SITE MASTER FILE
v.04FEB2020

GENERAL INFORMATION

1. General information on the company and particularly, any information relevant to understand the manufacturing and/or repackaging operations
2. Any other manufacturing and/or repackaging activities carried out on the site
3. It covers both medical devices and non-medical devices activities
4. Name and address of site:
    a. Name of Company including postal address
    b. Telephone number
    c. Fax number
    d. E-mail address
5. Type of actual products manufactured and/or repacked on the site, mentioning the way they are processes
6. Short description of the site
    a. The location plan and immediate environment
    b. The floor plan and types of building
7. Number of employees engaged in the quality assurance, quality control, production, storage and distribution, and technical and engineering support services
8. Use of outside scientific, analytical or other technical assistance in relation to manufacture and analysis, and repack
    a. Name of Company including postal address
    b. Telephone number
    c. Fax number
    d. E-mail address

REQUIREMENTS

1. Personnel
    a. Organizational chart showing the arrangements for quality assurance, including production and quality control
    b. Qualifications, experience and responsibilities of key personnel
    c. Outline of arrangements for basic and in-service training and how records are maintained
    d. Health requirements for personnel engaged in production
    e. Personnel hygiene requirements, including clothing and changing area
2. Premises and Equipment
    a. Plan or description of manufacturing areas with scale
    b. Nature of construction and finishes
    c. Brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination. Classification of the room used for the manufacture of sterile products should be mentioned.
    d. Special areas for the handling of highly toxic, hazardous and sensitizing materials
    e. Planned preventive, corrective and predictive maintenance programs and recording system
    f. Brief description of major production and controlled laboratory equipment
    g. Qualification and calibration, including recording system
    h. Written procedures for cleaning manufacturing areas and equipment

3. Production
    a. Brief description of production operations using flowsheets and charts, if possible specifying important parameters
    b. Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage
    c. Arrangements for reprocessing or rework
    d. Arrangements for the handling of rejected materials and products
    e. Brief description of general policy for process validation
4. Quality Control
    a. Brief description of the quality control system and the procedures of the quality control department for the release of finished products
    b. Describe the elements of the quality control system e.g. specifications, test methods, and other quality related collection
    c. Brief description of the activities of analytical testing, packaging and component testing
    d. Outline the arrangements for the preparation, revision and distribution of documents
5. Self - Inspection
    a. Describe the self - inspection system that verifies the compliance of the activities with the set standard to ensure the quality of the manufacturing process,
    b. Verify the effectiveness of the quality system
    c. Ensure the presence of documented procedures for the self – inspection system and for the follow – up actions
    d. Documentation that will ensure that the findings of the self – inspection system was discussed with the responsible person in the area inspected and the activities verified
    e. Documentation that will ensure that those responsible in the area or for the activity/ies took timely corrective actions on the noted deficiencies
6. Documentation
    a. Arrangements for the preparation and revision and distribution of documentation
        - Description of the documentation system
        - Responsible for the preparation, revision and distribution of documents
        - Storage of the master documents
        - Procedures on the preparation of the documents
        - Control of the documentation
    b. Related to product quality
        - Equipment specification
        - Standard operating procedures
        - Quality control procedures
        - Training procedures
        - Documentation control of process deviations
        - Calibration and test documents
        - Validation documents
        - Reconciliation of batches of raw materials, major packing components
        - Distribution, complaints and product recall