MDREX

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[MDREX Newsletter] New Guidelines on addresses of manufacturing sites for KGMP certification of medical devices

The Ministry of Food and Drug Safety ("MFDS") in Korea released new 'Guidelines on addresses of KGMP manufacturing sites for medical devices' ("Guidelines")on June 2, 2023. This new guidelines provides clear guidance on how to insert addresses as well as the format for KGMP certification application of manufacturing sites of medical devices. As a reference, the addresses inserted in the application for KGMP certification will also be reflected in the certifications itself and only the addresses that have been included in the certification will permitted to export medical devices to the Korean market. If a product that is manufactured from a non-KGMP certified manufacturing site is imported into Korea, the importer of the medical device can be liable for administrative and criminal sanctions such as business suspension and/or prison term/criminal fines. Please see a summary of the Guidelines as follows:

1. For a sole manufacturing site

   - ✓ If all manufacturing processes or major processes are carried out at a single manufacturing site, applicants can use this address as the KGMP manufacturing site.
   - ✓ However, if there are any workshops, storage, and testing sites classified in the manufacturing site and such location number (address) is different, all address information must be described in the KGMP application.

2. If the address of the head office and the manufacturing site is different

   - ✓ If a sole manufacturer has a separate headquarter site where the office is engaged in office tasks (e.g., customer complaints, purchasing work, etc.) and a separate manufacturing site exists, both addresses of the headquarters and the manufacturing site must be described in the application.

3. In the case of consignment/outsourcing manufacturing due to a contractual relationship

   - ✓ If there is a separate process of consignment production of all or major processes, then such sites must submit separate applications for KGMP certifications either as a 'contracted manufacturer' and/or as the 'manufacturer'.

- ✓ If the manufacturer has a separate site where it inspects and stores the products sent by the contract manufacturer, then such sites must also be included in the KGMP certification application as "inspection site/storage".

4. Manufacturing at multiple manufacturing sites

- ✓ If a product is manufactured at multiple manufacturing sites at the same time, or if a single product is manufactured via multiple manufacturer sites, all manufacturing addresses must be included in the application.

5. If a contracted manufacturer re-contracts to another manufacturer

- ✓ Each manufacturing site must be included in the KGMP application and these various manufacturing sites must also be designated as either the manufacturer, contracted manufacturer, or re-contracted manufacturer in the KGMP application so that the MFDS has full oversight over the manufacturing relationship between the parties.

6. If only some products are transferred from a manufacturing site that manufacturers multiple KGMP certified products, to another manufacturing site

- ✓ Newly added manufacturing sites are classified as new applicants subject to KGMP initial auditing/screening process. Therefore, these new sites must apply for a new KGMP certification including the location of addresses for the newly added manufacturing sites.

Please feel free to reach out to us at MDREX (pro@mdrex.co.kr) if you have any questions regarding KGMP certification to commercialize in the Korean market.

Kind regards,

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MDREX is a boutique Korea Medical Device Regulatory, Quality, Compliance, Reimbursement and Clinical Consulting Firm dedicated to providing strategic and operational consulting service to medical device and digital health companies.