, the Quality Assurance Officer must provide evidence that he or she has undertaken at least 7 hours per year or equivalent of CPD training at courses, seminars or any other form of training approved by the Committee.

2.2.2 The Person-in-charge of Secondary Packaging are encouraged to undertake at least 7 hours per year or equivalent of CPD training on topics relevant to their role and duties on self-regulatory and voluntary basis.

3. Calculation of CPD Hours

3.1 A CPD year is a period of 12 months starting from 1 December of the previous year to 30 November of the current year. In general, one CPD hour is considered to be equivalent to one hour spent on the CPD training, subject to the approval of the Committee.

3.2 New APs and other new key personnel are required to complete their CPD requirements on a pro-rata basis.

3.3 It is the AP's and other key personnel's responsibilities to record and calculate how many CPD hours have taken place. Any excess CPD hours accumulated within a particular CPD year cannot be carried forward to any other CPD years.

3.4 A list of approved CPD training programmes and the respective CPD hours allocated by the Committee will be available and periodically updated on the websites of the Board and the Drug Office.

4. Details of the CPD Training Programme

4.1 CPD training programme is divided into two Category 1 and Category 2 CPD activities. Category 1 CPD training is defined as an activity that has been evaluated and approved by the Committee. Category 2 CPD training is defined as a learning activity that is relevant to the role and duties of the trainee and may enhance the current competency of or instil new knowledge or skills into the trainee. Those activities may not be approved by the Committee.

4.2 The CPD requirements for different groups of personnel are as follows:

4.2.1 The registered APs should complete at least 20 hours per CPD year of Category 1 CPD activities while Quality Assurance Officers should complete at least 7 hours per CPD year of Category 1 CPD activities to fulfil their CPD requirements. APs and Quality Assurance Officers are also encouraged to participate in Category 2 activities.

4.2.2 Other key personnel (including Heads of Production or Quality Control of Pharmaceutical Manufacturers and Persons-in-charge of Secondary Packaging) are encouraged to participate in either Category 1 or Category 2 CPD trainings to fulfil their CPD requirements. The CPD requirement for Heads of Production or Quality Control of Licensed Manufacturers is at least 14 hours per CPD year or equivalent while the Persons-in-Charge of Secondary Packaging was 7 hours per CPD year or equivalent.

Table 1. CPD Requirements for Different Groups of Personnel

	Hours of activities required to attend per CPD year	
	Category 1 activities	**Category 2 activities**
The registered APs	≥ 20 hours	Encouraged
Quality Assurance Officers	≥ 7 hours	Encouraged
Heads of Production	Encouraged ≥ 14 hours of either Category 1 or 2 activities	
Heads of Quality Control	Encouraged ≥ 14 hours of either Category 1 or 2 activities	
Persons-in-charge of secondary packaging	Encouraged ≥ 7 hours of either Category 1 or 2 activities	

4.2.3 Examples of Category 1 and Category 2 CPD Activities are as follows:

Table 2. Category 1 Activities

Item	Description of Activity
1A	**Attending a lecture, a course, a seminar or a webinar recognised by the Committee**
1B	**Presenting at or attending conferences or professional meetings recognised by the Committee**
1C	**Reading reference materials prescribed by the Committee** The date, time spent and reference materials read should be noted in a personal logbook.
1D	**Writing for publication on relevant GMP topics (e.g. journal articles, books, education materials)**
1E	**Teaching a programme on relevant GMP topics approved by the Committee** Repeated presentation of the same materials will not be counted as CPD activity unless the repeated work entails updating of the presentation material. In this case only the time spent on research and updating the material should be counted as CPD hours.

Table 3. Category 2 Activities

Item	Description of Activity
2A	**Attending a lecture, a course, a seminar, a webinar or a conference**
2B	**Participating in a professional reading and discussion group (e.g. in-house training, a journal club, invited talks and presentations)**
2C	**Reading professional journals or books** The date, time spent and literature read should be noted in a personal logbook.
2D	**Audio-visual viewing / Information technology / Printed media** Non-assessed audio / videotapes and information technology accessed via printed or electronic media (such as CD ROMs, the internet, etc.), either used privately by individuals or in a discussion group.

Notes:

1. Normal work activities carried out (e.g. lectures, presentations, researches or teaching and learning activities) as part of or wholly the AP's or key personnel's duties would not be awarded any CPD hours.

2. Reading, reviewing and writing reference materials, professional journals or books could claim a maximum of 6 CPD hours per year in Category 1 and/or Category 2 for key personnel for Pharmaceutical Manufacturers and 3 CPD hours per year in Category 1 and/or Category 2 for key personnel for Secondary Packaging Manufacturers.

3. Repeated attendance of a CPD activity of the same level on the same topic within two years would not be awarded any CPD hours.

5. Recognition of CPD training activities

5.1 To apply for recognition of CPD training, training providers should demonstrate their management capabilities in respect of CPD training programme. To this end, training providers should submit the following documents to the Committee for assessment:

5.1.1 Organizational management, including accreditation status, policy, quality assurance, and operational framework, etc.;

5.1.2 Physical resources;

5.1.3 Staffing, including qualification of teaching staff and experience in the field;

5.1.4 Pre-requisite and admission requirements;

5.1.5 Teaching methodology and learning objectives;

5.1.6 Assessment of the training effectiveness;

5.1.7 Record and information management;

5.1.8 Detailed programme structure and content (suggested CPD training topics are outlined in section 8 of the Guidance on Qualification, Experience and Training Requirements for Authorized Persons and other Key Personnel of Licensed Manufacturers in Hong Kong); and

5.1.9 Other information required by the Committee.

6. CPD Record Keeping

6.1 It is the AP's and other key personnel's responsibilities to maintain their CPD training records and the respective supporting documents for review upon request. When and as requested by the Committee, AP or Quality Assurance Officer must provide their CPD training records together with supporting documents within the appointed time. For auditing purposes, the CPD training records should be retained for at least 2 years after the period to which they relate. A CPD record sheet template is provided in Appendix 1.

6.2 CPD training is also a requirement for renewing the AP and Quality Assurance Officer registration. For renewal of registration, APs and Quality Assurance Officers should submit their completed CPD record sheets together with the Application Form for Renewal of Registration as Authorized Person to the Drug Office 1 month prior to expiry of the registration certificate submitted to the Drug Office, Department of Health.

Licensing and Compliance Division
Drug Office, Department of Health
Rm 3817, 38/F, Revenue Tower,
5 Gloucester Road, Wanchai, Hong Kong
Tel: 2594 7647 Fax: 3904 1225
Email: gmp@dh.gov.hk

Monday to Friday
9:00 am to 1:00 pm
2:00 pm to 5:45 pm
(up to 6:00 pm on Monday)
(Closed on Saturdays, Sundays and Public Holidays)

Appendix 1

Continuing Professional Development (CPD) Record Form

CPD Record Form for 1 December _____ to 30 November _____

Name: _____ **Post:** _____

CPD Activities		Training Provider & Title	Time Period	CPD Hours	
				Category 1	Category 2
(1)					
(2)					
(3)					
(4)					
(5)					
(6)					
(7)					
(8)					
(9)					
(10)					
(11)					
(12)					
			Total CPD Hours:		

I certify that the information provided is true and correct; the CPD training courses listed above have not been repeatedly attended in previous 24 months.

*Signature:*_____

Annex D: Criteria for Recognition of a Certified GMP Training for Authorized Persons (i.e. Quality Assurance Officers) and Persons-in-charge of Secondary Packaging Manufacturers

1. Introduction

1.1 According to the Guidance on Qualification, Experience and Training Requirements for Authorized Persons and Other Key Personnel of Licensed Manufacturers in Hong Kong, a person having post-secondary qualification applying for registration as an AP solely for secondary packaging operations (i.e. a Quality Assurance Officer) or a Person-in-charge in Secondary Packaging has to provide evidence showing that they obtain 1 year of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products; or 6 months of above experience together with a certified GMP training. For applicants with secondary qualification, he or she should have 2 years of experience in GMP pharmaceutical manufacturing and/or secondary packaging of pharmaceutical products; or 1 year of above experience together with a certified GMP training.

1.2 This paper outlines the criteria for recognition of a certified GMP training for the Quality Assurance Officer and Person-in-charge of Secondary Packaging in Hong Kong.

2. Criteria for Recognition

2.1 Training providers

2.1.1. The training providers should demonstrate their management capabilities in respect of the implementation of a certified GMP training.

2.2 Staff qualification

2.2.1. The trainers should be specialized in the field of pharmaceutical manufacturing or secondary packaging of pharmaceutical products and that he or she has experience in the packaging development, testing, legislation and project management across applications.

2.3 Course design

2.3.1 A certified GMP training should cover the skills and knowledge which apply to the needs and professional standards of Quality Assurance Officer and Person-in-charge of Secondary Packaging, including but not limited to:

a. Pharmaceutical law and administration in Hong Kong;
b. The role and professional duties of Quality Assurance Officer and Person-in-charge of Secondary Packaging;
c. The Hong Kong Guide to GMP for the Secondary Packaging of Pharmaceutical Products;
d. Code of Practice for Licensed Manufacturers and Registered Authorized Persons; and
e. Other guidance(s) for industry issued by the Drug Office (if applicable).

2.4 Mode of teaching

2.4.1 A minimum of 14 hours of classroom instruction with oral or written assessments is required for recognition of a certified GMP training. A Certificate of Completion should only be issued upon fulfilling attendance requirement of 90% or above and satisfactorily completing all required assessments.

3. Application Submission

3.1 There is no prescribed form for the application. The application must be made in writing by the course provider, the application letter with the course portfolio and the documentary proof which the course fulfils the criteria set above should be submitted to the Drug Office, Department of Health.

Licensing and Compliance Division,
Drug Office, Department of Health
Room 3817,
38/F, Revenue Tower,
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Monday to Friday
9:00 am to 1:00 pm
2:00 pm to 5:45 pm (up to 6:00 pm on Monday)
(Closed on Saturdays, Sundays and Public Holidays)

Note: A meeting with the course provider may be held. The course provider should present specific information about the course as request by the Committee.

Document Information

Version	Date	Description of Change
1.0	May 2015	First version
2.0	Apr 2018	Update on the requirements and implementation details for the CPD
3.0	Sep 2018	Revision of the scope and addition of qualification, experience and training requirements for AP and other key personnel for ATP Manufacturers. Addition of explanatory notes for recognition of a course for registration as AP.
4.0	Jul 2019	Addition of a new category under the qualification and experience requirements of AP for ATP manufacturers and other key personnel for ATP Manufacturers. Addition of a new mode of collaboration under the additional requirements for release of ATPs of AP for ATP Manufacturers. Re-organization of the outline of the document and grouping of the CPD for AP and other key personnel under an individual section.
4.1	Oct 2019	Update on the definitions of ATP according to the Pharmacy and Poisons (Amendment) Bill 2019 of Gazette (18 Oct 2019). Addition of document information.
4.2	Dec 2019	Update on the name of "Traders Licensing & Compliance Division" to "Licensing & Compliance Division".
4.3	Jun 2021	Deletion of the Annex on proposed definitions of ATPs. Update on the implementation of CPD requirements. Textual alignments with the "Code of Practice for Licensed Manufacturers and Registered Authorized Persons" and Regulation 30A of the Pharmacy and Poions Regulations, Cap. 138A.
4.4	May 2023	Update the address and telephone number due to relocation of office.
5.0	XXX 2023	Revision of the scope and addition of qualification, experience and training requirements for AP and other key personnel for Medical Gas Manufacturers.

DOCUMENT END