Good Manufacturing Practice (GMP) for Medical Devices

[Effective on Nov. 13, 2023] [Ministry of Food and Drug Safety Notice No. 2023-31, May 12, 2023, Partial Amendment]

Ministry of Food and Drug Safety (Medical Device Management Division), 043-719-3804

Article 1 (Purpose) The purpose of this GMP is to set forth detailed requirements for the manufacture or import of medical devices (including investigational devices), the procedures for designation and management of certification bodies and training organizations for quality manager, and other necessary matters pursuant to Articles 6, 6 (2), 10, 12, 13, 15, 28, and 45 of the Medical Devices Act; Articles 8, 14, 15, 24, 26, 27, 31, 33, 34, and 48, and Annexes 2 and 4 of the Enforcement Rule of the Medical Devices Act; Article 24 of the Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices; Article 15 of the Regulations on Support, Management, Etc. of Innovative Medical Devices.

Article 2 (Definitions) The definition of the terms used in this standard shall be as per Annex 1.

Article 3 (Scope) (1) The scope of application of this standard shall be as follows:

1. persons who intend to obtain a medical device manufacturing and import license or manufacturing and import certification, or to make a manufacturing and import notification;
2. persons who intend to manufacture or import investigational devices;
3. medical device manufacturers or importers who want to take GMP audit or take a periodic audit (hereinafter referred to as “GMP Audit”);
4. persons who have been designated or intend to be designated as certification body; and
5. persons who have been designated or intend to be designated as training organizations for quality manager.

(2) Notwithstanding paragraph (1) subparagraphs 1 through 3, a person who intends to manufacture and import a medical device manufactured solely for export (hereinafter referred to as “medical devices for export”) or to manufacture or import a Class 1 medical device shall comply with this standard with the exception of GMP audit.

Article 4 (Classification of GMP Audit) (1) GMP audit under this standard shall be conducted according to the following criteria:

1. the first audit that a manufacturing site shall take to be deemed complying with this standard (hereinafter referred to as “initial audit”);
2. an audit (hereinafter referred to as “additional audit”) required for a manufacturing site that additionally manufactures a medical device from another product group under Annex 3; and
3. an audit required as a new GMP audit due to a change in the manufacturing site’s address (hereinafter referred to as “modification audit”). Provided, That changes in storage and laboratories, or address changes of manufacturing sites for software medical device, which are insignificantly related to the quality of the product, are excluded.

(2) Manufacturing site shall take a periodic audit once every three years for each product group in subparagraph 2 (e) 2) of Annex 2 of the Enforcement Regulations of the Medical Devices Act (hereinafter referred to as the "Enforcement Regulations"); subparagraph 3 (b) of Annex 4; Article 15 (1) 2 (d) and (e) of the Regulations on Support, Management, Etc. of Innovative Medical Devices.

(3) Notwithstanding Article 3 (2) and paragraph (2), a manufacturing site may be exempt from periodic audit if it has been GMP certified for a medical device falling under any of the following:

1. medical device for export;
2. Class 1 medical device;
3. investigational device; and
4. drugs or quasi-drugs as part of combined or composite convergence medical devices.

Article 5 (Standard for GMP Audit) (1) The standard for GMP Audit under Annexes 2 and 4 of the Enforcement Rule and Article 15 of the Regulations on Support, Management, Etc. of Innovative Medical Devices shall be as per Annex 2.

(2) Notwithstanding paragraph (1), Annex 2 may partially apply if it falls under any of the following:

1. where the applicant intends to manufacture or import an investigational device, Sections 7.1. 7.3, 7.4.3, 7.5, 7.6, 8.2.6, and 8.3 shall apply;
2. for a modification audit under Article 4 (1) 3, Sections 4.1, 4.2, 6.1, 6.3, 6.4, 7.5, 7.6, 8.2.2, 8.2.3, 8.2.6, 8.3, and 8.5 shall apply; and
3. notwithstanding Article 3 (2), if a Class 1 medical device is to be subjected to GMP Audit under this standard, Sections 4.1, 4.2, 5.5, 6.4, 7.1, 7.4, 7.5, 7.6, 8.2.1, 8.2.2, 8.2.3, 8.2.6, 8.3, and 8.5 shall apply.

Article 6 (Method of GMP Audit, Etc.) (1) In GMP Audit under subparagraph 2 (e) and (f) of Annex 2 and subparagraph 3 of Annex 4 of the Enforcement Rule and Article 15 of the Regulations on Support, Management, Etc. of Innovative Medical Devices, the head of the Regional Office of Food and Drug Safety (hereinafter referred to as "the head of the Regional Office of Food and Drug Safety") and the head of the certification body shall jointly conduct document review and on-site inspection for each product group of the manufacturing site. Manufacturing sites that contract in or out of the manufacturing process (hereinafter referred to as "legal manufacturer-manufacturer") may also be subject to document review and on-site inspection. For a manufacturing site of convergence medical devices (including a legal manufacturer-manufacturer) may be subject to document review and on-site inspection conducted separately.

(2) Notwithstanding paragraph (1), only the document review may be conducted in accordance with subparagraph 2 (f) 2) of Annex 2 of the Enforcement Rule and Article 15 of the Regulations on Support, Management, Etc. of Innovative Medical Devices shall be conducted if it falls under any of the following:

1. where an additional audit pursuant to Article 4 (1) 2 is conducted;
2. where modification audit is conducted after documents listed in Article 7 (1) 2 for the manufacturing site with address change in accordance with Article 4 (1) 3 are submitted;
3. where another manufacturer or importer holds a valid GMP certificate in accordance with this standard for the manufacturing site concerned;
4. where an audit is conducted for a manufacturing site other than the manufacturing site subject to on-site inspection

when the manufacturer has two or more manufacturing sites subject to periodic audit pursuant to Article 4 (2); and

5. where another manufacturer or importer of in vitro diagnostic medical devices under the Act on In Vitro Diagnostic Medical Devices holds a GMP certificate (only the valid certificate is applicable) for the manufacturing site following an on-site inspection and document review in accordance with Good Manufacturing Practice for In Vitro Diagnostic Medical Devices.

(3) Notwithstanding paragraph (2), an on-site inspection shall be conducted in the following:

1. deleted;
2. where it is determined to be a potentially hazardous manufacturing site; and
3. where the manufacturer or importer of the medical device requests an on-site inspection because documents referred to in Article 7 (1) 2 for reasons such as trade secrets.

(4) Notwithstanding Article 4, initial audit shall be conducted in the following:

1. where a GMP-certified manufacturing site of a medical device for export, Class 1 medical device, or investigational device has expired and the manufacturing site intends to be recertified because the validity period of the GMP certificate is expired;
2. where a GMP-certified manufacturing site of a medical device for export intends to manufacture it for domestic sale;
3. where the legal manufacturer of a legal manufacturer-manufacturer that has taken GMP Audit is changed or deleted;
4. where the GMP-certified manufacturing site of an investigational device pursuant to Article 5 (2) 1 changes its address, adds an investigational device in another product group, or intends to manufacture or import for sale; and
5. where a GMP-certified manufacturing site of a Class 1 medical device under Article 5 (2) 3 intends to manufacture or import a Class 2, 3, or 4 medical device.

(5) The auditing body and method of GMP Audit under paragraphs (1) through (4) shall be as per Annex 4.

(6) If an on-site inspection cannot be conducted for the manufacturing site subject to on-site inspection due to situations such as wars, epidemics, natural disasters, etc., the on-site inspection shall be temporarily suspended, and only a document review shall be conducted.

(7) A manufacturer or importer who took only a document review pursuant to paragraph (6) shall submit a test report in accordance with its in-house quality control test specifications to the head of the Regional Office of Food and Drug Safety for each manufacturing or importing unit.

Article 7 (Application for GMP Audit) (1) If a person falling under subparagraphs 1 to 3 of Article 3 (1) intends to take GMP Audit in accordance with this GMP, he/she shall submit an application in Form 1 to the head of the certification body, along with the documents listed below. The manufacturing site shall have a track record of quality control of at least one lot. The preferred date of on-site inspection on the application shall be set at least 20 days before the start date of on-site inspection.

1. A copy of the medical device manufacturing (import) business license or a copy of the conditional medical device manufacturing (import) business license (except for applicants with no medical device (conditional) manufacturing (import) business license, such as applicants for initial audit or audit of investigational device)

2. Documents that fall under each of the following:
   (a) Overview (including the name of manufacturing site and the address of each facility; if multiple manufacturing sites, names of all manufacturing sites), organization chart, number of employees, medical devices manufactured, etc. of the manufacturing site
   (b) A copy of the quality management system GMP certificate issued by the regulatory authority or an institution delegated by the regulatory authority (only where Article 6 (2) or Article 6 (6) applies) and due diligence data (only where Article 6 (2) 2 or Article 6 (6) applies; follow-up measures based on the on-site inspection result should be included)
   (c) Facility status (floor plan that includes work areas, laboratories, and storages [for a manufacturing site of Software as a Medical Device (SaMD), include a floor plan for the facility, if a manufacturing site has work areas, laboratories, and storages], and a list of facilities and equipment), clean room procedures (only if applicable), and monitoring and measuring equipment procedures that confirm the monitoring cycle of measuring instruments, etc. of each manufacturing site to be evaluated
   (d) Quality manual (including quality policy) of the manufacturing site
   (e) Procedures and test results of finished product testing (e.g., final shipment inspection) for representative items of the manufacturing site (if sterilized product, include the evidence of sterilization)
   (f) Purchasing and contracting procedures for and names of major suppliers (including contractors) of representative items of the manufacturing site and scope of respective work
   (g) Manufacturing site's device master record for representative items (including descriptions of specific manufacturing processes such as sterilization, software, etc.) and sterilization validation procedures (only if applicable)
   (h) Annex 2 GMP Checklist for Manufacturing Site
   (i) Annex 2 GMP Declaration of Compliance
   (j) Letters of designation of representative items as innovative medical devices (applicable to innovative medical devices only).

(2) The required documents for representative items falling under items (e), (f), (g), and (j) of paragraph (1) 2 shall concern items falling under the following:

1. if the applicant has two or more items for application, the item in the highest class per product group of the manufacturing site;
2. notwithstanding paragraph (1), if the application is for a periodic audit under Article 4 (2), the item in the highest class of the manufacturing site with the highest production or import volume among the items to be audited; and
3. notwithstanding paragraph (1), if the application is for a modification audit pursuant to Article 4 (3), the item in the highest class per product group of the manufacturing site with the highest production and import volume.

(3) Manufacturers and importers of medical devices that are required to take periodic audit pursuant to Article 4 (2) shall apply for periodic audit to the head of the certification body by submitting an application in Form 1 along with documents under subparagraphs 1 and 2 of paragraph (1) no later than three months before the expiration of the validity period stated in the GMP certificate. The preferred date of on-site inspection on the application shall be set 20 days

before the expiration date of the validity period stated in the certificate. If the preferred date of on-site inspection on the application is not set at the time of submission of the application, the applicant shall request the date in writing 20 days before the start date of the preferred date of on-site inspection.

(4) Medical device manufacturers and importers with multiple manufacturing sites subject to periodic audit under paragraph (3) may submit a blanket application for periodic audits.

(5) A person who intends to submit a blanket application for periodic audits under paragraph (4) shall submit the documents under paragraph (3) and a summary table of manufacturing sites in Form 1 to the head of the certification body.

(6) If a manufacturing site falls under Article 6 (2) 3 and another manufacturing site or importer holds a valid GMP certificate for it under this standard, the applicant may submit only the following documents in the application in Form 1 among the documents submitted under paragraph (1):

1. a copy of the medical device manufacturing or import business license or a copy of the conditional medical device manufacturing or import business license (except for applicants with no medical device (conditional) manufacturing (import) business license, such as applicants for initial audit or audit of investigational device);
2. documents referred to in items (g) (excluding the sterilization validation procedure) and (j) of paragraph (1) 2; and
3. documents of the manufacturing site that can confirm that the product is manufactured under the same system at the same manufacturing site.

(7) A manufacturer or importer with a manufacturing site whose on-site inspection has been suspended pursuant to Article 6 (6) shall submit an application in Form 1 to the head of the certification body within 10 days from the date of termination of the situation at the location or region of the manufacturing site. In such case, the applicant may omit required supporting documents for the application in Form 1.

(8) The head of the certification body shall report to the head of the Regional Office of Food and Drug Safety the name, representative, etc. of the company if a person who is required to apply for a periodic audit does not apply for it at least three months before the expiry date of the validity period under paragraph (3).

(9) a manufacturing site subject to on-site inspection pursuant to Article 6 (5) may not submit documents listed in paragraph (1) 2 (b), (h), and (j).

(10) Expenses related to GMP Audit shall be in accordance with Annex 2 of the Enforcement Rule.

Article 8 (Procedure for GMP Audit) (1) The head of the certification body shall, upon receiving an application for GMP Audit pursuant to Article 7, report the fact of receipt to the head of the Regional Office of Food and Drug Safety in accordance with the following subparagraphs and request confirmation of whether to conduct an on-site inspection pursuant to Article 6 (3). Provided, That he or she may not report the fact of receipt to the head of the Regional Office of Food and Drug Safety, if the auditing body is “independent” in accordance with Article 6 (5) and Annex 4 and does not fall under Article 6 (6).

1. The head of the certification body shall check the submission status of required supporting documents pursuant to Article 7 (1) through (7) within five days and, if there is no issue, shall make a report and request within seven days after receipt.
2. If there is an issue, such as incomplete submission, according to the checks conducted pursuant to subparagraph

1, the head of the certification body shall request the applicant's supplementation by setting a deadline for the supplementation as stipulated in the Administrative Procedures Act.

3. Notwithstanding subparagraph 1, if the applicant confirms the preferred date for an additional on-site inspection, the head of the certification body shall make a report and request by the next day after receipt.

(2) The head of the Regional Office of Food and Drug Safety shall, within 10 days from the date of receipt of the report and request pursuant to paragraph (1) from the head of the certification body, determine whether to conduct an on-site inspection pursuant to Article 6 (3), the auditing body and method pursuant to Article 6 (5) and notify the head of the certification body. The head of the certification body shall notify the applicant of the content of the notification.

(3) The head of the certification body shall notify the applicant in writing of the results of the audit under Article 6 within 30 days from the date of receipt of the application for GMP Audit. Provided, That the period from the date of notification to the applicant to the start date of on-site inspection under paragraph (3) shall not be counted towards the deadline, if an on-site inspection of the manufacturing site is required under paragraph (2).

(4) Where an on-site inspection of a manufacturing site is required under paragraph (2), the head of the certification body organization shall conduct the on-site inspection in accordance with the following:

1. the auditing body determined under paragraph (2) shall conduct the on-site inspection on the inspection date notified to the applicant, and the head of the certification body shall notify the applicant of the results in writing within seven days from the date of the business travel for the on-site inspection ended or within the processing deadline under paragraph (3); provided, that the head of the certification body shall immediately report to the head of the Regional Office of Food and Drug Safety, if it is determined that the manufacturing is non-compliant according to the results of the on-site inspection;
2. if the on-site inspection is not possible due to circumstances such as wars, epidemics, natural disasters, etc. during the period of on-site inspection under subparagraph 1, or if it is difficult to conduct the on-site inspection normally due to delay or refusal to submit the inspection data, the on-site inspection may be suspended. In such case, the applicant shall be notified in writing immediately, stating the reason for the suspension, and the fact shall be reported to the head of the Regional Office of Food and Drug Safety; and
3. once it is confirmed that the reason for suspension under subparagraph 2 has been resolved, the on-site inspection may be resumed. The applicant shall be notified of the result in writing within seven days from the date that the business travel for the on-site inspection ended or within the processing deadline under paragraph (3).

(5) Where it is not possible to notify the applicant of the results of GMP Audit within the processing deadline under paragraphs (3) and (4) due to unavoidable reasons such as force majeure, the head of the certification body shall notify the applicant of the delay in advance.

(6) If supplementation is required, the head of the certification body shall take the following actions with respect to the results of GMP Audit:

1. the applicant shall be requested to make supplementation in accordance with the supplementation procedure and deadline as stipulated in the Act on Civil Complaint Handling. The auditing body under paragraph (2) shall review the response to the supplementation request submitted by the applicant and evaluate whether they are adequate;
2. if the applicant does not submit the supplementation within the supplementation deadline, the auditing body under

paragraph (2) shall determine the application non-compliant; and

3. where a determination of non-compliance is made under subparagraph 2, the head of the certification body shall immediately report to the head of the Regional Office of Food and Drug Safety and notify the applicant in writing.

(7) The head of the certification body shall prepare a report on the results of the audit in Form 3 and submit it to the head of the Regional Office of Food and Drug Safety in accordance with the following subparagraphs. Provided, That it may not be submitted if the auditing body is "independent" in accordance with Article 6 (5) and Annex 4 and does not fall under Article 6 (6).

1. The audit result under paragraph (3) shall be submitted within the processing deadline under paragraph (3).
2. The audit result under paragraph (4) 1 shall be submitted within seven days from the date the on-site inspection ended.
3. If the on-site inspection is resumed under paragraph (4) 3, it shall be submitted within seven days from the date that the business travel for the on-site inspection ended or within the processing deadline under paragraph (3).

(8) The head of the certification body shall issue a GMP certificate for medical devices (hereinafter referred to as "GMP certificate") in Form 2 or Form 2-2 in accordance with Annex 5 to the applicant if the result of GMP Audit is compliant under Article 6. Provided, That the temporary GMP certificate may be issued if the result of document review under Article 6 (6) is compliant.

(9) The applicant may appeal to the head of the certification body pursuant to the Act on Civil Complaint Handling if he or she objects to the audit result under Article 6.

(10) The head of the certification body that receives an appeal under paragraph (9) shall report the details and the outcome of handling it to the head of the Regional Office of Food and Drug Safety.

(11) For a blanket application for multiple manufacturing sites subject to a periodic audit made under Article 7 (4), the head of the Regional Office of Food and Drug Safety and the head of the certification body may conduct an on-site inspection of one manufacturing site by considering all of the following criteria together:

1. the manufacturing site with the item in the highest class;
2. the manufacturing site with a high volume of domestic production and imports; and
3. the manufacturing site that has never been subjected to an on-site inspection.

(12) For a manufacturing site that has applied for GMP Audit pursuant to Article 7 (8), the head of the certification body shall conduct an on-site inspection within 90 days from the date of application.

Article 9 (Validity Period of GMP Certificate) (1) The validity period of the GMP certificate based on the initial audit shall be three years from the date of its issuance.

(2) The compliance certified by an additional audit or modification audit determines shall not affect the validity period.

(3) The validity period of the GMP certificate based on periodic audit shall be three years from the day after the expiry date of the existing GMP certificate. Provided, That the validity period shall be three years from the date the GMP certificate is issued, if the date the GMP certificate is issued is later than the expiry date of the existing certificate or if a blanket application for periodic audit is made.

(4) For GMP Audit under Article 6 (2) 3, the validity period shall be calculated the same as that of the manufacturing site or importer who has previously received GMP Audit.

(5) For GMP Audit under Article 6 (2) 5, the validity period shall be calculated the same as that of the manufacturing site or importer of in vitro diagnostic medical devices who has previously received GMP Audit.

Article 10 (Reissuance of GMP Certificate) (1) A manufacturer or importer who has been issued a GMP certificate pursuant to Article 8 (8) may apply for a reissuance to the certification body that issued the certificate if it needs to be reissued due to its loss or for other reasons.

(2) The head of a certification body shall, upon receiving an application for reissuance of the GMP certificate under paragraph (1), reissue it in accordance with Annex 5.

(3) The manufacturer or importer of a medical device may obtain a GMP certificate reissued for any of the following changes or write the changes on the back of the certificate:

1. change in the name of the place of manufacturing or importing business;
2. change in address of the manufacturing business (limited to changes under the proviso to Article 4 (1) 3);
3. change in the address of the importing business;
4. change in the name of the legal manufacturer or manufacturer; and
5. change in the address of the legal manufacturer or manufacturer (limited to changes under the proviso to Article 4 (1) 3).

(4) If writing the changes on the back of the certificate pursuant to paragraph (3), the manufacturer or importer of a medical device shall add the date they obtained the permission for the changes and the details of the changes.

Article 10-2 (Return of GMP Certificate) (1) A manufacturer or importer that has been issued a GMP certificate pursuant to Article 8 (8) may return the certificate to the certification body that issued it, specifying the reasons, if any of the following occur:

1. the manufacturing or import business permission is revoked;
2. the manufacturing or import license or certification is revoked; and
3. there are other reasons for the manufacturer or importer to return the GMP certificate.

(2) The head of a certification body to whom the GMP certificate has been returned pursuant to paragraph (1) shall report the return to the head of the Regional Office of Food and Drug Safety immediately upon the return.

Article 11 (Mark of GMP Audit) Manufacturers and importers of medical devices may display the mark of GMP Audit under Annex 6 for a medical device in the same product group of a manufacturing site that has taken GMP Audit.

Article 12 (Duties of Certification Body) The duties of the certification body shall be as follows:

1. conducting GMP Audit for medical devices;
2. issuing GMP certificates;
3. providing statistics and support for GMP Audit; and
4. other matters necessary for GMP Audit.

Article 13 (Evaluation and Designation of Certification Body) (1) The Minister of Food and Drug Safety shall, upon receiving an application for the designation of a certification body pursuant to Article 48 (1) of the Enforcement Rule, conduct a document review of the application and other submitted documents and an on-site evaluation.

(2) The Minister of Food and Drug Safety shall establish a plan for the on-site evaluation referred to in paragraph (1) and shall notify the applicant of the following at least seven days prior to the on-site evaluation:

1. the site and schedule of the on-site evaluation;
2. the composition of the on-site evaluation team; and
3. matters requiring cooperation under the on-site evaluation.

(3) The evaluation criteria for the designation of a certification body under paragraph (1) shall be as per Annex 7.

Article 14 (Management and Operations Standards for Certification Body) (1) The head of the certification body shall prepare the detailed regulations on operations necessary for GMP Audit.

(2) The head of the certification body shall obtain the approval of the Minister of Food and Drug Safety when establishing or amending the operating procedure pursuant to paragraph (1).

(3) An auditor of a certification body shall maintain impartiality and integrity during GMP Audit.

(4) An auditor of a certification body shall not disclose information learned in connection with GMP Audit to others or use it for purposes other than his or her duties.

(5) A company subject to GMP Audit may apply for recusal against a specific auditor for special reasons that make it difficult to expect a fair audit. The head of the certification body may replace the auditor if the recusal application is deemed valid.

(6) Other management and operations standards to be observed by the certification body shall be as per Annex 8.

Article 15 (Reporting) (1) The head of the certification body shall make the Medical Device GMP Audit Periodic Report in Form 4 and report the Detailed List of Medical Device GMP Audit, Etc. Results in Form 5 to the Minister of Food and Drug Safety and the head of the Regional Office of Food and Drug Safety within 20 days after the end of each quarter. Provided, That, if the Minister of Food and Drug Safety and the head of the Regional Office of Food and Drug Safety make a specific request for a submission, the relevant information shall be submitted within seven days from the date of the request.

(2) The head of the certification body shall report to the Minister of Food and Drug Safety within seven days if there is a change in personnel, such as changes in auditor’s position or employment status.

Article 16 (Assessment of the Certification Body) (1) The Minister of Food and Drug Safety shall provide annual assessment to the certification body on the proper conduct of GMP Audit and whether the certification body operates in accordance with the management and operations standards of the certification body.

(2) The Minister of Food and Drug Safety may provide assessment as frequently as needed to the certification body deemed to have problems in conducting GMP Audit as demonstrated by inadequate GMP Audit, complaints, etc.

(3) The Minister of Food and Drug Safety shall establish the detailed standard assessment of certification body pursuant to paragraphs (1) and (2).

Article 17 (Application for Designation as Training Organization for Quality manager) (1) If the Minister of Food and Drug Safety intends to designate an additional training organization for quality manager, he or she shall set a certain period as the application period to ensure that an institution or organization falling under Article 14 (1) of the Enforcement Rule can apply for designation as a training organization for quality manager.

(2) The specific criteria for the designation of a training organization for quality manager pursuant to Article 14 (6) of the Enforcement Rule shall be as per Annex 9.

Article 18 (Evaluation and Designation of Training Organization for Quality manager) (1) If the Minister of Food and Drug Safety receives an application for the designation as a training organization for quality manager pursuant to Article 17 (1), the Minister of Food and Drug Safety shall conduct a document review of the submission, including the application, and an inspection pursuant to Article 14 (2) of the Enforcement Rule.

(2) The Minister of Food and Drug Safety shall establish a plan for the inspection referred to in paragraph (1) and shall notify the applicant of the following at least seven days before the inspection:

1. the site and schedule of the inspection;
2. the composition of the inspection team; and
3. matters requiring cooperation under the inspection.

Article 19 (Public Announcement of Designation of Training Organizations for Quality manager) The Minister of Food and Drug Safety shall publicly announce training organizations for quality manager that meet the provisions of Article 17.

Article 20 (Content of Training) Pursuant to Article 13 (1) 4 of the Enforcement Rule, the head of the training organization for quality manager shall establish a training plan to include the following in the curriculum:

1. scope of duties of the quality manager under Article 12 of the Enforcement Rule;
2. information on safety in handling hazardous substances such as radiation;
3. matters that require the latest scientific and technical training on medical devices; and
4. other information on the latest amendments in the laws and regulations on medical devices.

Article 21 (Obligations, Etc. of the Head of Training Organizations for Quality manager) (1) The head of the training organization for quality manager shall obtain approval from the Minister of Food and Drug Safety for any amendments in the regulations on training implementation as per Annex 9.

(2) Pursuant to Article 15 (2) of the Enforcement Rule, the head of the training organization for quality manager shall establish a training plan that includes information under Article 20 and the following:

1. names of trainees and expected number by type of trainee;
2. venue;
3. fees (including justification for fees);
4. training method (by type of trainee, by region, etc.);
5. curriculum;
6. subjects, hours, and content by curriculum (including training materials);
7. instructors;
8. annual training schedule; and
9. other details necessary for the implementation of training.

(3) If the training plan under paragraph (2) is changed, the change plan shall be submitted to the Minister of Food and Drug Safety at least one month before the start of the training.

(4) The Minister of Food and Drug Safety shall review the training plan submitted under paragraph (2) and may require correction or supplementation if necessary.

(5) The Minister of Food and Drug Safety shall approve the training plan submitted pursuant to Article 15 (2) of the Enforcement Rule within 15 days from the date it is submitted.

Article 22 (Guidance and Inspection on Training Organizations for Quality manager) (1) The Minister of Food and Drug Safety shall provide guidance and inspection to training organizations for quality manager annually on whether they conduct appropriate training and operate in accordance with the regulations on training implementation.

(2) The Minister of Food and Drug Safety may provide guidance and monitoring as frequently as needed to the training organizations deemed to have problems in training implementation as demonstrated by inadequate training, complaints, etc.

(3) The Minister of Food and Drug Safety shall establish the detailed standard for guidance and monitoring necessary to conduct guidance and monitoring pursuant to paragraphs (1) and (2).

Article 23 (Reexamination of Regulations) Pursuant to Article 8 of the Framework Act on Administrative Regulations and the Regulations on Issuance and Management of Directives, Rules, etc., this standard shall be reexamined every three years from January 1, 2014 (meaning until December 31 of every third year) to determine its validity, and actions for improvement, etc. shall be taken.

ADDENDA <Act No. 2023-31, May 12, 2023>

Article 1 (Enforcement Date) This Notice shall enter into force on the day 6 months after announcement. Provided, That the amended provisions of Article 1, Article 7 (1) 2 (limited to the amendment of deleting item (r) of the same subparagraph), Article 8, and Annex 4 shall enter into force on the date of announcement.

Article 2 (Applicability) This amended notice shall apply to manufacturing sites that apply for GMP Audit for Medical Devices after the enforcement of this Notice.

Article 3 (Transitional Measures) (1) If a GMP certificate for medical device was issued under the previous notice at the time of enforcement of this notification, the GMP certificate for medical device shall be deemed to have been issued under this amended notice.

(2) Applications for GMP Audit for Medical Devices in progress shall be governed by previous provisions.

Annexes / Forms

[Annex 1] Terms and Definitions (Related to Article 2)

[Annex 2] The Standard for GMP Audit for Medical Devices (Related to Articles 5 and 6)

[Annex 3] GMP Product Groups for Medical Devices (Related to Articles 4, 6, and 7)

[Annex 4] The Auditing Body and Methods of GMP Audit (Related to Articles 6 and 8)

[Annex 5] Issuance and Management of GMP Certificate (Articles 8 (8), 9, and 10)

[Annex 6] Mark of GMP Audit (Related to Article 11)

[Annex 7] Evaluation Criteria for Medical Device Certification Body (Related to Article 13)

[Annex 8] Management and Operations Standards of Medical Device Certification Body (Related to Article 14)

[Annex 9] Designation Criteria for Training Organizations for Quality manager (Related to Article 17)

[Form 1] Application for GMP Audit for Medical Devices

[Form 2] Certificate of Good Manufacturing Practice for Medical Devices

[Form 2-2] Certificate of Good Manufacturing Practice for Medical Devices

[Form 3] GMP Audit Report for Medical Device

[Form 4] GMP Audit Periodic Report for Medical Device

[Form 5] Detailed List of GMP Audit Results for Medical Device