

Medical Device Good Distribution Practice
Reference Manual

SME Development Fund Project
“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”

About this Reference Manual

Hong Kong Medical and Healthcare Device Industries Association and the Hong Kong Productivity Council have completed a project through the funding of the “SME Development Fund” by the Trade and Industry Department. This project aims at enhancing the competitiveness of Hong Kong's SMEs in medical and healthcare device industry through upgrade of their distribution operations.

It is expected that this project can assist the small and medium enterprise (SME) in Hong Kong to understand the requirements and benefits of the “Medical Device Good Distribution Practice” (MDGDP). This project included a pilot scheme which supported three local medical device distributors to establish MDGDP. This reference manual summarizes the procedures and key elements of the implementation and establishment of MDGDP. It also records the experience of the project team on the implementation of MDGDP, including gap analysis, internal audit and improvements towards nonconformities, etc.

This reference manual begins with the definition of MDGDP, the future regulatory directions and the benefits for the SMEs to conform with MDGDP. The manual also introduces the current voluntary listing requirements for medical device, and how MDGDP shall facilitate the local distributors to get better ready towards the fulfillment of the future regulation on medical device distribution activities.

This reference manual offers step-by step guidance on how to set up MDGDP. Firstly, the local SMEs shall begin with project planning including resources planning, definition of implementation scope. Secondly, the corporate shall proceed to system building including formation of implementation team, gap analysis, Set up of the Quality Policy and Quality Objectives, staff training, etc. Thirdly, the corporate shall perform system trial and data collection including internal audit, management review, supplier review, customer feedback survey, corrective and preventive actions, etc. SMEs can either develop MDGDP themselves, or to contact the assessment body to arrange audit procedure, to certify the conformity of MDGDP.

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1. Overview

Due to aging population and the increasing of health concern, the demand of medical services increases by double digit in the past few years, which leads to an increasing demand on medical device. The huge business opportunity arisen from the medical device industry attracts many SMEs in extending their business into the manufacturing or distribution of medical devices. Nevertheless, there are stringent requirements on medical devices manufacturing and distribution process, in order to ensure their safety and efficiency. Some of the ASEAN countries are either in the process of drafting the regulations or implementing their mandatory regulations on medical device. For example, Singapore has imposed regulation to monitor medical device distribution in 2007.

In order to better prepare our local medical and healthcare device industry for the global trend of stringent medical device regulatory establishment and enforcement, Hong Kong Medical and Healthcare Device Industries Association (HKMHDIA) and the Hong Kong Productivity Council (HKPC) have completed a project through the funding of “SME Development Fund” by the Trade and Industry Department of the HKSAR Government. The project titled “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”, included a pilot scheme in which three local SMEs participating in medical device distribution were selected and implemented the Medical Device Good Distribution Practice (MDGDP). These three pilot companies were representative among local medical device distributors in terms of corporate size, business models and operations. In the end of the project, all the three pilot companies successfully passed the mock audit performed by the conformity assessment body. HKMHDIA expected that this project and its deliverables can serve as reference for local medical device distributors in upgrading their distribution operations, in order to be well prepared for the mandatory local regulations in the future and international standards.

The publication of the MDGDP “Reference Manual” and “Case Book” share the experiences gained during the project implementation. It is expected the experience and accomplishments gained from this project may serve as a reference to the local SMEs.

This “Reference Manual” introduces the framework of MDGDP, and also provides guidance to the SMEs on establishing a quality management system fulfilling MDGDP requirements.

Based on the difference in medical device categories and aftersales services, MDGDP shall be inclusive of different needs and characteristics of distribution activities. Apart from describing the basic requirements, this manual summarized the specific, characteristic distribution requirements of the three pilot companies.

It is expected that local SMEs could improve the operations of medical device distribution through the MDGDP implementation, so as to further enhance the overall standard of the local medical device industry, and to better safeguard the safety, efficiency and quality of medical device within the distribution process.

2. What is MDGDP?

Medical Device Good Distribution Practice (MDGDP) is a set of documented requirements governing various procedures during the processes of distribution. SMEs could follow MDGDP to establish a safe and effective best practice.

Until now, the government has established and implemented a voluntary regulation to govern the local medical device distribution procedures. Therefore, this project would introduce MDGDP based on the practical distribution operation model of the local SME and outline the three recommended routes towards the compliance with MDGDP.

The three routes towards MDGDP compliance also reference to the medical device distribution systems in Europe and South-east Asia countries. The suggested routes also follow the Medical Device Administrative Control System (MDACS) established by the Medical Device Control Office (MDCO) of the Department of Health.

The three suggested MDGDP routes:

Routes	Description of requirements
Route 1	Only implement the related specific requirements issued by MDCO
Route 2	Implement both ISO 9001:2008 and the related specific requirements issued by MDCO
Route 3	Implement both ISO 13485:2003 and the related specific requirements by issued MDCO

The above three routes are sequenced in an order of system stringency. Route 1 only based on the related specific requirements by MDCO, and can be regarded as comparatively easier to handle; whereas Route 3 adopted ISO 13485:2003, and is generally regarded as comparatively harder to handle.

3. Current Requirements on Medical Device Regulations

Preparation for the medical device regulation is currently being taken care by the Medical Device Control Office (MDCO) under the Department of Health.

Depends on the nature and characteristics of the medical devices concerned (e.g. X-ray and medicated wound dressings), they may be also regulated by other legislative articles, for instance, “Pharmacy and Poisons Ordinance” (Chapter 138), Radiation Ordinance (Chapter 303) and “Telecommunications Ordinance” (Chapter 106).

There is currently no overarching legislation that regulates the manufacture, import, sale and use of medical devices in Hong Kong. Distributing processes in Hong Kong as of the date of publication of this reference manual. However, it is generally believed that the statutory regulation of medical device in Hong Kong is inevitable.

Since 26 November 2004, Hong Kong SAR government has started to promote “Medical Device Control Administrative System”, to increase the awareness of important of handling and operating medical device, in order to have early preparation to exercise the guidance, and ultimately to smooth out the bridging to the enforcement.

The key elements of Medical Device Control Administrative System are as follow:

- Listing system is available for the manufacturers and importers to voluntarily list themselves and their related medical devices; and
- With the MDCAS, medical device manufacturers, importers, end-users and the public are able to report any reportable or potential reportable adverse incidents of the listed medical device for investigation and evaluation, in order to minimize the risk of the adverse incidents reoccurrence or their effects.

MDCAS has been implemented in various phase as list below:

First Phase	-	Listing of Class IV medical devices
Second Phase	-	Listing of Class III and Class II medical devices
Third Phase	-	The Conformity Assessment Body Recognition Scheme
Forth Phase	-	Listing of local manufacturers.
Fifth Phase	-	Listing of importers of medical devices.
Sixth Phase	-	Listing of Class D in-vitro diagnostic (IVD) medical devices.

4. Why is it necessary to Regulate Medical Device?

Different from general products, the quality of medical devices directly affects the users' safety and health. Specially noted that these users of medical device are mainly patients, elderly, disabled and medical professionals who are more vulnerable to diseases. Medical devices may also be used in high risk surgical procedures, while improper uses may cause server casualty or even death.

In worldwide, many countries including Europe, America, Australia, Canada and Japan have already established medical device related regulations, while many Asian countries such as China, Philippines, Indonesia, South Korea, Thailand, Singapore and Malaysia are now regulating medical devices distribution. Any device that does not fulfill corresponding local requirements shall not be authorized to be distributed to the market.

The table below listed some of the major medical device regulations in globe:

Country/ District	Name of medical device regulations (Document number)
Europe	Medical Device Directive (93/42/EEC)
	In-Vitro Diagnostic Devices Directives (98/79/EC)
	Active Implantable Medical Devices Directive (90/385/EEC)
America	Quality Management Regulations (21 CFR Part 820)
	Labeling (21 CFR Part 801)
	Medical Device Reporting (21 CFR Part 803)
	Medical Devices; Reports of Corrections And Removals (21 CFR Part 806)
	Establishment Registration and Device Listing for Manufacturers and Importers of Devices (21 CFR Part 807)
	Medical Device Tracking Requirements (21 CFR Part 821)
Canada	Canadian Medical Devices Regulation (SOR 98-282)
	Guidance on Medical Device Establishment Licensing and Medical Device Establishment License Fees (GUI-0016)
Japan	Quality Systems Regulations (MHLW Ordinance #169)
	Standards for Post-market Safety Assurance (MHLW Ordinance #135)
Malaysia	Good Distribution Practice for Medical Devices (GDPMD)

In Hong Kong, the major problems for not legislating mandatory medical device regulations are:

- (1) No pre-market control to assess the safety, efficacy and quality of medical devices to safeguard public health
- (2) No formal post-market surveillance system including adverse incident reporting
- (3) Inadequate product information for the public and operators to make informed choices on the safe use of medical devices.

Base on the current situation, the government is preparing to implement mandatory medical device regulations to ensure that the medical device is safe and qualified before distributing to the local market. The Medical Device Control Office (MDCO) under the Department of Health had already implemented a voluntary "Medical Device Administrative Control System" (MDACS) to govern medical device distribution on 26th November, 2004.

Chapter 4. Why is it necessary to Regulate Medical Device?

The MDACS is referenced to the documents issued by an international organization called Global Harmonization Task Force (GHTF)¹. This system implemented the medical device listing procedures in several stages. The implementation of the first phase of the system commenced with the listing of Class IV medical devices. Then, the Second Phase of the MDACS was extended to cover Class III and Class II medical devices on 14th November 2005. Later on, the MDACS was launched with the listing of local manufacturers, listing of importers of medical devices, listing of Class D in-vitro diagnostic (IVD) medical devices and the Conformity Assessment Body Recognition Scheme. The listed medical device and operators could be found in website on MDCO.

On top of the medical device listing procedure, the MDACS also included the Principles of Medical Devices Classification, Local Responsible Persons registration system, Adverse Incident Reporting System, Additional Medical Device Labelling Requirements and the Principles of Conformity Assessment for Medical Devices.

However, the “Medical Device Administrative Control System” is currently in voluntary basis; the mandatory regulation shall very likely be implemented in the near future. The government is now drafting the regulations, but the scope of regulation shall consider various aspects such as the business environment of the local small and medium enterprises (SMEs), the strictness of the regulations and the extra cost needed to cater the new regulations, etc. The government may also offer a grace period for the local SMEs to establish or update their quality management system in order to fulfill the regulation requirements right after the implementation of the mandatory regulations.

If the implemented regulations are beyond the capability of the local SMEs and the SMEs do not obtain sufficient consultation before the implementation, this may result in the closing down of many local SME due to the tremendous increase of operation cost. There may have a chance that the supply chain of the medical devices breaks down and finally affects the whole medical device industry.

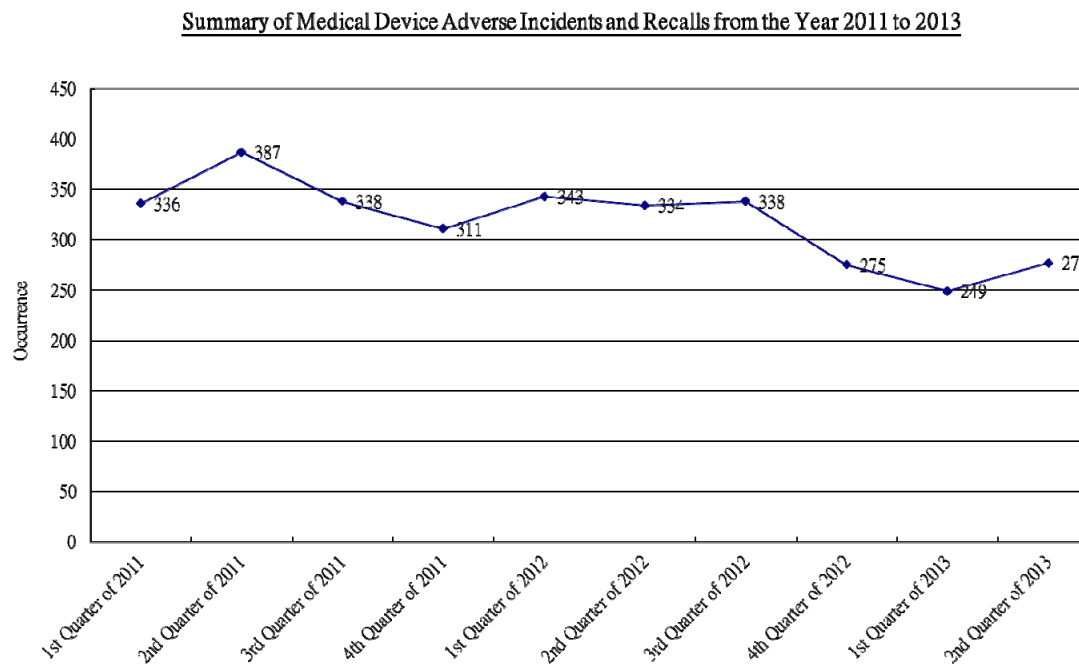
Mandatory regulation shall allow the SMEs to build up effective and safe medical device distribution management procedures under the comparatively strict regulation framework. However, the definition of “comparatively strict” varies among the SMEs.

The main objective of this government funded project is to investigate what are the difficulties SMEs may face when implementing MDGDP, and how they can adopt the best solution. These SMEs can be of different sizes and business types, and thus their difficulties and the corresponding solutions may also be different. The results of this project shall assist the whole medical device industry to equip themselves in the early sign, in order to sustain from the mandatory regulations to be imposed in the future.

¹ Abbreviate as GHTF, dismissed in 2011 and later took up by International Medical Device Regulators Forum (IMDRF).

5. Benefits of Implementing MDGDP

According to the published data issued by MDCO (See below figure), there were 1,372 and 1,290 adverse incidents and recalls recorded in year 2011 and 2012 respectively. As of the first and second quarters of 2013, 249 and 277 adverse incidents and recalls have been recorded.



MDGDP can enhance the safety and effectiveness of medical device during the distribution procedures, and to well define the responsibility of distributors. Medical device distributors are responsible to support the adverse incident reporting procedures when there are nonconformities during the design, manufacturing, import or retail processes.

It is worth to note that local SMEs in Hong Kong mainly participate in distribution activities and barely involve in the medical device design and manufacturing procedures, and thus less risk factors are required to consider. But if their distribution activities involve medical device additional labeling or secondary packaging procedures, these distributors shall bear a higher risk.

To conclude, MDGDP possesses the following advantages:

- (1) Improve the traceability of medical devices;
- (2) Systemize the control and maintenance of records and documents;
- (3) Standardize the overall distribution procedures of medical devices;
- (4) Strengthen the consistency of the distribution activities (from customer order handling, procurement, warehouse management, devices delivery to maintenance);
- (5) Optimize warehouse management and equipment maintenance;
- (6) Effectively implement the procedures to recall nonconforming products, issue advisory notice, build up effective communication channels with regulatory bodies and users, handle customer complaints, etc.

6. Prepare for Local Requirements on Medical Device Distribution

Future regulating requirements on medical device distribution may include the following elements:

- Maintain effective distribution records
- Handle adverse incidents and product recalls
- Handle customer complaints
- Establish an effective products alert procedure
- Realize medical device traceability system
- Conduct appropriate corrective and preventive actions in the market
- Re-evaluate the recalled medical device
- Maintain effective communication with regulatory authorities and customers

MDGDP suggests three routes to achieve the above requirements. Local medical device SMEs can consider one of the following three routes by selecting the route that best fits their business natures.

The three suggested MDGDP routes:

Routes	Description of requirements
Route 1	Only implement the related specific requirements issued by MDCO
Route 2	Implement both ISO 9001:2008 and the related specific requirements issued by MDCO
Route 3	Implement both ISO 13485:2003 and the related specific requirements by issued MDCO

The above three routes are sequenced in an order of system stringency. Route 1 only based on the related specific requirements by MDCO, and can be regarded as comparatively easier to handle; whereas Route 3 adopted ISO 13485:2003, and is generally regarded as comparatively harder to handle.

7. Resources Required for MDGDP System Establishment

The time and resources required for system establishment depends on (1) the robustness of current management system and (2) conformity of the current system compare to MDGDP. Before participating in this pilot scheme, the three pilot companies had already established an effective and comprehensive management system based on their experience. Through the scheme, it is aimed to translate the conventional operations into documented procedures. The average time required for the three companies to complete MDGDP is about 6 months; the whole process included the system establishment, system trials run and system implementation. During the project, the pilot companies were assisted by the Hong Kong Productivity Council, therefore, the overall completion time was reduced. If the medical device SMEs establish the system themselves, the time required shall be longer, estimated around 10-12 months.

The resources required for the establishment of MDGDP are based on several elements. For example, the complexity of the system structure, number of employees, business scope, customer groups, use of establishing and measuring equipment, size of warehouse, category of intended purpose of device, etc. If the structure of the corporate is relatively more complicated, distributing a wide variety of devices, distributing devices with specific requirements (for example sterile medical device) or a relatively larger business scope (for example provide variety of repair and maintenance services), the time for system establishment might also be increased.

Basic workflow for establishing MDGDP:

- Define System Requirement and Scope
- Recognize management commitment and encouragement
- Establish Quality Management Team
- Perform Gap Analysis
- Draft Documented Procedures
- Perform Awareness Training
- Perform System Trial and Optimization
- Perform Internal Audit
- Conduct Corrective and Preventive Actions based on audit results
- Define Frequency of Management Review

8. Define System Requirement and Scope

Before establishing MDGDP, corporate shall first define unambiguously some basic elements including its business nature and scope, devices classification, responsible staff, etc. **The purposes are to:**

- Evaluate the system complexity of MDGDP based on corporate structure and number of employees;
- Plan the resources for MDGDP establishment based on system complexity, and to assure that sufficient resources are allocated;
- Plan the tentative schedule of MDGDP establishment and anticipate the time required for the establishment of each procedure;
- Explain the steps for MDGDP establishment to the employees in order to reduce their worry and anxiety due to misunderstanding.

Clearly define the above items prior to MDGDP establishment can enhance the effectiveness on preparing the documented procedures and reduce any unnecessary resource redundancy. Medical device distribution can cover a wide range of scopes including logistic management, maintenance, installation, device-embedded software update, etc. Local medical device classification is defined by the document “TR-003 Technical Reference on Classification Rules of Medical Devices”, issued by MDCO. Currently, medical devices are classified into four grades based on risk level, while the devices’ intended uses are critical to determine the device classes.

Below table compares 3 different routes for conforming MDGDP:

System Requirements (Note 1: include sterile medical devices, active implantable medical devices)		Routes to conform with MDGDP		
		Route 1	Route 2	Route 3
		Only implement the related specific requirements issued by MDCO	Implement both ISO 9001:2008 and the related specific requirements issued by MDCO	Implement both ISO 13485:2003 and the related specific requirements issued by MDCO
Tier 1 Document: Quality Manual			✓	✓
Tier 2 Document: Corporate Operation Procedures				
1	Document Control	✓	✓	✓
2	Management Review		✓	✓
3	Regulatory Requirements	✓	✓	✓
4	Staff Development	✓	✓	✓
5	Internal Audit	✓	✓	✓
6	Aftersales Servicing	✓	✓	✓
7	Product Identification	✓	✓	✓
8	Product Traceability	✓	✓	✓
9	Customer Property Handling		✓	✓
10	Infrastructure and Work Environment Management	✓	✓	✓
11	Products Verification, Validation and Acceptance	✓	✓	✓
12	Warehouse Management	✓	✓	✓
13	Customer Order Handling	✓	✓	✓
14	Product Delivery		✓	✓
15	Customer Satisfaction Investigation		✓	
16	Customer Feedback and Complaint	✓	✓	✓
17	Specific Requirements for Medical Devices (Note 1)			✓
18	Nonconforming Product (and Service) Handling	✓	✓	✓
19	Corrective and Preventive Action	✓	✓	✓
20	Advisory Notice	✓	✓	✓
21	Products Recall	✓	✓	✓
22	Risk Management			✓
23	Adverse Incident Reporting	✓	✓	✓
24	Supplier Evaluation		✓	✓
25	Procurement		✓	✓
26	Calibration of Measuring Equipment	✓	✓	✓
27	Products Repair and Maintenance	✓	✓	✓
28	Medical Devices Installation		✓	✓
Tier 3 Document: Work Instruction			✓	✓
Tier 4 Document: Forms		✓	✓	✓

Corporate shall define the scope of implementing MDGDP, or in other words which medical devices are managed under MDGDP. Since currently there is no overarching legislation that regulates the manufacture, import, sale and use of medical devices in Hong Kong, corporate can determine by itself which medical devices and services shall be managed under MDGDP. If the corporate passes the certification audit, it may request HKMHDIA and/or HKPC to issue a MDGDP certificate. This certificate lists out some details including the company name, address and the expiry date of the certificate.

Sample of MDGDP certificate:

<p>Certificate Number: XX/YYYY</p> <p>Certificate of Medical Device Good Distribution Practice (MDGDP)</p> <p>This is to certify that</p> <p>(ABC Medical Device Distribution Co., Ltd.) (Corporate Address)</p> <p>Fulfilled all the requirements of MDGDP for the following scope: Local distribution, maintenance and repair services of (Medical Device A, B, C and D)</p> <p>Expiry Date: Signature and Stamp of the Assessment Body:</p>
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The above certification and contents are for reference only, the actual layout and contents of the certification may be different.

9. Management Commitment

Followed by the confirmation to implement MDGDP, the management shall notify all employees with the future implementation arrangements which include but not limited to:

- Formally announce the commencement of MDGDP and its scope;
- Schedule a timetable to list out all stages for MDGDP establishment, and set a deadline for each stage;
- Establish a quality management team responsible for MDGDP establishment and maintenance of system effectiveness;
- Explain the support from employees needed for the establishment and implementation of MDGDP;
- Illustrate the advantages of MDGDP, and encourage all employees to support and participate;
- Highlight the requirement of MDGDP.

The importance of management commitment are:

(1) Provide support to employees for the upcoming reform of management system.

Changes to the current management system in this corporate are unavoidable during MDGDP implementation. Employees may feel uncomfortable or confused to those changes. Staff may get lose to the existing operation system, and question the necessity of adopting the more stringent MDGDP system, which includes the increase of documentary work.

Management needs to well communicate with their employees the benefits of MDGDP (including documents standardization and improved products traceability). Sufficient MDGDP system training shall also be provided to staff members to enable their familiarity of the requirements.

(2) Avoid unnecessary over-react, worries and anxiety of employees

Some staff members may not familiar with international standard (e.g. ISO, IEC), and feel worry when the corporate starts the implementation of MDGDP. Such worries usually come from the inadequate understanding of the practice. It can be a common worry that the practice shall greatly increase workload of staff members, or the staff members worry that they do not have the capability to fulfill the requirements.

To lower the stress and worries of employees due to the implementation of MDGDP, the key is to increase communication and understanding. Effective ways include the organization of staff meetings, where management can formally announce the implementation of MDGDP, explain what MDGDP is in the meeting, and to encourage staff members proactively participate and raise out their own opinion. As such, cooperate can introspect its own insufficiencies and improve itself accordingly.

Content of staff meeting can include:

- Encourage employees to participate in MDGDP
- Introduce the flow and work plan of MDGDP establishment
- Define requirements and scope of MDGDP
- Illustrate all system requirements of MDGDP with elaborations.
- Explain how MDGDP requirements shall be fit into operations.

10. Establish Quality Management Team

Quality management team shall be assigned by top management; the number of team member depends on the size of the Corporate. Multinational corporation normally set up its own quality management department. Comparatively, local SMEs may consider arranging the quality management role to an existing department or employee due to resources constraints. Depend on needs; the team size can be ranging from two to ten members.

Main responsibilities of quality management team are:

- Establish MDGDP system;
- Prepare and revise four-tiers documentations including Quality Manual, Cooperate Operation Procedure, Work Instruction and Form;
- Arrange training to employees on MDGDP;
- Guide the employees to implement MDGDP properly, including how to fill in and revise the records;
- Responsible for medical device quality management issues including quality inspection, nonconformity identification and segregation;
- Inspect and analyze the nonconforming procedures, implement corrective and preventive actions and monitor related department to complete the actions;
- Conduct internal audit;
- Support third party audit;
- Regularly monitor any updates on MDGDP and other related regulations, and renew management system.

11. Perform Gap Analysis

What is Gap analysis and how to perform?

Gap analysis is the comparison of the current operation procedures or quality management system with MDGDP requirements, and the execution of any changes to the operation or system so as to fulfill all MDGDP requirements.

Before kicking start the gap analysis, the quality management team shall first obtain the 4-tiers documentation (if available) from the corporate, followed by outlining management flow, listing the responsibilities of each department, and finally drafting the gap analysis plan.

Depends on the size of corporate and the number of employee, the time required for gap analysis would be different. In this project, three pilot companies consist not more than 50 employees each, the gap analysis were completed within one to two days. It is worth to note that, gap analysis shall inspect and analyze all departments including the Account Department, Administration Department and Logistics Department.

When gap analysis starts, quality management team shall first conduct separate meetings with the top management, department manager and management-level employees of each department to collect and analyze the corporate structure and documented procedures of each department. The analysis shall especially focus on the interactions between departments, process flow, document approval and record maintenance processes.

12. Establish Quality Policy and Quality Objectives

Quality Policy expresses the Quality Objectives, the acceptable level of quality and the duties of specific departments to ensure quality. Quality Objectives are the parameters to evaluate the degree of accomplishment of Quality Policy. Quality Objectives shall be measurable and consistent with Quality Policy.

Top Management shall formulate and announce the Quality Policy and Quality Objectives, and ensure that their contents are conveyed and disseminated well to all employees.

Notes to Quality Policy establishment:

- (1) Fulfill enterprise purpose
Enterprise purpose are not only limited to the quality of products and services, but may also include the elements such as environment protection, occupational safety and development strategy;
- (2) Satisfy customer and regulatory requirements
Customer requirements shall be described in the purchase order or tender documents issued by the customers. Before accepting the order, Corporate shall review its capability to fulfill all the requirements. Customer requirements may cover the device function, size, brand, price, maintenance, delivery date, or even the qualifications accredited by the devices or corporate itself;
- (3) Commit to maintain the effectiveness and continual improvement of the system
Effectiveness means how the quality management system fulfills (1) MDGDP requirements and (2) Quality Objectives. Continual improvement means how the quality management system be evaluated and improved in a regular basis, in order to better fulfill the above requirements;
- (4) Provide framework for Quality Objectives implementation and evaluation.

Samples of Quality Policy:

- Ensure the safety and effectiveness of every single repair service.
- Provide high quality distribution service for single-use medical device.
- Ensure good communication within the corporate, and between the Corporate, customers and regulatory authorities.
- Ensure the customer and regulatory requirements are fully satisfied;
- Continual improve the quality management system, upgrade the operation process and satisfy MDGDP requirements.

Notes to Quality Objectives establishment:

- (1) Match with the Quality Policy
Quality Objectives are the parameters to evaluate the degree of accomplishment of Quality Policy. Thus, Quality Objectives shall cover all the contents of Quality Policy. For example regarding the Quality Policy of “Ensure the customer requirements are fully satisfied”, corresponding Quality Objectives shall define a quantitative index to evaluate the degree of customer satisfaction.

Chapter 12. Establish Quality Policy and Quality Objectives

- (2) The contents shall be measurable, realistic and evaluable.
“Measurable” means the Quality Objectives are tangible and able to be represented as numerical values, instead of just abstract wordings. Corporate shall define clear objectives (e.g. more than X% of on-time products delivery, or less than Y% of returned products from the customers). Any objectives that fail to be satisfied at the year-end shall be reported in the management review meeting, and any suggested improvements shall be raised.
- (3) Set evaluation intervals to Quality Objectives
Quality Objectives shall be evaluated within a defined interval, one of the examples is that corporate shall receive less than X customer complaints per year.
- (4) Do not set factual, intangible Quality Objectives
Quality Objectives such as “Do not distribute nonconforming products to customer” and “Serve customers with good attitude” shall not be included, because these are the must-do items to the corporate.

Samples of Quality Objectives:

- The quantity of returned medical devices shall be less than X% of the total distributed quantity per year.
- Medical device recall shall be less than X cases per year.
- Delayed products delivery shall be less than X% of the total distributed quantity per year.
- Customers and regulatory authorities shall be informed within X hours with any safety alert issued by medical device manufacturers.
- Customer complaints shall be less than X cases per year;
- Customer satisfactory survey shall be scored higher than X in the average overall mark.
- Quality management system shall be upgraded to fulfill MDGDP requirements by dd/mm/yyyy.

Once Quality Policy and Quality Objectives are set, corporate shall:

- (1) Promote Quality Policy and Quality Objectives within corporate
Proper promotion can assure that all employees well understand the contents of Quality Policy and Quality Objectives. Corporate can display both onto employee notice board or eye-catching place in the working environment. Corporate can also promote via internal communications (such as meeting, email, website, etc.) or print onto corporate items (such as corporate uniform and staff card).
- (2) Conduct regular review to evaluate the suitability of Quality Policy and Quality Objectives
Enterprise purpose, business strategy, customer groups, customer requirements, regulatory requirements, etc., may change from time to time. Therefore, corporate shall review the Quality Policy and Quality Objectives regularly during the management review meeting or at any time, and make necessary amendments to suit the changes.

13. Perform System Trial and Refinement

Step 1: Identify the procedures that needed to be documented.

Depends on business nature, different corporates may have different sets of documented procedures. MDGDP consists of some basic documented procedures, and some additional documented procedures only required by some specific medical devices.

For example, radioactive devices' installation, maintenance and repair shall follow the guidelines issued by device manufacturers, Radiation Board of Hong Kong (RBHK) and other related institutions. Possession and use of radioactive materials and devices shall be monitored by Hong Kong CAP 303 "Radiation Ordinance". These local regulatory requirements shall be included in MDGDP documentation.

Basic Documented Procedures
Document Control Procedure
Management Review Procedure
Staff Development Procedure
Internal Audit Procedure
Aftersales Service Procedure
Product Labeling and Traceability Procedure
Infrastructure and Work Environment Management Procedure
Receipt, Verification and Acceptance of Incoming Goods Procedure
Storage and Stock Monitoring Procedure
Customer Order Handling Procedure
Customer Feedback and Complaint Handling Procedure
Control of Nonconforming Products Procedure
Corrective and Preventive Action Procedure
Advisory Notice Handling Procedure
Products Recall Procedure
Adverse Incident Reporting Procedure
Calibration of Measuring Equipment Procedure

Additional Documented Procedures
Requirements of Specific Medical Devices (including sterile medical devices, active and non-active implantable devices, radioactive devices)
Third Party Suppliers Monitor Procedure
Device Repair and Maintenance Procedure
Device Installation Procedure

Step 2: Prepare documented procedures

Documented procedures explain the implementation procedures of each distribution process and the responsibility of each department. These documents are linked up with each other, thus corporate shall plan the order of documents establishment. It is suggested to begin the preparation with simple procedures such as those related to daily operations, followed by more complicated procedures.

Flowchart for establishing documented procedures	
Distribution Processes	Involved documented procedures
(1) Customer order handling (From receiving customer orders, purchasing products, issuing quotation, arranging delivery, and finally issuing invoice)	<ul style="list-style-type: none"> • Customer Order Handling Procedure • Aftersales Service Procedure • Products Delivery Procedure
(2) Warehouse management (From allocating stock area, establishing segregation area, installing measuring devices, examining import and exporting products, arranging logistics, and finally identifying and tracking products)	<ul style="list-style-type: none"> • Storage and Stock Monitoring Procedure • Infrastructure and Work Environment Management Procedure • Receipt, Verification and Acceptance of Incoming Goods Procedure • Measuring Equipment Calibration Procedure • Product Labeling and Traceability Procedure
(3) Corporate management (including the identification and fulfillment of employees' specific competence requirements, internal communication, maintenance of system effectiveness, documents and records control)	<ul style="list-style-type: none"> • Staff Development Procedure • Internal Audit Procedure • Document Control Procedure • Regulatory Control Procedure
(4) Collection of Customer Feedback	<ul style="list-style-type: none"> • Customer Feedback and Complaint Handling Procedure
(5) Handling of nonconformities (include the handling of nonconforming products, post-market surveillance, communication with regulatory authorities)	<ul style="list-style-type: none"> • Control of Nonconforming Products Procedure • Corrective and Preventive Action Procedure • Advisory Notice Handling Procedure • Products Recall Procedure • Adverse Incident Reporting Procedure

Step 3: Prepare work instruction and form

Work instruction describes the steps and reminders under some specific procedures, such as device installation and repair. Apart from text description, pictures may be added for better illustrating the different steps.

Form is the format of record, or in other words, record is the filled form. Form shall be legible, informative and clear. For example, “corrective and preventive action form” shall be designed with specific areas for filling in the description of nonconformities, root causes investigation and results of nonconformities, suggested corrective and preventive actions, follow-up actions and results, etc.

Step 4: System Trial

Before system trial starts, quality management team shall provide MDGDP training to all employees, to allow them to be more familiar with the system operation and documented procedures requirements. Employees can also seize this opportunity to raise any comments/suggestions for further amendments of the documented procedures. System trial process usually lasts for two to three weeks.

During system trial, all documents amendment shall follow the Document Control Procedure, that is document revision, deposition, obsolete documents/records maintenance etc. Once system trial completes and implementation formally kicks start, documents amendment shall still follow the Document Control Procedure.

14. Perform Internal Audit

Audits can be categorized in three groups, that is first-party, second-party and third-party audit.

First-party audit is conducted by corporate itself. Second-party audit is conducted by corporate cooperating partners such as products manufacturers, suppliers and customers. Request for second-party audit may be raised by these cooperating partners before signing the contract. Third-party audit is conducted by a third-party certified body independent from the corporate.

Below are some examples:

- (1) Internal audit is regarded as first-party audit.
- (2) To audit your supplier's performance before signing the service contract is regarded as second-party audit;
- (3) To employ an assessment body to conduct certification audit is regarded as third-party audit.

Internal audit flow

Corporate are required to regularly conduct internal audits according to MDGDP. Its audit procedures are similar to the second-party audit and third-party audit. In general, internal audit can be divided as:

- (1) Audit Planning**
- (2) Audit Implementation**
- (3) Audit Reporting**
- (4) Follow-up Audit**

14.1. Audit Planning

Establish audit team

The composition and number of audit team members shall be determined as according to the corporate size, audit scope, etc. Audit team is usually comprised of one audit team leader and several audit team members.

Before internal audit commences, audit team shall receive internal audit training, or possess qualifications according to the specific quality management to be audited. Internal audit training could be conducted by audit team leader or subcontracted body. After training, the corporate shall evaluate the training performance, fill in the evaluation results onto "Staff Training Record" and maintain training records such as training certificate.

Prepare audit plan

Audit plan lists out the audit date and time of different departments, names of the responsible audit team members and his/her duties. Purpose of the audit plan is to (1) ensure that audit is performed systematically and with sufficient coverage (2) ease the management, surveillance and control of audit processes. It is usually prepared by the audit team leader.

One fundamental audit rule is that auditors shall not audit their own duties. In another words, all work done by "auditor A" shall not be audited by him/herself and shall be audited by "auditor B", who is independent to those work.

Sample of an audit plan:

ABC Medical Device Distribution Company. – Audit Plan					
Name of Standards or Practice				Version of this audit plan	
Prepared by	Date	Reviewed by	Date	Approved by	Date
No.	Audit Procedures	Auditor	Year		
			Month / Day	Month / Day	
1	QM Quality Manual COP Management Review	Auditor B	✓		
2	COP Infrastructure and Working Environment Management COP Device Verification, Validation and Acceptance COP Warehouse Management COP Product Delivery COP Customer Property Handling COP Nonconformity Handling COP Product Traceability COP Product Labeling	Auditor A	✓		
3	COP Aftersales Servicing COP Measuring Equipment Calibration COP Product Repair and Maintenance COP Product Installation	Auditor A	✓		
4	COP Document Control	Auditor B	✓		
5	COP Staff Development	Auditor B	✓		
6	COP Risk Management	Auditor A	✓		
7	COP Regulatory Monitoring COP Product Recall COP Adverse Incident Reporting COP Advisory Notice Handling	Auditor B		✓	
8	COP Customer Order Handling COP Supplier Evaluation	Auditor A		✓	
9	COP Customer Satisfactory Investigation COP Customer Feedback and Complaint	Auditor B		✓	
10	COP Internal Audit	Auditor C		✓	
11	COP Corrective and Preventive Action	Auditor B		✓	
12	COP Particular Requirements for Medical Devices (including Sterile Device, Active/Non Active Implantable Device)	Auditor A		✓	
13	WI Warehouse Instruction WI Product Repackaging WI Incoming/Outgoing Goods Inspection WI Product Identification and Segregation WI Product Deposition	Auditor A		✓	

Chapter 14. Perform Internal Audit**Prepare audit checklist**

Before conducting the audit, auditors shall prepare an audit checklist, to list out all the inspection items based on MDGDP requirements. During audit, auditors shall examine every inspection item and record the audit details (including the audit method, document number of the COP, WI or records audited, nonconformities, etc.)

Notes for audit checklist preparation

- Ensure sufficient quantity of records being audited during random sampling.
- Make use of PDCA process approach to prepare inspection items of the audit checklist. PDCA means audit objectives (Plan), audit method (Do), audit monitoring and surveillance (Check) and corrective and preventive actions corresponding to each specific nonconformity (Act).
- Recall the following four questions during audit: (1) Are the procedures clearly and appropriately defined and described; (2) Are the responsibilities allocated effectively; (3) Are the operations completely implemented; (4) Do the results satisfy the standard or practice requirements.
- The audit check list shall be designed with the name of audit document, auditing department to be audited, date of audit, name of auditor, audit item, audit record, conformity level, etc.

Chapter 14. Perform Internal Audit

Sample of an audit checklist

Document To Be Audited: Quality Manual			
Department To Be Audited:		Date of Audit:	Name of Auditor:
Audit Method (Already Prepared For)		(a) Audited Items (b) Non-conformity and Audit Findings	Conformity Lv.
1	Examine the description of corporate structure.	(a) QM chapter 0.4.1 records the corporate overview description. (b) N/A	✓
2	Examine the corporate structure.	(a) QM chapter 0.4.4 records the corporate structural diagram. (b) N/A	✓
3	Examine the products scope covered by MDGDP.	(a) QM chapter 1.1 records the products scope covered by MDGDP. (b) N/A	✓
4	Examine whether the Quality Manual can cover all the MDGDP requirements.	(a) QM chapter 0.4.3 lists out all the exempted clauses of MDGDP system. QM chapter 2 lists out the version of quality management system. (b) N/A	✓
5	Examine the appointment of Management Representative	(a) The assignment of Management Representative is shown on QM chapter 0.4.4 corporate structure. (b) N/A	✓
6	Examine the establishment of Quality Policy, Quality Objectives, Quality Manual, Documented Procedures and Work Instructions.	(a) QM chapter 2.0 records the Quality Policy. QM chapter 3.0 records the Quality Objectives. The lists of Documented Procedures and Work Instructions are inside QM chapter 9.0 (b) N/A	✓
7	Examine if the Quality Objectives are measurable parameters.	(a) Checked the three Quality Objectives are measurable parameters. (b) N/A	✓
8	Examine the promotion of Quality Policy.	(a) Checked Quality Policy is posted at staff notice board in the office, and verified to be the latest version. (b) N/A	✓
9	Examine the evaluation results record of Quality Policy.	(a) Checked evaluation of Quality Policy was performed during management review meeting dated Jan 2013, evaluation results were recorded in that meeting minutes. (b) N/A	✓
10	Examine whether Quality Objectives are correlated to Quality Policy.	(a) Checked the three Quality Objectives are correlated and echoed with Quality Policy in the QM. (b) N/A	✓

Chapter 14. Perform Internal Audit

11	Examine whether Quality Objectives are successfully achieved.	(a) As according to management review meeting minutes dated Jan 2013, all the three Quality Objectives was successfully fulfilled. (b) N/A	✓
12	Random inspection of one employee on his/her understanding of Quality Policy and Quality Objectives.	(a) Chatted with Employees A, confirmed his clear understanding of Quality Policy and Quality Objectives. (b) N/A	✓
13	Examine whether the documented procedures and the corresponding records are available as required by MDGDP.	(a) QM chapter 9.0 lists out all the documented procedures and records of the corporate, and confirmed that all these procedures and records are available as requested by MDGDP. (b) N/A	✓
14	Examine the flow chart of Quality System.	(a) QM chapter 4.2.4 shows the workflow of the procedures. (b) N/A	✓
15	Examine the descriptions of procedures and procedure relationships in the Quality Manual	(a) Procedures flow chart in Chapter 4.2.4 shows the effect of the quality manual on the procedures and operations. (b) N/A	✓
16	Examine whether the procedure descriptions and relationships correlate with the actual situation.	(a) Description of the procedures and their relationships are verified. (b) N/A	✓
17	Examine the documents checklist, check if 4-tiers documentations are correctly named, numbered and cross-linked with MDGDP clauses.	(a) Checked documents checklist as appeared in QM chapter 9.0, confirmed that 4-tiers documentations are correctly named, numbered and cross-linked with MDGDP clauses. (b) N/A	✓
18	Examine the exempted MDGDP clauses in Quality Manual	(a) Checked the exempted MDGDP clauses as appeared in QM chapter 0.4.3. (b) N/A	✓
Conformity level : — : Not applicable ✓ : Complied O : Partially complied ? : Further investigation required X : Not complied			

14.2. Audit Implementation

Conduct on-site audit

During on-site audit, auditor shall collect evidence. In general, evidence shall be collected via the following means:

(1) Interview with employees

Directly communicate with employees, evaluate their understandings on self-responsibilities and check whether their works are the same as the content listed in the documented procedures.

(2) Review documents and record

On the document side, auditor shall check whether corporate operations followed the documented procedures and whether the documents fulfill MDGDP requirements.

On the record side, not all records can be audited due to limited time, where there are numerous records generated during daily operations. Thus, when preparing the audit checklist, auditor shall define record sampling quantities and to sample & inspect the record in random order.

(3) Conduct on-site inspection

Auditor shall check whether the documented procedures are implemented effectively. For example, they shall check whether the controlled documents are stored at specific and designated location, the devices segregation area is correctly allocated in the warehouse etc. The auditor shall also ensure that the stock is having the same quantity as stated in record. For example, if “Product Recall Form” listed the number of recalled medical device; the auditor shall count the number of recalled devices in warehouse during the on-site audit for verification.

(4) Verify the consistency of the records against actual operation activities

Auditor shall verify whether the records are consistent with actual operation activities. For example, if the “Corrective and Preventive Actions Record” mentioned the re-training of an employee on a specific date, the auditor shall then check the “Staff Training Record” to verify whether such re-training was correctly recorded.

Record nonconformities

If any nonconformity is discovered during the random inspection of records, auditor shall mark the corresponding record number and the descriptions of that nonconformity on the audit checklist. After checking all inspection items on the audit checklist, auditor shall note all the nonconformities discovered at the audit report and notify the responsible person of the corresponding department and the corporate. The corporate shall perform corrective and preventive actions (CAPA) in response to the nonconformities, and report the implementation progress and the results of CAPA within a defined time frame.

Nonconformities can be classified into three types:**(1) Major nonconformity**

- Corporate's operation does not satisfy MDGDP requirements, leading to a total or partial failure of the whole system. For example, several nonconformities occur concurrently within a particular requirement in MDGDP.
- Any nonconformity that may lead to the distribution of nonconforming medical devices to users.
- Any potential situation that may cause the malfunction of or lower the functionality of the medical device and after-sales services.
- Any nonconformity that may lead to malfunction of the Corporate's quality management system, or may lead to the decrease of products quality controls or operation controls.

(2) Minor nonconformity

- Corporate's quality management system or practice partially non-conforms with MDGDP requirements.
- Identify one or multiple minor system operation error(s) or mistake(s).

(3) Observation

- Corporate's quality management system or practice is discovered with problem(s) while these problem(s) may potentially transform to a nonconformity.
- Observation items help the corporate to achieve continuous improvement, thus its content shall be recorded in the final audit report.

14.3. Audit Reporting

Prepare audit report

The audit team shall conduct audit based on the audit checklist and audit plan.

When the audit completes, the audit team shall consolidate all the nonconformities and observations into an audit report and present the report during management review meeting. The report shall describe all the nonconformities and observations in details, the progress of the corrective and preventive actions (CAPA) implementation. The audit report shall also be attached to the minutes of the review meeting and signed by the chairman of the meeting.

14.4. Audit Follow-up

For all the CAPA (either completed or currently under progress), record shall include the descriptions of nonconformities and observations, the proposed CAPA and the implementation progress of these CAPA. CAPA shall be completed within a targeted period. Upon the completion of CAPA, the audit team shall audit the actions taken, record the results and report in the next management review meeting.

15. Conducting Corrective and Preventive Action based on Audit Results

Differences between correction, corrective action, preventive action and improvement:

- Correction is the action to eliminate a detected nonconformity;
- Corrective action is the action to eliminate the cause of a detected nonconformity or other undesirable situation;
- Preventive action is the action to eliminate the cause of a potential nonconformity or other undesirable potential situation;
- Improvement is the recurring activity to maintain the ability to fulfill requirements.

Simply to say, if medical devices (with lot number XXX) are found to be expired in the warehouse:

“Correction” is to relocate that the medical devices, with particular lot number XXX, into the segregation area, identify them properly with labeling, fill in the “Nonconforming Products Report” and decide the disposition methods of these medical devices (by discarding or repackaging the medical devices).

“Corrective action” is to investigate the root causes for not identifying the medical device, with particular lot number XXX, before the nonconformity occurs. The root causes may be due to mistake caused by the responsible staff, for example, failed to follow the procedure of checking expiry date of the medical device. Thus, the corrective action can be the re-training of the responsible staff on that procedure, and to perform the same checking for all the other lot of device.

“Preventive action” is to investigate any potential hazard/risk within the procedure of checking expiry date, and eliminate those potential sources of nonconformity.

16. Conduct Management Review Meeting

Corporate shall conduct management review meeting regularly in order to (1) evaluate the sufficiency, appropriateness and effectiveness of her quality management system, and (2) to ensure that Quality Policy and Quality Objectives are fully implemented.

In normal situation, management review meeting shall be conducted at least once a year. However, under the following special situations, the corporate can decide to **increase the meeting frequency**:

- When there are huge changes in the corporate structure, products and/or services scope, resource, business strategy, market environment, etc.;
- When there are serious adverse incidents related to products quality, environmental safety or healthcare safety, or when the corporate receives numerous complaints successively;
- When there are tremendous changes of the quality management system due to updates on the local regulations or standards;
- Other reasons (e.g. before the commencement of third-party audit)

The participants of management review meeting shall at least include the Top Management, Management Representative, Department Heads, Employee Representative etc. Other employees may also be invited to the meeting. It is recommended to circulate the meeting date, time, venue, meeting agenda, review inputs, etc. to the employees through email or notice one or two weeks before the meeting.

Before the meeting, documents related to review inputs and review outputs shall be prepared, and be ready to be distributed during the management review meeting.

Review inputs include

- Results of audits (including internal audit and third-party audit),
- Customer feedback,
- Process performance and product conformity,
- Status of corrective and preventive actions,
- Follow-up actions from previous management reviews,
- Changes that could affect the quality management system,
- Recommendations for improvement,
- New or revised regulatory requirements.

The review outputs include

- Improvements needed to maintain the effectiveness of the quality management system and its processes,
- Improvements of product and service related to customer requirements,
- Resources needs.

During the meeting, documents related to review inputs and review outputs shall be prepared and presented by the corresponding department(s). It is recommended that meeting minutes shall be issued to the present and absent staffs within two weeks after the meeting.

Sample of management review meeting minutes

Meeting Minutes of Management Review Meeting

Date: DD/MM/YYYY
Time:
Venue:
Present: (Chair of the meeting) Name and Position
(Management representative) Name and Position
(Employee A) Name and Position
(Employee B) Name and Position
(Employee C) Name and Position
(Employee D) Name and Position
(Employee E) Name and Position
(Employee F) Name and Position
(Employee G) Name and Position

Absent: No

According to the requirements of MDGDP and management review procedures, our corporate shall conduct management review meeting annually in order to ensure that the appropriateness, sufficiency and effectiveness of the system.

The contents of the review are:

1. The approval of last meeting minutes by Chair of the meeting.
2. **Review input** – Employee A(Corresponding department) presented the audit reports (including first-party audit, second-party audit and third-party audit)
 - 2.1. An internal audit was conducted on DD/MM/YYYY. According to the audit results, it was observed there are X minor nonconformities, Y major nonconformities and Z improvement recommendations.
 - 2.2. (Minor nonconformity) Description of the nonconformity, CAPA and the follow-up progress.
 - 2.3. (Major nonconformity) Description of the nonconformity, CAPA and the follow-up progress.
 - 2.4. (Improvement Recommendation) Description of improvement recommendation and its implementation progress.
 - 2.5. Based on the audit results, corporate shall show compliance of her quality management system to MDGDP requirements.
3. **Review input** – Employee B presented the results of customer satisfactory survey, customer feedback and complaint handling.
 - 3.1. Results of customer satisfactory survey: A total number of X surveys were received, where Y number of surveys were below passing mark. Briefly describe the items with the lowest score, CAPA and the follow-up progress.
 - 3.2. Customer feedback and complaint handling: A total number of X customer feedbacks received, where Y number of customer feedbacks were confirmed to be customer complaints. Briefly describe the handling method, results, CAPA and the follow-up progress.

4. **Review input** – Employee C reported the progress on achieving Quality Policy and Quality Objectives.
 4.1. Quality Policy: All attendants agreed that the corporate achieves the Quality Policy requirements as shown in the below table.

ABC Medical Device Distribution Co., Ltd. Medical Device Good Distribution Practice (MDGDP)	
Quality Policy	
Our Corporate shall devote our best effort to maintain the effectiveness via the following means:	
(1)	Ensure that products are delivered to our customers with the best quality,
(2)	Ensure timely delivery of the products,
(3)	Strictly comply with the requirements of MDGDP and related local regulations,
(4)	Ensure that customers satisfy with our products and services.

- 4.2. Quality Objectives: Below table showed the degree of achieving Quality Objectives since MDGDP implementation. Our Corporate successfully fulfilled all the Quality Objectives.

	Description of Quality Objectives	Goal	Degree of achievement (From DD/MM/YYYY to the meeting date)
1	Percentage of delayed delivery versus the total number of delivery	Not more than 5%	1.1%
2	Number of confirmed customer complaints per year	Not more than 3cases	1case

5. **Review input** – Employee D reported the process performance and products conformity
 5.1. Process performance: Evaluate if our corporate’s quality management system fulfills all MDGDP requirements, and the necessity to make any amendments.
 5.2. Products conformity: Description of nonconforming products and services.
6. **Review input** – Employee E reported the follow-up progress of CAPA.
 6.1. Description of CAPA and the follow-up progress.
7. **Review input** – Employee F reported the implementation progress of follow-up actions of the last review meeting.
8. **Review input** – Employee G reported any change(s) that could affect the

quality management system.

8.1. Description of any change(s) that could affect the quality management system.

9. **Review input** – Any improvement recommendation received from the attendants.

10. **Review input** – Employee H reported any new or updated regulatory requirements.

11. **Review input** – Evaluate if it is necessary to enhance Quality Policy and Quality Objectives in order to achieve continual improvement.

11.1. Majority of the attendants *agreed/did not agree that the Quality Policy shall not be amended in the current stage.

11.2. Quality Objectives were *achieved/ not achieved. All attendants agreed that the Quality Objectives *need to be enhanced/ remain unchanged at the current stage.

11.3. Description of revised content of Quality Policy and Quality Objectives if applicable.

12. **Review input** – Improvements required to maintain effectiveness of the quality management system and its processes.

12.1. Majority of the attendants *agreed / not agreed that the quality management system and the implementation progress are satisfactory and *need to improve/ remain unchanged at the current stage.

12.2. Briefly describe the recommendations for improvement if available.

13. **Review input** – Product and service improvements related to customer requirements

13.1. Monitor any changes in the product and service requirements of customers, and reflect to manufacturers immediately.

13.2. List out customer feedback on product and service requirements.

14. **Review input** – Resources demand

14.1. List out all the resources demand including the necessity of purchasing new device/ employing new employees.

Attachment : Customer satisfactory analysis and figure, Degree of achieving Quality Objectives

*deleted as appropriate

Prepared by:	Date:
Approved by:	Date:

Sample of management review meeting minutes attachment 1

Customer Satisfactory Analysis

Year of survey:		Number of collected Customer Satisfactory Survey:	
Section One: Scores on customer satisfaction			
		Evaluation Criterion	Mean Score
1	Time for preparing quotation (shall not exceed 3 working days)		/5
2	Response time towards customer enquiry and complaints		/5
3	Sufficiently reply and satisfy customer enquiry		/5
4	On-time delivery of products		/5
5	Good Staff attitude		/5
6	Reasonable products price		/5
7	Maintain high quality of delivered products (in terms of product cleanliness, package conformity, etc.)		/5
8	Products fulfill customer requirements		/5
9	Products are safe and reliable		/5
Total Mean Score:			/45
Is there any customer gave score 1 to any one of the above criterion? (If yes, please list out the organization name and the corresponding question number)			
Summary of the improvement recommendations replied from customer: (Please list out the organization name and the summarized content)			
The lowest total score from the customer			
Organization name:		Score:	/45

Prepared by:	Date:
Approved by:	Date:

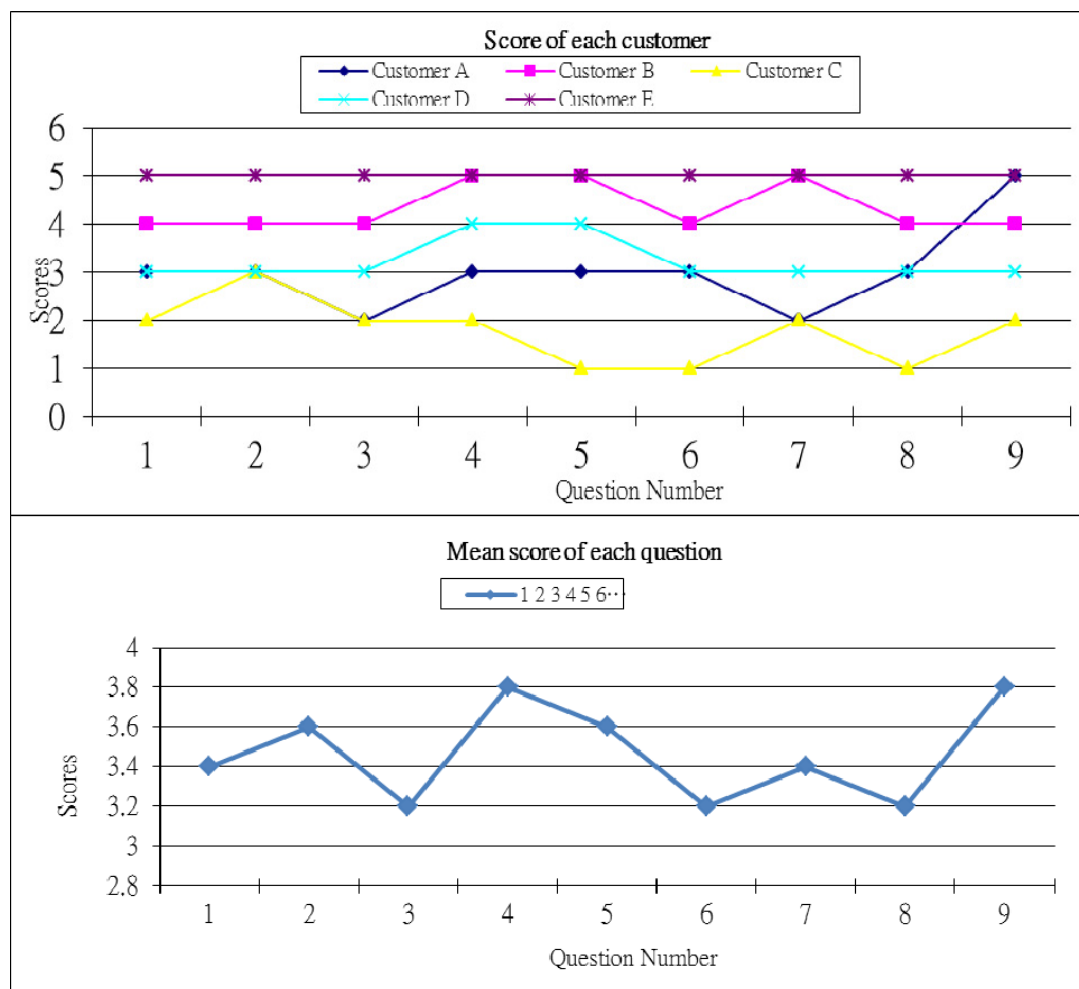
Sample of management review meeting minutes attachment 2

Customer Satisfactory Analysis (In figures)

Data Covered Year:	YYYY
Surveys collected:	5

Mean Score of each question:		
Question	Mean	Total
1	3.4	5
2	3.6	5
3	3.2	5
4	3.8	5
5	3.6	5
6	3.2	5
7	3.4	5
8	3.2	5
9	3.8	5
Total	31.2	45

Score of each customer											
	Customer Name	Scores of the questions on customer satisfactory survey									Total
		1	2	3	4	5	6	7	8	9	
1	Customer A	3	3	2	3	3	3	2	3	5	27
2	Customer B	4	4	4	5	5	4	5	4	4	39
3	Customer C	2	3	2	2	1	1	2	1	2	41
4	Customer D	3	3	3	4	4	3	3	3	3	29
5	Customer E	5	5	5	5	5	5	5	5	5	45



Sample of management review meeting minutes attachment 3

Degree of Achieving Quality Objectives

Data Covered Period: From DD/MM/YYYY to DD/MM/YYYY

Objective 1: Percentage of delayed delivery versus the total number of delivery shall not be more than 5%	
Total number of customer delivery (a)	
Number of delayed customer delivery (b)	
Percentage = (b)/(a) * 100%	
Analysis results : Objective 1 <input type="checkbox"/> achieved/ <input type="checkbox"/> not achieved.	
Objective 2: Number of confirmed customer complaints per year shall not be more than 3 cases	
Number of confirmed customer complaints	
Analysis results : Objective 2 <input type="checkbox"/> achieved/ <input type="checkbox"/> not achieved.	
Prepared by:	Prepared date:
Approved by:	Approved date:

17. Conduct Suppliers Evaluation

Suppliers are defined as those who supply medical device or related distribution service to the corporate. These suppliers include medical device manufacturers, outsourced logistic service providers, outsourced warehouse service providers, machine calibration service providers, shipping service providers, etc. Other suppliers, such as office equipment suppliers, are not necessary to be evaluated because its products/services do not directly related to the distribution of medical devices.

Supplier Evaluation can be classified into two groups

(1) Evaluation of new supplier

Before the procurement of any products or services, the corporate shall first define the quality requirements of those products or services. According to these quality requirements, marketing department shall gather relevant information from the market, and select one or more suppliers to evaluate its/their degree of fulfillment to the quality requirements. Once the best supplier is decided, it shall be added to the “Approved Supplier List”. Simultaneously, the corporate shall define and impose supplier surveillance process, for example regular inspection at the manufacturing site of the supplier, regular spot check of the external logistic supplier, etc.

(2) Re-evaluation of current supplier

Re-evaluation is normally conducted once a year. The re-evaluation of nonconforming supplier could also be conducted any time. If the suppliers could not pass the re-evaluation, they shall be deleted from the “Approved Supplier List”.

18. Collect Customer Feedback

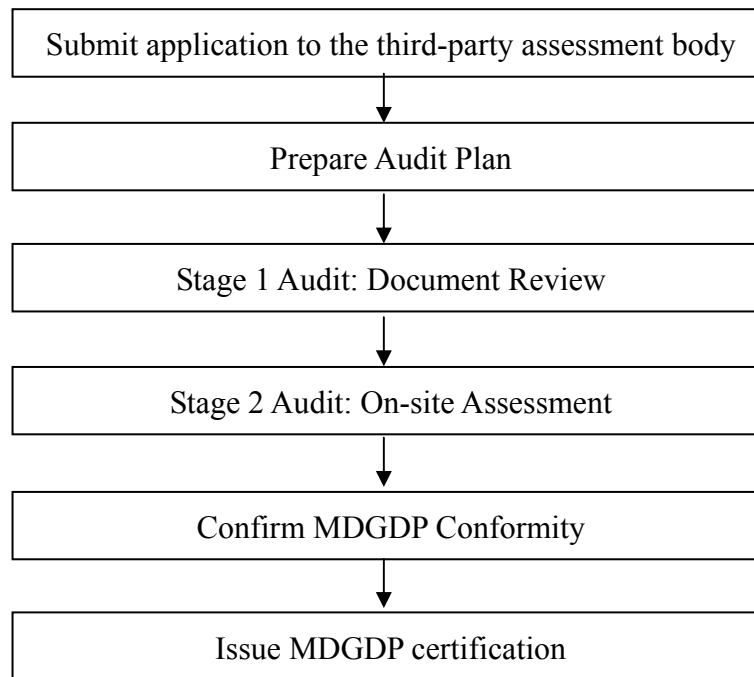
Collecting customer feedback is a crucial part of MDGDP. The corporate can enclose a “customer feedback form” inside the package of medical device, or conduct customer feedback survey annually to send out “customer feedback form” to the customers.

Apart from that, the corporate shall provide to customer her contact channels, so as to collect their feedback. These channels are usually phone, email and fax, which shall be displayed on the devices package or the labeling given by the distributors. Regarding the additional requirements on labeling, the corporate may refer to the document TR-005 “Additional Medical Device Labeling Requirements” under the Medical Device Administrative Control System (MDACS).

19. Recommended Methods for Acquiring Certification

MDGDP is the best practice for medical device distribution voluntarily formulated by the medical device industry. Corporates can develop their documented procedures by themselves according to MDGDP requirements. If corporates wish to employ third-party assessment body to conduct audit, in order to obtain MDGDP certificate, the recommended audit procedures are similar to normal audit procedures.

Recommended audit procedures:



20. Establish MDGDP by Corporate itself, or Obtain Certificate via Assessment Body

The corporate can fulfill MDGDP requirements by building up the documented procedures herself, or to obtain MDGDP certificate by employing assessment body to conduct third-party audit.

Third-party assessment bodies include:

- (1) Conformity Assessment Body
- (2) Notified Body
- (3) Consulting Firm

It is recommended that the corporates shall be eligible to receive the MDGDP certificate, if they pass the third-party audit on MDGDP.

21. System Trial before Obtaining Certification

The procedures for obtaining MDGDP certificate are similar to that of normal certificates. After the corporate developed its own quality management system, it shall start the system trial and data collection process. Assessment body shall request the corporate to maintain all the records and data generated during system trial implementation for at least three months before the compliance audit to be performed. Such records shall be audited by the assessment body during certification audit.

If the corporate wishes to acquire the certificate in the shortest time, application of certification shall be submitted to assessment body once the system starts implementation. The time to confirm the audit date varies, and depends on the available audit schedule of the assessment body. It shall normally need to schedule the audit date with the assessment body 2-3 months in advance.

All the records and data collected during the system trial implementation shall be comprehensive. The corporate shall perform all the major procedures including those procedures that are performed annually. For example, management review meeting and the internal audit which are usually to be conducted once a year. However, within the system trial implementation period, it is necessary to conduct them and maintain related records.

Documented procedures usually cover all the corporate operations. However, some of the procedures may not be triggered during the system trial implementation period, which means no records are filled in, and auditors cannot audit the records during certification audit. For example, the procedures on product recall and customer complaints may not be triggered if there is no recall or complain received, thus there will be no records of filled “Product Recall Form” or “Customer Complaint Feedback Form” during certification audit. However, the corporate usually has such record during system running in their operation, the assessment body may suspect the corporate’s capability to maintain zero complaints or whether the system is not implemented properly if there is still no such record 1-2 year after certification.

When filling in records, the corporate shall aware of the reasonableness and causality of the record contents. For example, if the warehouse temperature exceeds the normal range defined by the manufacturer due to malfunction of air-conditioner, the corporate shall fill in the “Corrective and Preventive Actions Record”. In the record session “Root causes of the nonconformity”, malfunction of air-conditioner shall be mentioned. While in the record session “Recommended corrective and preventive action”, solutions shall be specifically targeted to the above root causes. Examples of corrective and preventive actions include relocating the products into another air-conditioned warehouse or arranging repairing services immediately.

Apart from that, records shall be filled with detail. For example, when filling in the “Corrective and Preventive Actions Record”, the corporate shall clearly describe the date and time of identifying the nonconformity, which MDGDP requirements correspond to the nonconformity, the lot number and quantity of the nonconforming products and the description of the nonconformity. The advantages of following the above reminders are to ease the subsequent follow-up of the CAPA and allow the auditor to understand the whole event sensibly and logically. Please note if the record is filled in ambiguously or incompletely, the auditor may issue a minor nonconformity or observation.

22. Submit Application and Quotation

After the corporate requests audit services from the assessment body, it shall prepare **the following application documents:**

- (1) Basic information of the corporate, for example, the corporate name, address, person in charge, number of employees, etc.
- (2) Brands of the distributed medical devices.
- (3) The date when the corporate’s quality management system is ready to be audited. (The system shall be implemented at least three months before certificate audit)
- (4) Description of the major corporate businesses including distribution, repairing and maintenance services.
- (5) Products scope of this certification audit, including device names, description, intended purpose, classification etc. If the medical device is sterile, its sterilization method and sterilization location shall also be included.
- (6) Information of contractors and its business involved.
- (7) Recommended audit scope.
- (8) Certifications hold by the corporate, medical device manufacturers and contractors.

After submitting the application, the assessment body shall issue the quotation around one week later. The price is calculated based on man-day, the price of each man-day varies in different assessment bodies. When choosing the assessment body, the corporate may consider the international popularity and credibility of the assessment body. If the auditor is employed from the overseas, the quotation may include his/her travel ticket fee and accommodation fee.

Quotation can be classified into several items

Audit Stages	Quotation Contents
Initial certificate application	Fee of initial certificate application (including the Stage 1 Audit and Stage 2 Audit) Annual management fee
Surveillance audit in the 1st and 2nd year	Surveillance audit fee Annual management fee
Re-certification audit in the 3rd year	Re-certification audit fee Annual management fee

23. Certification Audit by the Assessment Body

Stage 1 Audit

Stage 1 audit is the documents audit. The assessment body shall request the 4-tiers documentation from the corporate. Gap analysis shall be conducted to identify the nonconformities before the on-site stage 2 audit. Usually, the major system problem can be identified in this Stage.

Stage 2 Audit

Stage 2 audit is the on-site audit. This stage involves random, on-site inspection of the records and products at the warehouse and office at a scheduled time. The time required for on-site inspection depends on the amount of documents. For example, in our project, one pilot company consists of no more than 20 employees. In that case, two auditors have spent two days (4 man-days) to complete the stage 2 audit. During the on-site audit, the auditors shall first conduct the meeting with the management to introduce the audit procedures, audit schedule of different departments. The auditors shall also visit the whole corporate area.

Then, the auditor shall follow the audit plan to audit each department. The audit shall focus on the documented procedures of each department. For example, when auditing the Marketing Department, the audit shall focus on the procedures of preparing/issuing quotation and the procedures of receiving customer order. During audit, auditor shall interview the employees for details of each documented procedures and check whether the actual operations coordinate with the documented procedures. At the same time, auditor shall check all the related records, to see their completeness and their availability of confirmation signature/stamp. Among all records, several records shall be chosen for in-depth inspection, to investigate the customer orders and the corresponding records, and to see if these procedures fulfill MDGDP requirements.

Sample questions and answers during audit (Quote):

Sales and Marketing Department

Interviewee: Department Manager

- (1) Who are the major customers of your corporate?
Customers of the medical device distributor are normally public or private hospital, chain store, elderly home, pharmacy, rehabilitation center etc.
- (2) Could you provide the list of all distributed devices?
Auditor shall extract at least one to two devices from each category on the list in order to conduct detailed inspection. For example, if the corporate is distributing 18 different models of blood pressure meters, the auditor may select 3 models to audit.
- (3) Please provide the promotional leaflets of the blood pressure monitor A and B.
Auditor shall examine the descriptions of the medical devices' specifications and maintenance period, etc., written on the leaflet.
- (4) Please provide the quotation reference index.
Auditor shall check the progress of following-up actions after the issue of the quotations, for example, which quotations are finally confirmed by

the customer.

- (5) Please provide quotation records of model A and B.
Auditor shall conduct sampling inspection. On the record, auditor shall check
- whether there are approvals from appropriate employees, for example, the corporate stamp or signature of authorized person;
 - the reference number of the quotation;
 - the valid date of the quotation; valid date is XX days after the issue date of the quotation;
 - Check if there is any discount provided to the customers. If yes, auditor shall verify if the discount is approved by the authorized employee and the approval record.
- Auditor shall record the information from quotation A and B, including the quotation number, issue date, customer name and code, product name, product quantity and product price.

Audited Documents: Quotation A and Quotation B

- (6) Please provide a revised quotation.
Customer may sometimes request the corporate to revise the issued quotation, for example, changing the products quantity on the quotation. As such, a revised quotation shall be issued to the customer, with a revised quotation number in a format such as “old quotation number (Revise X)”, where X is the number of times the quotation be revised. The purpose of inspecting the revised quotation is to check whether the customer requirements are fulfilled.

Audited Document: Revised Quotation C

- (7) Do the corporate participate in any tender? If yes, please provide all tender records.
The auditor shall check
- whether these tender records are approved by the authorized employees and the approval records;
 - whether all the customer requirements listed on the tender records are satisfied;
 - whether the tender records are filled in with correct information.

Audited Document: Tender Record D

- (8) Please provide the tender reference index.
Auditor shall check which tenders are successfully bid.
- (9) Please provide the signed service contract.
Including the contract signed after the successful tender bid, the contracts signed with service suppliers (include the outsourced logistic service, transportation agent, warehouse cleaning and pest control service, etc.), the contract signed with medical device suppliers, etc.

Auditor shall check whether

- The contract is within its valid period. If expired, a new contract shall be signed;
- The corporate is capable of fulfilling all the customer requirements as listed in the contract.

- (10) How the stock of medical devices be controlled?
Sales department shall be capable of anticipating the products demand. The corporate can request the Sales Department to regularly evaluate the

Chapter 23. Certification Audit by the Assessment Body

sufficiency of stock quantity, perform products procurement in advance so as to avoid any customer complaint due to stock-out.

Accounts Department

Interviewees: Department Manager, Accounting Clerk

(11) Please provide all the invoices and delivery notes.

Auditor shall check

- whether all the invoices are approved by authorized employees e.g. the accounts department manager, whether all the delivery notes are recorded with proof of products receipt from the customer such as customer company chop, signing, etc.
- whether the actual products delivery date matches with the date as requested by the customer.

(12) According to Quotation A and Quotation B, please provide corresponding invoice and delivery note.

Auditor shall check

- whether the invoice and delivery note contents (e.g. product model, quantity and price) match with that listed on the Quotation A and Quotation B;
- whether the actual products delivery date matches with the date as requested by the customer.

Audited Documents: Invoice C, Invoice D, Delivery Note E, Delivery Note F

(13) Please provide the purchase order issued to the manufacturers.

Auditor shall check whether the purchase orders listed out all the customer requirements of medical device defined by the corporate.

Audited Documents: Purchase Order G (include the purchase quantity of product H and the warehouse stock-in date)

Administration Department

Interviewee: Department Manager

(14) Is the software regularly validated?

The corporate shall prove that all the software that may affect the products quality and service is validated regularly.

(15) How the corporate store and create a backup of the records in the computer?

All the records are usually stored in one computer. But for some important records, the corporate shall create a backup in another device in order to prevent any information loss due to computer damage.

(16) Does the corporate define the staff competence requirements for certain position, and take into consideration these requirements during staff employment?

Some positions may require specific competence, for example, operation of the forklifts in the warehouse, conduction of microbiological tests on sterile devices, performance of quality evaluation, etc. When the corporate is recruiting such staff, all the specific competences shall be listed in the job descriptions during advertisement, and shall be evaluated during job interviews.

(17) Please provide the records of staff training, qualification and professional

Chapter 23. Certification Audit by the Assessment Body

license.

Auditor shall check whether the professional license is valid and whether the staff trainings are conducted regularly or on need basis, especially for those staff re-training as a result of CAPA. Besides, auditor shall check whether the staff trainings are effectively performed with evaluation records such as oral or written examination.

- (18) Does the corporate distribute product samples to the customers? If yes, please provide records to verify.
When medical device samples are distributed to the customers, it is recommended to properly identify the products by labeling. If the medical device samples are not suitable to be used on patients (maybe due to damaged package), it shall be clearly written on the label.
- (19) Please provide all the internal audit records.
Auditor shall check whether (a) the internal audit scope covered all the documented procedures and the work instructions, (b) the internal audit checklist is appropriately filled in, (c) all the nonconformities discovered are properly handled with CAPA and follow-up actions.

Logistics Department

Interviewee: Department Manager, Logistic employees

- (20) Any regular sampling inspection to check the conformity of products?
Regular sampling inspection procedures may involve the checking of damaged products, expiry date and the cleanliness of the product package. For some medical devices, additional inspection procedures that required the checking of appearance of mold/vapor on the medical device surface, etc.
- (21) Do the medical devices be inspected during the warehouse in and out processes? Please provide the inspection records.
Inspection usually involves the checking of (1) package, (2) device name, lot number, quantity, etc., (3) expiry date, (4) condition of the medical devices, especially for those medical devices which is easily fragile, temperature sensitive or humidity sensitive. After the inspection, the authorized employees shall confirm the inspection results by signing or stamping the corporate chop.
- (22) With refer to Purchase Order G, please provide the corresponding inspection record of product H during stock-in.
Auditor shall check whether the stock-in date, device name and lot number of product H written on the inspection record match with that written on the purchase order. The inspection record by the authorized employee (e.g. signature or company chop) shall also be checked.
- (23) With refer to Delivery Note E and Delivery Note F, please provide the corresponding inspection records during stock-out.
Auditor shall check whether the export date, device name and lot number written on the inspection record match with that written on the purchase order. The inspection record by the authorized employee (e.g. signature or company chop) shall also be checked.
- (24) Please provide the stock location and product quantity of the Medical Device I and Medical Device J.
Auditor shall conduct on-site inspection and check if its storage location and quantities match with the records.

- (25) Please provide the quantity of nonconforming products and their handling method.

Auditor shall conduct on-site inspection of the segregation area and check if (a) the nonconforming products are correctly labeled (non-conforming product, recall product, product sample, etc.), (b) the product quantities match with the records.

Management

Interviewees: Top Management, Management Representative, Leader of the Quality Management Team.

- (26) Did the corporate conduct management review meeting?

Auditor shall inquire the management representatives about the procedures of the management review meeting, including the scheduling of meeting, pre-meeting preparation, responsibility of each department, meeting agenda planning, meeting minutes compiling, etc.

- (27) Please provide the minutes of the last management review meeting.

Auditor shall check whether all the review inputs and review outputs are evaluated and recorded, whether the meeting is organized as according to documented procedures and whether all the CAPA and improvements suggested during the meeting are properly implemented.

24. Audit Report

In normal situation, the assessment body shall issue the audit report within one week after the on-site audit. The audit report summarizes all the nonconformities and observations found during the audit.

Sample of audit report:

Audit Report

Introduction

Name of the corporate being audited		Number of employees
Audit date/duration	Certificate/Standard	Site address
Audit objectives		
Audit scope		

Audit Results

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Areas Assessed and Findings

Top Management and Management Representative + System Evaluation
Device Calibration
Control of Documents + Information Technology
Competence, Awareness and Training
Sales and Marketing Strategies
Purchasing Procedures

Chapter 24. Audit Report

Warehouse Management and Logistic + Products Repackaging
Service and Maintenance

Descriptions of Minor Nonconformity, Major Nonconformity, Observation

Reference number	Scope	MDGDP clause
Details		
Requirements of MDGDP		
Objective Evidence		

Assessment Participants

Name	Position

Assessment Auditors

Name	Position

Report prepared by	Prepared date

25. Corrective and Preventive Actions based on Audit Results

After the on-site audit, assessment body shall announce in the closing meeting all the nonconformities found during the audit, and whether the corporate passes the audit. For those minor nonconformities, the corporate shall fill in the CAPA report describing the content of nonconformity, root cause investigation, suggested CAPA action and the follow-up progress. Filled CAPA report shall be submitted to assessment body within one week after the closing meeting. The CAPA report format can refer to the CAPA record.

In general, several minor nonconformities or observations may not result in failure of compliance during audit, but major nonconformity may possibly result in failure of compliance. Several minor nonconformities appear in the same procedure may result in total breakdown of the system therefore a non-compliance to meet MDGDP requirements, and become a major nonconformity.

26. Resources Required for MDGDP Establishment

The most important resource for establishing MDGDP is a quality management team with audit experience. As mentioned in the beginning of this reference manual, quality management team can either be formulated as an independent department or composed of several employees. Some corporate may also employ a third-party consulting firm in short term, for assisting the quality management team in system establishment and staff training.

Other resources include

- Small office area for storing the controlled documents, uncontrolled documents and records.
- A segregation area designated for storing nonconforming products, recall products, disposal products, sample products and products pending for further inspection.
- Budget for the printing of documents and records
- Budget for staff training
- Annual audit fee
- Budget for purchasing and re-calibration of measurement devices
- Other related resources

27. Third-party Consultancy Service

There are many consulting firms providing one-stop service, to assist the corporate in establishing the quality management system and training the employees.

Consulting firms understand the certification procedures, auditors' requirements, record filling requirements, etc. They can also provide on-site support to the corporate during audit, in order to ensure a smooth system building and audit process.

