Detailed Operating Guidelines for GMP Inspection on the Oversea Manufacturers of Import Medical Devices

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Korea Food & Drug Administration
Department of Medical Device Safety
Division of Device Quality Control
I. Purpose and Authority

Based on the authority of “Medical Device Regulation” and “Medical Device Production & Quality Control Measure” (Notice), the purpose is to establish Detailed Operating Guidelines for GMP Inspection on the oversea manufacturers of import medical devices.

- In accordance with adopting GMP Inspection on the oversea manufacturers of import medical devices, the goal is to provide the detailed operating guidelines regarding system, methods, and procedures therein, in order to seamlessly implement the said inspection.

Legal Authority

- “Medical Device Regulation” Section 15, Chapter.6
- “Medical Device Regulation & Enforcement” Section 20, Chapter 1, Sub 4-2, and [Appendix 3]
- “Medical Device Production & Quality Control Measure” (hereafter “GMP Notice”)

II. Detailed Operation Guidelines

1. GMP Inspection System

(Inspection Group) Inspection required of the oversea manufacturers

- In principle, GMP Inspection is required of oversea manufacturing sites (hereafter “Manufacturing Site(s)”) including Initial Inspection, Periodic Renewal Inspection (3 years), Additional Inspection (Product Group), and Modification Inspection (Location).

- (Initial Inspection) Inspection performed on the oversea manufacturers of import medical devices or the importers

  - Upon commencement of the revised GMP Notice (April 8th), the inspection is performed the first time on Manufacturing Site of the import product permit (declaration) or of Manufacturing Site that the importer applies for.

- (Periodic Renewal Inspection) It is performed at least once or more every 3 years for the periodic outside quality inspection.

- In case of renewing the said conformity certification upon its expiration of Certificate of Conformity
  - (Additional Inspection) It is performed when adding medical devices of other Product Group according to GMP Notice, Appendix 3 Manufacturing Site.
  - (Modification Inspection) It is performed when Manufacturing Site is changed.

- An exception is made to storages and laboratories with little relation to the product quality.

(Principal Applicants for Inspection) Importers of Medical Devices

- In principle, the importers of medical devices must apply for GMP Inspection of the overseas manufacturers identified on the certificate of product permit (declaration) for the imported medical devices.

(Scope of Inspection) Inspection by Product Group or Manufacturing Site

- In case of Initial or Additional Inspection(s), it is performed on the applicable Product Group per each Manufacturing Site.

- In case of Periodic Renewal or Modification Inspection(s), it is performed on the each Manufacturing Site.

(Principals of Inspection) Joint Inspection by MFDS and 3rd Party inspection

- The inspection team consisting of Medical Device Inspection Board (hereafter Inspectors) of Ministry of Drug and Food Safety (hereafter MFDS) and the quality auditors of 3rd Party Organization (hereafter 3rd Party) are to conduct Joint Inspection.

  - In case of Periodic Renewal Inspection, the principal Inspectors of MFDS are classified according to the highest class of the permitted (declaration) domestic products per Manufacturing Site that are held by the domestic importers. (GMP Notice Ch.6, Main Office: class 3~4, Regional Office: class 1~2)

(Inspection Method) Conducting Documentation or Site Inspection

- (Documentation Inspection) Without Site Inspection, per GMP Notice Sec.7, MFDS and 3rd Party jointly perform Documentation Inspection of the submitted materials.

- (Site Inspection) Per GMP Notice Sec.7, Documentation Inspection is performed on the submitted materials and Site Inspection is performed on Manufacturing
Site of the import medical devices, which is classified for the Independent or Joint Site Inspection.

- **(Independent Site Inspection)** MFDS performs Documentation Inspection based on findings of the documents reviewed and Site Inspection by 3rd Party.
- **(Joint Site Inspection)** MFDS and 3rd Party perform jointly the documents reviewed and Site Inspection.

☐ **(Subjects of Documentation Inspection)** In the following cases, Documentation Inspection is performed.

  - **(Initial Inspection) Class 1 (66 products subject to inspection) Medical Devices**
    - For newly developed medical devices or Manufacturing Site, in which a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years, Site Inspection is to be performed.
  
  - **(Additional Inspection) Class 1 (66 products subject to inspection) and Class 2, 3, 4 Medical Devices**
    - For newly developed medical devices or Manufacturing Site, in which a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years, Site Inspection is to be performed.
  
  - **(Modification Inspection) Class 1 (66 products subject to inspection) and Class 2, 3, 4 Medical Devices**
    - In case of Class 1 medical devices, for newly developed medical devices or Manufacturing Site, in which a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years, Site Inspection is to be performed.
    - In case of Class 2, 3, 4 medical devices, Documentation Inspection is performed when materials are submitted per Sub.2(d) and Sub.2(g) of GMP Notice Sec.7 Ch.1 Sub.2; Site Inspection is performed if said documents are not submitted, or for newly developed medical devices or Manufacturing Site, in which a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years.
  
  - **(Periodic Renewal Inspection) Class 1 (66 products subject to inspection) and Class 2 Medical Devices**

☐ **(Subjects of Independent Site Inspection)** In the following cases, Independent Site Inspection is performed.

  - **(Initial Inspection) Class 2 Medical Devices**
    - It is substituted for Documentation Inspection instead when other domestic importers hold GMP Certificate of Conformity on the corresponding Manufacturing Site; Site Inspection is performed if a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years.
  
  - **(Periodic Renewal Inspection) Class 3 Medical Devices**
    - It is performed only if no inadequate quality decision was given and no safety/efficacy issues occurred within the last 3 years from the expiration date of Certificate of Conformity.
    - For importers that import medical devices from 2 or more Manufacturing Sites, Site Inspection is performed on only 1 Manufacturing Site (Documentation Inspections on other sites) considering present circumstances (expense, manpower, etc.).

☐ **(Subjects of Joint Site Inspection)** In the following cases, Joint Site Inspection is performed.

  - **(Initial Inspection) Class 3, 4 Medical Devices**
    - It is substituted for Documentation Inspection instead when other domestic importers hold the GMP Certificate of Conformity on the corresponding Manufacturing Site; Site Inspection is performed if a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years.
  
  - **(Periodic Renewal Inspection) Class 3, 4 Medical Devices**
    - In case of Class 3 medical devices, it is performed if a non-compliance decision was given within the last 3 years from the expiration date of Certificate of Conformity or if safety/efficacy issues occurred within the last 3 years.
    - For importers that import medical devices from 2 or more Manufacturing Sites, Site Inspection is performed on only 1 Manufacturing Site (Documentation Inspection on other sites) considering present circumstances (expense, manpower, etc.).
### Summary of GMP Inspection System

<table>
<thead>
<tr>
<th>Division</th>
<th>Initial Inspection</th>
<th>Additional Inspection</th>
<th>Modification Inspection</th>
<th>Periodic Renewal Inspection a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1 Medical Devices</td>
<td>Documentation Inspection 1)</td>
<td>Documentation Inspection 2)</td>
<td>Documentation Inspection 2)</td>
<td>Documentation Inspection 2)</td>
</tr>
<tr>
<td>Class 2 Medical Devices</td>
<td>Independent Site Inspection 2)</td>
<td>Documentation Inspection 1)</td>
<td>Documentation Inspection 1)</td>
<td>Documentation Inspection 1)</td>
</tr>
<tr>
<td>Class 3 Medical Devices</td>
<td>Joint Site Inspection 3)</td>
<td>Documentation Inspection 1)</td>
<td>Documentation Inspection 1)</td>
<td>Independent Site Inspection 5)</td>
</tr>
<tr>
<td>Class 4 Medical Devices</td>
<td>Joint Site Inspection 3)</td>
<td>Documentation Inspection 1)</td>
<td>Documentation Inspection 1)</td>
<td>Joint Site Inspection 6)</td>
</tr>
</tbody>
</table>

1) Site Inspection is performed for newly developed medical devices, or if a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years. (Class 1, 2: Independent Site Inspection; Class 3, 4: Joint Site Inspection)

2) When other domestic importers hold GMP Certificate of Conformity on the corresponding Manufacturing Site, it is substituted for Documentation Inspection instead; Site Inspection is performed if a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years.

3) In case of Class 2, 3, 4 medical devise, Documentation Inspection is performed when materials are submitted per Sub.2(d) and Sub.2(g) of GMP Notice Sec.7 Ch.1 Sub.2; Site Inspection is performed if said documents are not submitted, or for newly developed medical devices or Manufacturing Site, in which a non-compliance decision was given or safety/efficacy issues occurred within the last 3 years. (Class 1, 2: Independent Site Inspection; Class 3, 4: Joint Site Inspection)

4) For importers that import medical devices from 2 or more Manufacturing Sites, Site Inspection is performed on only 1 Manufacturing Site (Documentation Inspection on other sites).

5) When no inadequate quality decision was given within the last 3 years from the expiration date of Certificate of Conformity and no safety/efficacy issues occurred within the last 3 years.

6) If a non-compliance decision was given within the last 3 years from the expiration date of Certificate of Conformity or safety/efficacy issues occurred within the last 3 years.

### GMP Inspection Method and Procedure

1. **Documents Submitted**
   - The Scope of Documents Submitted for GMP Inspection Application

2. **Application**
5

Korea Food & Drug Administration – translated and provided by Kobridge Consulting just for reference

Document Submission per GMP Notice Sec.7 Ch.1 and Ch.3
- GMP application is not allowed if all or part of materials are not submitted.
  **For the detailed information on submitted materials, refer to GMP Commentary on Medical Devices.
  ※Submitted Materials follow GHTF recommendations.
  Refer to the final documents of GHTF, Sub.6.a (Information required from the manufacturer) of Sec.6.6 (Auditing Planning) in the document GHTF/SG4/N30:2012 {Guidelines for Regulatory Auditing of Quality Management System of Medical Devices Manufacturers – Part 2: Regulatory Auditing Strategy.

<table>
<thead>
<tr>
<th>GMP Notice Sec.7 Ch.1 and Ch.3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Copy of Import Permit (or a conditional import permit)</td>
</tr>
<tr>
<td>2) a) Summary of Manufacturing Site (names and addresses of the sites, if multiple, names of all sites)</td>
</tr>
<tr>
<td>b) Total number of employees that participate in the operation of manufacturing and product quality related.</td>
</tr>
<tr>
<td>c) List of medical devices manufactured at the corresponding Manufacturing Site (including product name and class)</td>
</tr>
<tr>
<td>d) Copy of Certificate of Conformity in product management system (if applicable)</td>
</tr>
<tr>
<td>e) Summary of equipment at Manufacturing Site to be evaluated (including blueprint, facility and equipment list)</td>
</tr>
<tr>
<td>f) Site location and business scope of major suppliers (including contracts for consignment processing)</td>
</tr>
<tr>
<td>g) Data from the evaluation reports received from other certifying agencies (if applicable)</td>
</tr>
</tbody>
</table>
  * Data from the evaluation reports: For Manufacturing Site that received the inspection from certifying agencies of foreign product quality system within the last 3 years, the verifiable report or data summary data from the said evaluation reports (certifying agency, inspection type, period, result) |
|  h) Product User Manual |

<table>
<thead>
<tr>
<th>Manufacturing Sponsor – Manufacturing Site consisting of manufacturer shall submit the following data:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Manufacturing Sponsor) Materials per Sub.2(a), Sub.2(d), and Sub.2(g) of GMP Notice Sec.7 Ch.1 Sub.2</td>
</tr>
<tr>
<td>(Manufacturer) All materials per GMP Notice Sec.7 Ch.1 Sub.1 and Sub.2</td>
</tr>
<tr>
<td>Summary regarding Quality Management System of the manufacturing sponsor/manufacturer (the interaction, roles, managing practices, etc. relating Quality Management System)</td>
</tr>
<tr>
<td>The copy of the permit for the corresponding product in the case of Initial Inspection for the manufacturing sponsor/manufacturer.</td>
</tr>
</tbody>
</table>

** (Duration of Inspection) The duration of GMP Site Inspection
- 3~5 days per Manufacturing Site (4 days standard)
  - The number of days required for the inspection is determined by considering the number of products for domestic permit (declaration), the number of employees for Manufacturing Site, the complexity of
manufacturing process, the travel schedule (estimated time of the expected arrival), and etc.

☐ (Personnel for Inspection) The personnel for GMP Site Inspection
- **Total Personnel:** 1~3 persons
- The personnel for Site Inspection is determined by considering the number of products for inspection, manufacturing process, the particulars of Manufacturing Site, and etc.
- Independent Site Inspection: 1 person from 3rd Party
- Joint Site Inspection: 1~2 persons from MFDS, 1 person from 3rd Party

☐ (Inspection Expenses and Payment Method) Expenses Incurred for GMP Inspection
- The expenses incurred for the inspection, in principle, is “paid by the beneficiaries (the applicants).”
  - The grounds for the authority: Medical Device Regulation & Enforcement [Appendix 3] Sub.7(e) and Rules regarding Beneficiary Responsibility of Overseas Travel Expenses (MFDS Standard Operating Procedure) Sec.2 Ch.7
- The expenses incurred for the inspections are subcategorized into the application fee*, inspection charges (Site or Documentation), and the travel expenses** (only applicable to Site Inspection).
  - * The application fee is paid at the time of application for GMP Certificate of Conformity (Initial, Additional, Modification, Periodic), and paid only once if the importers apply for a batch Periodic Renewal Inspection.
  - ** The travel expenses shall only incur the actual spent [Appendix 3] according to Regulatory Officials Travel Expenses Order (Executive Order) and Business Expenses Reimbursement Criteria (Ministry of Public Administration & Safety SOP), and consist of airfare, daily allowance, meals and accommodation, and etc.
    - ※ For airfare, the system for Government Transportation Regulations (GTR) is applicable (in principle, the airline of its nationality-origin is to be used).
- The language used for submitted materials and the inspection during GMP Inspection
  - All submitted documents, in principle, are to be composed and submitted in the Korean language.
  - The documents (records) issued by Manufacturing Site or outside agencies may be submitted in English such as Product User Manual, Device Master Record, GMP Certificate, and etc.
    - ※ The foreign languages (Japanese, German, etc.) other than English are accepted only when the original and the Koran translation are accompanied.
- The language used during Site Inspection shall be Korean.
  - Utilizing translators (professional translators, related personnel of the importers, etc.)
  - The overseas manufacturers shall prepare thoroughly for GMP Inspection to be performed flawlessly
    - ※ The troubles stemming from language and translation may affect adversely to the inspection results.

☐ (Timing of Inspection Application) The timing to apply for GMP Inspection
- The importers must remit the inspection expenses before commencing the inspecting, and the inspection schedule may be cancelled if the said expenses are unpaid.
- Payment methods for Inspection expenses
  - Remittance to 3rd Party (Application Fee, Inspection Charges, Travel Expenses)
  - Remittance to MFDS (Travel Expenses): Remitted to a bank using the MFDS issued bill.
  - ※ For expenses, the respective agencies determine the amount and bill for payment.

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- All submitted documents, in principle, are to be composed and submitted in the Korean language.
  - The documents (records) issued by Manufacturing Site or outside agencies may be submitted in English such as Product User Manual, Device Master Record, GMP Certificate, and etc.
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- The language used during Site Inspection shall be Korean.
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  - The overseas manufacturers shall prepare thoroughly for GMP Inspection to be performed flawlessly
    - ※ The troubles stemming from language and translation may affect adversely to the inspection results.

☐ (Timing of Inspection Application) The timing to apply for GMP Inspection
- The importers must obtain the GMP Certificate of Conformity of the corresponding Manufacturing Site prior to commencing the sale of Import Medical Devices.
It is acceptable if the inspection is performed prior to the same of medical devices, and it is possible to apply even before the product permit (declaration).

The importers can choose at their discretion the timing to apply for the inspection after having considered the respective applicability of Site Inspection according to the inspection group (Initial, Periodic, Additional, and Modification).

As for Periodic Renewal Inspection, however, it must be applied at least 3 months before the expiration of Certificate of Conformity (GMP Notice Sec.7 Ch.2)

* The application in GMP Notice Appendix 1 form should be filled in and submitted to 3rd Party.

When the importers hold multiple Manufacturing Sites

- For importers that hold 2 or more Manufacturing Sites applicable for Periodic renewal Inspection, the Periodic Renewal Site Inspection is performed on only 1 Manufacturing Site, and Documentation Inspection is performed on other Manufacturing Sites, having considered the present circumstances (expense, manpower, etc.).

- In the relation between manufacturing sponsors (manufacturing consignors) and manufacturers (manufacturing fiduciaries), when overseas manufacturers hold 2 or more manufacturers to the same manufacturing sponsor, Site Inspection is performed on only 1 manufacturer, and Documentation Inspection is performed on the other manufacturers, but only if the following conditions are met.
  - The documents that substantiates the manufacturing sponsor-manufacturer relationship (relationship between the manufacturer and Manufacturing Site, etc.) must be submitted (e.g.: GMP Certificate of Conformity from the government or the government agencies of the corresponding Manufacturing Sites, or the certificate of manufacturing sales, etc.), and
  - The manufacturing sponsor-manufacturer relationship must be verifiable through the certificate of product permit (declaration),

- All materials of Sub.2(d) and 2(g) of GMP Notice Sec.7 Ch.1 Sub.2 must be submitted by both the manufacturing sponsor and the manufacturer.

  - In case of reagents (class 3) for the vitro diagnostic analyzer, Site Inspection is performed on only 1 Manufacturing Site, and Documentation Inspection is performed on the other sites, but only if all of the following conditions are met,
    - It must be the product of domestically selling Product Group before permit (before 12.31.2012),
    - Materials of Sub.2(d) and 2(g) of GMP Notice Sec.7 Ch.1 Sub.2 must be submitted.

Batch Application of Periodic Renewal Inspection

- When the importers are applying for Periodic Renewal Inspection due to the expiration of GMP Certificate of Conformity, it must be applied for each Manufacturing Site.
  - If there are multiple Manufacturing Sites, the batch application is acceptable by completing the generalized list of the application form (GMP Notice Appendix 1 form).
  - In this case, the application materials for Manufacturing Site in the generalized list must be submitted by each Manufacturing Site, and the application fee and inspection charges (documentation or site) be remitted to 3rd Party.
  - The importers may divide the applications by Manufacturing Site considering the circumstances of preparation for the materials submitted.

  ※ When applying by a batch application, Site Inspection is performed on only 1 Manufacturing Site of all the Manufacturing Sites with the same expiration date.

(Selecting Criteria of Site Inspection) The selecting criteria of Site Inspection for Periodic Renewal Inspection

- When Site Inspection is performed on part of the Manufacturing Sites because of a batch application by the importers with multiple Manufacturing Sites, the selecting criteria are,
- Manufacturing Site that with issues of non-compliance or safety/efficacy occurred;
- Manufacturing Site that contains products with high risks;
- Manufacturing Site with a great deal of amount in domestic imports;
- Manufacturing Site with no previous GMP Site Inspection
- Manufacturing Site that submitted the explanation regarding the submitted materials at the time of applying;
- Manufacturing Site that are otherwise deemed necessary by MFDS director for Site Inspection.

☐ (Inspection Results) Processing the Results of GMP Inspection
  o GMP Inspection Criteria & Evaluation Matrix: GMP Notice [Appendix 2]
  o Processing Criteria of GMP inspection (Site and Documentation): Distinguished for Conform, Need-to-Correct, and Not-Conform.
    - Criteria for Conform, Need-to-Correct, Not-Conform: refer to “Medical Device GMP Guidelines”.
    - In case of Conform, GMP Certificate of Conformity is issued to the corresponding importer.
    - In case of Not-Conform, the details of non-conformity and prohibition of sale are notified to the importers.
      ※ When Manufacturing Site receives Not-Conform, an aggregated audit is performed with regard to the corresponding importer.
      ※ In case of Need-to-Correct, 1) the importer is notified of details to be corrected → 2) the importer submit the corrective materials within the period of correction required → 3) the conformity is determined after reviewing the corrective documents (if not submitted, Not-Conform)
      ※ The corrective materials are submitted by the importers to the corresponding 3rd Party in a documented format.

☐ (Certificate of Conformity) Issuing Certificate of Conformity
  o Certificate of Conformity is issued to the importer that applied for GMP Inspection.

- Detailed Information: name of importer, location, executive officer, name and location of the inspected Manufacturing Site are concurrently documented.
  ※ If Manufacturing Site requires an additional Certificate of Conformity, it must be requested for the additional issuance (the fees for additional issuance must be paid) to the corresponding 3rd Party.

☐ Chart for the Process of Site Inspection

수입업자(외국제조소): Importer (Overseas Manufacturing Site)
품질관리 심사기관: Quality Control 3rd Party
식약청: MFDS

3. GMP Inspection Management Plan
When multiple importers are applying for the product permit (declaration) from the same Manufacturing Site,

- In principle, each importer must receive separate GMP Inspection regarding the corresponding Manufacturing Site.
  - Each importer must hold GMP Certificate of Conformity for its Manufacturing Site.
  - When another importer for the first time desires to import medical devices from Manufacturing Site that has received GMP Certificate of Conformity, and to receive GMP Certificate of Conformity, GMP conformity evaluation must be performed as ‘Initial Inspection’.
    - It is applicable to initially receiving the product permit (declaration), and etc.
    - The corresponding Manufacturing Site has already received GMP Certificate of Conformity, and since it is not considered a new Manufacturing Site, Documentation Inspection is performed.
    - It shall be valid given for the period of 3 years from the date of receiving conformity certification.
  - In case of the importers acquiring products in part or in whole from an existing importer, and the products are from Manufacturing Site that received GMP conformity certification,
    - GMP conformity evaluation is not newly needed.
    - The corresponding importer shall manage by ‘re-issuing of replacement’ based on documents that will validate the acquisition (MFDS official letter, etc.).
    - The re-issuing of replacement is issued by a request to the corresponding 3rd Party that already issued GMP Certificate of Conformity (remit the fees for re-issuing replacement).
    - The original expiration date is applicable to the re-issued replacement GMP Certificate of Conformity.
  - In case of Periodic Renewal Inspection, each importer is separately required to newly receive GMP conformity certification upon the expiration of Certificate of Conformity regarding the corresponding Manufacturing Site.

- However, multiple importers may receive an inspection by Periodic Renewal Inspection at the same time through a batch application even if each importer’s expiration date of GMP Certificate of Conformity from the same Manufacturing Site may be different.
  - When multiple importers apply at once by a batch application, the expenses required for GMP Inspection are to be determined among the corresponding importers at their discretion.
  - GMP Certificate of Conformity will be issued for each importer of the batch applicants, and the expiration date is 3 years from the date of receiving conformity certification.

- In case of Periodic Renewal Inspection, when the expiration date for Certificate of Conformity has elapsed on account of GMP Site Inspection of Manufacturing Site, the details of deferring action to ban sales
  - When the expiration date of GMP Certificate of Conformity has elapsed, the import medical devices of the corresponding Manufacturing Site, in principle, is prohibited from selling (GMP Notice Sec.9 is applicable)
    - However, the action to ban sales is deferred on the following reasons entailing the expiration of GMP Certificate of Conformity on account of GMP Site Inspection of Manufacturing Site, <The Basic Requirements>
      - Periodic renewal Inspection must be applied for within 90 days after the expiration date of GMP Certificate of Conformity has elapsed.
      - When the expiration date has elapsed for the reasons of determining the inspection schedule on Manufacturing Site of Site Inspection despite the importer has complied with the basic said requirements.
        - However, even in this case, if the inspection result is Need-to-Correct after Site Inspection, and the expiration date has elapsed as a result, the sale after the expiration date is prohibited.

- When the importer apply at once for a batch of Periodic Renewal Inspection of multiple overseas manufacturers for Site Inspection and Documentation
Inspection simultaneously, the time of issuing GMP Certificate of Conformity stemming from the difference in the duration of conducting investigations.  
- GMP Certificate of Conformity is issued counting from the date of the conformity certification according to the results of the inspections. 
- When the importer apply for a batch of Periodic Renewal Inspection, GMP Certificate of Conformity is issued based on the appropriate date for the final completion of Site or Documentation Inspection on all applied Manufacturing Sites.  
  ※ Only if within the expiration date of the current GMP Certificate of Conformity.  
  - However, among Manufacturing Sites on the batch application, when the conformity certification is made after the expiration date has elapsed for the reason of Site Inspection, each may be issued separately based on the results of Documentation Inspection and Site Inspection.

III. Action Measure and Administrative Matters

☐ This Guidelines shall be notified to the relevant agencies of Medical Device GMP Inspection and the importer, and publish on the homepage.  
☐ Also promote to quality control inspection agencies and related associations (Korea Medical Devices Industry Association, Korea Medical Devices Industrial Coop. Association, Korea Dental Industry Association, etc.)  
☐ This Guidelines will be in effect until the next revision date.

[Appendix 1]
[Appendix 2]
Chart for Periodic Renewal inspection and Detailed Description
Applying
- Submitted to 3rd Party
- Submitted Materials
- Submitted payment

Discussing Inspection
- MFDS <-> 3rd Party
- Determine Site Inspection Candidate
- Assemble Schedule and Inspection Team

Discussing Inspection
- 3rd Party -> Applicant (Schedule, Inspection Charges and Travel Expenses)
- MFDS -> Applicant (Bill for Travel Expenses if Overseas Manufacturing Site)

Notify Inspection
- 3rd Party -> Applicant (Schedule, Inspection Charges and Travel Expenses)
- MFDS -> Applicant (Bill for Travel Expenses if Overseas Manufacturing Site)

Review Documents
- Review Product User Manual
- Review Device Master Record
- Review GMP certificate of Overseas Manufacturing Site

Site Inspection
- Conformity of Facility Management
- Applicability of Establishing (Documentation) GMP System
- Appropriateness of applying GMP System

Notify Results
- Conform: Issue Certificate of Conformity
- Need-to Correct: Request Correction (30 Days Deadline)
- Not-Conform: Notify via Official Letter

Site Inspection Candidate
- Manufacturing site of newly developed Medical devices
- Manufacturing site of initial GMP Inspection
- Manufacturing site with Non-Conformity or safety/efficacy reports within the last 3 years

Inspection Schedule
- Overseas: 2-3 Persons, 3-5 Days
- Travel Expenses
  - Paid-by-Beneficiaries Principle Applicable

Additional Product Group
- System Applicability Regarding Additional Product Group
- Applicability of Overseas QMS Certificate of Conformity

Measures for Non-Conformity
- Require substantiation on Non-Compliance of GMP Criteria and Violation of Regulations
- Administrative Disposition, Audit Importer

Correction Request
- Correction Request within Period of 30 Days
- Submit Correction Result via Documentation
## Appendix 3 Overseas Travel Reimbursement Criteria for Regulatory Officials Travel Expense (Unit: US Dollars ($))

<table>
<thead>
<tr>
<th>Division</th>
<th>Level</th>
<th>Daily Allowance</th>
<th>Accommodation (Fixed Amount)</th>
<th>Foods</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Person corresponding to 2(a) of Appendix 1 - Section Leader, Officer, Researcher - Quality Control 3rd Party Inspectors</td>
<td>A</td>
<td>30</td>
<td>150</td>
<td>81</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>30</td>
<td>116</td>
<td>59</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>30</td>
<td>77</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>30</td>
<td>64</td>
<td>37</td>
</tr>
<tr>
<td>6. Person corresponding to 2(b) of Appendix 1 - Government Official Level 6 or Lower</td>
<td>A</td>
<td>26</td>
<td>132</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>26</td>
<td>105</td>
<td>49</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>26</td>
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<tr>
<td></td>
<td>D</td>
<td>26</td>
<td>60</td>
<td>30</td>
</tr>
</tbody>
</table>

○ The differentiation of level per country and city is as following.

a) Level A: Tokyo, New York, London, Los Angeles, Moscow, San Francisco, Washington DC, Paris, Hong Kong

b) Level B

1) Asia, Australia: Taiwan, Beijing, Singapore, Uzbekistan, India, Japan, Kazakhstan, Papua New Guinea

2) South, North America: Mexico, The United States, Brazil, Seychelles, St. Lucia, St. Kitts Nevis, Argentina, Haiti, Jamaica, Canada

3) Europe: Greece, The Netherlands, Norway, Denmark, Germany, Russia, Luxembourg, Belgium, Sweden, Swiss, Spain, Iceland, United Kingdom, Austria, Ukraine, Italy, Portugal, France, Finland, Hungary

4) Middle East, Africa: Gabon, South African Republic, Libya, Sudan, United Arab Emirates, Oman, Uganda, Israel, Egypt, Qatar, Côte d’Ivoire, Democratic Republic of Congo, Kuwait

c) Level C

1) Asia, Australia: New Zealand, Marshall Islands, Malaysia, Bangladesh, Vietnam, Brunei, Azerbaijan, Australia, Indonesia, China, Kyrgyz Republic, Thailand, Turkey, Pakistan

2) South, North America: Guyana, Nicaragua, Dominican Republic, Barbados, Venezuela, Belize, St. Vincent and the Grenadines, Antigua and Barbuda, Uruguay, Chile, Costa Rica, Trinidad and Tobago, Panama

3) Europe: Romania, Lithuania, Bulgaria, Ireland, Yugoslavia, Czech Republic, Poland


d) Level D

1) Asia, Australia: Nepal, Laos, Federated States of Micronesia, Mongolia, Myanmar, Sri Lanka, Cambodia, Fiji, The Philippines

2) South, North America: Guatemala, Bolivia, Suriname, Ecuador, El Salvador, Columbia, Paraguay, Peru,

3) Europe: Moldova, Bosnia and Herzegovina, Albania, Estonia, Croatia

4) Middle East, Africa: Gambia, Guinea-Bissau, Guinea, Namibia, Lebanon, Lesotho, Rwanda, Madagascar, Malawi, Mali, Mauritania, Somalia, Algeria, Yemen, Iraq, Iran, Zambia, Zimbabwe, Tunisia

※ For countries not listed in the country/city levels, the level of a country with the shortest distance from the proposed worksite to the capital of that country shall be applicable.