

**SME Development Fund (SDF)/
Dedicated Fund on Branding, Upgrading and Domestic Sales (BUD Fund)
(Organisation Support Programme) (OSP)**

Final Report on Approved Project

Project ref. no.	:	D13 003 006
Project title	:	A Support Programme for SMEs in the Pharmaceutical Industry to Comply with the New PIC/S GMP Regulatory Requirement
Period covered	:	From 20 FEB 2014 to 19 OCT 2015 (dd/mm/yy) (dd/mm/yy)

1. Project Details

(Please mark with "*" if any of the following project details is different from that in the project proposal appended to the project agreement.)

Project Summary (in about 150 words)

The purpose of this project is supporting local SMEs to upgrade the manufacturing (secondary packaging) operations and quality systems of the pharmaceutical secondary packaging and related industries to fulfil the new PIC/S GMP regulatory requirement. This program will comprise of an awareness seminar, gap assessments, a training program, an overseas benchmarking study and research on PIC/S implementation, an operation model, and invitation of an overseas PIC/S specialist for evaluation of a developed operation model. An implementation manual and a reference guide on PIC/S GMP will also be compiled. This program will be beneficial not only to HK SMEs involved in pharmaceutical product secondary packaging, but also to all Hong Kong citizen for safely purchase of drugs.

Project Objective(s) (in about 80 words)

1. To promote and encourage scientific advances in all aspects of biotechnology;
2. To promote and encourage the development of a successful and prosperous modern biotechnology in Hong Kong;
3. To carry out research, development, and experimental work in biotechnology and its application and use, either independently or jointly with governmental bodies, educational and research institutions;

Grantee/Collaborating Organisation/Implementation Agent

Grantee : The Pharmaceutical Distributors Association of Hong Kong Limited

Collaborating Organisation(s) : The Hong Kong Institute of Biotechnology Ltd.
Hong Kong Medical and Healthcare Device Industries Association Ltd.
Hong Kong Plastic Bag Manufacturers' Association
Hong Kong Mould and Product Technology Association

Implementation Agent(s) : Hong Kong Productivity Council

Key Personnel

	<u>Name</u>	<u>Company/Organisation</u>	<u>Tel No. & Fax No.</u>
Project Co-ordinator	Mr. William Tsui	The Pharmaceutical Distributors Association of Hong Kong Limited	2774 8338
Deputy Project Co-ordinator	Ms. Tina Yap	The Pharmaceutical Distributors Association of Hong Kong Limited	2527 8898

Project Period

	<u>Commencement Date</u> (day/month/year)	<u>Completion Date</u> (day/month/year)	<u>Project Duration</u> (No. of months)
As stated in project agreement	20 FEB 2014	19 OCT 2015	20
Revised (if applicable)			

2. Summary of Project Results

Project Deliverables

(Please list out the project deliverables as stated in the project proposal appended to the project agreement and provide details related to the actual result achieved for each of them.)

	Project deliverable	Quantifiable target number (e.g. 100 participants)	Actual result achieved (e.g. 90 participants)	Reasons for not achieving the target, if applicable (e.g. The total number of registered participants was over 120. However, some of them did not show up eventually. Will strengthen promotion and try to make up for the shortfall in the following two seminars.)
a.)	A Steering committee comprising representatives of applicant (PDAHK), HKPC, HKIB have been formed to monitor the project progress. [fulfil the project deliverables mentioned in Section C, 3.1]	N/A	N/A	
b.)	A half-day awareness seminar have been conducted on 7 April 2014 for project kick-off and promotion. [fulfil the project deliverables mentioned in Section C, 3.2]	100 participants	100 participants	
c.)	A detail overseas research have been made between 29 Mar - 5 Apr 2014 on Belgium and Netherland for benchmarking purpose and acquisition of knowledge and techniques in PIC/S GMP implementation. The study finding has been reported during the half-day awareness seminar. [fulfil the project deliverables mentioned in Section C, 3.3]	N/A	N/A	
d.)	The study finding has been reported during the half-day awareness seminar. [partial fulfil the project deliverables mentioned in Section C, 3.4]	51 companies	51 companies	
e.)	A check list has been sent related SMEs to self-evaluate their operational and management system for gap analysis. [fulfil the project deliverables mentioned in Section C, 3.5]	N/A	N/A	
f.)	We have set up a free of charge consultation center and hotline from October 2014 to October 2015 in order to answer the questions raised by the industry and public. [fulfil the project deliverables mentioned in Section C, 3.6]	N/A	N/A	
g.)	Questionnaire survey of 50 companies	50 companies	50 companies	

h.)	<p>A 5-day intensive training workshop comprises of 3 days lectures and 2 day on-site practical training has been conducted from July to September.</p> <p>[fulfil the project deliverables mentioned in Section C, 3.7]</p>	<p>There are on average 83 participants for the first 3 days lecture and 42 participants for the 2 days on-site practical training. The total number of participants is 67 on average which meet the proposed target.</p>	<p>The details are as follow:</p> <p>7 July, Basic Principles of Good Manufacturi ng Practices in the Pharmaceuti cal Industry following PIC/S guidance</p> <p>8 July, Good Distribution Practices (GDP) Training for Pharmaceuti cal Industry following PIC/S guidance</p> <p>30 July, Good Manufacturi ng Practices of secondary packaging following PIC/S guidance</p> <p>14 Aug and 4 Sept On site facility visit and coaching following PIC/S guidance</p>	
i.)	Questionnaire survey for 5-day intensive training's participant	60 participants	83 participants	
j.)	Design and production for 400 copies of the implementation manual. 50 copies of implementation manual will be kept in PDAHK office and HKPC for display and borrow by HK companies and practitioners.	N/A	N/A	
k.)	A full day debriefing workshop and half-day sharing seminar has been conducted from September and October.	60 participants	There are on average 65 participants for the full day debriefing workshop and half-day sharing seminar.	

			The total number of participants for debriefing workshop is 74 and for sharing seminar is 57 which meet the proposed target.	
l.)	Full day debriefing workshop (Questionnaire survey had been collected)	60 participants	65 participants	
m.)	Half-day sharing seminar's (Questionnaire survey had been collected)	60 participants	65 participants	
n.)	20 companies have been selected as pilot company for trial implementation of PIC/S GMP. For these 20 pilot companies.	N/A	We have conducted a half day on-site visit and pre-audit for preliminary study and gap assessment respectively. A 130 pages implementation manual and 70 pages references guide has been compiled.	
o.)	Half day on site visit had been conducted from Jun 2014 to Sep 2015 to evaluate to operation of 25 companies.	25 companies	25 companies	
p.)	Design and production for 1000 copies of the reference guide. 350 copies of reference guide will be kept in PDAHK office and HKPC for display and borrow by HK companies and practitioners.	N/A	N/A	

Details of the deliverables (e.g. date, duration, venue, speaker, topic discussed, etc.)
(Please list out in table format if necessary.)

Topic	Date	Duration	Venue	Speaker
a.) A Steering committee comprising representatives of applicant (PDAHK), HKPC, HKIB have been formed to monitor the project progress.	20 FEB 2014 to 19 OCT 2015	20 FEB 2014 to 19 OCT 2015	N/A	N/A
b.) A half-day awareness seminar have been conducted on 7 April 2014 for project kick-off and promotion.	7 APR 2014	Half-day	HKPC	(HKBI - Dr. Leung), (Director - Lina Wu - Department of Health), (HKPDA - Andrew, William), (HKPC - Alan)
c.) A detail overseas research have been made between 29 Mar - 5 Apr 2014 on Belgium and Netherland for benchmarking purpose and acquisition of knowledge and techniques in PIC/S GMP implementation; The study finding has been reported during the half-day awareness seminar.	29 MAR - 5 APR 2014	8 day	Belgium and Netherland	N/A
d.) A check list has been sent related SMEs to self-evaluate their operational and management system for gap analysis.	1 MAY 2014 to 22 OCT 2015	N/A	HK	N/A
e.) We have set up a free of charge consultation center and hotline from October 2014 to October 2015 in order to answer the questions raised by the industry and public.	OCT 2014 to OCT 2015	1 year	N/A	N/A
f.) Questionnaire survey of 50 companies	1 MAY 2014 to 22 OCT 2015	N/A	HK	N/A
g.) A 5-day intensive training workshop comprises of 3 days lectures and 2 day on-site practical training has been conducted from July to September.	7,8,30 JUL, 14 AUG, 4 SEP 2014	5 full day	HKPC and Fo Tan	Overseas expert - Dr. de Boer, SGS - Mr. Felix Gao, and HKPC consultant - Alan Tso
h.) Questionnaire survey for 5-day intensive training's participant	4 SEP 2015	5 full day	Fo Tan	Overseas expert - Dr. de Boer, SGS - Mr. Felix Gao, and HKPC consultant - Alan Tso
i.) Design and production for 400 copies of the implementation manual. 50 copies of implementation manual will be kept in PDAHK office and HKPC for display and borrow by HK companies and practitioners.	OCT 2015	N/A	N/A	N/A
j.) Design and production for 1000 copies of the reference guide. 350 copies of reference guide will be kept in PDAHK office and HKPC for display and borrow by HK companies and practitioners.	OCT 2015	N/A	N/A	N/A
k.) A full day debriefing workshop and half-day sharing seminar has been conducted from September and October.	30 SEP and 16 OCT 2015	Full day and half day	HKPC	HKPC consultant
l.) Questionnaire survey for a full day debriefing workshop and half-day sharing seminar's participant.	30 SEP and 16 OCT 2015	Full day and half day	HKPC	HKPC consultant
m.) Half day on site visit had been conducted from Jun 2014 to Sep 2015.	Jun 2015 to Sep 2015	Jun 2015 to Sep 2015	HK	SGS - Mr. Felix Gao, and HKPC consultant - Alan Tso

Milestones (in chronological order)

(# Please indicate if the milestone is completed (C), deferred (D) or not achieved (N). If it is deferred, please indicate the revised completion date. For those milestones which are deferred or not achieved, please also provide the reasons under item 2.4.)

	<u>Milestone</u> (as set out in the approved project proposal appended to the project agreement)	<u>Original target completion date</u>	<u>Revised completion date</u> (if applicable)	<u>Status</u> (C/D/N) #
(a)	To organize an awareness seminar	15/04/2014		C
	To conduct an overseas benchmarking study, a local preliminary study by questionnaire survey & short on-site operation visits as well as a debriefing workshop.	30/06/2014	28/02/2015 For debriefing workshop only	C
(b)	To compile a gap assessment checklist for SME's self-evaluation for compliance.	31/08/2014		C
(c)	To conduct a 5-day intensive training program with 5 one-day modules	30/09/2014		C
(d)	To compile an implementation manual and build an operation model. To put the implementation manual at PDAHK and HKPC for display and borrowing.	30/08/2015		C
(e)	To implement support program for 20 pilot cases	30/06/2015		C
(f)	To hold a full day debriefing workshop	30/09/2015		C
(g)	To hold a half-day sharing seminar	16/10/2015		C
(h)	To set up a free of charge consultation centre and telephone hotline on PIC/S GMP	19/10/2015		C
(i)	To compile a reference guide. To upload summary of reference guide to PDAHK website	19/10/2015		C
(j)				
(k)	Half day on-site visit of 25 companies	19/10/2015		C

Note:
N/A

Future Plan for Promoting the Project Deliverables (Nil if not applicable)

We will distribute the quality manual and references guide to all new secondary packaging manufacturers

Free-of-charge. The manufacturer can upgrade their quality management system by understanding the content of the manual and guide.