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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 00 of 2021

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1, LFN). 2004

GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS REGULATIONS, 2021

[*7th Day of July,* 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap N1 LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and all other 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 Minister of Health makes the following Regulations—

Scope of application.

1.—(1) These Regulations prescribe the minimum Good Manufacturing practice, requirements for methods to be used, the facilities and controls to be usedfor manufacturing, processing, packaging or handling of a pharmaceutical product for human or animal use, to ensure that such pharmaceutical product meets safety requirements, has the identity and strength that meets the quality and purity characteristics that it purports to possess.

(2) These Regulations shall apply to the manufacturing, processing, packaging, or handling of a pharmaceutical product for human or animal use.

Prohibition.

2.—(1) A person shall not manufacture, process, package, or hold a pharmaceutical product except as provided in these Regulations.

(2) Failure to comply with any of the provisions of these Regulations shall render such pharmaceutical product substandard or adulterated and such pharmaceutical product, as well as the person responsible for the non-compliance, shall be liable to the penalty prescribed in regulation15 and 16 of these Regulations.

Pharmaceutical Quality System.

3.—(1) The manufacturer shall establish a quality system to 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 that the—

(*a*) quality system is in place, adequately rescurced and its effectiveness is continually improved and sustained ; and

(*b*) roles, responsibilities, and authorities are defined, communicated and implemented in 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.

Personnel.

4.—(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 done in relation to the operation that the employee performs and in good manufacturing practices as they relate to the employee's functions and the effectiveness of the training shall be verified and records of training kept.

(3) Where a holder of a Certificate of Registration engages a Consultants to advise on the manufacture, processing, packaging, or holding of pharmaceutical products shall have necessary education, training, and experience, or any combination, to advise on the subject for which they are retained and records shall be maintained stating the name, address, and qualifications of any consultants and the type of service they provide.

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

Premises and equipment.

5.—(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 different class of highly sensitive and 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 equipment and instruments, inclusive of GMP support facilities.

Qualification and validation.

6.—(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 system 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 required or re-validated prior to routine implementation.

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

Documentation.

7.—(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 and the 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 dateof 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.

Production.

8.—(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, 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) Every pharmaceutical product defect 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.

Materials management.

9.—(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 shall 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, sanitising and pest control materials shall not contaminate equipment and materials.

Quality control.

10.—(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 and 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 1 year after the expiry date, provided that other starting materials, with the exception of solvents, gases and water, shall be retained for a minimum of 2 years after the release of the product, if their stability allows.

Contract manufacture and analysis.

11.—(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 authorised 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.

Complaints and product recall.

12.—(1) 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.

Good distribution practice.

13. Distribution of medicinal products shall be in accordance with the current Agency's Good Distribution Practice Regulations.

Self-inspection.

14.—(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.

Non-compliance with GMP requirements.

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

Offences and penalties.

16.—(1) Any person who contravenes any of the provisions of these Regulations, commits an offence and shall be liable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(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 ;

(*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 purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for that offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

17. A person convicted of an offence under these Regulations shall forfeit to the Federal Government—

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

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

Enforcement of these Regulations.

18. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

19. In these Regulations—

"*Act*" means the NAFDAC Act Cap N1, LFN 2004 ;

Citation.

"*Address*" means a place where the business of the manufacturer, sale, distribution, storage and display of drug and related products are carried out, which includes the house number, plot number, street name town or city, state and country ;

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

"*Authorised 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 shall correspond to a defined fraction of the production, characterized by its intended homogeneity and 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;

"*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 ;

"*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 ;

"*Packaging material*" means any material employed in the packaging of a pharmaceutical 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 ;

"*Packaging*" means all operations, including filling and labelling, which a bulk product has to undergo in order to become a finished product, provided that 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;

"*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 and pharmaceutical products may also be referred to as medicinal products ;

"*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 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 and 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 organisational unit independent of production which fulfils both Quality Assurance (QA) and Quality Control (QC) responsibilities and this can be in the form of separate (QA) and units (QC) 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 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 ;

"*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 or weight, weight or volume, or unit dose or volume basis, 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 ; and

"*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.

20. These Regulations shall be cited as Good Manufacturing Practice for Pharmaceutical Products Regulations, 2021.

MADE at Abuja this 7th day of July, 2021

DR. OSAGIE E. EHANIRE, MD, FWACS
Honourable Minister of Health