

**FDA CIRCULAR**

No. \_\_\_\_\_

**SUBJECT : Adoption of Good Manufacturing Practices (GMP) Guidelines for Medical Devices Under the Philippine National Standard (PNS) ISO 13485:2019**

**I. RATIONALE**

Republic Act (RA) No. 9711<sup>1</sup> has declared the state's policy to adopt, establish and institutionalize processes, mechanisms and initiatives that protect and promote the right to health of the Filipino people. In line with this mandate, the FDA is empowered to develop and issue standards that cover health product establishments, including local manufacturers of medical devices and in-vitro diagnostic (IVD) medical devices.

Administrative Order (AO) No. 2024-0015<sup>2</sup> requires all covered establishments to demonstrate compliance with the standards appropriate to their authorized activity(ies). These standards include, but are not limited to: Good Manufacturing Practices (GMP), Good Laboratory Practices, Good Clinical Practices, and Good Distribution and Storage Practices.

Given the wide array of available medical devices, including IVD medical devices, and the rapid emergence of new technologies, it is essential for local manufacturers of medical devices, including IVD medical devices, to adhere to recognized manufacturing and control standards applicable to their processes. Compliance with these recognized standards, such as GMP standards, is essential to ensure product safety, quality, and effectiveness / performance, thereby safeguarding public health while minimizing manufacturing risks and reducing the occurrence of adverse events (AE).

In the interest of service, this Circular is hereby issued to adopt GMP guidelines for medical devices under PNS ISO 13485:2019<sup>3</sup> ensuring that all medical devices, including IVD medical devices, are manufactured in accordance with applicable quality standards.

**II. OBJECTIVE**

This Circular aims to adopt GMP guidelines for medical devices under PNS ISO 13485:2019.

**III. SCOPE**

A. This Circular shall apply to all local manufacturers of medical devices, including IVD medical devices.

<sup>1</sup> Food and Drug Administration (FDA) Act of 2009

<sup>2</sup> Prescribing the Rules, Requirements and Procedures in the Application for License to Operate of Covered Health Product Establishments with the Food and Drug Administration Repealing for the Purpose Administrative Order No. 2020-0017

<sup>3</sup> Medical devices — Quality management systems — Requirements for regulatory purposes

B. The following are considered manufacturers and, if operating locally, shall be covered by this Circular:

1. Packers, repackers, refurbishers and toll manufacturers;
2. All hospitals or establishments engaged in the 3D printing of medical devices;
3. Optical establishments engaged in the assembly of optical lenses and frames; and
4. Dental laboratories engaged in the manufacture of custom-made dental devices.

C. The following shall not be covered by this Circular:

1. Traders of medical devices, including IVD medical devices;
2. Establishments and research organizations utilizing medical devices exclusively for research, including Research-Use-Only (RUO) medical devices. These establishments and organizations shall be covered by separate guidelines.

#### IV. DEFINITION OF TERMS

The terms defined in RA No. 9711 and other related laws, regulations, and standards are hereby adopted. However, the following terms are hereby defined for greater clarity:

A. **Good Manufacturing Practice (GMP)** refers to the aspect of quality assurance that ensures that medical devices, including IVD medical devices, are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the product specification.

GMP defines quality measures for both production and quality control and defines general measures to ensure that processes necessary for production and testing are clearly defined, validated, reviewed, and documented, and that the personnel, premises and materials are suitable for the production of medical devices, including IVD medical devices. GMP also has legal components, covering responsibilities for distribution, contract manufacturing and testing, and responses to product defects and complaints.

B. **Manufacturer**, in relation to a health product, refers to an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packing, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution: *provided*, that the term shall not apply to the compounding and filling of prescriptions in drugstores and hospital pharmacies. A trader shall be categorized as a manufacturer.

C. **National Standard** refers to a standard developed/adopted and published by a National Standards Body and made available to the public. The Department of Trade and Industry, through the Bureau of Philippine Standards, is the responsible agency that develops and publishes Philippine National Standards (PNS).

- 1 D. **Packer** refers to any establishment that packages bulk products into its immediate  
2 container with the end view of storage, distribution, or sale of the product.  
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4 E. **Refurbisher** refers to an establishment engaged in the rebuilt of certain medical  
5 device (in whole or any part thereof), whether or not using parts from one or more  
6 used certain medical devices of the same kind, so as to create a medical device that  
7 can be used for the purpose originally intended by the product owner of the original  
8 medical device.  
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10 F. **Repacker** refers to any establishment that repacks a finished product into smaller  
11 quantities in a separate container and/or secondary packaging, including but not  
12 limited to relabeling, stickering, and bundling for promo packs with the end view of  
13 storage, distribution, or sale of the product.  
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15 G. **Research - Use Only** refers to the distribution of medical devices to  
16 institutions/laboratories to be subject to studies intended for collation of data only.  
17 The product is not intended for any medical purpose or objective.  
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19 H. **Standard** refers to a document approved by a recognized body that provides, for  
20 common and repeated use, rules, guidelines or characteristics for products or related  
21 processes and production methods, with which compliance is not mandatory. It may  
22 also include or deal exclusively with terminology, symbols, packaging, marking or  
23 labelling requirements as they apply to a product, process or production method.  
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25 I. **Trader** refers to any establishment which is a registered owner of a health product  
26 and procures the raw materials and packing components and provides the production  
27 monographs, quality control standards and procedures, but subcontract the  
28 manufacture of such product to a licensed manufacturer. In addition, a trader may  
29 also engage in the distribution and/or marketing of its products.  
30  
31 J. **Toll Manufacturer** refers to the manufacturer that conducts contract manufacturing  
32 where conditions of the contract are defined, agreed and controlled; and all aspects  
33 of contracted work are specified to obtain quality product/s conforming to the agreed  
34 standards.  
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36 K. **3D Printing** refers to the fabrication of objects through the deposition of a material  
37 using a print head, nozzle, or another printer technology.  
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## 40 V. GUIDELINES

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42 A. PNS ISO 13485:2019 shall be adopted as the FDA's official guideline on the conduct  
43 of GMP. All local manufacturers of medical devices, including IVD medical devices,  
44 shall adhere to the relevant provisions outlined in the said PNS.  
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46 B. All amendments and supplements to PNS ISO 13485:2019 shall be adopted  
47 automatically and shall be formally communicated through an FDA Advisory.  
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C. All local manufacturers of medical devices, including IVD medical devices, shall secure a copy of PNS ISO 13485:2019.

D. Compliance with PNS ISO 13485:2019 shall be verified during FDA-GMP related inspections.

E. Guidelines on the conduct of FDA-GMP inspection and issuance of GMP certificates shall be outlined in a separate FDA issuance.

## **VI. TRANSITORY PERIOD**

Upon effectivity of this Circular, all local manufacturers of medical devices, including IVD medical devices, shall be given two (2) years to comply with the new guidelines.

During the transitory period, local manufacturers of medical devices, including IVD medical devices, may continue to apply their existing GMP standards for the purposes of GMP inspections and GMP certificate applications. Following the end of the transitory period, they shall be required to implement the guidelines outlined in this Circular.

## **VII. PENALTY CLAUSE**

Any person found in violation of the provisions of this Circular shall be deemed in violation of RA No. 3720<sup>1</sup> as amended by RA No. 9711 and shall be penalized accordingly following the Uniform Rules of Procedures laid down under Book III of the Implementing Rules and Regulations of RA No. 9711.

## **VIII. SEPARABILITY CLAUSE**

Should any part, term or provision of this Circular be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions hereof shall not be affected and this Circular shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term or provision.

## **IX. REPEALING CLAUSE**

Any circulars, issuances, rules and regulations which are inconsistent with the provisions of this Circular are hereby repealed or amended accordingly.

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<sup>1</sup> Food, Drug, and Cosmetic Act

1   **X.     EFFECTIVITY**

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3       This Circular shall take effect fifteen (15) days after its publication in the Official Gazette  
4       or in any newspaper of general circulation and upon filing with the University of the  
5       Philippines Law Center Office of the National Administrative Register.  
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9                                   **EDWIN M. MERCADO, MD, MHA, MMSc**  
10                                   Secretary of Health

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DRAFT POLICY FOR REVIEW