PHARMACY AND POISONS BOARD OF HONG KONG

Guidelines for Accredited Pharmacy Internship Training Institutions for Pharmaceutical Manufacturing Companies

A. Basic Requirements for Qualification as Training Sites

1. The company must be a holder of Licence for Manufacturer and Certificate for Manufacturer under the Pharmacy and Poisons Ordinance to manufacture pharmaceutical products.

2. The company must have an in-house quality control laboratory.

3. At least 2 of the following types of pharmaceutical products:
   (a) solids
   (b) liquids
   (c) semi-solids
   (d) sterile products

4. If the company only manufactures ONE type of the above mentioned pharmaceutical products, the company must demonstrate to the satisfaction of the Committee that it has sufficient capability and resources to provide appropriate internship training which should include, but not limited to, the following additional information:

   (a) Number of staff directly involving in Quality Management System and GMP such as in Quality Assurance, Quality Control, Production and other department(s)
   (b) Number of pharmaceutical products actively produced
   (c) Number of batches of products produced annually in the past 3 years
   (d) Number of products of the each dose form actively produced (for example, Solid dose: number of products in tablet, number of products in capsule, number of products in powder etc.)
   (e) List out major production equipment and respective capacity
   (f) Indicate whether there are any research and development activities on improving quality of existing products and/or new product development etc.

B. Areas of Training to be Provided

(a) Mandatory Areas

I. Quality Assurance

1. Introduction to the internship training program
2. Introduction of the concept and basic of GMP
3. GMP guidelines
4. Introduction to Pharmaceutical Quality Management System

5. Introduction to Risk Management
6. Site master file
7. Validation master plan
8. Principle of validation
9. Documentation preparation and control system
10. Personal hygiene & environmental control
11. Material management and control system
12. Finished product management and release system
13. Deviation and change control system
14. Complaints and recalls
15. Quality audit and self-inspection
16. GMP Training program & materials
17. Chemical waste management

II. Quality Control

1. Principle of GLP
2. Safety handling of solvents, chemicals, reagents and chemical wastes
3. QC material handling and control system (incl sampling, testing and release)
4. QC intermediate product handling and control system (incl sampling, testing and release)
5. QC in-process production control (incl sampling, testing and release)
6. QC finished product control handling and control system (incl sampling, testing and release)
7. Procurement control of chemical reagents and reference standards
8. Stability testing program
9. Principle and operation of pharmaceutical analytical equipment and technique
10. Principle of method validation
11. Pharmaceutical purified water and environmental monitoring program
12. Principle of microbial testing and validation
13. Calibration and maintenance of QC equipment

III. Production

1. Production flow
2. Housekeeping, sanitation and hygiene practices
3. Dispensing process and control
4. Preparation of Production batch record
5. In-process production control
6. Manufacturing process for various dosage form products
7. Primary packaging process for various dosage form products
8. Secondary packaging and labelling process for various dosage form finished products

9. Understanding of the application of different excipients in preparation of pharmaceutical products
10. Calculation of yields and reconciliation
11. Introduction of process validation
12. Introduction of cleaning validation
13. Handling of starting materials, intermediate and finished products

IV. Regulatory Affairs

1. Understanding and application of Pharmaceutical product registration and renewal procedures
2. Understanding and application of Change of Particular procedures
3. P&P and other related Regulations

V. Procurement & Logistic / Warehouse

1. Procurement procedures of starting materials
2. Material receiving and issuing system
3. Material and product stock monitoring and control
4. Record keeping, storage and supply of pharmaceutical products
5. Storage and management of control chemicals

(b) Optional Areas

VI. Human Resources and/or Administration

1. Introduction to the background of the Company
2. Company policy and organization
3. Staff working information and/or handbook
4. Brief explanation of the HK Employment Ordinance
5. Departments and colleagues orientation
6. Safety policy and procedures

VII. Sales and Marketing

1. Fundamental of sales technique of pharmaceutical products
2. Marketing segmentation
3. Field visit

VIII. Others

1. Engaged in projects and assignments (if available)

A checklist of the training activities is illustrated in **Appendix I**.

C. Assessments

1. Intern's Performance
   The criteria for assessing intern's performance are outlined in **Appendix II**.

2. Intern's Assessment of Training Experience
   The criteria for assessing the training experience are outlined in **Appendix III**.

Appendix I

INTERN'S CHECKLIST FOR
TRAINING PROGRAMME AT PHARMACEUTICAL MANUFACTURING COMPANIES

Name of Intern : _____ Intern ID# _____
(first 4 characters including letter)

Name of Training Establishment : _____

Name of Preceptor :

Period of Internship Experience : ☐Jul – Sep 20□□ ☐Oct – Dec 20□□

☐Jan – Mar 20□□ ☐Apr – Jun 20□□

☐√ the appropriate box.

The intern has been exposed to or has participated in the following activities: (*please √☐)

(a) Mandatory Areas:

I. Quality Assurance

Check*	Training Activities
☐	Introduction to the internship training program
☐	Introduction of the concept and basic of GMP
☐	GMP guidelines
☐	Introduction to Pharmaceutical Quality Management System
☐	Introduction to Risk Management
☐	Site master file
☐	Validation master plan
☐	Principle of validation
☐	Documentation preparation and control system
☐	Personal hygiene & environmental control
☐	Material management and control system
☐	Finished product management and release system
☐	Deviation and change control system
☐	Complaints and recalls

☐	Quality audit and self-inspection
☐	GMP Training program & materials
☐	Chemical waste management

II. Quality Control

Check*	Training Activities
☐	Principle of GLP
☐	Safety handling of solvents, chemicals, reagents and chemical wastes
☐	QC material handling and control system (incl sampling, testing and release)
☐	QC intermediate product handling and control system (incl sampling, testing and release)
☐	QC in-process production control (incl sampling, testing and release)
☐	QC finished product control handling and control system (incl sampling, testing and release)
☐	Procurement control of chemical reagents and reference standards
☐	Stability testing program
☐	Principle and operation of pharmaceutical analytical equipment and technique
☐	Principle of method validation
☐	Pharmaceutical purified water and environmental monitoring program
☐	Principle of microbial testing and validation
☐	Calibration and maintenance of QC equipment

III. Production

Check*	Training Activities
☐	Production flow
☐	Housekeeping, sanitation and hygiene practices
☐	Dispensing process and control
☐	Preparation of Production batch record
☐	In-process production control
☐	Manufacturing process for various dosage form products
☐	Primary packaging process for various dosage form products

☐	Secondary packaging and labelling process for various dosage form finished products
☐	Understanding of the application of different excipients in preparation of pharmaceutical products
☐	Calculation of yields and reconciliation
☐	Introduction of process validation
☐	Introduction of cleaning validation
☐	Handling of starting materials, intermediate and finished products

IV. Regulatory Affairs

Check*	Training Activities
☐	Understanding and application of Pharmaceutical product registration and renewal procedures
☐	Understanding and application of Change of Particular procedures
☐	P&P and other related regulations

V. Procurement & Logistic / Warehouse

Check*	Training Activities
☐	Procurement procedures of starting materials
☐	Material receiving and issuing system
☐	Material and product stock monitoring and control
☐	Record keeping, storage and supply of pharmaceutical products
☐	Storage and management of control chemicals

(b) Optional Areas:

VI. Human Resources and/or Administration

Check*	Training Activities
☐	Introduction to the background of the Company
☐	Company policy and organization
☐	Staff working information and/or handbook (including working hours, holiday etc.)
☐	Brief explanation of the HK Employment Ordinance
☐	Departments and colleagues orientation
☐	Safety policy and procedures

VII. Sales and Marketing

Check*	Training Activities
☐	Fundamental of sales technique of pharmaceutical products
☐	Marketing segmentation
☐	Field visit

VIII. Others

Check*	Training Activities
☐	Engaged in projects and assignments (if available)
☐	*Please specify:*
☐	*Please specify:*
☐	*Please specify:*

Signature of Intern: _____ Signature of Preceptor: _____ Date: _____

Appendix II

PHARMACY INTERN APPRAISAL FORM

IN

PHARMACEUTICAL MANUFACTURING COMPANY

PHARMACY INTERN APPRAISAL FORM

Personal Particulars of Intern

Full Name : _____

HK ID No. :
(first 4 characters including letter) _____

_____

Name and Address of
Training Establishment : _____

_____

_____

_____

The Period of Internship Experience to which This Form Relate

Commenced on

_____

_____

Completed on :

_____

_____

Module No. :

_____

Personal Particulars of Preceptor

Full Name : _____

HK Pharmacist
Registration No. : _____

Rank/Title : _____

General Notes for Preceptors and Interns

Interns will be appraised at quarterly intervals depending on the period of their training in accordance with the following schedule:

1. *Module 1* (July – September), **due end of September**

2. *Module 2* (October – December), **due end of December**

3. *Module 3* (January – March), **due end of March**

4. *Module 4* (April – June), **due end of June**

The appraisal scheme is a vital component of the internship training, since it covers the professional competencies expected of the newly-registered pharmacist, i.e. those aspects of performance which underpin practice and which, taken together, demonstrate a professional attitude and appropriate sense of responsibility. In this respect, the appraisal scheme is essential as it:

- assesses aspects of the interns' skills and attitudes in a systematic manner.
- provides a record of the interns' progress in these aspects during the year.
- identifies effectively areas of performance which the interns require further training and development.
- provides feedback to interns about their progress.
- is used to judge fitness for registration at the end of the internship.

The Appraisal Form

The assessment for the interns is based on two key aspects of training, contained in Part A and Part B of the form. Part A of the appraisal form lists out all the competency elements (learning outcomes) expected of the interns. Preceptors will evaluate the performance of their interns against these elements and allocate an achievement level (From rating scale "1" to "6") for each of the element. If preceptors are unable to assess their interns against any of the elements, they will check off the box labelled N/A to indicate "not applicable" and give a brief explanation in the 'Remarks' box. Also, preceptors will give specific comments in the 'Remarks' box, such as examples of competency and areas for improvement, especially for elements accorded "1" or "6".

Part B of the form will be used for assessing the personality and attitude of interns. Preceptors are asked to rate the performance of their interns (From rating scale "1" to "6") on aspects such as attitude to work and co-workers and personal behaviour. In addition, an overall rating for the interns should be given in Part C of the form with due regard to the performance evaluation for both Parts A and B.

Preceptors to Note

The appraisal form for each of the training modules will be bound into a booklet and distributed to the preceptors at the commencement of the internship year. These booklets should be kept by the preceptors and handed to the interns at the time of the appraisal for them to sign and to add comments. Upon completion of the form by all the concerned parties, preceptor(s) should forward the original copy to the Pharmacy Internship Training Committee of the Pharmacy and Poisons Board.

PART A – PHARMACY INTERN COMPETENCIES APPRAISAL

How to Complete Part A

(a) This part of the appraisal form lists out all the competency elements for the five or six key functions. For each element, put a tick in the box which best fits the intern's usual performance. If you cannot assess your intern on any particular element, place a tick under the box labelled N/A for "not applicable" and explain briefly in the "Remarks" box why you cannot assess these. If the listed competency elements cannot apply to interns posted at particular department(s)/sections in the company, the preceptors involved are requested to list out other competency areas under "Additional Competencies and Competency Elements" for training and assessment purposes.

(b) Try to consider the elements independently from one another. You can expect your intern to be strong in some areas and to have considerable difficulty with others. Do not hesitate to allocate rating scale "1" or "6" where these are deserved. The rating descriptions are as follows:

Rating Scale	Rating Description
1	*The Intern always exceeds the competency requirements.*
2	*The intern always meets and sometimes exceeds the competency requirements.*
3	*The intern usually meets the competency requirements.*
4	*The intern often meets the competency requirements but needs some improvement.*
5	*The intern sometimes meets the competency requirements and needs further improvement.*
6	*The intern rarely or never meets the competency requirements and needs significant improvement.*
N/A	*Not applicable to the job.*

PART A: PHARMACY INTERN COMPETENCIES APPRAISAL							
1. Quality Management System & Quality Assurance	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Understand the principle of QMS							
(b) Read and interpret GMP guidelines and guidance notes							
(c) Understand documentation control and system							
(d) Prepare standard operating procedures and records							
(e) Handle deviations and change control							
(f) Understand of complaints and recalls procedures							
(g) Prepare validation protocols and reports							
(h) Prepare training materials and assessments							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

☐ The element was not covered in this module (for N/A rating).
☐ Others:

2. Quality Control	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Understand the principle of GLP							
(b) Handle starting material sample receiving and testing							
(c) Handle intermediate product sample receiving and testing							
(d) Handle finished product sample receiving and testing							
(e) Handle chemical reagents and reference standards							
(f) Understand stability testing program							
(g) Prepare method validation protocol and report							
(h) Understand microbial testing and validation							
(i) Understand pharmaceutical purified water monitoring program							
(j) Understand environmental monitoring program							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

☐ The element was not covered in this module (for N/A rating).
☐ Others:

3. Production	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Understand the principles of formulations for pharmaceutical products to be manufactured							
(b) Calculate quantities of ingredients required for preparation of pharmaceutical products							
(c) Understand the application of different ingredients for preparation of pharmaceutical products							
(d) Perform the manufacturing of pharmaceutical products and the implementation of GMP							
(e) Understand and accurately calculate yields and reconciliation							
(f) Perform quality assurance procedures (eg line clearance)							
(g) Perform in process quality control procedures							
(h) Prepare production batch record							
(i) Understand the principles of process validation							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

☐ The element was not covered in this module (for N/A rating).
☐ Others:

4. Knowledge of the Application of the Following Legal Requirements in Relation to Pharmaceutical Manufacturing	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Understand the Regulatory Bodies Relating to Pharmacy Practice							
(b) Understand the Laws Governing the Sale, Supply & Control of Pharmaceutical Products							
(c) Understand the Laws Governing the Sale, Supply and Control of Dangerous Drugs							
(d) Understand the Laws Governing the Sale, Supply and Control of Antibiotics							
(e) Understand the Laws Pertaining to Authorized Sellers of Poisons and Listed Sellers of Poisons							
(f) Understand the Laws Governing the Procedures in Applying for the Registration and Change of Particulars of Pharmaceutical Products							
(g) Understand the Laws Governing the Manufacturing of Pharmaceutical Products							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

☐ The element was not covered in this module (for N/A rating).
☐ Others:

5. Apply General Organizational Skills and Professional Ethics in Pharmaceutical Manufacturing	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Understand the general operation of pharmaceutical manufacturing company							
(b) Understand effective staff management							
(c) Understand effective material and product stock management							
(d) Understand effective contingency management							
(e) Understand other administrative and management issues							
(f) Understand ethical and professional responsibilities							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

☐ The element was not covered in this module (for N/A rating).
☐ Others:

6. ADDITIONAL COMPETENCIES AND COMPETENCY ELEMENTS *(As agreed between intern and preceptor)*	Rating (√ as appropriate)					
	1	2	3	4	5	6

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1' or '6' in respect of all of the above competency elements)*

PART B – PHARMACY INTERN PERSONAL ATTRIBUTES APPRAISAL

How to Complete Part B

(a) In completing this part, please appraise the intern's progress and overall performance so far. Try to remember that you are assessing an intern over a period of time. Isolated incidents should not influence your assessment.

(b) For each item / performance characteristic, put a tick in the box which best fits the intern's usual performance. Do not hesitate to give rating scale "1" or "6" where deserved. Try not to let the intern's strength or weakness in one quality cloud your judgment of his/ her standing in another. It is quite normal for an individual to be above average in some respects and to fall short in others. If you are unable to evaluate a particular item / performance characteristic, place a tick under the box labelled N/A for "not applicable".

(c) Comments are always helpful, particularly to explain an unusual rating or when an unqualified rating might not present a true picture. The rating descriptions are as follows:

Rating Scale	**Rating Description**
1	*The Intern always exceeds the requirements for the job.*
2	*The intern always meets and sometimes exceeds the requirements for the job.*
3	*The intern usually meets the requirements for the job.*
4	*The intern often meets the requirements for the job but needs some improvement.*
5	*The intern sometimes meets the requirements for the job and needs further improvement.*
6	*The intern rarely or never meets the requirements for the job and needs significant improvement.*
N/A	*Not applicable to the job.*

PART B: PHARMACY INTERN PERSONAL ATTRIBUTES APPRAISAL

1. Application to Work	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Punctuality							
(b) Willingness to work							
(c) Ability to grasp essentials							
(d) Demonstrates initiative and enthusiasm							
(e) Use of opportunities to extend knowledge and skills							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

2. Quality of Work	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Ability to maintain high standard of work (in general)							
(b) Ability to apply theoretical knowledge to practical work							
(c) Reliability in carrying out instructions and following procedures							
(d) Ability to plan and complete own work/organize work of others							
(e) Self reliance and resourcefulness							
(f) Ability to make clear and concise written communication							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

3. Attitude to Co-workers	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Acceptance by colleagues and co-workers							
(b) Ability to communicate with colleagues and co-workers							
(c) Courtesy and helpfulness							
(d) Ability to accept instruction, advice, constructive criticism							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

4. Personal Behaviour	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Neatness and grooming							
(b) Ability to handle difficult situations							
(c) Professional attitude							

Remarks: *(Any specific comments such as examples of competency, areas for improvement, especially for items accorded '1', '6' or 'N/A', in respect of all of the above competency elements)*

PART C – SUMMARY OF OVERALL PERFORMANCE

Overall Rating
(Please indicate the intern's overall performance by marking the appropriate box. In arriving at the decision, the assessments of both Parts A and B should be considered.)

- ☐ Outstanding performance - Consistently well above the requirements for the job.
- ☐ Superior performance - Frequently exceeds the requirements for the job.
- ☐ Good performance - Occasionally exceeds the requirements for the job.
- ☐ Effective performance - Meets the basic requirements for the job.
- ☐ Marginal performance - Some aspects of performance are below the requirements for the job. Further improvement is necessary.
- ☐ Below-standard performance - Significant improvement in performance is essential to meet the required standard for the job.

General Comments by the Preceptor (particularly on overall performance and development progress under the review period)

The intern has/has not* completed the training satisfactorily for the specified period (***please delete as appropriate**)

Signature of Preceptor

Name/Position

Date

PART D – COUNTERSIGNING MANAGER'S (OFFICER-IN-CHARGE) ASSESSMENT

Comments

Name of Countersigning Manager/ Senior Management

Position

Signature

Date

PART E – INTERN'S COMMENTS

Comments (including comments on the training, suggestion for improvement and development, or any other points)

Signature of Intern

Date

Appendix III

INTERN'S ASSESSMENT OF PHARMACEUTICAL MANUFACTURING COMPANY TRAINING PROGRAMME

Name of Intern : _____ Intern ID# _____
(first 4 characters including letter)

Name of Training Establishment : _____

Name of Preceptor : _____

Period of Internship Experience : ☐ July – Sept 20☐☐ ☐ Oct – Dec 20☐☐
☐ Jan – Mar 20☐☐ ☐ Apr – June 20☐☐

☐ √ the appropriate box.

The rating descriptions are as follows:

Rating Scale	Rating Description
1	Strongly Agree
2	Agree
3	Neutral
4	Disagree
5	Strongly Disagree

1. EVALUATION OF TRAINING ACTIVITIES	Rating (√ as appropriate)				
	1	2	3	4	5
(a) The training experience increased my ability to communicate with different levels of colleagues and other health care providers if applicable.					
(b) The training provided opportunity to increase my knowledge of pharmaceutical manufacturing and formulation knowledge.					
(c) I gain a good understanding of overall appreciation of principles of GMP.					
(d) I gain a good understanding of registration and sale of pharmaceutical products.					
(e) I gain a good understanding of the general set-up and daily operations of a pharmaceutical manufacturing company.					

2. EVALUATION OF PRECEPTOR	Rating (√ as appropriate)				
	1	2	3	4	5
(a) The preceptor demonstrated professionalism in his/her work.					
(b) The preceptor communicated effectively with me.					
(c) The preceptor taught with enthusiasm.					
(d) The preceptor provided constructive criticism for my improvement.					
(e) The preceptor provided adequate support and supervision during the training.					

3. BRIEFLY SUMMARIZE YOUR TRAINING EXPERIENCE (BOTH POSITIVE AND NEGATIVE ASPECTS) IN THE SPACE BELOW.

Signature of Intern

Date