



Detailed Operational Guidelines for GMP Inspection on the Overseas Manufacturers of Import Medical Devices

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Ministry of Food and Drug Safety

Department of Medical Device Safety

Division of Medical Device Safety Evaluation

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□ Purpose and Legal Reference

- Based on the authority of “Medical Device Regulation” and “Medical Device Production & Quality Control Measure” (Notice), the purpose is to establish Detailed Operational Guidelines for **the consistency and transparency of** GMP inspection on the overseas manufacturers of import medical devices.
- In accordance with GMP Inspection on the overseas manufacturers of import medical devices, the goal is to provide the detailed operational guidelines regarding system, methods, and procedures therein, in order to seamlessly implement the said inspection.
- Legal Authority
 - “Medical Device Regulation” Section 15, Chapter 4
 - “Medical Device Regulation & Enforcement” Section 31, Chapter 1, [Appendix 4] and Section 33, Chapter 1,-5
 - “Medical Device Production & Quality Control Measure” (hereafter “GMP Notice”)

□ Detailed Operation Guidelines

○ GMP Inspection System

- (Inspection Group) Inspection Required for Overseas Manufacturers
 - Overseas manufacturers and Manufacturing sponsors of their class 2, 3 and 4 medical devices must be inspected as GMP Inspection Group [Initial Inspection, Regular Inspection (3 years), Additional Inspection (Product Group), and Change Assessment (Location)].
 - (Initial Inspection) Inspection performed for the overseas manufacturers of import medical devices or the importers
 - Initial inspection is performed for the manufacturer that obtains the import license for the first time or for the manufacturer that the importer has requested **firstly**.

- (Regular Inspection) It is performed at least once every 3 years for the periodic quality system assessment
 - In case of renewing the said conformity certification upon its expiration.
- (Additional Inspection) It is performed when adding medical devices of other Product Group according to GMP Notice, **Appendix 3(medical device GMP Product Group)**.
- (Change Assessment) It is performed when the manufacturing site is changed.
 - An exception is made to storages and laboratories with little impact on 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.**
 - (Scope of Inspection) Inspection by Product Group of overseas Manufacturer.
 - In case of Initial or Additional Inspection(s), it is performed on the applicable Product Group per each Manufacturer.
 - **In case of Regular Inspection or Change Assessment, it is performed on Product Group licensed per each manufacturer.**
 - (Principals of Inspection) **Joint Inspection by Regional Ministry of Food and Drug Safety (here after Regional MFDS) and Quality Control 3rd Party.**
 - The inspection team consisting of Medical Device Inspection Board (hereafter Inspectors) of Regional Ministry of Food and Drug Safety (hereafter regional MFDS) and the quality auditors of Quality Control 3rd Party (hereafter 3rd Party) are to conduct joint inspection{GMP Notice Sec. 6, Sec. 8 and [Appendix 4]}.
- (Inspection Method) Conducting Documentation or Document + Site Inspection
 - (Document Inspection) Without Site Inspection, **Regional MFDS and 3rd Party jointly perform Document Inspection of the submitted materials per GMP Notice Sec.7.**
 - (Site Inspection) **Document Inspection is performed on the submitted materials per GMP Notice Sec.7** and Site Inspection is performed on the

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manufacturer of the imported medical devices, as per classification for Independent or Joint Site Inspection.

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

□ Inspection Criteria and Operations

○ (Initial Inspection)

- (On-site inspection) For first registration of the manufacturer by domestic importer
 - ❖ Class 2: independent site inspection; Class 3,4: joint site inspection:
 - (Document inspection) if other domestic importer already has a GMP certificate for the manufacturer, document inspection is performed.
 - Although the manufacturer is qualified as document inspection, for manufacturer of newly developed medical devices, or manufacturer for which a quality non-conformity decision was given within 3 years, or safety issues, Joint Site Inspection is to be performed regardless of the class.
 - Last 3 years: within 3 years after the date of the most recent conformity certification received
 - If the overseas manufacturer has any difficulties due to confidentiality concerns, after the documents describing the reasons are submitted, Site Inspection is performed.
 - (Period of validity): the validity period of the GMP certificate is 3 years in case of site visit inspection, and in case of document inspection only, the effective date of the certificate will be aligned with the certificate held by other license holder if such license exists
- #### ○ (Additional Inspection)
- (On-site inspection) For manufacturer of newly developed medical devices, or manufacturer for which a quality non-conformity decision was given

within 3 years, or safety issues, Joint Site Inspection is to be performed regardless of the class.

- Last 3 years: within 3 years after the date of the most recent conformity certification received
 - If the overseas manufacturer has any difficulties due to confidentiality concerns, after the documents describing the reasons are submitted, Site Inspection is performed.
 - (Document inspection) In case of Additional Inspections, document submission only will be accepted for the compliance certificate
 - (Period of Validity) Since Additional Inspections can be performed for partial inspection instead of full inspection depending on the results of the regular inspection, the validity date of the certificate will be aligned with the period of validity of the initial compliance certificate without extending of Validity Period.
- #### ○ (Change Assessment)
- (On-site Inspection) Site Inspection is performed if said documents are not submitted per sub. 2(d) and Sub. 2(g) of GMP Notice Sec.7 Ch.1 Sub.2.
 - For manufacturer of newly developed medical devices, or manufacturer for which a quality non-conformity decision was given within 3 years, or safety issues, Joint Site Inspection is to be performed regardless of the class.
 - Last 3 years: within 3 years after the date of the most recent conformity certification received
 - If the overseas manufacturer has any difficulties due to confidentiality concerns, after the documents describing the reasons are submitted, Site Inspection is performed.
 - (Document Inspection) 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;
Sub. 2(d): Copy of valid certificate of conformity of quality management system by the government of the manufacturer or its delegating

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authority (materials only for conformity certification of relocation).

Sub. 2(g): Site inspection reports received from other certifying agencies (for relocated manufacturers only).

- (Valid Term) Partial inspection instead of full inspection depending on the results of the regular inspection can be performed. The validity date of the certificate will be aligned with the period of validity of the Initial Inspection or Regular Inspection compliance certificate without extending of Validity Period.
- o (Regular Inspection)
 - (On-site Inspection) it is conducted at least once every 3 years
 - However, as of the date for GMP application, if there are multiple manufacturing sites which have less than 1 year valid period, the summarized list for the manufacturing sites (Representative device, Manufacturer, Manufacturer-Specific device, Terms between sites, etc.) shall be submitted, and then site inspection will be performed on one or more manufacturing sites among the submitted list of the manufacturing sites.
 - ❖ However, if the selected manufacturing site has an issue, an inspection target will be re-selected among the listed sites, and site inspection will then be performed.
 - (Document Inspection) In case of batch applications of GMP on behalf of several manufacturers, as long as one site is receiving inspection, the other sites can be inspected based on documents
 - For manufacturer of newly developed medical devices, or manufacturer for which a quality non-conformity decision was given within 3 years, or safety issues, Joint Site Inspection is to be performed regardless of the class.
 - If the overseas manufacturer has any difficulties due to confidentiality concerns, after the documents describing the reasons are submitted, Site Inspection is performed.
 - If Site Inspection applied by the other domestic importer was already performed, and thus the manufacturer already has a valid GMP conformity

certificate, document inspection will be performed. The validity date will be aligned with the period of validity on the certificate.

- ※ [Appendix 1] Chart of GMP Inspection Procedure and detail explanations.
- ※ [Appendix2] Summary of GMP Inspection System.

2 GMP Inspection Method and Procedure

- (Documents submitted and Scope of Approval)
 - o Document Submission per GMP Notice Sec.7 Ch.1 Sub.1 and Sub.2
 - If all or parts of materials are not submitted, the materials shall be made up immediately after GMP Inspection application.
 - ※ [Appendix4] Scope of Approval for GMP Inspection Materials Submitted.
- (prior consultation) GMP prior consultation
 - o Importer (including overseas manufacturer) and Responsible Inspectors should do prior consultation about all of activities associated with Site Inspection.
 - For inspection schedules, personnel for inspection, duration of inspection, airline schedules, inspection criteria, etc., prior consultation should be done
- (Duration of Inspection) The Duration of GMP Site Inspection
 - o 3~5 days per manufacturing site
 - The number of days required for the inspection is determined by considering the number of products import license, the number of employees for Manufacturing Site, the complexity of manufacturing process, the schedule (estimated time of the expected arrival), and etc.
 - ※ Decision Criteria for duration of Site Inspection
 - 3 days: In case of the manufacturing processes using simple software, medical apps, and etc., or in case of processes of not using software, medical apps, and etc., or in case of change assessment, duration of GMP Site Inspection could be taken as 3 days.
 - 4 days : In other cases.

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- 5 days : In case of any Special Processes(processes of removing pathogenic substances, such as bacteria and virus using human tissues or animal-derived materials, processes using EO and high temperature-high pressure, and radiation sterilization process, not general sterilizing process), or in case of inspection for two or more manufacturers.
- (Personnel for Inspection) The Personnel for GMP Site Inspection
 - Total Personnel: 1~3 person(s)
 - 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: 1 person from 3rd Party
 - Joint: 1~2 person(s) from **Regional 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 legal justification: Medical Device Regulation & Enforcement [**Appendix 2] Sub.2(f) 5**] 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 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.
 - ** Travel expenses shall only incur the actual spent [Appendix 3] according to the Regulation Order of officials’ Travel Expenses (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 (**Recommendations**), and it is determined in consultation with the applicants.
- The application fee and the inspection charges are based on the posted amount by each 3rd Party.
- The importers must remit the inspection expenses before starting the inspection, and the inspection schedule may be **cancelled or adjourned** if the said expenses are unpaid.
- In case of extension of the duration (from departure to arrival) of the inspection due to natural disaster (earthquake, flood, **airline schedule cancelled, and etc.**) all cost (daily expense, meal, accommodation) incurred will be paid separately.
- **If the inspection is terminated early than expected, a portion of the screening costs should be refunded.**
 - * **Inspection charges, Airfare, Daily expenses, Meal expenses, Accommodation costs, Preparation costs (Travel Insurance).**
- Payment methods for Inspection expenses
 - Remittance to 3rd Party (application fee, inspection charges, travel expenses)
 - Remittance to **Regional MFDS** (travel expenses): Remitted to a bank using **the Regional MFDS** issued bill.
 - ※ **For expenses, the respective agencies determine the amount and the bill for payment is issued. Payment, in principle, should be processed before the beginning of the GMP inspection. The inspection schedule may be cancelled or adjourned if the said expenses are unpaid.**
- (Inspection Language) The language used for submitted materials and the inspection during GMP Inspection
 - All submitted documents, in principle, are to be composed and submitted in both languages (Korean and original language).

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- The documents (records) issued by Manufacturer or outside agencies may be submitted in English such as Quality Manual, Device Master Record, GMP Certificate, and etc.
 - ※ The foreign languages(Japanese, German, and etc.)other than English are accepted only when the original and the Korean translation are accompanied.
 - For Manufacturer of non-English speaking countries, GMP inspection is based on original documents in their original language, and for facilitating communication between both languages, an interpreter is used.
 - The language used during Site Inspection shall be Korean.
 - Utilizing translation (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 shall not ill affect the result of inspection.
 - (Timing of Inspection Application) The Timing to Apply for GMP Inspection
 - The importers must obtain the GMP Certificate of Conformity of the corresponding manufacturer prior to commencing the sale* of import medical devices.
 - It is acceptable if the inspection is performed prior to the product license application, and it is possible to apply even before the product license.
 - * Due to the revision of medical device active since [pre-registration GMP] acts, the pre-sale is changed to pre-registration.
 - Regular Inspection must be applied at least **90 days** before the expiration of Certificate of Conformity (GMP Notice Sec.7 Ch.3).
 - However, Site Inspection must be applied at least **20 days** before the expiration of Certificate of Conformity. In case of application without the desired inspection date, it must be applied by documents at least **20 days** before the starting date of the inspection.
- *The application in GMP Notice Appendix 1 form should be filled in and submitted to 3rd Party.
 - Foreign Source of Manufacturing (Manufacturing Sponsor and Manufacturers) Inspection
 - As for manufacturing sponsor and manufacturers, documents to be submitted are as below.
 - (Manufacturing sponsor): Material of Sub.2 (a), Sub.2 (d), Sub.2 (g), Sub.2 (h) of GMP Notice Sec.7 Ch.1. Sub.2
 - (Manufacturers): All material of GMP Notice Sec.7 Ch.1 Sub 1 and Sub 2.
 - * The Sub.2 (d), Sub.2 (g) materials for manufacturing sponsor and manufacturers are limited to the relevant [Appendix4].
 - Overview of the quality management system for manufacturing sponsor and manufacturer (mutual relations in the quality management system, role, and management methods, and 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 Document Inspection is performed on the other manufacturers, but only if the following conditions are met.
 - * The first GMP inspection corresponds only (except for regular inspection).
 - The documents that substantiates the manufacturing sponsor-manufacturer relationship and the manufacturing process managed under the same condition of the quality management system must be submitted
- [e.g.: GMP Certificate of Conformity from the government or the government agencies of the corresponding manufacturer, or letter from the corresponding manufacturer (signature contains)].

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- Relationship between the manufacturing sponsor and manufacturer must be verifiable through the certificate of product permit (if GMP is executed before permission, not applicable).
- 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.
 - ※ 「Medical Device Manufacturing and Quality Control Standards」 Sec.7 Ch.1 Sub 2.
 - † Sub.2(d): Copy of the Certificate of Conformity of the Quality Management System issued from the manufacturer's government or 3rd party delegated by the corresponding government.
 - † Sub.2(g): Inspection result data received from other certificate authorities.
 - Although both of requirements are satisfied,
 - If the manufacturer of newly developed medical devices, or manufacturer for which a quality non-conformity decision was given within 3 years, or safety issues, Joint Site Inspection is to be performed regardless of the class.
 - If the overseas manufacturer has any difficulties due to confidentiality concerns, after the documents describing the reasons are submitted, Site Inspection is performed.
- Determination criteria and control procedures for manufacturers with safety concerns
 - If an adverse event is encountered due to problem of product itself: joint site inspection is performed.
 - If it is difficult to determine that the adverse event caused by product itself,
 - Follow-up action documents (CAPA Reports) related to adverse event shall be submitted by manufacturer. And then confirm whether the follow-up actions (in progress included)* were conducted or not.
- * Confirm whether the appropriate actions, such as user precautions, use contraindications, safety measures, etc. have been implemented or are in progress.
- If follow-up actions were conducted or are in progress: Documents Inspection
- If follow-up actions were not conducted or did not submit the Related documents: Joint Site Inspection
 - ※ If CAPA report is not submitted within 30 days from the mailing date of official document: Joint Site Inspection
 - If a side effect is not due to problem of product itself: Documents Inspection
- GMP Inspection of in-vitro diagnostic medical devices (domestic manufacturer included)
 - For in-vitro diagnostic devices reclassified from drugs ('14.11.10), Site Inspection is performed on only 1 manufacturing site, and Document Inspection is performed on the other sites.
 - *In case of reagents for the in-vitro diagnostic analyzer, the same system as the general medical device GMP inspection system should be applied.
 - *Transition period for the in-vitro diagnostic analyzer: class3,4 (2015.11.10), class2 (2016.11.10).
 - *Site investigation selection criteria should be applied mutatis mutandis to GMP Notice Sec.8 ch.11.
 - Documents Inspection is performed only if the following requirements are satisfied.
 - The manufacturer subject to inspection shall submit the materials for 「Medical Device Manufacturing and Quality Control Standards」Sec.7, Ch.1, Sub.2(d) and Sub.2(g).
 - *If the manufacturing site subject to inspection is in the relation of Manufacturing sponsor and Manufacturer, both of them shall submit the materials of Sub.2(d) and Sub.2(g),

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- In the event that the manufacturer cannot receive the GMP inspection due to the occurrence of war, infectious diseases, natural disasters, and etc.,
 - For a limited time the site investigation is postponed, and document inspection only is performed.
 - For the Document Inspection the materials of GMP Notice Sec.7 Ch.1 shall be submitted, and also the following materials shall be submitted additionally.
 1. A copy of the quality management system conformity certificate issued by the manufacturer's Government or 3rd party authorized from the Government.
 2. Materials for actual inspection results that issued from other certificate authority (Follow-up requirements included).
 3. Finished product test report (If the products were sterilized on the factory inspection reports, included data that can demonstrate the sterilization)
 - If the result of documents inspection is appropriate, a limited-period conformity certificate is issued
- a limited-period conformity certificate is valid until the situation ends
 - * The same applied for all of Initial, Periodic, Change, and Additional Inspection.
- The importer who received a limited-period conformity certificate, shall submit Performance Test Reports etc. according to Self-Quality Control Test-Criteria to Regional MFDS, and shall be delivered after approving. Performance Test Reports etc.: Performance Test Reports for self-quality control, or System Guarantee Materials.
- If Site Inspection to be possible, within 10 days the Inspection preferred date is appointed, and shall notified to the Head of the Quality Control Inspection Agency. Site Inspection shall be performed within 2 months from the date of the situation terminating.
 - * However, if the Site Inspection could not be performed in unavoidable circumstances on the preferred date, the preferred date can be readjusted by consulting with the applicant. If the applicant did not notify within 10

days or did not receive Site Inspection within two months, Prohibition of sale will be notified to the importers.

- Batch Application of Regular 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 manufacturer.
 - As of the date for GMP application, if there are multiple manufacturers which have less than 1 year validity period, the batch application is acceptable by submitting the summarized list of the manufactory (Major Products mentioned). For one or more manufacturers which selected among manufacturers including in the summarized list, Site Inspections shall be performed.
 - ◇ But if the selected manufacture site has an issue, the site will be re-selected among the document inspection list, and thereafter site Inspection will be performed.
 - In this case, the application materials for the manufacturer in the summarized list must be submitted by each manufacturer, and the importers may divide the applications by manufacturer considering that the circumstances of preparing submitted materials are ready for GMP.
- (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 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 is otherwise deemed necessary by MFDS director and Regional MFDS director for Site Inspection.
 - ◇ The candidate of Site Inspection will be selected by considering 1, 2 and 3 above, but if the manufacturer which has been selected

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already as the Site Inspection candidate is selected again other manufacturer can be selected according to 4 above.

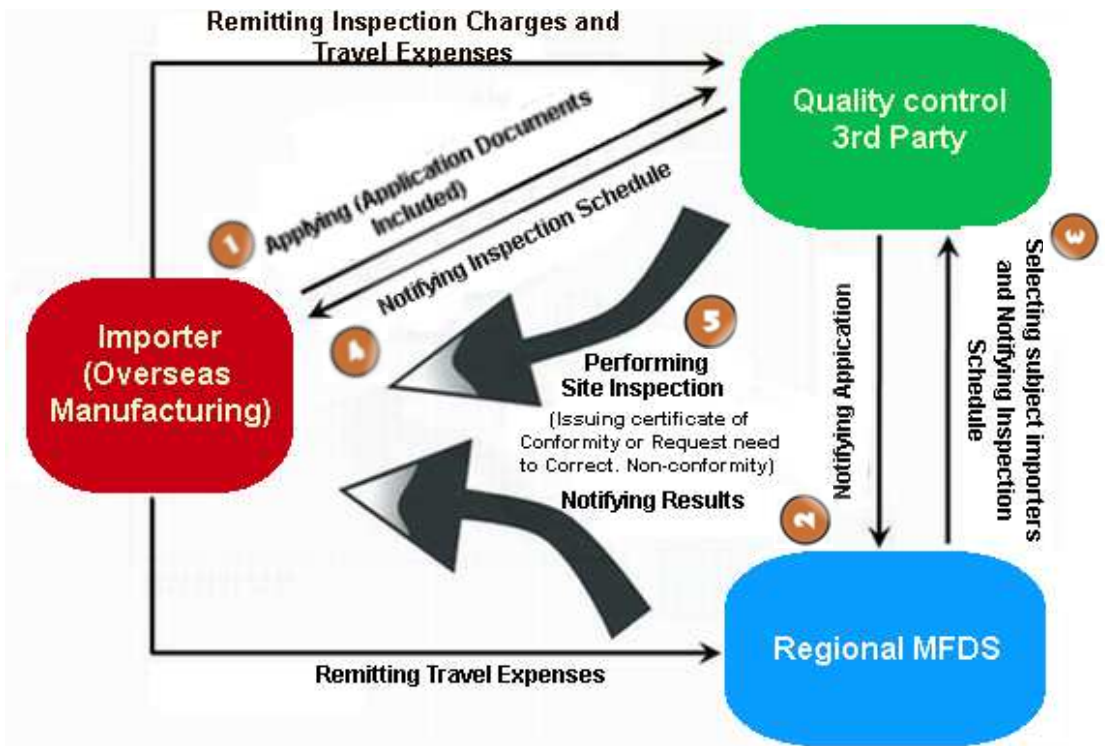
- ❖ Manufacturing Site questioned with the issue of non-compliance of quality or safety/efficacy: Joint site inspection will be performed.
- ❖ Manufacturing Site that submitted the explanation of company Confidential regarding the submitted materials among the document inspection manufactures : Joint site inspection will be performed

- (Inspection Results) Processing the Results of GMP Inspection
 - GMP Inspection Criteria & Evaluation Matrix: GMP Notice [Appendix 2]
 - Processing Criteria of GMP inspection (Site and Documentation): Distinguished for Conformity, Need-to-Correct, and Nonconformity
 - Criteria for Conformity, supplementation, Nonconformity: refer to “Medical Device GMP Guidelines”.
 - In case of Conformity, GMP Certificate of Conformity is issued to the corresponding importer.
 - In case of Nonconformity, the details of nonconformity 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 submits 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.
 - The importers that cannot finish the supplementation in the given period may request extension with a valid reason. (Request for extension is permitted two times only when the first supplementation is accepted)
 - The first extension period is 30 days unless there are any special reasons. If there are any reasonable reasons to extend renewal period, complement period extension may be determined after consulting with the complainant.

If the supplementation could not be finished within the extension period requested twice, the complementary period is 10 days.

- All the processes regarding the inspection are under the Civil Petitions Treatment Act and the Civil Petitions Treatment Regulation of MDFS.

- (Certificate of Conformity) Issue of Compliance Certificate
 - Certificate of Conformity is issued to the importer that applied for GMP Inspection.
 - Detailed Information: according to GMP Notice [Appendix 2]
 - ※ If Manufacturing Site requires an additional Certificate of Conformity, it shall request for the additional issuance (the fees for additional issuance must be paid) to the corresponding 3rd Party.
- Example Chart for the Process of Site Inspection



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3. GMP Inspection Management Plan

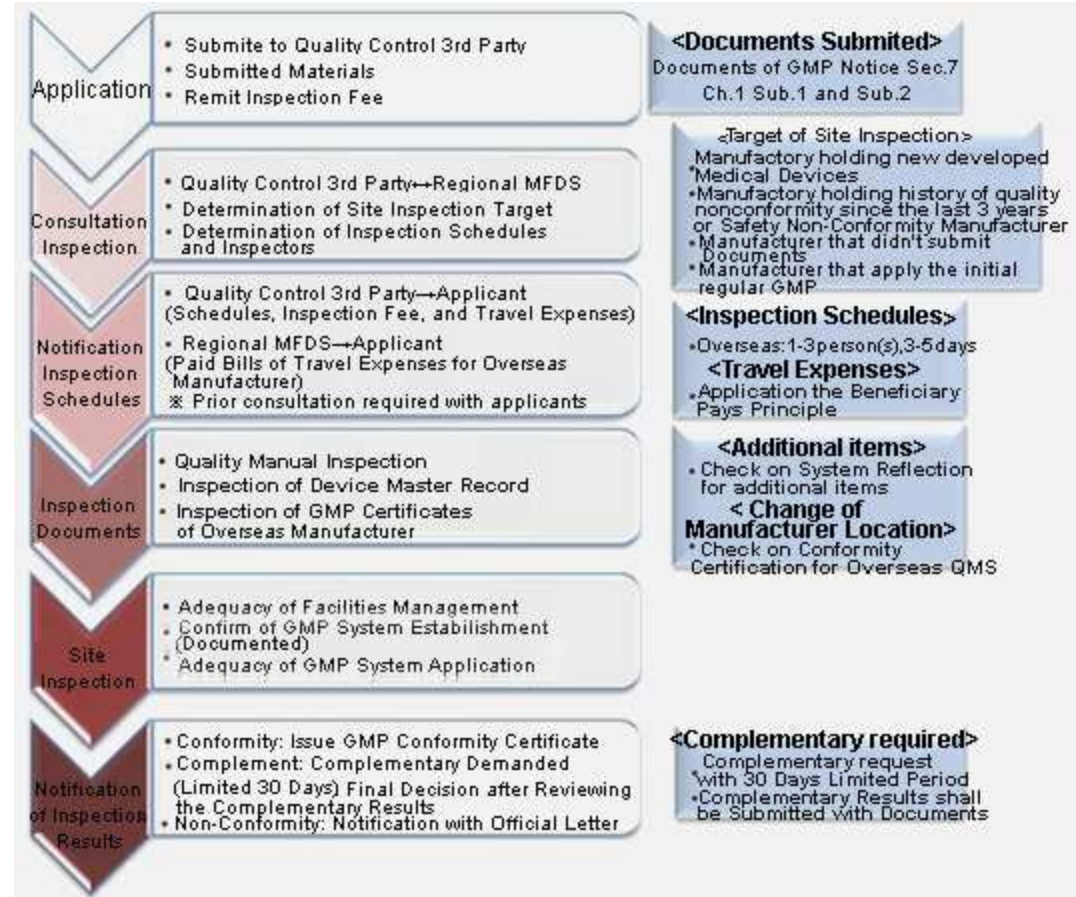
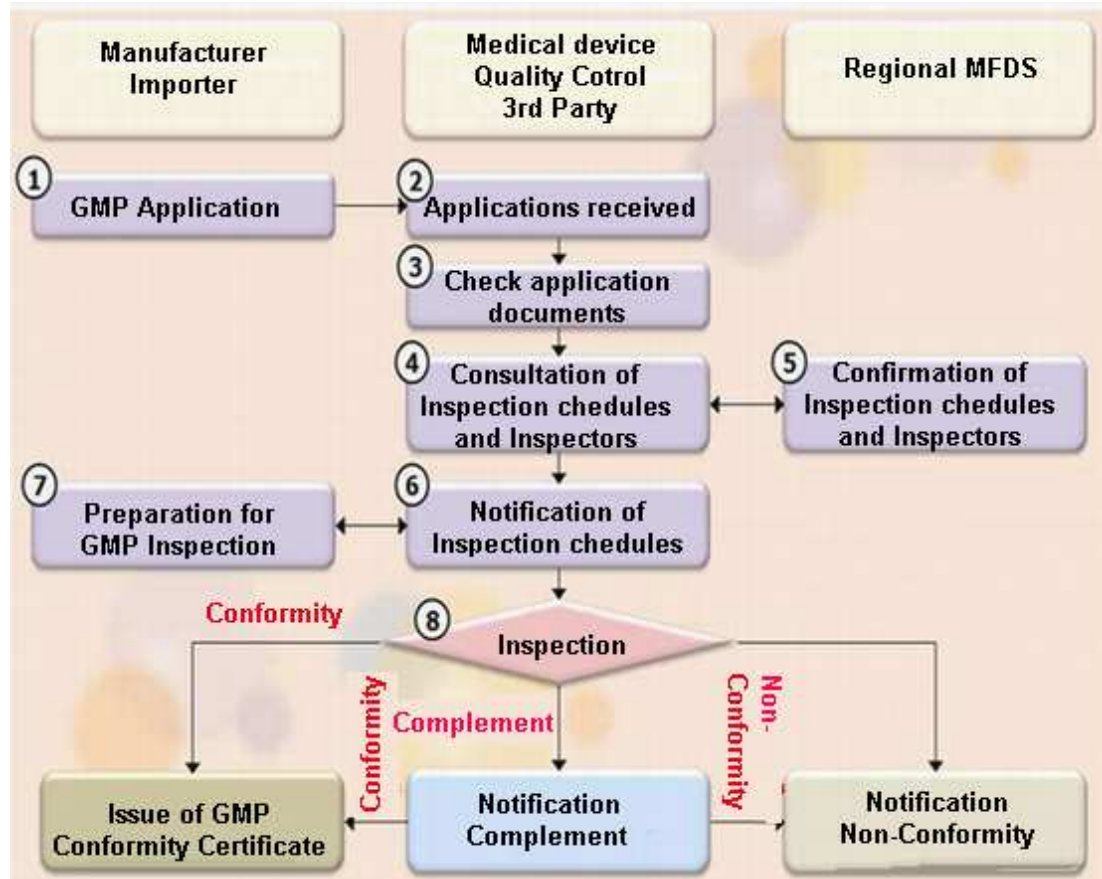
- When multiple importers are applying for the product permit (declaration) for products of the same Manufacturing Site,
 - In principle, each importer must receive separate GMP Inspection regarding the corresponding Manufacturing Site.
 - ※ Each importer must hold GMP Certificate of Conformity for its Manufacturing Site.
 - When another importer desires to import medical devices for the first time 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', and document inspection instead but the validity date of the certificate will be aligned with the initial GMP certificate. (Refer to the page 3~4, initial inspection)
 - In case of Regular Inspection, each importer is required to newly receive GMP conformity certification **prior to** the expiration of Certificate of Conformity regarding the corresponding Manufacturing Site.
 - Multiple importers may receive regular 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, 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 the alienation(transfer) or the take-over for the medical devices which the GMP compliance certificate has been issued,

- If the importers received transfer-takeover from an existing importer in part or in whole the products of Manufacturing Site that received already GMP compliance certificate:
 - GMP conformity evaluation is not needed again if it is not expired.
 - The corresponding importer shall apply for the re-issuing replacement (remitting the fee of re-issuing) of the GMP Conformity Certificate to the corresponding 3rd party based on documents (the official letter from MFDS, etc.) that will validate the takeover (the transfer). Here, the corresponding 3rd party means the institute that had already issued the said GMP Certificate.
 - The original expiration date is applicable to the re-issued replacement GMP Certificate of Conformity.
 - However, if the said GMP Certification is expired and under a progress of administrative measure, it will need to receive regular inspection; if not, additional administrative measure will be taken.
 - ❖ According to Medical Act Sec 47.Ch 3. In case of transfer and takeover of the business for importing medical device, the status of the importer of the license product will be taken over as well as the obligation of regular inspection of GMP.
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- This Guideline will be in effect until the next revision date.

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[Appendix1] GMP Inspection procedures and detailed descriptions



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[Appendix 2] **Summary of GMP Inspection System**

Division	Initial Inspection	Additional Inspection	Modification Inspection	Periodic Renewal Inspection ³⁾
Class 2 Medical Devices	Independent Site Inspection ¹⁾	Document Inspection	Document Inspection ²⁾	Independent Site Inspection ⁴⁾ Joint Site Inspection ⁵⁾
Class 3 Medical Devices	Joint Site Inspection ¹⁾	Document Inspection	Document Inspection ²⁾	Independent Site Inspection ⁴⁾ Joint Site Inspection ⁶⁾
Class 4 Medical Devices	Joint Site Inspection ¹⁾	Document Inspection	Document Inspection ²⁾	Joint Site Inspection

❖ Site inspection will be performed if the manufacturer cannot submit the materials in part due to confidentiality concerns and when submitting the document describing the reasons. If manufacturer holds newly developed medical device, or manufacturer for which a quality non-conformity decision was given within 3 years, or safety issues, Joint Site Inspection is to be performed regardless of the class.

* The last 3 years: Within three years from the day that received the conformity certificate at the latest initial inspection or the latest periodic renewal inspection.

1) When other domestic importers hold GMP Certificate of Conformity on the corresponding Manufacturer, it is substituted for Document Inspection instead; In this case the same expiration period is given.

2) Document 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.

3) For importers that import medical devices from 2 or more Manufacturing Sites, Site Inspection is performed on only 1 Manufacturing Site (Document Inspection on other sites). When other domestic importers hold the effective GMP Certificate of Conformity on the corresponding Manufacturing Site which was performed site inspection, it is substituted for Document Inspection instead; In this case the same expiration period is given.

4) If within the last 3 years a non-compliance decision or a complementary decision was not given or safety/efficacy issues did not occur,

5) If within the last 3 years a non-compliance decision or a complementary decision was given or safety/efficacy issues occurred,

[Appendix 3] Reimbursement criteria according to the regulation of public officials’ overseas travel expenses (Unit: US Dollars (\$))

Division	Level	Daily Allowance	Accommodation		Foods
			Actual Cost upper limit	Discount Fixed Amount	
5. Person corresponding to 2(a) of Appendix 1 -Section Leader, Officer, researcher -Quality Control 3rd Party Inspectors	A	30	176	150	81
	B	30	137	116	59
	C	30	106	90	44
	D	30	81	69	37
6. Person corresponding to 2(b) of Appendix 1 - Government Official Level 6 or Lower	A	26	155	132	67
	B	26	123	105	49
	C	26	90	77	37
	D	26	77	65	30

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○ The differentiation of level per country and city is as follows:

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

b) Level B

1) **Asia and Oceania**: Taiwan, Beijing, India, Japan, Kazakhstan, Papua New Guinea,

2) South, North America: Mexico, USA, Brazil, Saint Lucia, Saint Kitts and Nevis, Argentina, Haiti, Antigua and Barbuda, Jamaica, Canada

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

4) Middle East, Africa: Gabon, South Africa, Libya, Sudan, **South Sudan, Bahrain, Saudi Arabia, Seychelles**, United Arab Emirates, **Angola, Oman**, Uganda, Israel, Egypt, **Ethiopia, Equatorial Guinea**, Qatar, **Ivory Coast**, Democratic Republic of the Congo.

c) Level C

1) **Asia and Oceania**: New Zealand, Marshall Islands, Malaysia, Bangladesh, Brunei, Azerbaijan, Australia, Indonesia, **Uzbekistan**, China, Kyrgyz Republic, Thailand, Turkey, **Tajikistan, Turkmenistan**, Pakistan

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

3) Europe: **Latvia**, Romania, Lithuania, Bulgaria, Ireland, **Serbia, Montenegro, Slovenia, Slovakia**, the Czech Republic, Poland.

4) Middle East, Africa: Ghana, **Guinea**, Nigeria, Niger, Liberia, Morocco, Mauritius, Mozambique, Botswana, Burkina Faso, Sao Tome and Principe, Senegal, Swaziland, Sierra

Leone, **Afghanistan, Algeria, Jordan, Iraq, Zambia**, Central African Republic, Cameroon Kenya, Tanzania.

d) Level D

1) Asia and Oceania: Nepal, **East Timor**, Laos, **Micronesia**, Mongolia, Myanmar, **Vietnam**, Sri Lanka, Cambodia, Fiji, Philippines.

2) South, North America: Guatemala, **Nicaragua**, Bolivia, Suriname, Ecuador, El Salvador, **Honduras**, Colombia, Paraguay, Peru

3) Europe: Macedonia, Moldova, Bosnia and Herzegovina, **Belarus**, Albania, Estonia, Croatia.

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

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

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[Appendix 4] Scope of Accreditation for Materials Submitted

No	Kinds of Submission Materials	Scope of Accreditation
1	<p>Copies of Manufacturing (Import) License</p> <p>or Copies of Conditional Manufacturing (Import) License</p> <p>(Except for the first Inspection or Clinical Trials Medical Devices)</p>	<p align="center">Confirm at the manufacturing site.</p> <p>Not required for the first inspection or clinical trials required applications</p> <p>☞ Copies of the License (or copies of Conditional License) submitted</p>
2-A	<p>Manufacturer Overview</p> <p>(Name and address of the manufacturer, of all when several manufacturers are included.)</p>	<p>☞ Fill up in the documents the manufacturer's name, location, Manufacturing scope, and quality manufacturing officer's name and contact information (overseas manufacturer)</p> <p>- Manufacturing sponsor: company name, address, (if the company have some manufacturing processes) Manufacturing scope, quality manager's name and contact information (overseas manufacturer)</p> <p>- Manufacturer: company name, location, Manufacturing scope, quality manager name and contact information * Manufacturing scope: manufacturing processes that is carried out in the corresponding manufacture site.</p> <p>☞ written information can be described by the importers on the basis of the data of the manufacturer</p>

2-B	<p>The total number of employees engaged in the manufacturing and quality related work</p>	<p>☞ Including all operators involved directly or indirectly in the manufacture and quality control of medical devices.</p> <p>* However, research center or office that are not related to those products are excluded</p> <p>☞ Materials that can confirm the total number of employees of the manufacturer are as follows:</p> <ol style="list-style-type: none"> 1. Letter of manufacturer or importer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager) ; or 2. Approved and valid documents of the manufacturer issued by quality.
2-C		<p>☞ written information of items and classes for all medical devices that are manufactured in the manufacturer and that are imported by the importers. In case for multiple manufacturer and products, denote separately for each representative item.</p> <p>* However, it can be omitted for the domestic unauthorized items.</p> <p>* When performing GMP approval before permission, choose a representative item including the categories of products from the application</p>

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	<p>List of medical devices that are manufactured by the manufacturer (Item names, including the class)</p>	<p align="center">☞ Submit representative item</p> <p>* Selection of representative item: The highest class of risk among the inspected target products of the manufacturer. Highest volume of production</p> <p>☞ The list of the importing medical devices shall be described by the importer on the basis of the data of the manufacturer.</p> <p>* The manufacturer information include the following</p> <ol style="list-style-type: none"> 1. Letter of manufacturer or importer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager) ; or 2. Approved and valid documents of the manufacturer issued by quality.
2-D	<p>A copy of the quality management system certificate issued by the manufacturer's Government or the appropriate authority delegated by the manufacturer's Government.</p>	<p>☞ The quality management system certificate means a GMP compliance certificate of the corresponding government, or ISO 13485 compliance certificate, and ISO 9001 certificate is not allowed.</p> <p>* Copy of GMP compliance certificate of the manufacturing country for United States (FDA), Canada (CAM / CAS), Japan (JPAL), and etc.</p> <p>Or copy of ISO 13485 compliance certificate (EN, BS,</p>

		<p align="center">etc. National Standards)</p> <p align="center">☞ (If applicable only) is as follows;</p> <ol style="list-style-type: none"> 1. If documents inspection is conducted for GMP change assessment for overseas manufacturer of the importing medical devices, 2. If the manufacturing sponsor has more than 2 manufacturers (in relation to the manufacturers-manufacturing sponsor), and If documents inspection is conducted for the rest of manufacturers excluding the manufacturers that received site inspections, 3. If documents inspection is conducted for in vitro diagnostic medical devices which switched from drugs to medical devices, and for the remainder excluding the manufacturer that received site inspection as the manufacturer that the products sold out already, 4. Documents to confirming the relation to the manufacturers-manufacturing sponsor (manufacturer's letter is available). 5. If it is impossible to perform site inspection due to in circumstances such as war or natural disasters,
2-E	<p>Facility overview of each manufacturer which are subjected (including plan view, facilities equipment list)</p>	<p>☞ Submission of layout view by separating workshop, storage room, laboratory of the manufacturer.</p> <p>* However, layout view can be provided as a reflect of the process steps</p> <p>☞ For a manufacturer to manage the cleanliness, the</p>

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		<p>clean areas and the cleanliness (Class) shall be expressed on the layout view.</p> <p>* However, if it is impossible to express on the layout view, submit the evidence data (cleanliness evidence).</p> <p>☞ Submit the facilities equipment list. It is a list of the major manufacturing, and is displayed on it the name-purpose of the testing facilities including equipment needed for production and quality control.</p> <p>☞ Evidence materials for plan view and cleanliness. Materials that can confirm the equipment of major manufacturing and test facilities.</p> <p>1. Letter of manufacturer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager); or</p> <p>2. Approved and valid documents of the manufacturer issued by quality.</p>
2-F	Name of major supplier and scope of task (Included the consignment process contracts, etc.)	<p>☞ Major supplier name, address (country), and details of the supply products (describe for raw materials, components, etc. and describe briefly about products characteristics).</p> <p>☞ consignment company name, address (country), characteristics of the consignment process (sterilization, special manufacturing processes, etc.)</p> <p>☞ Materials that can confirm the major supplier and</p>

		<p>the consignment company.</p> <p>1. Letter of manufacturer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager); or</p> <p>2. Approved and valid documents of the manufacturer issued by quality.</p>
2-G	Inspection result data received from another certification authority (if applicable only)	<p>☞ Submission of the report demonstrating conformity over the last 3 years (included certification authority, inspection type, valid date, results data)</p> <p>* However, Summary Report issued by a certification authority is also possible, but certification authority, inspection type, valid date, and results should be included.</p> <p>* Last 3 years: 3 years from the initial date of issuing of the current certificate</p> <p>☞(if applicable only) is as follows;</p> <p>1. If documents inspection is conducted for GMP change assessment for overseas manufacturer of the importing medical devices,</p> <p>2. If the manufacturers manufacturing sponsor has more than 2 manufacturers and If documents inspection is conducted for the rest of manufacturers excluding the manufacturers that received site</p>

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		<p align="center">inspections</p> <p>3. If documents inspection is conducted for in vitro diagnostic medical devices which switched from drugs to medical devices, and for the remainder excluding the manufacturer that received site inspection as the manufacturer that the products sold out already,</p> <p>4. Documents confirming the relation to the manufacturers-manufacturing sponsor (manufacturer's letter is available).</p> <p>5. If it is impossible to perform site inspection due to in circumstances such as war or natural disasters,</p>
2-H	Quality Manual (Including quality policy)	<p>☞ Submission of the established-approval requirements and a valid quality manual, associated with 「Medical Device Manufacturing and Quality Control Criteria」, [Appendix 2] 4.2.2, quality claim,</p> <p>☞ Data to verify the quality manual (with a quality policy)</p> <p>* Approved and valid quality documentation of the manufacturer.</p>
2-I	Device Master Record of corresponding Items (Sterilization, software, etc. including description for a special manufacturing process)	<p align="center">1) Shape and Structure</p> <p>☞ Submission of photo and drawing materials containing information associated with the permit requirements (including technical documentation) such as item (model), class, dimensions, shape, etc.</p>

<p>However, submission of Device Master Record for the highest class item among the equivalent products group of the corresponding manufacturer.</p>	<p>* However, if type names for same items are multiple, materials of the representative type name must be submitted, and the representative type name shall be corresponded for the worst case.</p> <p>☞ Materials that the shape and structure could be identified.</p> <p>1. Letter of manufacturer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager); or</p> <p>2. Approved and valid documents of the corresponding manufacturer associated with quality.</p> <p>2) Raw materials and Specification of Raw materials</p> <p>☞ Submission of materials(including changes) that are present from the original submission (including technical file)</p> <p>* However, if the documents describing the raw materials are too details (ingredients etc.), table compared with the domestic submission and manufacturer's materials can be submitted, but the signature of quality manager should be included.</p> <p>* In the case of medical devices that use the software, the software name and version should be included.</p> <p>☞ Documents that are identify the name and specifications of the raw materials(in the case of</p>
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		<p>medical devices used software, included software name and version)</p> <ol style="list-style-type: none"> 1. Letter of manufacturer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager); or 2. Approved and valid documents of the manufacturer issued by quality. <p align="center">3) Method of Manufacturing</p> <ul style="list-style-type: none"> ☞ Submission of flow chart for overall manufacturing process from purchasing of raw material to shipment of final products, including processes of consignment, inspection, and sterilization. And description of every processes. ☞ If the product includes human tissues or animal-derived materials, the summary data about the special processes such as the removal process of pathogenic substances same as bacteria, viruses, etc. should be submitted. ☞ If the products are sterile or involve the sterilization process, the summary data about the sterilization method shall be submitted. ☞ If the special test equipment is used such as software, the summary data about name and version of the software shall be submitted.
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		<p>Submission of the data that include the period before-after use</p> <p>* Data that can identify the expiration of products are as follows:</p> <ol style="list-style-type: none"> 1. Letter of manufacturer (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager); or 2. Approved and valid documents of the manufacturer issued by quality. <p>6) Packing unit, Indications, and Mentioned Items</p> <p>☞ submissions of data as the packing unit (e.g. 1ea / box)</p> <p>☞ Indications and included items: Submission of the actual labels and the relevant documents of the foreign manufacturer (user manual, etc.), and additionally the actual label of domestic importers.</p>
2-J	<p>In case of Change Inspection,</p> <p>Device Master Record for product that is the best of import-export achievement as the highest class item among the equivalent products group of the</p>	<p>☞ In case of the initial, additional, change inspection excluding the regular inspection,</p> <p>Submission of the approved and valid DMR (Device Master Record) for representative product per products group.</p> <p>All contents of 2-I Section shall be contained in the</p>

	corresponding manufacturer	DMR.
2-K	Description documents for the products that require installation or servicing	<p>☞ DMR of the representative product per the product group of the corresponding manufacturer.</p> <p>☞ Documents describing installation or servicing (management) of the corresponding manufacturer.</p> <p>Approved and valid documents of the manufacturer issued by quality.</p>
Etc.	<p>Documents that can confirm that the products manufactured under the manufacturing system</p> <p>(Notice Sec.7 Ch.2 Sub.1-c)</p>	<p>☞ "Products manufactured under the same manufacturing system" means that the name, the location, and the products group of the manufacturer(manufacturing sponsor and manufacturer) must coincide with the existing other importer's manufacturer's them, and operate under the same QMS(Quality Management System).</p> <p>When configuring the manufacturer as "manufacturing sponsors - manufacturer", it shall be same as the existing other importer's "manufacturing sponsors - manufacturer".</p> <p>☞ In this case, it may apply for documents review with the submitting documents simplified.</p> <p>☞ Submission of manufacturer's letters that mentioned the operating under the same QMS(including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager).</p>

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Etc.	Document for verifying the relationship between “manufacturing sponsors-manufacturer” (Notice Sec 7 Ch 2 Sub1-c)	If the same manufacturing sponsor in relation of “manufacturing sponsors-manufacturer” add the manufacturer, it shall be submitted the following materials. ☞ Submit one selected material among the following materials verifying the relation. 1. Copy of the GMP conformity certification for USA (FDA), Canada (CAM / CAS), Japan (JPAL), etc. However, ISO 9001 conformity certificate is not acceptable. 2. The actual inspection results data that received from other certificate authorities. 3. The certificate of manufacturing and sales that issued by the corresponding government. 4. Letter of the manufacturing sponsor (including the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager) 5. Approved and valid quality documents of the manufacturing sponsor.
Etc.	Finished product test report (Notice Sec. 7, Ch. 7, Sub. 3)	☞ If the site is in the situation of war, infectious diseases, natural disasters, and etc. the following material shall be submitted. * Submission of the manufacturer’s factory certification

		for the importing medical devices.
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○Precautions for data submission.

- ① When submitting materials, if necessary, submit after writing a summary documents for each items of the table, and attach the evidence document (manufactured materials).
- ② The summary document could not be different from the evidence of the manufacturer.
- ③ When submitting the manufacturer’s letter, it should be included the signature of the quality manager, or the signature of the other person who has equivalent responsibility and authority to the quality manager.
- ④ All quality documents should be valid, legible, approved (including electronic signatures).
- ⑤ When submitting documents written in languages other than English, it shall be submitted as Korean translated with the original documents, or it is acceptable to attach English documents in parallel.

○Processing Results

- When not following "Precautions for data submission", supplement immediately.