

**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 003 008
Project title : To Enable the Local Opto-mechatronics SMEs in
Capturing the Business Opportunity in the High
Value-Added Healthcare and Medical Device Market
Period covered : From 15/05/14 to 14/05/16
(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)

This project aimed at enabling the local opto-mechatronics SMEs in further expanding their business into the medical and healthcare device market, through a) hands-holding pilot scheme to develop and demonstrate the know-how on upgrading from opto-mechatronics manufacturing operations into medical device complied manufacturing operations and quality management systems; b) a series of systematic and opto-mechatronics industry-specific training to the local SMEs, to equip them with the essential knowledge on medical device regulatory affairs, safety and compliance requirement in order to upgrade their business into "medical-grade ready".

Project Objective(s) (in about 80 words)

- To develop a systematic approach to enable the local opto-mechatronics industry in expanding their business into the high value-added medical and healthcare device market through hands-holding pilot scheme.
- To disseminate the industry-specific know-how on transforming the opto-mechatronics business into medical device compliance level.
- To sustain the competence and strength of the local opto-mechatronics industry by enabling their migration into the medical-grade of opto-mechatronics products, through training and capability building towards opto-mechatronics product-specific quality management system requirements for medical device manufacturing and distribution.

Grantee/Collaborating Organisation/Implementation Agent

Grantee : Hong Kong Opto-Mechatronics Industries Association Limited

Collaborating Organisation(s) : Hong Kong Medical and Healthcare Device Industries 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	: <u>Mr Hung Keung TSE</u>	<u>Hong Kong Opto-Mechatronics Industries Association Limited</u>	<u>3188 0240 / 3586 2765</u>
Deputy Project Co-ordinator	: <u>Mr Chi Man FOK</u>	<u>Hong Kong Opto-Mechatronics Industries Association Limited</u>	<u>3188 0240 / 3586 2765</u>

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	<u>15/05/2014</u>	<u>14/11/2015</u>	<u>18</u>
Revised (if applicable)	<u>15/05/2014</u>	<u>14/05/2016</u>	<u>24</u>

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)	Eight Awareness Workshop	Target Number of Participant: 240	Actual Number of Participant: 126	<p>1) As most of the workshops are related to opto-mechatronics/medical specific technology sharing and the workshop material would be posted online, potential participants may decide to go through the online material instead of attending the workshops for the technology details.</p> <p>2) As the content of the workshop was designed to share opto-mechatronics specific manufacturing technology, the management of these manufacturers much prefer to invite their technical staff members to join the workshops, such as engineers, QA/QC managers, etc. These positions were used to take up by Hong Kong local employees, who should be able to join the seminars more conveniently; with the recent economic environment and demand to cut cost, these technical positions were taken up by the employees in mainland and travelling across the border for a seminar during weekday may not be very favourable to the mainland employees. Hence, the overall participation rate of the seminars was lower than expected.</p>
i)	One Experience Sharing Seminar	Target Number of Participant: 50	Actual Number of Participant: 9	Please refer to Section 2.1(a)
j)	Implementation of Pilot Scheme	Target Number of Pilot Companies: 3	Actual Number of Pilot Companies: 3	N.A.
k)	Design and Editing of Industry-Specific Guidebook	Target Number of Guidance Completed: 1	Actual Number of Guidance Completed: 1	N.A.
l)	Project Dedicated Website	Target Number of Project Website: 1	Actual Number of Project Website: 1	N.A.
m)	Help Desk Service	Target Number of the Help Desk	Actual Number of Help Desk	N.A.

		Service:1	Service: 1	
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Details of the deliverables (e.g. date, duration, venue, speaker, topic discussed, etc.)

(Please list out in table format if necessary.)

	Project Deliverable	Date	Duration	Venue	Speakers/Authors	Topic Discussed
a)	1 st Awareness Workshop (Introduction to Upgrading Local Opto-mechatronics SMEs to High Value-Added Medical and Healthcare Device Industries)	24 Oct 2014	2:00pm-5:00pm	Classroom 104, Hong Kong Productivity Council (HKPC)	Mr William Yim, Vice Chairman of the Project Steering Committee Prof Aaron Ho, Professor of the Department of Electronic Engineering, CUHK Dr David Luk, Associate Consultant, Department of Paediatrics & Adolescent Medicine, United Christian Hospital Mr Henry Fong, Associate Consultant, HKPC Ir Bryan So, Principal Consultant, HKPC	<ul style="list-style-type: none"> ● Trend and Development of Opto-mechatronics Technology, ● Opto-mechatronics Technology with Medical Application ● Experience Sharing on New Market Exploration ● Introduction to the Quality Requirements for Medical Device Production and Introduction to the Pilot Scheme of HKOMIA SDF Project ● Opportunities for Opto-mechatronics Technology Development in Medical Device Industry
b)	2 nd Awareness Workshop (Introduction of Medical Device Quality Management System, Current Good Manufacturing Practices and Good Clinical Practices for Opto-mechatronics and Other Related Industry)	29 Jan 2016	2:00pm-5:00pm	HKPC	Ms Carol Liu, Consultant, HKPC Mr Henry Fong, Consultant, HKPC	<ul style="list-style-type: none"> ● Good Clinical Practices of Medical Devices ● Requirements of Quality Management System for Medical Devices
c)	3 rd Awareness Workshop (Introduction of Medical Device International Regulatory Requirements (U.S., E.U. and China))	4 Mar 2016	2:15pm-5:15pm	HKPC	Ir Bryan So, Principal Consultant, HKPC Mr Jerry Hu, Senior Consultant and Trainer, Shenzhen Association of Medical Devices Ir Albert Poon, Deputy Chairman, Biomedical Discipline Advisory Panel, The Hong	<ul style="list-style-type: none"> ● Introduction of Global Regulatory Requirement (Europe) ● Medical Device Laws and Regulations in China ● Overview of US Regulatory Compliance on Medical Device

					Kong Institution of Engineers	
d)	4 th Awareness Workshop (Manufacturing Technology for Medical Devices/Components)	15 Apr 2016	9:30am-12:30pm	HKPC	Mr Yan Lu Shun, Application Department Manager, ARBURG Machine and Trading (Shenzhen) Co., Ltd. Ir Bryan So, Principal Consultant, HKPC	<ul style="list-style-type: none"> ● Latest Injection Molding Technology for Medical Devices Manufacturing ● Ultra-precision Manufacturing Technology for Optical Medical Products
e)	5 th Awareness Workshop (Risk Management and Traceability for Medical Devices)	15 Apr 2016	2:15pm-5:15pm	HKPC	Mr Henry Fong, Consultant, HKPC Mr Dick Ng, Manager, Logistics & Healthcare, GS1	<ul style="list-style-type: none"> ● Risk Management for Manufacturing of Medical Devices ● Traceability and Its Implementation for Medical Devices
f)	6 th Awareness Workshop (Realization of Medical Electronic and Optical Devices)	22 Apr 2016	2:30pm-5:30pm	HKPC	Ir Dr Cheung Ching Ching, Vice President, Aviton Care Limited Mr Fok Chi Man, President, Diffractive Optics	<ul style="list-style-type: none"> ● Consideration for the Design and Manufacturing of Electronic Medical Devices ● Experience Sharing on the Transition from Traditional Optical Products to Medical Optical Products
g)	7 th Awareness Workshop (Sterilization Method for Medical Device/Components Manufacturing and Clinical Trial for Medical Devices)	5 May 2016	2:30pm-5:30pm	HKPC	Mr Samuel Law, Cluster Operations Manager, Central Sterile Supplies Department, Hospital Authority Ms Kaman Chan, Trainee Consultant, HKPC	<ul style="list-style-type: none"> ● Sterilization Method for Medical Device Manufacturing ● Medical Device Lifecycle: Clinical Evaluation
h)	8 th Awareness Workshop (Handling of Medical Device Adverse Events and Environmental Control for Medical Device's Production)	6 May 2016	9:30am-12:30pm	HKPC	Mr Kyle Liu, Cadet Engineer, HKPC Mr Jerry Cheung, Vincent Medical Manufacturing Company Limited	<ul style="list-style-type: none"> ● Adverse Event Handling for Medical Devices ● Environment Control for Medical Device Manufacturing
i)	Experience Sharing Seminar (Establishment of Medical Device Quality)	6 May 2016	2:30pm-5:30pm	HKPC	Mr Henry Fong, Consultant, HKPC Mr Michael Li, Client Manager, BSI	<ul style="list-style-type: none"> ● Sharing on the Pilot Scheme ● Revision of the Medical Device Quality Management System and Audit Experience Sharing

	Management System, Introduction on ISO13485:2016 Version and Audit Experience Sharing)					
j)	Implementation of Pilot Scheme	4 February 2016 (Sanwa Biotech Limited) 6 April 2016 (Diffractive Optics Limited) 7 April 2016 (Forward Electronics Company Limited)	N.A.	N.A.	N.A.	N.A.
k)	Design and Editing of Industry-Specific Guidebook	30 May 2016	N.A.	N.A.	HKPC: Mr Derek LOUIE, Mr Bryan SO, Mr Henry FONG, Ms Kaman CHAN, HKOMIA: Mr Christopher TSE, Mr FOK Chi Man, Mr William YIM, Mr Alan AU, Mr Jack TAM, Mr CHEAH Kok Wai	Book Title: Industry-specific Guidebook for Opto-mechatronics Industries to Enter Medical Device and Healthcare Market
l)	Construction of Project Website	N.A.	N.A.	N.A.	N.A.	http://hkomia2016.wix.com/sme-hkomia
m)	Setting Up of Help Desk Service	N.A.	N.A.	N.A.	N.A.	http://hkomia2016.wixsite.com/sme-hkomia/contact

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)	Literature Search	14/06/2014		C
	Selection of Pilot Companies and On-site	14/08/2014	31/10/2016	C
(b)	Industry Evaluation			
	Implementation of Pilot Scheme through setting up of Opto-mechatronics specific Medical Device Quality Management	14/06/2015	7/4/2016	C
(c)	System & Risk Management System			
	Publish of the Industry-Specific	14/11/2015	1/5/2016	C
(d)	Guidebook			

Future Plan for Promoting the Project Deliverables (N.A. if not applicable)

The help desk service and project website had been set up. The summary about the awareness training workshops, experience sharing seminar, industry-specific guidance manual has been updated at the project website. It provides a convenient platform for the beneficiaries to collect the valuable and useful information for capturing business opportunity in the healthcare and medical device market.
