

PHARMACY AND POISONS BOARD OF HONG KONG

Guidelines for Accredited Pharmacy Internship Training Institutions for Pharmaceutical Wholesale Companies

A. Basic Requirements for Qualification as Training Sites

1. The company must hold a wholesale dealer licence under the Pharmacy and Poisons Ordinance.
2. The company must be a holder of certificates of registration of pharmaceutical products.

B. Areas of Training to be Provided

(a) **Mandatory Areas**

1. Compliance to legal requirements
2. Registration of pharmaceutical products
3. Medical affairs
4. Medical information
5. Quality assurance
6. Adverse drug reactions monitoring
7. Sales and marketing

(b) **Optional Areas**

8. Clinical research
9. Medical quality and compliance
10. Disposal of unserviceable pharmaceutical products
11. Medical detailing
12. Training of sales staff.

_____ 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**.

**INTERN'S CHECKLIST FOR
TRAINING PROGRAMME AT PHARMACEUTICAL WHOLESALERS 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 intern has been exposed to or has participated in the following activities: *(please)

Mandatory Areas:

Check*	Training Activities
<input type="checkbox"/>	Orientation to compliance to legal requirements
<input type="checkbox"/>	Orientation to registration of pharmaceutical products
<input type="checkbox"/>	Orientation to medical affairs
<input type="checkbox"/>	Orientation to medical information
<input type="checkbox"/>	Orientation to quality assurance
<input type="checkbox"/>	Orientation to adverse drug reactions monitoring
<input type="checkbox"/>	Orientation to sales and marketing

Optional Areas:

Check*	Training Activities
<input type="checkbox"/>	Orientation to clinical research
<input type="checkbox"/>	Orientation to medical quality and compliance
<input type="checkbox"/>	Orientation to disposal of unserviceable pharmaceutical products
<input type="checkbox"/>	Orientation to medical detailing
<input type="checkbox"/>	Orientation to training of sales staff
<input type="checkbox"/>	Engaged in projects and assignments (if available)

Other activities, please list:

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

**PHARMACY INTERN
APPRAISAL FORM**

IN

**PHARMACEUTICAL
WHOLESALE COMPANY**

PHARMACY INTERN APPRAISAL FORM

Personal Particulars of Intern

Full Name : _____

HKID No.
(first 4 characters including letter) : _____

Name & 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.

Assessment Criteria

At the end of each unit, the assessor will conduct an evaluation with the intern. The assessment is based on the extent of the performance criteria the intern is able to achieve. The rating is divided into a scale of 6 according to the table below.

The overall grade will be the average of total score achieved in each unit and the final evaluation of the preceptor.

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

PART A
PHARMACY INTERN
COMPETENCIES
APPRAISAL

Mandatory

Unit 1: Compliance to Legal Requirements

Performance Criteria	Rating (✓ as appropriate)						
	1	2	3	4	5	6	N/A
Familiarize with the ordinances, regulations, licensing requirements governing the Pharmaceutical Wholesale Company							
Understand the functions and roles of the Department of Health and regulatory bodies relating to the control of pharmaceutical products							
Acquire the knowledge and ability to apply the laws governing the sale, supply, control, storage and record keeping of poisons, dangerous drugs and antibiotics ^{Note} <u>Note:</u> A visit can be arranged to the distributor if applicable							
Acquire the knowledge on the application of the laws of unregistered drugs							
Understand the procedure for application of import and export license for poisons and dangerous drugs							
Score:							
Comments:							
<input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 2: Registration of Pharmaceutical Products

Performance Criteria	Rating (✓ as appropriate)						
	1	2	3	4	5	6	N/A
Understand the requirements and processes for submissions to the DOH for registration of New Chemical Entity (NCE) pharmaceutical products							
Understand the requirements and processes for submissions to the DOH for product line extension							
Understand the requirements and processes for product license renewal							
Understand the requirements and processes for change of particulars							
Understand the labeling requirements of the pharmaceutical products							
Understand the interaction with all stakeholders in all processes involved							
Understand the registration and sale of pharmaceutical products							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 3: Medical Affairs

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Acknowledge the importance of promoting rational and safe use of drugs							
Understand the Undesirable Medical Advertisements Ordinance (Cap 231) and guideline set for promotional materials							
Able to conduct promotional materials review and screening							
Have a general concept of Disease Management							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 4: Medical Information

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Understand how pharmaceutical drug information service works							
Use common medical information databases to handle queries							
Able to provide verbal and written reply in an appropriate manner to customers							
Familiarize with the local medical information guidance							
Familiarize with the local medical information system to document inquiries and different channels to interact with customers							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 5: Quality Assurance

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Familiarize with the process and the importance in handling product complaint							
Be able to formulate a plan to communicate verbal/written reply in an appropriate manner to all customers							
Familiarize with the process and procedure of product recall							
Familiarize with the process of managing distributors							
Familiarize with the regulatory requirements on performing secondary repackaging							
Familiarize with sample room drug storage management and the regulatory requirements							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 6: Adverse Drug Reaction Monitoring

Performance Criteria	Rating (✓ as appropriate)						
	1	2	3	4	5	6	N/A
Understand the importance of pharmacovigilance to a pharmaceutical company							
Understand the scope of activities for pharmacovigilance							
Understand the definition of adverse event reporting & adverse drug reaction monitoring and the process of handling relevant cases							
Understand the regulatory requirements in adverse event reporting and adverse drug reaction monitoring							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 7: Sales and Marketing

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Understand the roles of sales and marketing and their relationship with the medical team							
Understand the partnership between pharmacists and physicians							
Understand the importance of customer networking							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:	Preceptor's Signature:					Date:	

Optional

Unit 8: Clinical Research

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Have a general concept on Good Clinical Practice (GCP)							
Understand the requirements of conducting clinical trial and process involved in Hong Kong							
Understand the importance of interaction with site personnel and Sponsor							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 9: Medical Quality and Compliance

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Understand the importance of Inspection Readiness and Good Documentation Practice (GDP)							
Understand the general concept of Quality Management System							
Be able to demonstrate critical thinking and perform root cause analysis on given case studies							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 10: Disposal of Unserviceable Pharmaceutical Products

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Have a general concept on the definition of unserviceable pharmaceutical products							
Understand the role of chemical waste producer, chemical waste collector and their interactions with Environmental Protection Department (EPD)							
Familiarize with the procedures required in Hong Kong for such disposal							
Able to work with other parties in conducting pharmaceutical waste disposal e.g. distributor							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 11: Medical Detailing

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Familiarize with the content of the detailing material being in use							
Have a good sense and understanding in delivery skills							
Have a good understanding of what can be discussed (on-label use) and what cannot be promoted (off-label use)							
Able to handle the questions raised in a logical and professional manner							
Able to handle objection with scientific substantiation							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

Unit 12: Training of Sales Staff

Performance Criteria	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
Understand the function of training sales staff							
Able to produce training materials systematically and in a way that is conducive to the participants							
Able to deliver interactive training sessions to increase the dynamics of the company							
Able to handle questions raised in a logical and professional manner							
Score:							
Comments: <input type="checkbox"/> The element was not covered in this module (for N/A rating). <input type="checkbox"/> Others:							
Preceptor's Name:			Preceptor's Signature:			Date:	

PART B – PHARMACY INTERN PERSONAL ATTRIBUTES APPRAISAL

1. Attitude / Attendance	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Attendance is reliable, punctual							
(b) Demonstrates initiative, enthusiasm							
(c) Demonstrates professional behavior							
<p>Remarks: (Any specific comments such as examples of areas for improvement, especially for items accorded "1", "6" or "N/A", in respect of the above performance characteristics)</p>							
2. Participation / Persistence	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Gives complete, thoughtful answers to questions directed to him/her							
(b) Works energetically, without procrastination							
(c) Completes self-initiated or assigned tasks without constant supervision							
<p>Remarks: (Any specific comments such as examples of areas for improvement, especially for items accorded "1", "6" or "N/A", in respect of the above performance characteristics)</p>							
3. Organization / Planning	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Efficiently organizes the work/tasks							
(b) Attends to detail and quality of work							
(c) Appropriately assigns priorities to tasks							
<p>Remarks: (Any specific comments such as examples of areas for improvement, especially for items accorded "1", "6" or "N/A", in respect of the above performance characteristics)</p>							

4. Communication skills	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Demonstrates ability to write clearly and precisely (grammatically and scientifically)							
(b) Demonstrates ability to communicate verbally in an organized, concise fashion							
(c) Communicates without reservation to patients/customers or health care providers							
<p>Remarks: (Any specific comments such as examples of areas for improvement, especially for items accorded "1", "6" or "N/A", in respect of the above performance characteristics)</p>							
5. Self-Development	Rating (√ as appropriate)						
	1	2	3	4	5	6	N/A
(a) Demonstrates diligence and eagerness to learn							
(b) Recognizes own deficiencies and seeks to improve							
(c) Uses opportunities beyond rotation objectives to broaden insight and competence							
<p>Remarks: (Any specific comments such as examples of areas for improvement, especially for items accorded "1", "6" or "N/A", in respect of the above performance characteristics)</p>							

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

**INTERN'S ASSESSMENT OF
PHARMACEUTICAL WHOLESALE COMPANY TRAINING PROGRAMME**

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 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 patients and/or other health care providers if applicable.					
(b) The training provided opportunity to increase my knowledge of pharmacotherapy.					
(c) I gain a good understanding of registration and sale of pharmaceutical products.					
(d) I gain a good understanding of post-marketing duties, e.g. ADR monitoring, recalls management.					
(e) I gain a good understanding of the general set-up and daily operations of a pharmaceutical wholesale company.					

2. EVALUATION OF THE 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