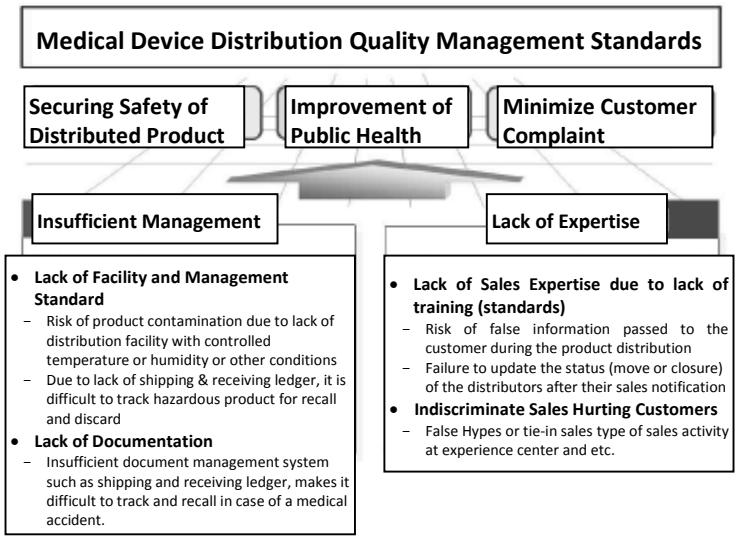
Medical Device Distribution Quality Management Standards Summary

1. Background

- The demand for medical device is rising due to aging population, but the management standard for medical device distribution is insufficient and causing following problems
  - Insufficient medical device storage facility standard → product contamination
  - Insufficient record management for its own medical devices → difficult to track hazardous product
  - Insufficient training on Medical Device Act → lack of expertise

- Therefore, by introducing " Medical Device Distribution Quality Management Standards", the goal is to ensure the safety of the medical device distributed from manufacturing · import stage to the final consumption stage, and to minimize the customer complaint and ultimately to tribute to the improvement of public health.



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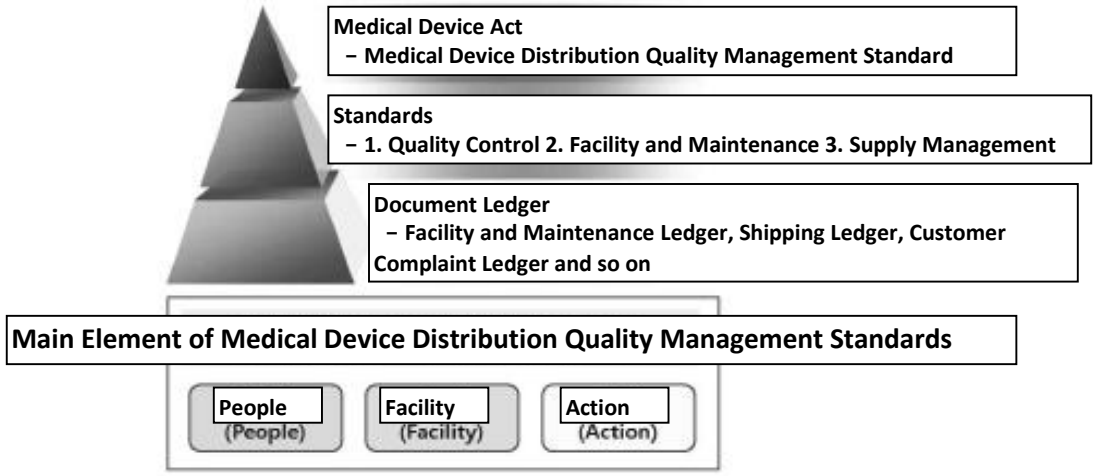
2. System and Structure

System of Medical Device Distribution Quality Management

- Creation of the Standards (facility and maintenance, supply management, quality control) and placement is recommended



Structure of Medical Device Distribution Quality Management Standards

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3. Related Act

- Medical Device Act
  - ○ Article 17 (Notification of Sales business and etc)
    1. Those who sell medical devices as a job(referred to dealer) or those who give rents (referred to leasing vendor) need to notify their sales or rental business to chiefs of the local government such as mayors, and governors or heads of special self-governing province or counties or autonomous districts.
    2. If the case falls under one of the following circumstances, the notification according to the claim 1, can be skipped.
       1) Case that the manufacturer or the importer sell or rent the manufactured or imported medical device to the medical device carrier.
       2) Case that those who notified as a sales business, runs a rental business.
       3) Case that pharmacy retailer or pharmaceutical wholesaler sell or rent medical devices
       4) Case of selling pregnancy controlling product by the Ordinance of the Prime Minister or self-diagnosis product used in other than medical facility.
  - ○ Article 18 (Regulation in Sales Business)
    1. Who is authorized to sell or rent medical devices by this act, as stated in Ordinance of the President, must follow the method on ensuring method of quality medical devices at the office, and keep out of matters relating to sales order maintenance.
  - ○ Article 36 (Cancelation of permit and suspension of business)
    1. If the manufacturers and other s falls under one of the condition below (omitted) the cancelation of permit, closure of the office, ban of manufacturing, import and sales of the categories or items, or suspension of all or part of the business within the range of 1 year can be ordered.
       1) ~10) Omitted
       11) Violating the Article 18 Claim 1, the case that he/she failed to follow the subjects like sales order maintenance
  - ○ Article 54 (Punishment) Who falls under one of the following conditions, is the subject of under 5 million won fine.
    1. Who violated Article 18 Claim 1 ~

- Medical Device Act Enforcement Ordinance
  - ○ By the article 18 claim 1, the sales or rental dealers must follow the following item.
    1. By Ordinance of the Prime Minister, subjects related to the method to ensure the quality of medical device, and the safety related sales order maintenance.

- Medical Device Act Enforcement Regulation
  - ○ Article 24-2 (Dealers and Leasing Vendors' compliance)

    By the law article 17 Paragraph 2 Claim 4, the medical devices that is eligible to be sold without the notification are as following,
    1. Condoms

2. Cellular phones or electrical appliances with the function of checking blood glucose level, or combined with blood glucose meter

3.Self diagnosis medical devices announced by commissioner of KFDA with consideration of hazardous level and safety, such as combined with other industrial products.

○ Article 25 (Method to ensure the quality of medical devices of Dealers and Leasing Vendors)

- By the Article 18 Paragraph 1 and [Medical Device Act Enforcement Ordinance] Article 10-2 Claim 1, the medical device quality ensuring methods are as following.

1.~ 3. Omitted

4. Obey the Medical Sales Quality Management Standard in attached table 6-2.

<Supplementary Regulation> Ordinance of Prime Minister, Claim1081. 2014.5.9

- Article 1 (Enforcement Date) This regulation takes effect from the day of its announcement. However, following claims will take effect on its categorized date.

  2. Article 25 Paragraph 2 Claim 4, Attached Table 6-2, Attached Table 7, Claim 18 of II Revised Regulation : Jan. 1st in 2015

- Article 16 (Interim Action from Enforcement of Sales Quality Management Standard) Who notified sales business or rent business on the enforcement date from Supplementary Regulation Article 1 Claim2, is considered to have the method to ensure the medical device quality, obeying the revised regulation of Article 25 Paragraph 1 Claim 4. However, he/she should be properly following the standard from the revised regulation of the attached table 6-2 before Dec. 31st in 2015