

Date of Receipt

31 Dec 2013

## 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.)

### 1.1 Project Reference and Title

To Upgrade the Overall Competence of the Local Medical and Healthcare Device Industry SMEs in Operation and Distribution in order to Enhance their Competitiveness in the Global Market

### 1.2 Project Summary (in not more than 150 words)

The number of adverse events and recalls of medical devices in Hong Kong has been increasing in the recent years, which might contribute from the globalization of manufacturing, and the enhanced surveillance and alert systems among healthcare regulatory bodies worldwide. More importantly, many local SME distributors and importers on medical devices are not implementing any quality management system (QMS) or not setting up any good practices in distribution and operation. Those inadequate practices and operation systems are putting high risks to the public health, and causing economic damages to the SMEs. It also adversely affected the healthy growth of the industry. We have received strong demands from the medical device industries to support their upgrade and competence building on distribution operations. Those SMEs are lacking competence and resources to upgrade their manpower and system in order to improve their operations (especially those with products in Class I and II), and to get ready for surviving their business in the impending and tightening of regulatory measures as a global trend; and the future local statutory regulatory of medical devices. In case of adverse events or recalls of medical devices, one shall rely intensively on the effective distribution records, which should enable the regulatory body, authorized representative(s) and distributor(s) to identify the quantity, distributed locations, appropriated and pre-determined recall procedures, etc., in order to effectively handle and recall the affected batch of products in the market. In order to safeguard the public health by ensuring an effective distribution operation, for the safety and efficacy of the distribution and use of medical devices, it is crucial to provide support to the local SME in medical and healthcare industries, in order to upgrade the industry-wise competence in their distribution operations.

### 1.3 Project Objective(s) (in not more than 80 words)

- To develop a systematic approach in preparing and equipping the local medical and healthcare devices SMEs, to upgrade their competence and effectiveness in operation and distribution, to assist them in ensuring the quality, effectiveness and integrity of medical devices throughout the distribution process;
- To minimize the economic damages to the local SMEs on recall of medical devices due to adverse incidents;
- To get ready our local medical and healthcare device SMEs to the impending and tightening of regulatory measures as a global trend, as well as the stringent post-market surveillance measures and future statutory regulatory of medical devices in Hong Kong;
- In order to achieve the ultimate goal of further enhancing patient safety and safeguard public health.

### 1.4 Grantee /Collaborating/Implementation Organisation Agent

Grantee : Hong Kong Medical and Healthcare Device Industries Association Limited  
Collaborating Organisation(s) : Nil  
Implementation Agent(s) : Hong Kong Productivity Council (HKPC)

### 1.5 Key Personnel

|                             | <u>Name</u>             | <u>Company/Organisation</u>                                    | <u>Tel No. &amp; Fax No.</u> |
|-----------------------------|-------------------------|--|------------------------------|
| Project Co-ordinator        | : <u>Prof John CHAI</u> | Hong Kong Medical and Healthcare Device Industries Association | 27885507/<br>27885522        |
| Deputy Project Co-ordinator | : <u>Dr Andros CHAN</u> | Hong Kong Medical and Healthcare Device Industries Association | 27885507/<br>27885522        |



## 1.6 Project Period

|                                | <u>Commencement Date</u><br>(day/month/year) | <u>Completion Date</u><br>(day/month/year) | <u>Project Duration</u><br>(No. of months) |
|--------------------------------|--|--|--|
| As stated in project agreement | 1 October 2011                               | 31 March 2013                              | 18 months                                  |
| Revised (if applicable)        | 1 October 2011                               | 30 September 2013                          | 24 months                                  |

## 1.7 Methodology Employed

This SDF project aimed at implementing a pilot scheme of establishing Medical Device Good Distribution Practice (MDGDP) for 3 pilot companies, the knowledge gained during the scheme would be disseminated through training workshops, dissemination seminars, newspaper advertisements & supplement, and publication of Reference Manual and Case Book. The details of the methodology are as below:

- 1) Pilot Scheme: Through the Awareness Seminar held on 6 Jan 2012 and the newspaper advertisement posted on 3 Jan 2012, the details of the pilot scheme implementation and invitation of application were announced. All SMEs medical and healthcare device distributors were invited to apply for joining the scheme. Six applications were received by the deadline. The project applicant, Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA), formed a steering committee to select the three pilot companies from the applications based on their company scale, classification of medical devices being distributed, distribution process, etc. Each pilot company committed to sponsor this project with HK\$30,000.- in cash. HKPC project team held an opening meeting, performed onsite gap analysis, provided awareness and internal auditor trainings to each pilot company based on the selected route of MDGDP compliance through either implementing, (1) the related specific requirements issued by Medical Device Control Office, Department of Health (MDCO), (2) both ISO 9001:2008 and the related specific requirements issued by MDCO, or (3) both ISO 13485:2003 and the related specific requirements issued by MDCO. Based on the improvement area identified, HKPC provided the hands-holding consultancy service to each company on establishing their MDGDP by upgrading their operation practices, overall system and documentations. In parallel, HKPC together with HKMHDIA drafted the requirements of quotation for recruiting a conformity assessment body (CAB), to perform pre-assessment at each pilot company. Based on the audit report issued by the appointed CAB, HKPC and HKMHDIA together issued a certificate to illustrate the systems established by the pilot companies were complied with the requirements of MDGDP.
- 2) Reference Manual and Case Book: Based on the knowledge gained from the pilot scheme above, HKPC compiled a Reference Manual and Case Book in both Chinese and English to provide guidelines to the local medical and healthcare device SME distributors on establishing their MDGDP and introducing the corresponding requirements, process of obtaining certification & its maintenance, consideration of costs, etc. This knowledge transfer tool allowed the SME distributors to perform self-evaluation and upgrade their operation practices to fulfill the requirements of MDGDP. The Reference Manual and Case Book were printed in 1,500 copies in both Chinese and English, which were distributed during the training workshop on 30 Sep 2013; they were also introduced in the newspaper advertisement posted on 23 Sep 2013. In addition, through the promotion at HKPC News Flash and HKPC Industry Focus, the success of the pilot scheme and the publications of the Reference Manual and Case Book were also announced.
- 3) Seminars and Training Workshops: A total of one Awareness Seminar, seven Training Workshops and three Dissemination Seminars, were organized to introduce the project details & pilot scheme application invitations, provide training to the local SMEs on the crucial process and requirements on establishing MDGDP, the experience sharing of pilot companies, etc. The recruitment of these seminars and workshops were mainly through the newspaper advertisements, issuing electronic direct marketing emails, inviting members from the related societies and associations to participate, etc. All seminars and training workshops were held in HKPC Building, which should be convenient to most industrial stakeholders. The date, topic and number of SMEs participants of each workshop and seminar are listed in section 2.5 in this report.
- 4) Project Website and Help Desk Service: A designated project website, <http://www.hkpc.org/mdgdp/>, was established as a dissemination tool to introduce the project deliverables to the public particularly the medical and healthcare device SMEs. The website also listed the useful link of the MDGDP regulatory bodies in the region. In addition, the contacts of HKMHDIA and HKPC project team are available on the website as a long term help desk service to respond for any query to the project and/or establishment of MDGDP.

### 1.8 Sources of Funding (HK\$)

|   |           | <u>% of Total Project Expenditure</u> |    |
|---|-----------|---------------------------------------|----|
| Amount of grant:  | : 982,800 | ( 90                                  | %) |
| Contribution from grantee and sponsorship<br>from other sources, if any | : 109,200 | ( 10                                  | %) |

## 2. Summary of Project Results

### 2.1 Project Deliverables

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

(i) A research study on international practices, customer requirements, industrial practices, technical specifications, and common problems faced by SMEs in the medical and healthcare devices sector.

(ii) A pilot scheme to guide through 3 representative medical device SMEs on setting up the effective operation and distribution system.

(iii) A reference manual on good distribution practices based on the findings and experience of the pilot scheme which will serve as self-learning materials to help SME distributors set up their own distribution systems.

(iv) A case book containing specific cases on the building of effective storage, stock handling and delivery operation, maintenance of distribution records, setting up of complaint handling procedures, maintenance and service arrangements, tracking of specific medical devices, recall procedures and issue of alerts and modification.

(v) One awareness seminar, three dissemination seminars and seven training workshops to disseminate the project results to the industry.

(vi) A help desk to handle email and phone enquiries.

(vii) A project website for promoting the project deliverables and free download.

### 2.2 Actual Benefits to SMEs/Enterprises

(Please indicate *in clear, specific, tangible and quantifiable terms* the benefits of the project and its contribution to enhancing the competitiveness of Hong Kong's SMEs / enterprises in general or SMEs / enterprises in specific sectors / assist Hong Kong enterprises in general or in specific sectors in developing brands, upgrading and restructuring business operations, and promoting domestic sales in the Mainland, in not more than 400 words.)

There were 3 pilot companies selected to join the Pilot Scheme of implementing MDGDP, out of the 6 applications received. These companies have gone through the process from MDGDP route selection, gap analysis, awareness & internal auditor training, documentation establishment, system enhancement, CAB pre-assessment, etc.

During the implementation of Pilot Scheme, a total of 11 workshops and seminars were organized with around 300 participants; in these events, most speakers were local experts in the related field, whereas, 2 overseas speakers were invited to share their experience on auditing MDGDP and views on the regulation enforcement process in Singapore and Malaysia. In order to better promote the project deliverables, 5 quarter-page newspaper advertisements and 1 one-page newspaper supplement were published in between Jan 2012 and Sep 2013.

Based on the knowledge gained from the pilot scheme and the experience of regulatory enforcement in the region, HKPC project team and the HKMHDIA compiled a set of Reference Manual and Case Book in both Chinese and English, which were published in 1,500 copies to be distributed for free to the medical and healthcare device industry stakeholders.



### 2.3 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><br>(as set out in the approved project proposal appended to the project agreement) |   | <u>Original target completion date</u> | <u>Revised target completion date</u><br>(if applicable) | <u>Status</u><br>(C/D/N) # |
|---|---|--|--|----------------------------|
| (a)   | Literature Search                         | 30/11/2011                             | NA   | C                          |
|   | Selection of Pilot Companies and On-site  |  |  |                            |
| (b)   | Industry Evaluation                       | 15/03/2012                             | NA   | C                          |
| (c)   | Development of the Good Practice          | 30/08/2012                             | NA   | C                          |
| (d)   | Trial Implementation of the Good Practice | 31/05/2013                             | NA   | C                          |
|   | Fine-tuning of the Practice and           |  |  |                            |
| (e)   | Dissemination                             | 30/09/2013                             | NA   | C                          |
| (f)   | Project Promotion and Dissemination       | 30/09/2013                             | NA   | C                          |

## 2.4 Reasons for Deferring or Not Achieving certain Milestones, if any.

N/A

## 2.5 Marketing/Dissemination Activities (in chronological order)

(Please provide details of all completed and on-going promotional and/or dissemination activities for each of the project deliverables. Such activities may include advertisements, seminars, workshops, etc.)

| <u>Date/<br/>Period</u>  | <u>Description</u>   | <u>No. of beneficiaries<br/>(SMEs/Enterprises*)</u><br>*please delete as appropriate |
|--|--|--|
| <i>Awareness Seminar, Dissemination Seminar and Training Workshops</i> |  |  |
| 6 Jan 2012   | <u>Awareness Seminar</u> : SME Pilot Scheme on MDGDP   | 44   |
| 31 Aug 2012  | <u>Training Workshop</u> : Experience Sharing on Medical Device Good Distribution Practice   | 31   |
| 19 Oct 2012  | <u>Training Workshop</u> : Advanced Automation Technologies for Medical Devices Tracking and Regulatory Compliances  | 32   |
| 8 Mar 2013   | <u>Training Workshop</u> : Calibration and Verification of Measuring and Testing Equipment for Medical Device  | 38   |
| 24 May 2013  | <u>Training Workshop</u> : Advanced Technology and Good Practice for Handling Sterile Medical Devices  | 38   |
| 6 Sep 2013   | <u>Training Workshop</u> : Risk Management System for Medical Device   | 13   |
| 26 Jul 2013  | <u>Training Workshop</u> : Experience Sharing from GDP Application in Regulated Markets  | 21   |
| 30 Sep 2013  | <u>Training Workshop</u> : Introduction to Reference Manual and Case Book  | 49   |
| 23 Aug 2013  | <u>Dissemination Seminar</u> : Handling of Sterile Medical Device  | 4  |
| 30 Aug 2013  | <u>Dissemination Seminar</u> : Quality Management System Establishment   | 9  |
| 5 Sep 2013   | <u>Dissemination Seminar</u> : Handling of Active Medical Device and Implant   | 9  |
| <i>Advertisement and Newspaper Supplement</i>                          |  |  |
| 3 Jan 2012   | <u>Quarter Page Newspaper Advertisement</u> : Awareness Seminar for the SME Pilot Scheme on Medical Device Good Distribution Practice (GDP)  | NA   |
| 20 May 2013  | <u>Quarter Page Newspaper Advertisement</u> : Medical Device Good Distribution Practice Free Seminar - Advanced Technology and Good Practice for Handling Sterile Medical Devices    | NA   |
| 24 Jun 2013  | <u>1-Page Newspaper Supplement</u> : Medical Device Good Distribution Practice – The Route of Success for SMEs   | NA   |
| 22 Jul 2013  | <u>Quarter Page Newspaper Advertisement</u> : Medical Device Good Distribution Practice Free Seminar – Medical Device Risk Management System   | NA   |
| 15 Jul 2013  | <u>Quarter Page Newspaper Advertisement</u> : Medical Device Good Distribution Practice Free Seminar – Experience from ASEAN Regulated Markets to Regulation Establishment Direction | NA   |
| 23 Sep 2013  | <u>Quarter Page Newspaper Advertisement</u> : Medical Device Good Distribution Practice Free Seminar – Introduction to Reference Manual and Case Book                                | NA   |

*Pilot Scheme and Seminar Recruitment*

|              |   |     |
|--------------|---|-----|
| Dec 2011     | Flyers sent to the medical device distributors on Yellow Page by mail for pilot scheme recruitment and seminar promotion                        | 51  |
| Dec 2011     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for pilot scheme recruitment and seminar promotion | 130 |
| Dec 2011     | Flyers were mailed to the medical device industry through HKPC database for pilot scheme recruitment and seminar promotion                      | 382 |
| Aug 2012     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 150 |
| Aug 2012     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 382 |
| Oct 2012     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 130 |
| Oct 2012     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 382 |
| Feb 2013     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 132 |
| Feb 2013     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 382 |
| May 2013     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 165 |
| May 2013     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 438 |
| Jul 2013     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 160 |
| Jul 2013     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 438 |
| Aug 2013     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 161 |
| Aug 2013     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 438 |
| Aug-Sep 2013 | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 161 |
| Aug-Sep 2013 | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 438 |
| Sep 2013     | Flyers were circulated within Hong Kong Medical and Healthcare Device Industries Association for seminar promotion                              | 163 |
| Sep 2013     | Flyers were mailed to the medical device industry through HKPC database for seminar promotion   | 438 |

*Other Promotion Channels*

|            |   |    |
|------------|---|----|
| 1 Oct 2013 | <u>HKPC Industry Focus Magazine</u> : Medical Device Good | NA |
|------------|---|----|



|                              |  |        |
|------------------------------|--|--------|
|                              | Distribution Practice Establish Bridging with the International Regulatory   |        |
| 4 Nov 2013                   | <u>HKPC News Flash Weekly News:</u> Medical Device Good Distribution Practice Establish Bridging with the International Regulatory | NA     |
| Total no. of beneficiaries : |  | >5,409 |

**2.6 Future Plan for Promoting the Project Deliverables**

NA

**2.7 Problems/Outstanding Issues (if any)**

NA

**2.8 Remedial Actions during the project period**

NA

**2.9 Intellectual Property Rights Application (if applicable)**

| <u>Application</u> | <u>Registration</u> | <u>Description</u> |
|--------------------|---------------------|--------------------|
| <u>Date</u>        | <u>Date</u>         |                    |
| NA                 |                     |                    |

**3. Financial Position**

From 1 October 2011 To 30 September 2013  
 (dd/mm/yy) (dd/mm/yy)

(Please provide details of expenditure of manpower, equipment, other direct costs, and sponsorship at the **Appendix**. Please mark "\*" if any of the financial details above is different from that in the project proposal appended to the project agreement.)

| <b>Income</b>  |  |   | <b>In HKS</b>               |
|--|--|---|-----------------------------|
| <u>Items</u>   | <u>Amount as set out in the approved cashflow projection</u> | <u>Actual amount up to report period*</u> | <u>Remarks</u>              |
| 1. Funding Amount  | 982,800  | 982,800                                   |                             |
| 2. Contribution from the applicant and sponsor (if any)                  |  |   |                             |
| (a) Cash   | 90,000   | 90,000                                    |                             |
| (b) In-kind  | 19,200   | 19,200                                    |                             |
| <b>Subtotal:</b>   | <b>1,092,000</b>   | <b>1,092,000 (A)</b>                      |                             |
| 3. Interest Accrued  |  | 67.07                                     |                             |
| 4. Income generated from the project (Please specify)                    |  | N.A.                                      |                             |
| <b>Subtotal:</b>   |  | <b>67.07 (B)</b>                          |                             |
| <b>Expenditure</b>   |  |   |                             |
| 5. Manpower  | 0  | 0   |                             |
| 6. Equipment   | 0  | 0   |                             |
| 7. Other direct costs  | 1,092,000  | 1,109,053.45                              |                             |
| <b>Subtotal:</b>   | <b>1,092,000 (D)</b>   | <b>1,109,053.45 (C)</b>                   | <b>Deficit: \$17,053.45</b> |
|  |  |   |                             |
| <b>Residual Funds (A) – [(C) or (D) (whichever is the less)] = 0 (E)</b> |  |   |                             |
| <b>Interest income and income generated from the project (B) = 67.07</b> |  |   |                             |
| <b>Amount to be refunded to the Government (E)+(B)-(F) = 67.07</b>       |  |   |                             |

**Notes:**

Prior written approval from DGTI is required if:

- the actual expenditure in any individual item exceeds the original budgeted expenditure for that item by 20%; or
- total expenditure exceeds the original budgeted expenditure; or
- there is a need to create new expenditure item; or
- there is a need to transfer to new expenditure item (e.g. for new/revised rank of project staff, new equipment item, new consumable item, etc.)



3.1 Please provide breakdown for expenses / income incurred but not yet paid / received during project period, if applicable (i.e. receivables and accrued expenses shown in the audited accounts).

#### 4. Information for Public Access on the Web

(If you do not wish certain information provided under items 1.1 to 1.7, 2.1 to 2.2 and 2.5 to 2.6 to be published on the web for public access, please set out your request and provide justification under this item.)

Nil

#### 5. Additional Information

(Please provide any information not covered elsewhere in this report.)

Nil

Report completed by :



Authorised signature with organisation  
chop

Hong Kong Medical and Healthcare  
Device Industries Association Limited  
Name of organisation

Mr Albert LEE  
Name of signatory

Chairman  
Position

2788 5507  
Tel No.

2788 5522  
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Email Address

31 December 2013  
Date

**SDF/BUD Fund (Organisation Support Programme)**  
**Final Report of Approved Project**

Project Reference No. : D11 001 015  
 Period Covered : 1 Oct 2011 to 30 Sept 2013

**A. Manpower (in chronological order)**

| <u>Description</u><br>(Name,<br>post title)   | <u>Hourly/<br/>Monthly<br/>Rate</u><br>(HK\$) | <u>No. of Hours/<br/>Months Charged</u><br>in the Report Period | <u>Employer's Contribution to<br/>the Mandatory Provident<br/>Fund during the Report<br/>Period</u> | <u>Starting Date<br/>of Employment</u> | <u>Completion<br/>Date<br/>of Employment</u> | <u>Manpower cost</u><br>(HK\$) |
|---|---|---|---|--|--|--------------------------------|
|   | (A)   | (B)   | (C)   |  |  | [(A) x (B)] + (C)              |
| Senior Personnel (e.g. project managers, consultants, engineers, other professionals) |   |   |   |  |  |                                |
| NA  |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
| Other Personnel   |   |   |   |  |  |                                |
| NA  |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
|   |   |   |   |  |  |                                |
| Subtotal:   |   |   |   |  |  | NA                             |



Please indicate if the following staff recruitment procedures have been implemented, in accordance with the *SDF/BUD Fund (Organisation Support Programme) General Guidelines on Staff Recruitment..*

^Yes / No 1. Staff is recruited through an open and competitive system. If not (e.g. direct appointment), please describe the recruitment process and provide reasons for not going through open recruitment :

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If answer to 1. is Yes, please indicate the following:

^Yes / No 2. Job vacancies were widely advertised through media, including \_\_\_\_\_ (e.g. newspapers, websites, magazines, etc.)

^Yes / No 3. Selection interviews were conducted. If not, please advise the assessment method used:

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^Yes / No 4. Proper records have been kept for applications received / assessment of candidates / recommendations of panel members.

^Please delete as appropriate.

**B. Equipment** (in chronological order)

| <u>Item</u> | <u>Date of<br/>Procuring or<br/>Leasing</u> | <u>Name of<br/>Equipment</u> | <u>Nature/<br/>Function</u> | <u>Procured (P) or<br/>Leased (L)</u> | <u>Unit Cost</u><br><br>(HK\$) | <u>Quantity</u> | <u>Total Cost</u><br><br>(HK\$) |
|-------------|---|------------------------------|-----------------------------|---------------------------------------|--------------------------------|-----------------|---------------------------------|
| NA          |   |                              |                             |                                       |                                |                 |                                 |
|             |   |                              |                             |                                       |                                |                 |                                 |
|             |   |                              |                             |                                       |                                |                 |                                 |
|             |   |                              |                             |                                       |                                |                 |                                 |
|             |   |                              |                             |                                       |                                |                 |                                 |
|             |   |                              |                             |                                       |                                |                 |                                 |
| Sub-total:  |   |                              |                             |                                       |                                |                 | NA                              |



**C. Other direct costs (in chronological order)**

| <u>Item</u>   | <u>Date of Procuring</u> | <u>Item</u>  | <u>Unit Cost</u><br>(HK\$) | <u>Quantity</u> | <u>Total Cost</u><br>(HK\$) |
|---|--------------------------|--|----------------------------|-----------------|-----------------------------|
| <b>1. External Consultancy of HKPC ( Senior Consultant, Consultants, Associate Consultants, Engineers and Project Officers) (budget: \$700,000)</b> |                          |  |                            |                 |                             |
| 1   |                          | External Consultancy of HKPC   | 756,860.63                 | 1.0             | 756,860.63                  |
| Subtotal  |                          |  |                            |                 | 756,860.63                  |
| <b>2. External consultancy for CAB for technical input (budget: \$55,000)</b>   |                          |  |                            |                 |                             |
| 2   | 31-Aug-12                | Conformity Assessment Body (CAB) Consultancy Service on Medical Device Good Distribution Practice for Mock Audits of 3 Pilot Companies | 30,000.00                  | 1.0             | 30,000.00                   |
| Subtotal  |                          |  |                            |                 | 30,000.00                   |
| <b>3. Technology search and purchase of technical reference (budget: \$30,000)</b>  |                          |  |                            |                 |                             |
| 3   | 5-Apr-13                 | Procurement of ISO standards in PDF format   | 15,403.56                  | 1.0             | 15,403.56                   |
| 4   | 5-Apr-13                 | Procurement of IEC standards in PDF format   | 14,075.35                  | 1.0             | 14,075.35                   |
| 5   | 9-May-13                 | Procurement of Reference Book Titled "Wohlers Report 2013"   | 3,861.00                   | 1.0             | 3,861.00                    |
| 6   | 23-May-13                | Procurement of Reference Book Titled "Medical Product Regulatory Affairs: Pharmaceuticals, Diagnostics, Medical Devices"               | 758.95                     | 1.0             | 758.95                      |
|   |                          |  |                            |                 | 34,098.86                   |
| <b>4. Organization of 1 awareness seminar, 3 dissemination seminars and 7 training workshops (budget: \$20,000)</b>                                 |                          |  |                            |                 |                             |
| 7   | 21-Dec-11                | Rental of High Function Room on 6 Jan 2012   | 1,575                      | 1.00            | 1,575                       |
| 8   | 4-Jan-12                 | Souvenirs for Awareness Seminar Speakers   | 525.00                     | 1.00            | 525.00                      |
| 9   | 20-Jul-12                | Speaker fee for Training Workshop Speaker Mr PENG Ying Kun on 31 Aug 2012  | 1,890.46                   | 1.00            | 1,890.46                    |

|   |           |   |           |      |           |
|---|-----------|---|-----------|------|-----------|
| 10  | 28-Jun-13 | Hotel Accommodation for Training Workshop Speaker Mr LAM Chee Choong Vincent on 25-27 Jul 2013                            | 2,500.00  | 1.00 | 2,500.00  |
| 11  | 28-Jun-13 | Air ticket for Training Workshop Speaker Mr LAM Chee Choong Vincent (Kuala Lumpur / HK / Kuala Lumpur) on 25 & 27Jul 2013 | 3,980.00  | 1.00 | 3,980.00  |
| 12  | 4-Jul-13  | Rental of Classroom for Training Workshop on 26 Jul 2013  | 1,424.50  | 1.00 | 1,424.50  |
| 13  | 31-Jul-13 | Rental of Classroom for Training Workshop on 23 Aug 2013  | 464.00    | 1.00 | 464.00    |
| 14  | 9-Aug-13  | Rental of Classroom for Training Workshop on 6 Sep 2013   | 330.00    | 1.00 | 330.00    |
|   |           |   |           |      | 12,688.96 |
| <b>5. Logistics arrangement for trial implementation</b>  |           |   |           |      |           |
|   | NA        | NA  | NA        | NA   | NA        |
| Subtotal  |           |   |           |      | 0.00      |
| <b>6. Promotion (5 quarter-page advertisement and 1 newspaper supplement) (budget: \$100,000)</b>                                 |           |   |           |      |           |
| 16  | 21-Dec-12 | Quarter-Page Newspaper Advertisement Posted on 3 Jan 2012 (In-kind Sponsorship)   | 9,600.00  | 1.00 | 9,600.00  |
| 17  | 18-Apr-13 | Quarter-Page Newspaper Advertisement Posted on 20 May 2013(In-kind Sponsorship)   | 9,600.00  | 1.00 | 9,600.00  |
| 18  | 20-May-13 | 1-Page Newspaper Advertisement Posted on 24 Jun 2013  | 40,845.00 | 1.00 | 40,845.00 |
| 19  | 26-Jun-12 | Quarter-Page Newspaper Advertisement Posted on 15 Jul 2013  | 9,600.00  | 1.00 | 9,600.00  |
| 20  | 5-Jul-13  | Quarter-Page Newspaper Advertisement Posted on 22 Jul 2013  | 9,600.00  | 1.00 | 9,600.00  |
| 21  | 29-Aug-13 | Quarter-Page Newspaper Advertisement Posted on 23 Sep 2013  | 9,940.00  | 1.00 | 9,940.00  |
|   |           |   |           |      | 89,185.00 |
| <b>7. Editing of Reference Manual and Case Book (cover design, content design, content editing and layout) (budget: \$50,000)</b> |           |   |           |      |           |



|          |   |   |           |      |           |
|----------|---|---|-----------|------|-----------|
| 22       | 28-Jun-13   | Design of Reference Manual and Casebook                     | 50,000.00 | 1.00 | 50,000.00 |
| Subtotal |   |   |           |      | 50,000.00 |
|          | <b>8. Printing</b>  |   |           |      |           |
|          | - Publication of Reference Manual (1,500 sets) (budget: \$56,500) |   |           |      |           |
| 23       | 28-Jun-13   | Production of Reference Manual and Casebook                 | 60,000.00 | 1.00 | 60,000.00 |
| Subtotal |   |   |           |      | 60,000.00 |
|          | - Publication of Case Book (1,500 sets) (budget: \$56,500)        |   |           |      |           |
| 24       | 28-Jun-13   | Production of Reference Manual and Casebook                 | 60,000.00 | 1.00 | 60,000.00 |
| Subtotal |   |   |           |      | 60,000.00 |
|          | - Leaflets and pamphlets (3,000 copies) (budget: \$2,000)         |   |           |      |           |
| 25       | 22-Dec-11   | Printing of Flyer for Awareness Seminar Promotion           | 1,080.00  | 1.00 | 1,080.00  |
| Subtotal |   |   |           |      | 1,080.00  |
|          | <b>9. External audit fee (budget: \$16,000)</b>                   |   |           |      |           |
| 26       | 10-Nov-10   | External Audit fee  | 7,000.00  | 1.00 | 7,000.00  |
| 27       | 10-Nov-10   | External Audit fee  | 7,000.00  | 1.00 | 7,000.00  |
| Subtotal |   |   |           |      | 14,000.00 |
|          | <b>10. Bank confirmation charges for audit (budget: \$2,000)</b>  |   |           |      |           |
| 28       | 30-Jun-12   | Bank Confirmation Charge for HKMHDIA's Project Bank Account | 400.00    | 1.00 | 400.00    |
| 29       | 30-Sep-13   | Bank Confirmation Charge for HKMHDIA's Project Bank Account | 600.00    | 1.00 | 600.00    |

|            |  |   |        |      |              |
|------------|--|---|--------|------|--------------|
| Subtotal   |  |   |        |      | 1,000.00     |
|            | 11. Postage and other logistics expenses (budget: \$4,000) |   |        |      |              |
| 30         | 31-Jul-12  | Purchase of Stamps for Promotion Material Postage | 140.00 | 1.00 | 140.00       |
| Subtotal   |  |   |        |      | 140.00       |
| Sub-total: |  |   |        |      | 1,109,053.45 |

**C-1. For expenses on Mainland/overseas travel, and/or provision of travel package to Mainland/overseas guests, please provide the following details:**

| <u>Item</u> | <u>Travel period</u> | <u>Purpose</u>  | <u>Capacity of traveler(s)</u> | <u>Amount for Air Ticket</u> | <u>Amount for Hotel</u> | <u>Place of departure &amp; arrival</u>       | <u>No. of nights for Hotel</u> |
|-------------|----------------------|---|--------------------------------|------------------------------|-------------------------|---|--------------------------------|
| 10-11       | 25-27 Jul 2013       | Travel from Malaysia to HK for Attending Workshop as a Speaker to Share the Regulatory Updates in ASEAN | Guest Speaker                  | 3,980.00                     | 2,500.00                | Departure: Kuala Lumpur<br>Arrival: Hong Kong | 2                              |
|             |                      |   |                                |                              |                         |   |                                |
|             |                      |   |                                |                              |                         |   |                                |
|             |                      |   |                                |                              |                         |   |                                |

**D. Sponsorship (in chronological order)**

| <u>Sponsor</u><br>(Name and address) | <u>Date of Contribution</u> | <u>Nature of contribution</u><br>(cash/in-kind) | <u>Amount Contributed</u><br>(HK\$) |
|--------------------------------------|-----------------------------|---|-------------------------------------|
| Pilot Companies                      | 29 May 2012                 | Cash  | \$90,000                            |
| Hong Kong Economic Times             | during project period       | In-kind   | \$19,200                            |
|                                      |                             |   |                                     |
| Sub-total:                           |                             |   | \$109,200                           |



**E. Quotations/Open tendering details**

(Please list details of quotations/open tendering conducted for items listed in B, C and C-1 above.)

| <u>Item</u> | <u>Name of Vendors</u>                        | <u>Quotation/Tender Price</u><br>(HK\$) | <u>Selected Vendor</u><br>(✓) | <u>Remark/Reasons for Selecting the Quotation/Tender, if the lowest offer was not selected</u> |
|-------------|---|---|-------------------------------|--|
| 2           | BSI Pacific Limited                           | 30,000                                  | ✓                             |  |
|             | SGS Hong Kong Limited                         | 68,250                                  |                               |  |
|             | TUV SUD Hong Kong Limited                     | N/A                                     |                               |  |
| 3           | International Organization of Standardization | 15,403.56                               | ✓                             | International Organization of Standardization is the sole supplier of ISO standards            |
| 4           | International Electrotechnical Commission     | 14,075.35                               | ✓                             |  |
|             | HIS Hong Kong Limited                         | 14,521.7                                |                               |  |
|             | BSI Pacific Limited                           | 18,296                                  |                               |  |
| 18          | Hong Kong Economic Times                      | 40,845                                  | ✓                             |  |
|             | Oriental Daily                                | 234,000                                 |                               |  |
|             | The Sun                                       | 132,000                                 |                               |  |
| 19          | Hong Kong Economic Times                      | 9,600                                   | ✓                             |  |
|             | Oriental Daily                                | 32,000                                  |                               |  |
|             | The Sun                                       | 20,000                                  |                               |  |
| 20          | Hong Kong Economic Times                      | 9,600                                   | ✓                             |  |

|       |                                |         |   |  |
|-------|--------------------------------|---------|---|--|
|       | Oriental Daily                 | 32,000  |   |  |
|       | The Sun                        | 20,000  |   |  |
| 21    | Sing Tao Limited               | 9,940   | ✓ |  |
|       | Ming Pao Newspaper Limited     | 10,000  |   |  |
| 22-24 | A-Tech Supports Company        | 170,000 | ✓ |  |
|       | Hong Kong Economic Times       | 220,000 |   |  |
|       | Tung Mei Design & Printing Ltd | 172,000 |   |  |
| 26-27 | Mazar CPA Limited              | 14,000  | ✓ |  |
|       | KPMG                           | 20,000  |   |  |
|       | Ernst & Young                  | 24,000  |   |  |