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NSi

NAMIBIAN STANDARDS INSTITUTION

CERTIFICATION BULLETIN

Good Manufacturing Practice (GMP) for SMEs in the Food Industry

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Information Bulletin on GMP for Small Medium Enterprises (SMEs)

This booklet provides generic information to assist all Food Handling Organisations (FHO) that recognize the potential benefits of implementing a Good Manufacturing Practices (GMP) in accordance with NAMS/SANS 10049:2020 Food Safety Management - Requirements for Prerequisite Programmes (PRPs).

1. Good Manufacturing Practices (GMP)

GMP is a system of processes, procedures, and documentation that helps to ensure that products are consistently produced and controlled according to food safety standards. These practices are required in order to conform to food safety foundation i.e. guidelines and regulations recommended by agencies that control authorization and licensing for the manufacture and sale of food, drug products, and active pharmaceutical products.

2. GMP Inspection Scheme

Focuses on the requirements for the inspection of Food Handling Organisations (FHO) according to the requirements of NAMS/SANS 10049: 2020 – Food Safety Management – Requirements for prerequisite programmes (PRPs). The GMP Scheme is operated on a voluntary basis. A copy of the NAMS/SANS 10049: 2020 standard can be obtained from NSI Standards Sales at **sales@nsi.com.na** for a reasonable fee.

"GMP compliance is widely-accepted as the best way to conduct business, putting product quality first."

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Ms. Etuukata Nashima,
Certification: Manager

3. Food Handling

Refers to the handling of food in its raw or unprocessed state, during production, processing, packaging, transportation, delivery and display. Food handling areas could therefore include farms, pack houses, fresh produce markets, manufacturing facilities (e.g. packaging material, food contact surfaces), factory shops, catering units and kitchens, restaurants, butcheries, retailers, distribution centres and transporting vehicles.

4. Purpose of GMP

a) To assist the Food Handling organisation (FHO) to manage its operations to prevent or control the contamination of food, either through direct contamination or as a result of cross-contamination.

b) To assist the FHO to initiate the operations of the business based on a basic level of hygiene.

5. Prerequisite Programmes (PRP)s

They are basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end food products and safe food for human consumption.

6. What are the Benefits of GMP Certification?

Every pharmaceutical and medical device manufacturers follow GMP rules and procedures while some have created their own guidelines that correspond with their legislation.

- Empower certification holders to opt great creation,
- Timely identify of manufactures and the management issues,
- Compliance with important laws and guidelines,
- Improve overall credibility and public image,
- Reduce safety risk in product quality and safety,
- Increases consumer confidence in your products,
- Helps to decrease operating costs due to rework and penalties due to non-compliance,
- Helps boost export opportunities,
- Reduced duplication of inspections,
- Cost saving.

Benefits For The Manufacturer

One of the primary benefits is significantly improved quality systems and quality compliance at the manufacturer. We have seen these improvements in the months leading up to GMP certification and continuing during the years immediately following GMP certification.

Benefits For The Customer

Customers will typically modify their oversight of manufacturers that have been GMP certified. Customers are aware that in order to be certified, the manufacturer must have systems in place and provide evidence that non-conformance and changes that require customer notification are handled appropriately. This assurance is typically not obtained through a one-day supplier audit that pharma companies carry out; rather, it is obtained as a result of thorough, multiple day audits of manufacturer as part of a certification audit program.

7. Prerequisite Requirements for the GMP certification

- Ensure that all requirements of the standard NAMS/SANS 10049:2020 are established, documented, implemented and maintained.

- Internal audit and management review of the management system are conducted prior to application, and submit the records together with the application form.

- Conduct a threat assessment and maintain documented methodology and results obtained.
- Apply using the PRC-GMP-P01-FA: GMP Application Form.
- Pay the applicable non-refundable application/ certification fee.
- Provide a company registration certificate, Fitness certificate and any other required supportive documents.
- Sign a binding contractual agreement with NSI and adhere to the rules therein which include;

  ·Use of the Attestation of Conformity
  ·Notification of changes to NSI
  ·Reference to Attestation of Conformity
  ·Re-Certification activities
  ·Actions to be taken upon suspension, withdrawal, or termination of Conformity.

- Allow the NSI inspection team to access areas to be inspected.

8. Application

Application forms are obtainable from the NSI website **www.nsi.com.na** or can be requested at **certification@nsi.com.na**

9. GMP certificate validity

One (1) year

10. Contact details

For more information and enquiries, please contact: Namibian Standards Institution, Certification Body, Tel: +264 (0) 61 386442, Email: **certification@nsi.com.na**

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NSI Head Office
37 Feld Street
Windhoek
+264 (0) 386 400
query@nsi.com.na

www.nsi.com.na