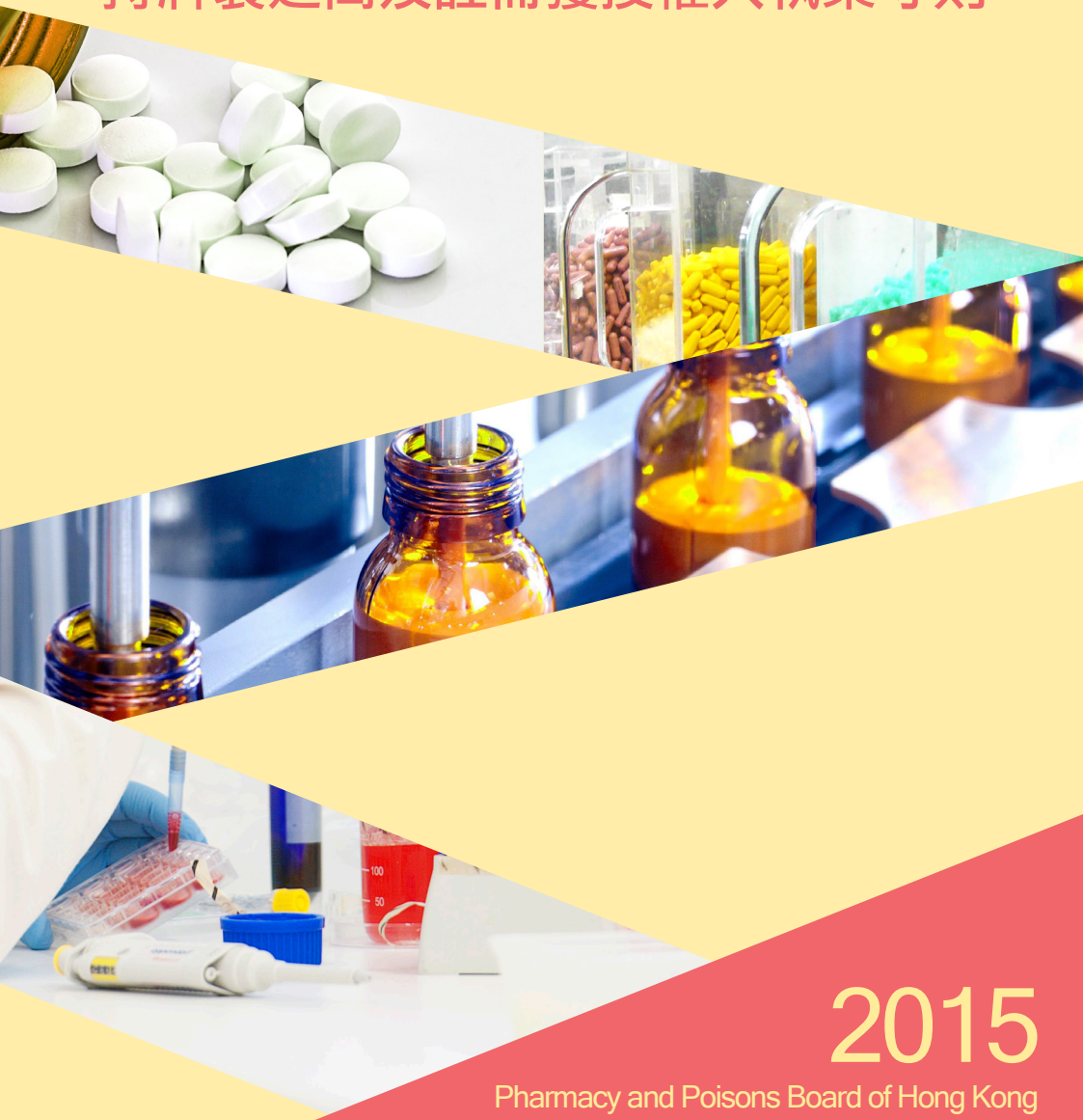
Code of Practice

for Licensed Manufacturers and Registered Authorized Persons

持牌製造商及註冊獲授權人執業守則



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Pharmacy and Poisons Board of Hong Kong

香港藥劑業及毒藥管理局

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http://www.ppbhk.org.hk

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第 1 條 背景

Licensed Manufacturers

1.1 According to regulation 29(1) of the Pharmacy and Poisons Regulations (Cap. 138A, Laws of Hong Kong), no person shall manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products ("manufacturer licence") on those premises. Manufacture of pharmaceutical products includes secondary packaging, which means the labelling, re-labelling, cartoning, re-cartoning or adding additional information (including inserts) to pharmaceutical products which are already enclosed in the container in which they are to be sold or supplied.

1.2 The issuing authority for manufacturer licence is the Pharmacy and Poisons (Manufacturers Licensing) Committee ("the Committee") of the Pharmacy and Poisons Board ("the Board"). The various criteria that the Committee

持牌製造商

1.1 根據《藥劑業及毒藥規例》(香港法例第 138A 章)第 29(1) 條，任何人不得在任何處所製造藥劑製品，但如該人持有牌照在該處所製造藥劑製品(「製造商牌照」)，則屬例外。藥劑製品的製造包括外包裝，外包裝指為已密封在容器內將予銷售或供應的藥劑製品加上標籤、重新加上標籤、裝盒、重新裝盒或加上補充資料(包括說明書)。

1.2 製造商牌照的簽發當局是藥劑業及毒藥管理局(「管理局」)轄下藥劑業及毒藥(製造商牌照)委員會(「委員會」)。委員會在批出和續發製造商牌照時，會考

may consider in granting and renewing a manufacturer licence includes the following:

a. supervison of the manufacturing process by a registered pharmacist or a person approved by the Board;

b. proper labelling of pharmaceutical products manufactured;

c. suitable premises used in the manufacturing, testing, packing and despatch of pharmaceutical products;

d. adequate hygiene control of personnel and premises to avoid contamination of pharmaceutical products;

e. quality assurance of raw materials and finished products with retention of control samples and all related records; and

慮下列各項準則：

a. 製造過程由註冊藥劑師或管理局批准的人士監督；

b. 所製造的藥劑製品有適當標籤；

c. 處所適合用作製造、測試、包裝和發送藥劑製品；

d. 對人員及處所的衞生有足夠監控，以防藥劑製品受到污染；

e. 原材料及製成品具品質保證，並保留對照樣本及所有相關記錄；以及

f. compliance with the current Good Manufacturing Practice (GMP) guide issued or adopted by the Board in respect of pharmaceutical products.

Registered Authorized Persons

1.3 Both the Pharmaceutical Inspection Co-operation Scheme's Guide to Good Manufacturing Practice for Medicinal Products ("PIC/S Guide to GMP") and the Hong Kong Guide to Good Manufacturing Practice for the Secondary Packaging of Pharmaceutical Products require that pharmaceutical products may not be sold or supplied unless a registered Authorised Person has certified that each batch of the products is produced and controlled in accordance with the requirements of the marketing authorisation and any other regulations relevant to the production, control and release of the products.

f. 遵從管理局發出或採用的現行藥劑製品生產質量管理規範指引。

註冊獲授權人

1.3 《國際醫藥品稽查協約組織藥品生產質量管理規範指引》(「《協約組織 GMP 指引》」)和《香港藥劑製品外包裝生產質量管理規範指引》載明除非在註冊獲授權人證明每個批次的藥劑製品已按銷售許可的規定及任何其他與生產、管制和放行藥品有關的規例生產和管制，否則不可銷售或供應藥劑製品。

1.4 To ensure compliance with the required standards in the manufacture of pharmaceutical products, the registered Authorized Person employed by Licensed Manufacturers of pharmaceutical products ("Pharmaceutical Manufacturers"), including the registered Authorized Person employed by manufacturers to carry out only secondary packaging of pharmaceutical products ("Secondary Packaging Manufacturers"), who is referred to as the Quality Assurance Officer, must be suitably qualified, experienced and competent for the types of manufacturing and packaging operations undertaken by the company that he or she works for.

1.4 為確保符合製造藥劑製品的標準要求，持牌藥劑製品製造商(「藥物製造商」)所僱用的註冊獲授權人，包括只為藥劑製品進行外包裝的製造商(「外包裝製造商」)所僱用的註冊獲授權人(即品質保證主任)，必須具備就其受僱公司進行的各種製造及包裝程序而言屬適當的資格、經驗及技能。

1.5 A system of registering Authorized Persons is established to ensure that only suitable persons will undertake this role.

1.5 獲授權人設有一套註冊制度，以確保這角色只由合適人士擔任。

Section 2 Purpose of this Code of Practice
第 2 條 本執業守則的目的

2.1 This Code of Practice sets out, in addition to those in the relevant GMP guide issued by the Board, the minimum standards, obligations and requirements to be followed by Licensed Manufacturers and registered Authorized Persons. Its purpose is to provide Licensed Manufacturers and registered Authorized Persons with practical guidance and directions for manufacturing of pharmaceutical products with a view to safeguarding the interest of the public.

2.1 本執業守則列明持牌製造商及註冊獲授權人，除由管理局發出相關的生產質量管理規範指引外，須遵從的最低標準、責任及規定，目的是向持牌製造商及註冊獲授權人提供有關製造藥劑製品的實際指引及指示，以保障公眾利益。

2.2 Compliance with this Code is one of the conditions upon which the Committee issues a manufacturer licence as well as conditions of registration of Authorized Person. All Licensed Manufacturers and registered Authorized Persons must observe the standards set out in this Code and be aware of the consequences of non-compliance.

2.2 遵從本守則的規定，是委員會發出製造商牌照的其中一項條件，亦是獲授權人的註冊條件。所有持牌製造商及註冊獲授權人必須遵循本守則所列明的標準，以及知悉不遵從規定的後果。

Section 3 Scope
第 3 條 涵蓋範圍

3.1 Part I of this Code of Practice applies to Licensed Manufacturers, including the Secondary Packaging Manufacturers.

3.1 本執業守則第 I 部適用於持牌製造商，包括外包裝製造商。

3.2 Part II of this Code of Practice applies to registered Authorized Persons employed by the Pharmaceutical Manufacturers, including registered Authorized Persons employed by Secondary Packaging Manufacturers, namely the Quality Assurance Officer.

3.2 本執業守則第 II 部適用於藥物製造商所僱用的註冊獲授權人，包括外包裝製造商所僱用的註冊獲授權人（稱為品質保證主任）。

Part I 第 I 部

Section 4 Obligations and Requirements for Licensed Manufacturers
第 4 條 持牌製造商須履行的責任及遵從的規定

Licensed Manufacturers of pharmaceutical products must ensure that the following obligations and requirements are met:

持牌藥劑製品製造商必須確保履行下列責任及規定：

4.1 Pharmaceutical products are manufactured and packaged in a manner which will ensure that they are fit for their intended use, comply with the registered particulars and will not place patients at risk due to inadequate safety, quality or efficacy of the pharmaceutical products.

4.1 藥劑製品的製造及包裝方式，須確保藥劑製品適合用於擬作的用途及符合註冊詳情，並且不會因藥劑製品的安全、品質或效能欠佳而令病人蒙受風險。

4.2 All manufacturing processes, packaging processes, and activities conducted on their licensed premises are carried out in a manner compliant with the relevant legislation, which include but are not limited to:

4.2 所有製造工序、包裝工序及在其持牌處所進行的活動，均以符合相關法例的方式進行。有關法例包括但不限於：

- the Import and Export Ordinance (Cap. 60);
- 《進出口條例》(第 60 章)；
- the Pharmacy and Poisons Ordinance (Cap. 138);
- 《藥劑業及毒藥條例》(第 138 章)；

- the Dangerous Drugs Ordinance (Cap. 134);
- 《危險藥物條例》(第 134 章);
- the Antibiotics Ordinance (Cap. 137);
- 《抗生素條例》(第 137 章);
- the Public Health and Municipal Services Ordinance (Cap. 132);
- 《公眾衞生及市政條例》(第 132 章);
- the Undesirable Medical Advertisements Ordinance (Cap. 231); and
- 《不良廣告(醫藥)條例》(第 231 章);以及
- the Trade Descriptions Ordinance (Cap. 362).
- 《商品説明條例》(362 章)。

4.3 Pharmaceutical products are manufactured, packaged and tested in accordance with the conditions specified on the manufacturer licence.

4.3 藥劑製品已按照製造商牌照載明的條件製造、包裝和測試。

4.4 All parts of the Quality Management System referred to in the current GMP guide issued by the Board are adequately resourced with competent

4.4 管理局發出的現行生產質量管理規範指引所提及的品質管理系統的各個部分,均獲提供足夠資源,

personnel and suitable and sufficient premises, equipment and facilities.

包括稱職的人員，以及合適和充足的處所、設備及設施。

4.5 Approval from the Committee has been obtained prior to any change in key personnel. The key personnel include the registered Authorized Person, Head of Production and Head of Quality Control, or, for Secondary Packaging Manufacturers, the Quality Assurance Officer and the Person in charge of secondary packaging.

4.5 關鍵人員如有任何變更，須先獲委員會批准。關鍵人員包括註冊獲授權人、生產部主管及品質控制部主管；或就外包裝製造商而言，關鍵人員為品質保證主任及外包裝負責人。

4.6 Approval from the Committee has been obtained prior to any change in manufacturing premises that may affect the quality of the product.

4.6 製造處所如有任何影響產品品質的變更，須先獲委員會批准。

4.7 An Authorized Person registered by the Board is employed to, inter alia, take responsibility for the quality of pharmaceutical products produced and packaged on the premises and to authorise the release for sale or

4.7 僱用經管理局註冊的獲授權人，負責確保在處所生產和包裝的藥劑製品品質，以及批准放行銷售或分發每批藥劑製品製成品等工作，包括證明每批製

distribution of each batch of finished pharmaceutical products, including certifying that each batch of 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 in compliance with the registered particulars for that product.

品已遵照管理局發出的現行藥劑製品生產質量管理規範指引的規定製造或包裝，以及符合該製品的註冊詳情。

4.8 The registered Authorized Person is either:

4.8 註冊獲授權人：

a. appointed as a board member of the Licensed Manufacturer; or

a. 獲委任為持牌製造商董事局成員；或

b. invited to attend board meetings of the Licensed Manufacturer and allowed to speak on matters where safety, efficacy and quality issues of products are concerned and his/her remarks will be put on record.

b. 獲邀出席持牌製造商董事局會議，並獲准就關乎製品安全、效能及品質問題的事宜發言，其意見會記錄在案。

The Licensed Manufacturer provide its registered Authorized Person with the

持牌製造商給予註冊獲授權人在執行職責時所需的

necessary authority for and provide every support to the decisions of the registered Authorized Person made in the performance of his/her duties.

權力，並為註冊獲授權人在執行職責時所作的決定提供一切支援。

4.9 All key personnel have appropriate qualifications and experience as required by the Board.

4.9 所有關鍵人員均具備管理局所規定的適當資格及經驗。

4.10 Key personnel and company staff are provided with training necessary to enable them to undertake their respective duties in accordance with the GMP requirements and appropriate records of such training are maintained.

4.10 向關鍵人員及公司員工提供所需的培訓，使他們能夠按照生產質量管理規範的規定履行各自的職責，並就有關培訓備存適當記錄。

4.11 Any defect impacting on the quality of products released for sale or distribution, including products intended for markets other than Hong Kong, is documented.

4.11 把任何影響已放行銷售或分發的製品品質的問題，一一記錄在案，當中包括擬於香港以外市場銷售或分發的製品。

4.12 Report to the Drug Office all serious adverse drug reactions in accordance with the Drug Office's "Guidance for

4.12 按照藥物辦公室的「藥劑業界指引—呈報藥物不良反應的要求」，向藥物辦

Pharmaceutical Industry - Adverse Drug Reaction Reporting Requirements".

公室呈報所有嚴重藥物不良反應。

4.13 Report to the Drug Office any conditions or significant changes or deviations which may affect the quality, safety or efficacy of a pharmaceutical product, including significant changes to key personnel, facilities, equipment, systems, procedures, etc.

4.13 向藥物辦公室呈報任何可能影響藥劑製品品質、安全或效能的情況或重大改變或偏離，包括關鍵人員、設施、設備、系統及程序等的重大變更。

4.14 Report to the Drug Office upon commencement of a product recall, submit pertinent product information related to the recall and comply with the current Pharmaceutical Products Recall Guidelines issued by the Drug Office.

4.14 展開製品回收行動時，向藥物辦公室呈報，以及提交與該回收行動有關的相關製品資料，並且遵從藥物辦公室發出的現行《藥劑製品回收指引》。

4.15 Any quality control testing required to be contracted out is contracted out to:

4.15 把任何需要外判的品質控制測試外判予：

a. a Licensed Manufacturer certified as a GMP manufacturer by the Committee; or

a. 獲委員會證明為符合生產質量管理規範製造商的持牌製造商；或

b. a laboratory:

i. accredited in accordance with ISO 17025, or equivalent, for the tests required to be performed; or

ii. inspected by inspectors of the Drug Office and the result of the inspection has shown to the satisfaction of the Committee that the laboratory has complied with such parts of GMP relevant to the quality control testing to be contracted out.

4.16 Allow public officers authorised by the Chairman of the Board to carry out inspections and to take samples, photos and copies of documentation as may be necessary for the purpose of inspection and, where inspection referred to in section 4.15(b)(ii) is required, to make relevant arrangement with the laboratory for the inspection.

b. 實驗所：

i. 該實驗所已按照 ISO 17025 或同等標準獲認可進行所需的測試；或

ii. 藥物辦公室督察已對該實驗所進行視察，而視察結果證明並令委員會信納，實驗所已遵從生產質量管理規範有關外判品質控制測試的各部分。

4.16 准許獲管理局主席授權的公職人員進行視察，並為進行視察而按需要提取樣本、拍攝照片及複製文件。此外，如須進行第 4.15(b)(ii) 條所提及的視察，應就有關視察與實驗所作出相關安排。

4.17 Not wilfully delay or obstruct authorised public officers in the carrying out of their duties during the course of inspection and investigation.

4.17 在視察及調查過程中，不得故意延誤或妨礙獲授權公職人員執行職責。

4.18 In case of suspected product quality defects, suspend distribution of or recall any defective products according to instruction of the Drug Office.

4.18 如懷疑製品品質有問題，須按藥物辦公室的指示暫停分發或回收任何有問題的製品。

4.19 An order in writing issued by the purchaser has been obtained before the completion of the sale of Part I Poisons, Dangerous Drugs and Antibiotics. Electronic communications (such as e-mail), fax and mail are accepted forms of written order. The order in writing should be kept for at least two years from the date of issue of the order.

4.19 須於完成銷售第 I 部毒藥、危險藥物及抗生素前，取得由購買人發出的書面定單。電子通訊（例如電郵）、傳真及信件是可接受的書面定單形式。書面定單應由定單發出日期起計，備存至少兩年。

Section 5 Consequence of breaching section 4 of this Code of Practice
第 5 條 違反本執業守則第 4 條的後果

5.1 Licensed Manufacturers found to have breached section 4 of this Code of Practice will be reported to the Committee for appropriate action.

5.1 如發現持牌製造商違反本執業守則第 4 條，會向委員會舉報，以採取適當行動。

5.2 Depending on the severity of individual case, the Committee may revoke the licence or suspend it for such period as it thinks fit, vary the licence condition(s) or issue a warning letter to the Licensed Manufacturer if, in its opinion, the Licensed Manaufacturer has failed to comply with section 4 of this Code of Practice.

5.2 視乎個別個案的嚴重程度，委員會如認為持牌製造商沒有遵從本執業守則第 4 條的規定，可撤銷有關牌照，或在其認為合適的期間內暫時吊銷該牌照、更改牌照條件、或向持牌製造商發出警告信。

5.3 Any Licensed Manufacturer aggrieved by a decision of the Committee may appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

5.3 任何持牌製造商如因委員會的決定而感到受屈，可就該決定向藥劑業及毒藥上訴審裁處提出上訴。

Part II 第 II 部

Section 6 Obligations and Requirements for Registered Authorized Persons
第 6 條 註冊獲授權人須履行的責任及遵從的規定

Registered Authorized Persons employed by Licensed Manufacturers in Hong Kong must ensure that the following obligations and requirements are met:

本港持牌製造商所僱用的註冊獲授權人，必須確保履行下列責任及規定：

6.1 He or she is listed on the Register of Authorized Persons maintained by the Board.

6.1 他或她名列管理局備存的獲授權人名冊。

6.2 Take responsibility for the quality of the pharmaceutical products manufactured or packaged on the premises of the manufacturer.

6.2 負責確保在製造商處所製造或包裝的藥劑製品品質。

6.3 Authorise the release for sale or distribution of each batch of finished pharmaceutical products manufactured or packaged, including certifying before the release that each batch of the products 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 in compliance with the registered particulars for the products.

6.3 批准放行銷售或分發所製造或包裝的每批藥劑製成品，包括在放行前證明每批製品已遵照管理局發出的現行藥劑製品生產質量管理規範指引的規定製造或包裝，以及符合該製品的註冊詳情。

6.4	Maintain a register (or equivalent document) as a record of product batches certified prior to batch release.	6.4	備存登記冊(或同等文件),記錄在批次放行前經證明的製品批次。
6.5	The appropriate senior management is made fully aware of any manufacturing and/or testing difficulties which may cast doubt on the certification of batches or which may post facto require a product recall and, where there is any aspect of manufacturer's Quality Management System which is not in compliance with the current GMP guide issued by the Board, such non-compliance is brought to the attention of the senior management and appropriate corrective measures are taken.	6.5	如有任何製造及/或測試問題,可能令人質疑批次證明,或可能導致事後需要回收製品,須全面告知適當的高層管理人員。此外,如製造商品質管理系統的任何方面沒有遵從管理局發出的現行生產質量管理規範指引,須通知高層管理人員有關違規情況,並採取適當糾正措施。
6.6	Authorised public officers are not wilfully delayed or obstructed in the carrying out of their duties during the course of inspection and investigation.	6.6	在視察及調查過程中,不得故意延誤或妨礙獲授權公職人員執行職責。
6.7	Keep knowledge, experience and competence up-to-date through continuing professional development.	6.7	通過持續專業進修,增進知識、經驗及技能。

Guidance on how some of the above obligations and requirements for registered Authorized Persons can be met is listed in Appendix A and Appendix B to this Code of Practice.

有關註冊獲授權人如何履行上述某些責任及規定的指引，載列於本執業守則附錄 A 及附錄 B。

Section 7 Consequence of breaching section 6 of this Code of Practice
第 7 條 違反本執業守則第 6 條的後果

7.1 Registered Authorized Persons found to have breached section 6 of this Code of Practice, or found to be incompetent, will be reported to the Committee for appropriate action.

7.1 如發現註冊獲授權人違反本執業守則第 6 條或不稱職，會向委員會舉報，以採取適當行動。

7.2 Depending on the severity of individual case, the Committee may cancel or suspend the registration of an Authorized Person, vary the registration condition(s) or issue a warning letter to the registered Authorized Person, if, in its opinion, the registered Authorized Person is incompetent or not undertaking appropriate continuing professional development.

7.2 視乎個別個案的嚴重程度，委員會如認為註冊獲授權人並不稱職或沒有進行適當的持續專業進修，可取消或暫時吊銷該註冊獲授權人的註冊、更改註冊條件，或向該註冊獲授權人發出警告信。

7.3 Any registered Authorized Person aggrieved by a decision of the Committee may appeal to the Pharmacy and Poisons Appeal Tribunal against that decision.

7.3 任何註冊獲授權人如因委員會的決定而感到受屈，可就該決定向藥劑業及毒藥上訴審裁處提出上訴。

Appendix A: Duties of Registered Authorized Person relating to release of finished products
附錄 A　：註冊獲授權人在放行製成品方面的職責

Each batch of finished product must be certified by a registered Authorised Person before being released for sale. The certification should **ensure** that the following requirements have been met:

每批製成品須先經註冊獲授權人證明，方可放行銷售。有關證明應**確保**符合下列規定：

(The meaning of the word "ensure" in this context is that the registered Authorized Person must be confident that various actions, which may not be under his/her direct control, have in fact been taken).

(「確保」一詞在此的意思，是註冊獲授權人必須肯定，各項可能不由其直接控制的行動，已確實執行。)

A.1 The licensing conditions of the manufacturer licence and the registered particulars of pharmaceutical product have been met for the batch concerned.

A.1 有關批次符合製造商牌照的發牌條件及藥劑製品的註冊詳情。

A.2 The current GMP guide issued by the Board have been followed in all manufacturing, packaging, testing and warehousing activities.

A.2 所有製造、包裝、測試及存倉活動已遵循管理局發出的現行生產質量管理規範指引。

A.3 Critical manufacturing processes and quality control test methods have been validated.

A.3 關鍵的製造工序及品質控制測試方法已獲驗證。

A.4 All the necessary quality control checking and testing have been performed, and account has been taken of the manufacturing and packaging conditions including a review of the batch records.

A.4 已進行所有必要的品質控制檢查及測試，並已考慮製造及包裝情況，包括檢閱批次記錄。

A.5 Any changes or deviations in manufacturing, packaging or quality control have been processed in accordance with well-defined systems, including reporting of such changes or deviations to the Authorized Person before any product batch is released.

A.5 已按照明確的制度處理任何製造、包裝或品質控制方面的變更或偏離，包括在放行任何製品批次前，向獲授權人呈報有關變更或偏離。

A.6 Any additional sampling, inspection, tests and checks have been carried out or initiated, as appropriate, to cover changes or deviations in manufacturing, packaging or quality control.

A.6 已進行或提出進行任何額外抽樣、視察、測試及檢查（視何者適用而定），以涵蓋製造、包裝或品質控制方面的變更或偏離。

A.7 All necessary manufacturing, packaging and associated documentation have been completed and endorsed by suitably authorised staff trained in the

A.7 所有必要的製造、包裝及相關文件記錄，已由曾接受品質管理及生產質量管理規範概念培訓的適當獲

concept of Quality Management and GMP.

授權員工完成及批簽。

A.8 Regular audits, self-inspections and spot checks have been carried out by experienced staff.

A.8 已由經驗豐富的員工進行定期審核、自行視察及抽樣檢查。

A.9 All relevant factors including any factor not specifically associated with the output batch directly under review (e.g. calibration and maintenance records, environmental monitoring, etc.) have been considered.

A.9 已考慮所有相關因素，包括任何與直接接受檢閱的生產批次沒有具體關係的因素（例如校正及保養記錄、環境監察等）。

A.10 The registered Authorized Person should recognise the need to consult other company's experts in a specific area so as to reinforce his/her knowledge on appropriate points when a doubtful situation arises (e.g. stability, unusual analytical results, process or equipment changes, potential environmental or microbiological risks, re-labelling, abnormal yields, cross contamination risks, etc.).

A.10 當出現可疑情況（例如穩定性問題、不尋常分析結果、工序或設備有所更改、潛在環境或微生物風險、重新加上標籤、異常產量、交叉感染風險等）時，註冊獲授權人有需要向其他公司的特定領域專家徵詢意見，以加強其在有關方面的知識。

A.11 A register (or equivalent document) is maintained as a record of product batches certified by the registered Authorized Person prior to batch release.

A.11 備存登記冊(或同等文件),記錄在批次放行前經註冊獲授權人證明的製品批次。

A.12 Reference samples and/or retention samples of each product batch are retained for a period of time specified in the current GMP guide issued by the Board in respect of pharmaceutical products.

A.12 保存每批製品的對照樣本及/或留存樣本,為期如委員會發出的現行藥劑製品生產質量管理規範指引所載明。

A.13 *[Not applicable to Quality Assurance Officer]* If the registered Authorized Person is not involved in the on-going stability testing program or the preparation of Product Quality Review ("PQR"), he or she should at least have access to the full results of such testing program and review (since the registered Authorized Person must consider the results of both as part of the release for sale/distribution process).

A.13 *[不適用於品質保證主任]* 如註冊獲授權人沒有參與持續進行的穩定性測試計劃或製品品質檢討的準備工作,他或她至少應獲准查閱持續進行的穩定性測試及製品品質檢討的詳細結果(因註冊獲授權人在放行銷售/分發的過程中,必須考慮兩者的結果。)

In considering how to perform the above duties, the registered Authorized Person should take into account the nature and size of the operations involved. For example, registered Authorized Person employed to work in a very small company manufacturing a limited range of products may have to take direct responsibility for some or all of the duties outlined above, whereas the registered Authorized Person working in larger organisations may have to be more dependent upon the knowledge and expertise of his/her colleagues in undertaking some or all of such duties.

在考慮如何履行上述職責時，註冊獲授權人應顧及所涉及運作的性質及規模。舉例說，受僱於一家製造有限種類製品的非常小型公司的註冊獲授權人，可能直接負責上述部分或全部工作。至於在較大型機構工作的註冊獲授權人，則較依賴同事的知識及專長進行部分或全部工作。

In any event, it is of paramount importance that the registered Authorized Person must take steps, within a well-planned Quality Management System, to assure himself or herself that the tasks allocated are being performed satisfactorily. The duties of the registered Authorized Person depend very much upon a team effort wherein the individuals involved realise the position and responsibility of the registered Authorized

在任何情況下，註冊獲授權人必須在規劃完善的品質管理系統內，採取措施確保自己妥善進行獲分配的工作，這點至關重要。註冊獲授權人的職責，十分依賴團隊努力，參與人士須了解註冊獲授權人的崗位及責任，並提供一切支援。

Person and provide every support.

A registered Authorized Person who failed to discharge his/her duties relating to release of finished products may be subjected to disciplinary actions.

註冊獲授權人如未能履行在放行製成品方面的職責，可能會遭紀律處分。

Appendix B : Continuing professional development (CPD)
附錄 B : 持續專業進修

B.1. Registered Authorized Persons have a personal and professional duty to keep up-to-date their knowledge and experience on the current state of pharmaceutical quality management, regulatory aspects and GMP standards, product manufacturing and control technology, and general work practices.

B.1. 註冊獲授權人有個人及專業責任，不斷增進其在藥劑品質管理、規管事宜及生產質量管理規範標準、製品製造及監控科技，以及一般工作實務的現況方面的知識及經驗。

B.2. Records of continuing professional development should be kept to reflect the registered Authorized Person's continued performance of professional duties.

B.2. 應備存持續專業進修記錄，以顯示註冊獲授權人持續履行專業職責。

B.3. In the event of a significant change in an registered Authorized Person's professional responsibilities, for example changing employment from one with a company making only non-sterile oral solid dosage forms to one with a company making a wider range of products including sterile products; or from one with a company packaging oral solid dosage forms to one with

B.3. 如註冊獲授權人的專業責任有重大改變（例如由受僱於一家只製造非無菌口服固體劑型的公司，轉為受僱於一家製造多種製品（包括無菌製品）的公司；或由一家為口服固體劑型進行包裝的公司，轉為受僱於一家為注射用製品進行包裝並需要冷鏈管理的

a company packaging parenternal products requiring cold chain management, the registered Authorized Person and the senior management of the company involved should recognise the need for receiving additional training/education and demonstrate that adequate steps have been taken to receive or provide such additional training/education, which should have been undertaken before the registered Authorized Person commences his or her work in the new positions.

公司），註冊獲授權人及所涉的公司高層管理人員應知道需要接受額外培訓／教育，並證明已採取充分步驟接受或提供該等額外培訓／教育。有關培訓／教育應在註冊獲授權人展開新崗位的工作前進行。

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