

## Medical Device Act Implementation Rules

[Enacted Jan. 17, 2025] [Prime Ministerial Decree No. 1936, Jan. 16, 2024, as amended].

Ministry of Food and Drug Safety (Medical Device Policy Division) 043-719-3778, 3783

**Article 11 (Qualification of Quality Manager, etc.)** ① A person who intends to obtain a manufacturing license pursuant to Article 6 (1) of the Act shall have at least one quality manager for each manufacturing plant.

② Quality Officer duties may be performed by a person qualified under any of the following subparagraphs. < Revised June 15, 2016, April 13, 2020, and December 19, 2022.

1. a person who holds a license under each of the following classifications under the Medical Technicians, etc. Act
  - a. If you manufacture or import eyeglasses and lenses: Opticians
  - B. Manufacturing and importing dental materials: dental technicians and dental hygienists
  - C. Manufactures and imports radiation generating devices: Radiologists
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  - E. Manufacturing and importing medical devices necessary for physical therapy or rehabilitation training: Physical therapists
2. a person qualified as a medical engineer or quality management engineer under the National Technical Qualification Act
- 2.2. A person who is qualified as a medical device RA (Regulatory Affairs) expert certified by the Minister of Food and Drug Safety under Article 19 (1) of the Basic Act on Qualifications
3. a person who has obtained a bachelor's degree from a school (excluding a vocational college pursuant to Article 2, paragraph 4 of the Higher Education Act (hereinafter referred to in this Article as "university") (including a person who has been recognized as having such a level of education or higher in accordance with laws and regulations; hereinafter referred to in this Article as "university") and majored in a field related to natural science, engineering, or medicine (hereinafter referred to in this Article as "medical device-related field") pursuant to Article 2, paragraph 9 of the Regulations for the Establishment and Operation of Universities
4. a person who has obtained a bachelor's degree in a field other than a medical device-related field from a university or other institution, and has obtained a master's degree or higher in a medical device-related field from a graduate school in accordance with Article 29 of the Higher Education Act
5. a person who has a bachelor's degree in a field other than a medical device-related field from a university or college, and has at least one year of experience in quality control work at a medical device manufacturer or importer (including experience prior to obtaining the degree or recognition of the degree)
6. a person who has graduated from a vocational college pursuant to Article 2, paragraph 4 of the Higher Education Act

(including a person who has been recognized as having such a level of education or higher in accordance with the law (hereinafter referred to in this Article)), who has majored in a field related to medical devices and has worked in quality control at a medical device manufacturer or importer for at least one year (including work experience prior to graduation or recognition of education)

7. a graduate of a vocational college pursuant to Article 2, paragraph 4 of the Higher Education Act, who majored in a field other than a medical device-related field and has worked in quality control at a medical device manufacturer or importer for at least three years (two years in the case of a graduate of a vocational college with three years of classes pursuant to Article 48, paragraph 1 of the Higher Education Act) (including work experience prior to graduation or recognition of academic credentials)
  8. a graduate of a high school or technical school pursuant to Article 2, paragraph 3 of the Elementary and Secondary Education Act (including a person recognized as having such a level of education or higher in accordance with laws and regulations, but excluding cases falling under paragraph 9) who has worked in quality control at a medical device manufacturer or importer for more than five years
  9. a graduate of a high school customized for industrial needs in a medical device-related field pursuant to Article 90 (1) (10) of the Enforcement Decree of the Elementary and Secondary Education Act, and has worked in quality control at a medical device manufacturer or importer for at least three years
  10. 6 or more years of experience in quality control at a medical device manufacturer or importer
- ③ If a manufacturer has two or more quality officers pursuant to paragraph (1), the manufacturer shall divide the duties of the quality officers and clarify the limits of the responsibilities of each quality officer.