NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

NAFDAC Good Manufacturing Practice (for Medical Devices and Related Products) Regulations, 2024

Comments are Welcomed from Stakeholders Within 60 Calendar Days (Ending 23rd January, 2025).

Please Send All Input to regulatoryaffairs@nafdac.gov.ng

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Arrangement of Regulations

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[ ] Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control ('the Governing Council') by Section 30 of the National Agency for Food and Drug Administration and Control Act, Cap. N1, LFN, 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act. Cap. F33. LFN, 2004 and of all the powers enabling it in that behalf, the Governing Council with the approval of the Minister makes the following Regulations: -

PART 1
OBJECTIVE AND APPLICATION

23. **Objective**

The objective of these Regulations is to provide regulatory framework for the required minimum good manufacturing practice for medical devices, In Vitro Diagnostics (IVDs) and related products manufactured, imported, exported, advertised, sold, displayed for sale, distributed, or used in Nigeria.

24. **Application**

(1) These Regulations prescribe the minimum good manufacturing practice requirements for methods to be used in, and the facilities and controls to be used for, the manufacture, processing, packaging, or holding of medical device, IVDs or related product for human or animal use, to ensure that such product meets the requirements of the essential principles for safety and performance and meets the quality characteristics that it purports or is represented to possess.

(2) These Regulations shall apply to the manufacture, processing, packaging, or holding of medical device, IVD or related product for human or animal use

Part 2
Registration, Labeling and Advertisement, Quality System, Personnel, Premises and Equipment, Design Controls, Qualification and Validation

25. **Registration, Labeling and Advertisement**

The registration, labelling and advertisement of medical devices, IVD and related products shall be in accordance with the NAFDAC Medical Devices and Related Products (Registration, Labelling and Advertisement) Regulations 2024.

26. **Quality System**

(1) A manufacturer shall establish

(a) and maintain a quality system that is appropriate for the specific medical device, IVD or related product designed or manufactured, and that meets the requirements of this part.

(b) a quality system which shall cover organisational structure, responsibilities, policies, procedures, processes and application of the principles of risk management, as well as appropriate resource, compliance and records management.

(2) Top management of the organization shall have the responsibility to ensure that an effective quality system is in place, adequately resourced, the effectiveness continually improved, and roles, responsibilities, and authorities are defined, communicated and implemented throughout the organisation.

(3) The organizational structure shall clearly define the responsibilities, authorities, interrelationships and qualifications of all personnel in the organization as well as its place in the parent organization, where applicable.

27. **Personnel**

(1) A manufacturer shall have sufficient number of competent and appropriately qualified personnel to perform assigned functions and achieve the quality management objectives.

(2) Initial and continuing training shall be in the particular operations that the employee performs and in good manufacturing practices as they relate to the employee's functions and the training effectiveness shall be verified and records of training shall be kept.

(3) Consultants advising on the manufacture, processing, packaging, or holding of medical device, IVD or related products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

(4) Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall include procedures relating to health, hygiene practice and clothing of personnel.

28. **Premises and Equipment**

(1) Building and equipment used in the manufacture, processing, packaging, or holding of medical devices, IVD and related product shall be adequately located, designed, constructed, adapted, maintained and of suitable size to facilitate cleaning, maintenance, proper operations and safety of operators as appropriate to the type and stage of manufacture.

(2) Building shall have adequate space for the orderly placement of equipment and materials and shall have orderly flow of personnel, materials and processes through the building to prevent mix-ups, contamination, cross contamination and any adverse effect on the quality of the product.

(3) There shall be dedicated and self-contained facilities for the production of different classes of medical device, IVD and related product to minimize the risk of serious medical hazards due to cross-contamination, where applicable.

(4) The manufacturer shall establish a program for preventive and breakdown maintenance of all equipment and instrument inclusive of all GMP support facilities.

29. **Design Controls**

A Manufacturer shall

(a) create and maintain plans that outline design and development activities. All inputs and outputs shall be documented and reviewed.

(b) ensure that design outputs align with design inputs and that devices conform to intended uses.

30. **Qualification and validation**

(1) Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.

(2) Critical processes and GMP support systems shall be validated, continually monitored and periodically re-validated.

(3) Changes to processes, systems, equipment, or materials that may affect product quality or process reproducibility shall be requalified or re-validated prior to routine implementation.

Part 3
Documentation, Production, Purchasing and Materials management, Quality Assurance & Quality Control, Contract manufacture and analysis

31. **Documentation**

(1) A manufacturer shall

(a) ensure adherence to good documentation practices.

(b) establish and maintain a documentation system based upon instructions, records and reports covering the various manufacturing and control operations and all activities performed as appropriate to the quality system.

(2) Pre-established procedures for general manufacturing operations and conditions shall be kept available together with specific documents for the manufacture and control of each batch or lot and the documents shall enable the history of the manufacture of each batch or lot of medical devices, IVD and related products traced.

(3) Manufacturing records pertaining to medical device, IVD and related product shall be maintained for at least 1 year after the expiration date of the product.

(4) Data may be stored by means of electronic, photographic or other data processing systems which shall first be validated to ensure that the data will be appropriately stored during the anticipated period of storage.

(5) Data stored by those systems shall be made readily available in legible form and shall be provided to the Agency on request.

(6) The electronically stored data shall be protected by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.

(7) Adequate measures to ensure data integrity, confidentiality and security shall be established, implemented and maintained.

32. **Production**

(1) Procedures and instructions shall be established for production and process control to ensure that medical device, IVD and related product has the identity, safety, performance, and reliability it purports or is represented to possess, and the procedures and instructions shall be followed, and records maintained.

(2) Any deviation from the procedures and instructions shall be reported, investigated, recorded and justified.

(3) Medical device, IVD and related product defects shall be documented and thoroughly investigated for determination of root cause and appropriate corrective and preventive actions.

(4) There shall be adequate in-process control for production operations which shall be sufficiently resourced.
(5) Measures shall be taken to mitigate risks of contamination and mix-ups.
(6) Procedures for rework or reprocessing of medical device, IVD and related product must be establish and detailed record maintained, including retesting and re-evaluation of the nonconforming product after rework or reprocessing to ensure it meets approved specifications.
(7) Manufacturer must maintain Device History Records (DHRs) for each batch, lot, or unit to demonstrate compliance with the Device Master Record (DMR) procedure.

33. **Purchasing and Materials management**
(1) A manufacturer shall maintain a list of approved suppliers from whom it shall source all materials and services.
(2) Adequate measures shall be taken to ensure that materials meet established specifications before use. Only materials released by the quality unit and within their shelf-life, where applicable, shall be used for manufacturing and control activities.
(3) Materials and products shall be stored under the appropriate conditions established by the manufacturer, and in an orderly manner, to permit batch segregation and stock rotation.
(4) Cleaning, lubricating, fumigating, sanitizing and pest control materials shall not contaminate equipment and materials.

34. **Quality Assurance & Quality Control**
(1) Manufacturer of medical device, IVD and related product shall establish and maintain a quality assurance department which shall be a distinct organizational unit that functions and reports to management independently of any other functional unit.
(2) Manufacturer of medical device, IVD and related product shall establish and maintain a quality control department under the authority of a person with appropriate qualifications and experience having at his disposal or have access to one or more control laboratories, which are adequately resourced to carry out the necessary examinations and testing of materials.
(3) Materials shall not be released for use, sale or distribution unless their quality has been adjudged satisfactory and approved by the authorized person.
(4) The manufacturer shall retain appropriate number of samples of each batch of finished medical device, IVD and related products for at least one year after the expiry date.

35. **Contract manufacture and analysis**
(1) Where the whole or a part of the manufacturing process or analysis of materials or products is contracted, the contract shall be in written form, clearly spelling out the responsibilities of each party.
(2) The contract shall clearly state the observance of good manufacturing practice and other relevant requirements to be followed by the contract acceptor and the manner in which each batch is to be released by the authorized person.
(3) The contract acceptor shall be subject to inspections carried out by the Agency and the contract giver.
(4) The contract acceptor shall not subcontract any of the work entrusted to him under the contract without written authorization from the contract-giver.

Part 4
Complaints and product recall, Quality Audit, Non-compliance with GMP requirements, Prohibition

36. **Complaints and product recall**

(1) Complaints and other information concerning potentially defective products shall be carefully investigated, recorded and reviewed according to written procedures by the manufacturer.

(2) A manufacturer shall

(a) establish and maintain a system to recall from the market, promptly and effectively, products known or suspected to be defective.

(b) inform the Agency of any defect that could result in the recall or abnormal restriction on supply of a medical device, IVD and related product within and outside the country as well as any regulatory action taken against the company by relevant authorities by virtue of non-compliance with requirements.

37. **Quality Audit**

(1) The manufacturer shall establish a routinely implemented quality audit programme designed to monitor the implementation of GMP and compliance of the quality system with established requirements.

(2) The recommended corrective and preventive actions shall be implemented, and records maintained.

38. **Non-compliance with GMP requirements**

The Agency may as part of control measures withdraw, cancel or suspend the manufacturing authorization of any company that contravenes the provisions of these Regulations.

39. **Prohibition**

A person shall not manufacture, process, package, or hold a medical device, IVD or related products except as provided in these Regulations.

Part 5
Offences and Penalty, Forfeiture after conviction

40. **Offences and Penalties**

(1) Any person who contravenes any of the provisions of these Regulations commits an offence and liable on conviction. In the case of: -

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N800,000:00 or both,

(b) a body corporate, to a fine not exceeding N5,000, 000:00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or any other association of individuals, every: -

(a) director, manager, secretary or other similar officer of the body corporate;

(b) partner or officer of the firm;

(c) trustee of the body concerned;

(d) person concerned in the management of the affairs of the association; or

(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, commits an offence and liable to be proceeded against and punished in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

41. **Forfeiture after conviction**

(1) A person convicted of an offence under these Regulations shall forfeit to the Federal Government:-

(a) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence; and

(b) any of the person's property or instruments used in any manner to commit or to facilitate the commission of the offence.

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

Part 6
Miscellaneous

42. **Interpretations**

In these Regulations, unless the context otherwise requires:

Agency means National Agency for Food and Drug Administration and Control;

Authorized person means the person recognised by the Agency as having the necessary basic scientific and technical background and experience; and who is responsible for ensuring that each batch of finished product has been manufactured, tested and approved for release in compliance with regulations of the Agency;

Batch means a specific quantity of a medical device that is intended to have uniform character and quality, within specified limit, and is produced according to a single manufacturing order during the same cycle of manufacturing process;

Contamination means the undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport;

Good Manufacturing Practice (GMP) means that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the Certificate of Registration;

In-process control means checks performed during production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control;

Lot refer to a batch or a specific identified portion of a batch that has uniform character and quality within specified limit or a specific identified amount produced in a unit of time;;

Manufacture means all operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of medical devices or related products, and the related controls;

Manufacturer means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of medical devices and related products;

Materials means a general term used to denote design components, raw materials, process aids, intermediates, device containers, closures, packaging and labelling materials including finished devices.

Medical device means any instrument, apparatus, machine appliance, implant, reagent for in vitro use, software, material, or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes;

Packaging material means any material employed in the packaging of a device product, excluding any outer packaging used for transportation or shipment and packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product;

Proceeds means any property derived or obtained, directly or indirectly, through the commission of the offence.

Production means all operations involved in the preparation of a medical device or related product, from receipt of materials, through processing and packaging, to its completion as a finished product;

Quality control (QC) means the part of GMP that is concerned with sampling, specifications, testing, documentation, and release procedures which ensures that materials are not released for use, and that medical device and related products are not released for sale or supply, until their quality has been deemed satisfactory;

Regulatory action includes but not limited to product hold, recall, forfeiture, or destruction, sealing of manufacturing line or facility, withdrawal of GMP certificate or product license or registration certificate, prosecution;

Specifications means a list of detailed requirements with which the products or materials used or obtained during manufacture have to conform and they serve as a basis for quality evaluation;

Validation means a documented program that provides a high degree of assurance that a specific process, method, or system will consistently produce a result meeting pre-determined criterion.

43. **Enforcement of the Regulations**
The Agency is exclusively responsible for the enforcement of these Regulations**.**

44. **Citation**
These Regulations may be cited as NAFDAC Good Manufacturing Practice for Medical Devices and Related Products Regulations, 2024

MADE at Abuja this ……. day of ……... 2020

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Dr. Mansur Kabir
Chairman of the Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)