

**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. : D17 001 005  
Project title : To enhance the ability and upgrade the local electronics  
industry for entering the smart medical and healthcare  
device industry focusing on parts and components market  
Period covered : From 01/10/2017 to 31/07/2019  
(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)

#### (a) Industry and market background

According to a research report published by the Central Policy Unit of the Government of the HKSAR on Smart City in late 2015<sup>1</sup>, Smart Living – Healthcare was listed as one of the six major components in the whole development blueprint for Smart City. Also, the trend of aging population and increasing health consciousness have boosted the global demand for various medical and healthcare devices, and HKSAR Government has addressed this trend and the needs on healthy aging in many occasions. According to the latest announcement published by the China Government in Feb 2017<sup>2</sup>, more emphasis will be placed on the development of products suited for aging population in the areas of wearable devices, treatment of chronic disease, rehabilitation devices, emergency devices, communication devices, etc. Among them, the global smart medical devices market was valued at US\$33.7 billion in 2015, and it is estimated to be valued at US\$66.1 billion by end of 2024<sup>3</sup>. With this foreseeable market trend, many high technologies local companies are now focusing on the development of innovative smart medical and healthcare products for healthy ageing.

In general, smart medical and healthcare devices are the medical and healthcare devices that can connected to the internet and be able to identify themselves to other devices, such that these smart devices are aware of their context, and can communicate and assimilate information to facilitate healthcare decisions.<sup>4</sup> Such intelligence and communication heavily rely on the advanced hardware (such as sensors, microprocessors, integrated circuits (ICs), actuators which are mostly electronic-based, etc.), as well as algorithm for signal acquisition and processing. The increased demand for smart medical and healthcare devices will require more specialised electronics components, such as sensors, actuators, LCD monitors, integrated circuit (IC), printed circuit board (PCB), etc., which account for a huge amount of business for electronics industry (providers of such components cover around 70% of the whole Hong Kong electronics components industry).

Hong Kong's electronics industry is the largest merchandise export earner of the territory, accounting for 65.5% of Hong Kong's total exports in 2016. Parts and components constitute about three quarters of Hong Kong's electronics exports<sup>5</sup>. With cut-throat price competition and accelerating number of market competitors from the Mainland, Taiwan, and Singapore in the traditional electronics industry, local electronics industry are now facing great challenges in maintaining their business on the market of traditional electronics products (e.g. toys, computers, mobile phones, cameras, washing machines and TV, etc.). With foreseeable huge market opportunity on smart medical and healthcare devices, local electronics industry has great interest and very eager to enter the high-value added smart medical device and healthcare device industry, for sustaining their current business in the long run. However, even though with the extensive knowledge and experience on electronics development, local electronics companies are still finding difficulties in stepping into smart medical and healthcare device industry with the greatest entry barrier on the compliance of medical device Quality Management System (QMS) and stringent international market entry requirements.

Traditional electronics manufacturing processes include PCB production, mounting of components onto the PCB with Surface Mount Technology (SMT)<sup>6</sup>, microcontroller programming<sup>7</sup>, sputtering deposition for LCD<sup>8</sup> production, etc., any discrepancy during these critical processes may lead to serious defects to the final medical and healthcare devices such as malfunctioning and inaccuracy data generation. Therefore, comprehensive control (validation and testing) to these manufacturing processes would be crucial to the safety and effectiveness to the smart medical and healthcare devices. Due to the requirements on stringent supplier management for ensuring the supply of qualified medical devices, even though it is not mandatory for component suppliers of smart medical and healthcare devices to comply with any quality standards, it has become a common trade practice for smart medical and healthcare devices manufacturers to select those who have obtained certification on quality standard for medical devices, especially with the newly released standard requirements on risk management for supplier (e.g. ISO 13485<sup>9</sup>, 21 CFR 820<sup>10</sup>, etc.). Component suppliers will be considered as qualified suppliers only after they have met the requirements of the medical device quality management. As such, the electronics component manufacturers will need to upgrade their existing QMS (e.g. ISO9001) to more stringent level which can fulfil the requirements of relevant international requirements. Since US and EU are the largest markets for medical and healthcare devices<sup>9</sup>, ISO 13485 (which is adopted as a harmonized standard for



Quality Management System in EU and formally recognised under the Conformity Assessment Standards Order in Australia as a standard for the manufacture of all kinds of medical devices that require a quality management system for conformity assessment) and 21 CFR 820 (Quality System Regulation) for US are the two major requirements on QMS by manufacturers of medical and healthcare devices.

For medical device manufacturing, traceability, design and manufacturing validation, risk management, process verification and validation, supplier management, compliance testing are some critical elements for ensuring the final medical devices are safe and effective. However, these requirements are not common in traditional electronics business, which pose a great obstacle for local electronics SMEs to upgrade their current QMS to ensure the quality of the products. Without the capability to carry out process control as required by Quality Management System, it will be difficult for local electronic component manufacturers to step into the smart medical and healthcare device industry. Currently local electronics SMEs can engage consultancy for upgrading their QMS, but the cost for such upgrading is very high and local SMEs need a considerable amount of time to understand the process and to establish their new QMS.

Due to the difficulties, The Hong Kong Electronic Industries Association (HKEIA) has received various feedback from the industry on the needs to assist and guide them to minimize the aforementioned gaps for their future entry to high-value added smart medical and healthcare device market. As such, HKEIA proposes to provide guidance for local electronics industry on upgrading their QMS. With the help of this project, it is expected that the cost for upgrading the Hong Kong electronics industry through this project can be greatly reduced. Upon the completion of this project, it is expected that the local electronics industry will be able to enhance their competence in performing process and quality control on their products. With such capability and compliance owned by the electronics companies, they will be able to be selected by smart medical and healthcare devices companies, and gain confidence from their buyers (finished products manufacturers) to start business on supplying components with good quality, and thus, allowing them to capture the high potential smart medical and healthcare devices components market.

<sup>1</sup> [http://www.cpu.gov.hk/doc/en/research\\_reports/CPU%20research%20report%20-%20Smart%20City\(en\).pdf](http://www.cpu.gov.hk/doc/en/research_reports/CPU%20research%20report%20-%20Smart%20City(en).pdf)

<sup>2</sup> [http://www.gov.cn/zhengce/content/2017-03/06/content\\_5173930.htm](http://www.gov.cn/zhengce/content/2017-03/06/content_5173930.htm)

<sup>3</sup> <http://www.transparencymarketresearch.com/pressrelease/global-smart-medical-devices-industry.htm>

<sup>4</sup> <http://perso.telecom-paristech.fr/~chollet/Projets/SmartHome/Articles/futurehomeSandia.pdf>

<sup>5</sup> <http://hong-kong-economy-research.hktdc.com/business-news/article/Hong-Kong-Industry-Profiles/Electronics-Industry-in-Hong-Kong/hkip/en/1/1X000000/1X00401Z.htm>

<sup>6</sup> Surface mount technology refers to the use of robotic machines to precisely place electronic components onto PCBs.

<sup>7</sup> Microcontroller programming refers to the embedment of applications in the small computer on an IC.

<sup>8</sup> Sputtering deposition refers to the deposition of film onto a surface.

<sup>9</sup> <http://marketrealist.com/2015/11/must-read-overview-medical-device-industry/>

\* ISO13485 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

# 21 CFR 820 is the US regulation on medical device Good Manufacturing Practices

### **Project Objective(s) (in about 80 words)**

1. To enhance the capability of local electronics SMEs on understanding the international regulatory requirements and appropriate manufacturing practices for future development of smart medical and healthcare devices.
2. To develop local best practice with reference to the medical device quality management system for upgrading the operation processes of the local electronics companies
3. To disseminate the knowledge and know-how gained from this project to the industries, in order to maximize the beneficiary, and to avoid the repeated resources, time and efforts by the industries on handling similar challenges while getting into the new medical device sector..

### **Grantee/Collaborating Organisation/Implementation Agent**

Grantee	: <u>The Hong Kong Electronic Industries Association Limited (HKEIA)</u> <u>Hong Kong Federation Of Innovative Technologies And Manufacturing Industries Limited, Hong Kong Printed Circuit Association Limited, Hong Kong Wireless Technology Industry Association Limited, Hong Kong Electronics &amp; Technologies Association Limited, Hong Kong Trade Development Council, The Chinese Manufacturers' Association of Hong Kong</u>
Collaborating Organisation(s)	: <u>Kong</u>
Implementation Agent(s)	: <u>Hong Kong Productivity Council (HKPC)</u>

## Key Personnel

	<u>Name</u>	<u>Company/Organisation</u>	<u>Tel No. &amp; Fax No.</u>
Project Co-ordinator :	<u>Mr Basil Wai</u>	<u>HKEIA</u>	<u>Tel: 2778 8328</u> <u>Fax: 2788 2200</u>
Deputy Project Co- :	<u>Mr Rick Mo</u>	<u>HKPC</u>	<u>Tel: 2788 5022</u> <u>Fax: 3187 4575</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>01/10/2017</u>	<u>31/01/2019</u>	<u>16</u>
Revised (if applicable)	<u>01/10/2017</u>	<u>31/07/2019</u>	<u>22</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)	Formation of Steering Committee	1 Steering Committee	1 Steering Committee	NIL
b)	Implementation of Industry Competence Assessment Scheme for 5 Electronics Companies	5 companies	5 companies	NIL
c)	Organization of 3 Local Half-day Seminars	240 participants	259 participants  1 <sup>st</sup> : 137 2 <sup>nd</sup> : 62 3 <sup>rd</sup> : 60	NIL
d)	Organization of 5 Local Training Workshops	150 participants	114 participants  1 <sup>st</sup> : 28 2 <sup>nd</sup> : 23 3 <sup>rd</sup> : 23 4 <sup>th</sup> : 22 5 <sup>th</sup> : 18	U.S was once considered as a major market for medical device. However, due to the China-US Trade War, it affected the whole medical devices' supply chain. HK SMEs then took an observe attitude while they were trying to enter the new market as well as knowing the requirements of U.S market system.
e)	Compilation of Industry-Specific Guidebook	1 booklet	1 booklet	NIL
f)	Provision of Content for Project Webpages	1 website	1 website	NIL
g)	Provision of Helpdesk Services	1 service	1 service	NIL
h)	Project Promotion	1. Promotion materials of the Industry-wide Enhancement Scheme shall be conducted via eDM service of applicant, implementation agent and	1 service	NIL

		collaborating organizations.		
		2. Advertisement in Local Trade Association Magazines for Promoting the Scheme -5 issues in FHKI 《Industrialist》, -5 issues in HKEIA 《Bulletin》	-1 issue in FHKI, -5 issues in HKEIA	- 1 Issue in FHKI 《Industrialist》 (Feb 2018) ○ The project team has used e-dissemination for promoting the seminar and workshops so to save time costs. Therefore, only 1 issue for promoting the scheme was placed in 《Industrialist》.
		3. Posters for 3 seminars (total 150 copies) Posters for 5 workshops (total 150 copies)	1 service	Posters (50 copies) for the first seminar had been produced. For the remaining seminars, from environmental-friendly perspective the project team had decided to promote them through eDM and social media platforms.
		4. Leaflets for 3 Seminars (total 750 copies) Leaflets for 5 workshops (total 750 copies)	N.A.	For the promotion of workshops, from environmental-friendly perspective the project team had decided to promote them through eDM and social media platforms.

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

(Please list out in table format if necessary.)

Please refer to the table below:

Deliverables	Date	Duration	Venue	Speaker/ Author	Topic discussed/ Title
<b>1) Formation of Steering Committee</b>	01/10/2017-31/07/2019	22 months	N.A.	- Carrie Li – Cook Medical - Joe Wong – Sengital - Aaron Ho- CUHK - Basil Wai- HKEIA.	During the project period, steering committee provided advices for the project team
<b>2) Implementation of Industry Competence Assessment Scheme for 5 Electronics Companies</b>	31/03/2019	N.A.	1. Tinyway Electric (HK) Co., Limited 2. Bisa Technologies (Hong Kong) Limited 3. Compass Technology Company Limited	N.A.	In the program, we had conducted on-site visit for those companies and reviewed their documents and environments.



			4. Solarbrite Electronics Ltd		
			5. Sweda (Dongguan) Electronics Company Limited		

### 3) Organization of 3 Local Half-day Seminars

Seminar 1	14/10/2017	2:00 – 5:00 pm	Seminar Room, Hall 5FG, Hong Kong Convention & Exhibition Centre	Prof. Paul R. Stoddart (Director of Swinburne University of Technology)  Mr Terry Chan (Wireless Lab Manager of Intertek Hong Kong)  Mr. Bryan So (Principal Consultant, Smart Healthcare, MedTech & Optics Unit, HKPC)	Seminar on the Development and Compliance Requirements for Medical Sensor Technology
Seminar 2	26/07/2018	2:00 – 5:00 pm	Theatre 2, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong	Mr. EE Bin Liew (Member of the ISO/C210 JWG1)  Mr. William Fung (Association Consultant, Smart Healthcare, MedTech & Optics Unit, HKPC)	Good Traceability – To Win Your Customer With Value Adding Service in Medical Device Business – Half Day Seminar
Seminar 3	08/07/2019	2:00 – 5:30 pm	Theatre 1, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong	Mr. Adrian Valea (Managing Director at DVA Software Engineering GmbH)	Analysis, Evaluational Management for Electronics Components of Smart Medical and Healthcare Devices Technical Seminar

### 4) Organization of 5 Local Training Workshops

Workshop 1	21/06/2019	2:00 pm – 5:30 pm	Classroom 106, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong	Mr Charles Chai (廣州智華企業管理諮詢有限公司 首席顧問)  Ms. Keli Li (Lead Consultant, Smart Automotive Automotive and Electronics Division, HKPC)	ISO13485:2016 行業升級工作坊
Workshop 2	28/06/2019	2:00 pm – 5:30 pm	Classroom 106, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong		
Workshop 3	05/07/2019	2:00 pm - 5:30 pm	Classroom 106, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong		
Workshop 4	12/07/2019	2:00 pm – 5:30 pm	Classroom 106, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong		

Workshop 5	15/07/2019	2:00 pm – 5:30 pm	Classroom 106, 1/F, HKPC Building, 78 Tat Chee Avenue, Kowloon Tong		
<b>5) Compilation of Industry Guidebook</b>	14/05/2019	N.A.	N.A.	N.A.	“進入醫療器械行業實施指南”
<b>6) Project Website</b>	01/10/2017	N.A.	N.A.	N.A.	<a href="https://hkeiasdf.wixsite.com/hkeiasdf">https://hkeiasdf.wixsite.com/hkeiasdf</a>
<b>7) Helpdesk Service</b>	01/10/2017	N.A.	N.A.	N.A.	Ms. Belva Leung Tel: 2788 6355
<b>8) Promotion of the Industry Competence Assessment Scheme, seminars, workshops, and project dissemination</b>	15/07/2019	N.A.	N.A.	N.A.	<p>Advertisements:</p> <ul style="list-style-type: none"> <li>- 1 Issue in FHKI 《Industrialist》 (Feb 2018)</li> <li>- 5 issues in HKEIA 《Bulletin》 (Sep – Oct 2017, Jan – Feb, May – Jun 2018, May 2019, Jun 2019)</li> </ul> <p>Posters (50 copies) for the first seminar had been produced. For the remaining seminars, from environmental-friendly perspective the project team had decided to promote them through eDM and social medial platforms.</p> <p>For the promotion of workshops, from environmental-friendly perspective the project team had decided to promote them through eDM and social medial platforms.</p>



## 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</u> target completion <u>date</u>	<u>Revised</u> target completion <u>date</u> (if applicable)	<u>Status</u> (C/P/D) #	<u>Reason for deviation</u> from its original target <u>completion date</u>
Formation of Project Steering Committee, Promotion of Project to	30/11/2017		C	
(a) <u>the Industry and Literature Research</u>				
Construction of Project Webpages and	30/11/2017		C	
(b) <u>Helpdesk Service</u>				
Recruitment and Selection of 5 Pilot Companies for Industry Competence	31/01/2018	30/09/2018	D	See note (a)
(c) <u>Assessment Scheme</u>				
Conduction of Gap Analysis on 5 Pilot Companies under Industry	31/03/2019		C	
(d) <u>Competence Assessment Scheme</u>				
Organization of 3 Local Half-day	28/02/2019	08/07/2019	D	See note (b)
(e) <u>Seminars</u>				
(f) <u>Compilation of Industry Guidebook</u>	31/05/2019	14/05/2019	C	
Organization of 5 Local Half-day	31/07/2019	15/07/2019	C	
(g) <u>Training Workshops</u>				
Promotion of the Industry Competence Assessment Scheme, seminars, workshops, and project	31/07/2019	31/07/2019	P	
(h) <u>dissemination</u>				

### Note:

- As such we only confirmed 2 applications before reporting period, the responses from the industry in enquiring and joining the scheme is slower than expected. Some companies do not want to share their internal procedures or findings via the industry-specific guidebook to be published for the entire industry.
- As the response time from speakers were longer than expected, we need to reschedule the seminars so to fit with their schedule.

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

The help desk service and project website had been set up. The industry-specific guidebook 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 smart healthcare and medical device industry.

---

---