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.	:	D16 003 009
Project title	:	To enhance the awareness and capability of local medical device industries in fulfilling the upcoming new requirements in newly-launched ISO13485:2016 Medical Device Quality Management System (QMS)
Period covered	:	From 15/05/17 (dd/mm/yy) to 14/04/19 (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)

ISO13485 was updated from the version of ISO13485:2003 to ISO13485:2016 in March 2016. Compliance certificate for ISO13485:2003 will not be issued from March 2018 onwards and all ISO13485:2003 compliance certificate will be invalid from March 2019 onwards. Therefore, all companies holding ISO13485:2003 currently should take immediate actions to review and enhance their current QMS in order to accommodate the upcoming timeline for compulsory transition.
With risk management becomes the key focus of the ISO13485:2016, different SMEs and Conformity Assessment Bodies (CABs) may have different evaluation on the risk associated with the medical device. Therefore, the discrepancy in interpretation between different parties has created an obstacle for local SMEs to effectively determine the most cost-effective upgrade methodology for complying with ISO13485:2016.
In view of the upcoming timeline for recertification, Hong Kong Medical & Healthcare Device Industries Association (HKMHDIA) has received strong feedback from the industry on the needs to assist and guide them to enhance the current QMS to fulfil ISO13485:2016 requirements. Therefore, local medical device SMEs require immediate support from this project to review and upgrade their current QMS in order to accommodate the upcoming timeline for compulsory transition.

Project Objective(s) (in about 80 words)

- To enhance the capability of local medical device SMEs on understanding and interpreting the requirements in the newly-launched ISO13485:2016, and to offer practical implementation suggestions to the local SMEs for the compliance of ISO13485:2016 by conducting a series of local seminars.
- To minimize the discrepancy of interpretation on detail compliance criteria among different stakeholders, including SMEs in medical device design, manufacturing and distribution as well as different CABs in the local medical device industry by conducting an Industry-wide Enhancement Scheme and formation of Checklist.
- To disseminate the knowledge gained and recommendations consolidated from the Industry-wide Enhancement Scheme, through compilation of Industry Guidebook and conduction of local training workshops, to enable the local medical device SMEs in transition to ISO13485:2016 in a cost-effective manner, and to ultimately sustain their business.

Grantee/Collaborating Organisation/Implementation Agent

Grantee	:	Hong Kong Medical and Healthcare Device Industries Association Limited
Collaborating Organisation(s)	:	British Standards Institution SGS Hong Kong Limited Federation of Hong Kong Industries Hong Kong Trade Development Council Hong Kong Critical Components Manufacturers Association Limited
Implementation Agent(s)	:	Hong Kong Productivity Council

Key Personnel

		Name	Company/Organisation	Tel No. & Fax No.
Project Co-ordinator	:	Ir Dr Andros CHAN	Hong Kong Medical and Healthcare Device Industries Association Limited	2191 0923 / 2194 5082
Deputy Project Co-ordinator	:	Mr Samson TSOI	Hong Kong Medical and Healthcare Device Industries Association Limited	2191 0923 / 2194 5082

Project Period

	Commencement Date (day/month/year)	Completion Date (day/month/year)	Project Duration (No. of months)
As stated in project agreement	15/05/2017	14/11/2018	18
Revised (if applicable)	15/05/2017	14/04/2019	23

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	One steering committee will be formed	One steering committee will be formed	
b)	Organization of Local Half-day Seminars	4 seminars will be organized	4 seminars have been organized	
c)	Organization of 3 Training Workshops	3 workshops will be organized	3 workshops have been organized	
d)	Implementation of Industry-wide Enhancement Scheme	15 companies will be selected to go through their QMS. Foundlings will be presented in the industry specific guidebook	15 companies had been selected and underwent gap analysis.	
e)	Compilation of Industry Specific Guidebook	An Industry Specific Guidebook will be compiled	An Industry Specific Guidebook has been compiled	
f)	Compilation of Checklist	A checklist will be compiled	A checklist has been compiled	
g)	Construction of Project Website	An independent project website will be published	An independent project website has been published	
h)	Provision of Helpdesk Services	A service hotline and service email will be opened to industry	A service hotline and service email has be opened to industry	

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

<table>
<tr><td>1.</td><td>1. Formation of Steering Committee</td><td>The project steering committee has been formed, with inclusion of different industry stakeholders including
➢ Applicant,
➢ Implementation Agent,
➢ Conformity Assessment Bodies (CABs)
➢ Medical device industrialists with good representatives covering different modes of medical device operations (i.e. design, manufacturing & distribution) as well as the representable medical device categories (e.g. active medical device, disposable, implantable, rehabilitation devices, etc.),
➢ Professional biomedical engineer (Professionals applying engineering principles and design concepts to medicine and biology for healthcare purposes.),
➢ Medical device regulatory specialist (Professionals who provide services on regulatory compliance for medical devices and etc.), and
➢ Academic.</td></tr>
<tr><td>2.</td><td>Organization of 4 Local Half-day Seminars</td><td>4 Local Half-day Seminars had been hosted, details are as below.

<table>
<tr><td>1st Seminar</td><td></td></tr>
<tr><td>Topic:</td><td>Risk Assessment for Procurement & Supplier Evaluation on Medical Device</td></tr>
<tr><td>Date:</td><td>27 July 2018</td></tr>
<tr><td>Time:</td><td>9:30 a.m. – 12:30 p.m.</td></tr>
<tr><td>Venue:</td><td>Theatre 2, HKPC Building</td></tr>
<tr><td>Speaker:</td><td>Mr. Vincent Lam
Senior Product Specialist and Notified Body Auditor, TUV SUD Product Service</td></tr>
<tr><td>Attendance:</td><td>63</td></tr>
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<tr><td>2nd Seminar</td><td></td></tr>
<tr><td>Topic:</td><td>Risk Assessment for Procurement and Supplier Evaluation in Medical Device Life Cycle</td></tr>
<tr><td>Date:</td><td>27 Aug 2018</td></tr>
<tr><td>Time:</td><td>2:30 p.m.- 6:00 p.m.</td></tr>
<tr><td>Venue:</td><td>Theatre 1, 1/F. HKPC Building</td></tr>
<tr><td>Speaker:</td><td>Mr. Ee Bin LIEW
Member of ISO/TC210

Mr. James Fan
Sr. Quality Specialist & Project Management Officer
Medtronic Hong Kong Limited</td></tr>
<tr><td>Attendance:</td><td>58</td></tr>
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		3rd Seminar Topic: Seminar on Risk Management and Computer Software Validation in Manufacturing Process of Medical and Healthcare Device Date: 30 Jan 2019 Time: 2:00 p.m.- 5:00 p.m. Venue: Theatre 1, HKPC Building Speaker: Mr. Koen Cobbaert, Senior Manager - Quality, Standards Regulations, Philips; Mr. Wilson Tsui, Regional Operation Manager, DNV-GL Attendance: 60 4th Seminar Topic: Seminar on Track and Trace with Unique Device Identification Date: 13 Mar 2019 Time: 2:00 p.m. – 5:30 p.m. Venue: Theatre 1, HKPC Building Speaker: Ms. Tania Snioch, Director Healthcare, GS1 Global Office; Mr. KK Suen, Principal Consultant, GS1 Hong Kong Attendance: 46
3.	Organization of 3 Training Workshops	3 Training Workshops had been organized, details are as below. 1st Workshop Topic: Virtual Verification of Medical Device Design Workshop Date: 27 July 2018 Time: 2:30 p.m.- 6:00 p.m. Venue: Room 125, HKPC Building Speaker: Ms. Emma Hu, Materialised Ltd Attendance: 30 2nd Workshop Topic: Workshop on Effective Application of Risk / Hazard Analysis Tools for Medical Device Design and Development as According to ISO13485:2016 Date: 27 Aug 2018 Time: 9:30 a.m. – 12:30 p.m. Venue: Classroom 119, HKPC Building Speaker: Mr. Charles Chu, Engineering Supervisor, Vincent Medical Co. Ltd Attendance: 30 3rd Workshop Topic: ISO13485:2016 Upgrade Training Workshop Date: 25 Jan 2019 Time: 2:00 p.m. – 5:00 p.m. Venue: Classroom 106, HKPC Building Speaker: Mr. Koen Cobbaert Attendance: 30
4.	Implementation of Industry-wide Enhancement Scheme	As of 14 Feb 2018, 15 companies have been selected for the Scheme, on-site assessment and gap analysis had been done for

		all 15 companies
5.	Compilation of Industry Specific Guidebook	An Industry Specific Guidebook had been compiled.
6.	Compilation of Checklist	A Checklist had been compiled
7.	Construction of Project Website	The project website has been built. (https://hkmhdiasdf.wixsite.com/hkmhdiaiso13485)
8.	Provision of Helpdesk Service	The hotline and email address have been provided on the project website for public to ask for the project deliverables, and for advisory on further supports related to the QMS upgrade. (Hotline: 2788 5799, Email: hcmak@hkpc.org)

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.)

	Milestone (as set out in the approved project proposal appended to the project agreement)	Original target completion date	Revised completion date (if applicable)	Status (C/D/N) #
(a)	Formation of Project Steering Committee	14/06/2017		C
(b)	Promotion of Project to the industry	14/07/2017		C
(c)	Construction of Project Website	14/06/2017		C
(d)	Literature Research	14/06/2017		C
(e)	Provision of Helpdesk Service	14/11/2018	14/4/2019	C
(f)	Selection of Medical Device Companies for Industry-wide Enhancement Scheme	14/08/2017		C
(g)	Organization of 4 Local Half-day Seminars	14/07/2018	13/3/2019	C
(h)	Implementation of Industry-wide Enhancement Scheme	14/06/2018		C
(i)	Compilation of Industry-Specific Guidebook	14/08/2018		C
(j)	Compilation of Checklist	14/08/2018		C
(k)	Organization of 3 Training Workshops	14/11/2018	25/1/2019	C

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

Nil