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

GOOD MANUFACTURING PRACTICE FOR PHARMACEUTICAL PRODUCTS REGULATIONS 2019

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 2nd September, 2019).
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REGULATORYAFFAIRS@NAFDAC.GOV.NG

ARRANGEMENT OF REGULATIONS

Commencement

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all the powers enabling it in that behalf, THE GOVERNING COUNCIL OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL with the approval of the Honourable Minister of Health hereby makes the following Regulations:-

1. **Scope**

   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 a pharmaceutical product for human or animal use, to ensure that such pharmaceutical product meets the requirements of safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

2. **Applicability**

   These Regulations shall apply to the manufacture, processing, packaging, or holding of a pharmaceutical product for human or animal use

3. **Prohibition**

   (1) No person shall manufacture, process, package, or hold a pharmaceutical product except as provided in these Regulations.

   (2) Failure to comply with any provision set forth in these Regulations shall render such pharmaceutical product substandard and/or adulterated and such pharmaceutical product, as well as the person responsible for the non-compliance, shall be liable to the penalty set out in Regulation 15 of these Regulations.

4. **Pharmaceutical Quality System**

   (1) The manufacturer shall establish 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 management, compliance management and records management.

   (2) Top management of the organization shall have the responsibility to ensure an effective quality system is in place, adequately resourced, the effectiveness continually improved and that 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.

5. **Personnel**

(1) The 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. Training effectiveness shall be verified and records of training shall be kept.

(3) Consultants advising on the manufacture, processing, packaging, or holding of pharmaceutical 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.

6. **Premises and Equipment**

(1) Any building and equipment used in the manufacture, processing, packaging, or holding of a pharmaceutical 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) The 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 highly sensitizing and highly potent pharmaceutical products to minimize the risk of serious medical hazards due to cross-contamination.

(4) Highly toxic non-pharmaceutical materials shall not be manufactured or held in premises used for the manufacture of pharmaceutical products.

(5) The manufacturer shall establish a program for preventive and breakdown maintenance of all equipment and instruments.

7. **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) All critical processes 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 re-validated prior to implementation.

(4) Retrospective validation shall not be permitted in the production of parenteral preparations

8. **Documentation**

(1) The manufacturer shall 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 pharmaceutical 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. The set of documents shall enable the history of the manufacture of each batch of pharmaceutical product to be traced.

(3) The manufacturer shall ensure adherence to good documentation practices.

(4) All records pertaining to a pharmaceutical product shall be maintained for at least 1 year after the expiration date of the product.

(5) 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.

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

(7) 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.

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

9. **Production**

(1) Procedures and instructions shall be established for production and process control to ensure that a pharmaceutical product has the identity, strength, quality, and purity it purports or is represented to possess. 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) All pharmaceutical product defects shall be documented and thoroughly investigated

(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 cross-contamination and mix-ups.

(6) The reworking of finished pharmaceutical products shall not be permitted.

10. **Materials management**

(1) The 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 shall be used for manufacturing and control activities.

(3) All materials and products should be stored under the appropriate conditions established by the manufacturer, and in an orderly fashion, to permit batch segregation and stock rotation.

(4) Cleaning, lubricating, fumigating, sanitizing and pest control materials shall not contaminate equipment and materials.

11. **Quality Control**

(1) Each manufacturer of pharmaceutical products shall establish and maintain a quality control department which shall be a distinct organizational unit that functions and reports to management independently of any other functional unit.

(2) The quality control department shall be under the authority of a person with appropriate qualifications and experience and shall have at his disposal or have access to one or more control laboratories. The control laboratories shall be adequately resourced to carry out the necessary examinations and testing of materials and shall comply with good practices for pharmaceutical quality control laboratories.

(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 samples of each batch of finished pharmaceutical product and active pharmaceutical ingredient for at least one year after the expiry date. Other starting materials (with the exception of solvents, gases and water) shall be retained for a minimum of two years after the release of the product, if their stability allows.

12. **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, good practices for pharmaceutical quality control laboratories and registration 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.

13. **Complaints and product recall**

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

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

(3) The manufacturer shall inform the Agency of any defect that could result in the recall or abnormal restriction on supply of a pharmaceutical 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.

14. **Self-inspection**

(1) The manufacturer shall establish a routinely implemented self-inspection programme designed to monitor the implementation of GMP.

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

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

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

16. **Penalty.**

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

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and

(b) a body corporate, to a fine not exceeding N100, 000.

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

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

(b) partner or officer of the firm or

(c) trustee of the body concerned ;or

(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, is severally guilty of that offence and liable to be proceeded against and punished for that offence 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

17. **Interpretations**

In these regulations, unless the context otherwise requires the following terms shall have the meanings specified:

'Act' means the NAFDAC Act, Cap N1, LFN 2004

'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 defined quantity of starting material, packaging material, or product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches, which are later brought together to form a final homogeneous batch. In the case of terminal sterilization, the batch size is determined by the capacity of the autoclave. In continuous manufacture, the batch must correspond to a defined fraction of the production, characterized by its intended homogeneity. The batch size can be defined either as a fixed quantity or as the amount produced in a fixed time interval.

'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.

'Cross contamination' means contamination of a starting material, intermediate product or finished product with another starting material or product during production.
'Finished product' means A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.

'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.

'In-process material' means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the pharmaceutical product.

'Manufacture' means all operations of purchase of materials and products, production, quality control (QC), release, storage and distribution of pharmaceutical products, and the related controls.

'Manufacturer' means a company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceuticals.

'Materials' means a general term used to denote components, raw materials (starting materials, reagents, solvents), process aids, intermediates, APIs, product containers, closures, packaging and labelling materials and in-process materials.

'Pharmaceutical product' means any substance or combination of substances which may be administered to human beings or animals with a view to preventing diseases, making a medical diagnosis or restoring, correcting or modifying physiological functions in human beings or in

animals and also includes the definition of drug under the NAFDAC Act. Pharmaceutical products may also be referred to as medicinal products.

'Packaging' means all operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product.
Note: Filling of a sterile product under aseptic conditions or a product intended to be terminally sterilized, would not normally be regarded as part of packaging

'Packaging material' means any material employed in the packaging of a pharmaceutical product, excluding any outer packaging used for transportation or shipment. 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.

'Production' means all operations involved in the preparation of a pharmaceutical product, from receipt of materials, through processing and packaging, to its completion as a finished product.

'Qualification' means action of proving that any premises, systems and items of equipment work correctly and actually leads to the expected results. The word *validation* is sometimes widened to incorporate the concept of qualification.

'**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 pharmaceutical products are not released for sale or supply, until their quality has been deemed satisfactory.

'Quality unit' means an organizational unit independent of production which fulfils both Quality Assurance and quality control responsibilities. This can be in the form of separate QA and QC units or a single individual or group, depending upon the size and structure of the organization.

'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/registration certificate, prosecution

'Specifications' means a list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation.
'Starting material' means any substance of a defined quality used in the production of a pharmaceutical product, but excluding packaging materials.

'Strength' means the concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or the potency, that is, the therapeutic activity of the pharmaceutical product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

'System' means a regulated pattern of interacting activities and techniques which are united to form an organised whole.

'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 criteria.

Citation

These Regulations may be cited as Good Manufacturing Practice for Pharmaceutical Products Regulations 2019.

MADE at Abuja this …….day of ……..2019

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Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)