

Good Manufacturing Practices in the Food Industry

Ilyasu, U.S., Bala, J.D., Tauheed, F.L., Adabara, N.U., Auta, H.S. and Adedeji., A.S.
Department of Microbiology, School of Life Sciences, Federal University of Technology,
P.M.B 65, Minna, Niger State, Nigeria.

Corresponding Author: u.ilyasu@futminna.edu.ng; +2347064471376

Abstract: Good manufacturing practices (GMP) refers to an international set of regulations devised for implementation in the food and drug manufacturing industries to ensure safety of products. It requires documentation and periodic verification and it is enforced by the National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria. The application of good manufacturing practices in a food industry is therefore very necessary for the production of safe food. Good manufacturing practice is a prerequisite program that involve basic operational conditions and procedures. They include, correct construction and layout of the food premises, adequate maintenance of equipment and machinery used in processing, effective pest control program, quality control of raw materials and ingredients, storage and delivery. They also involve procedures such as employee training and personal hygiene, cleaning and sanitation, record keeping, traceability and recall. Good manufacturing practice is a fundamental management tool that should be applied in every quality system.

Key words: Food; Good Manufacturing Practices; Hazard; Safety

INTRODUCTION

Good manufacturing practices (GMPs) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of foods and beverages (Manning, 2018), cosmetics (Moore, 2009), pharmaceutical products (Nally, 2016), dietary supplements and medical devices (Ramakrishna *et al.*, 2015). The phrase “Good Manufacturing Practice” first appeared officially in the 1962 amendment to the U.S. Food, Drug and Cosmetic Act after a series of events that lead to the death of many, including children. Manufacturers and regulators alike have recognized their responsibilities, and are well aware just how vulnerable and unpredictable contamination can be if appropriate food safety measures are not firmly embedded in a manufacturer’s food safety management system.

These guidelines provide minimum requirements that a manufacturer must meet in order to assure that their products are consistently high in quality, from batch to batch, for their intended use. Many food safety and sanitary practices are regarded as good manufacturing practices (GMPs) that eliminate health hazards from foods or avoid unacceptable levels of hazards (Eresha and Niranjan, 2009). The rules that govern each

industry may differ significantly; however, the main purpose of GMP is always to prevent harm from occurring to the end user (Moore, 2009). Additional tenets include ensuring the end-product is free from contamination, that it is consistent in its manufacture, that its manufacture has been well documented, that personnel are well trained, and the product has been checked for quality more than just at the end phase. GMP is typically ensured through the effective use of a quality management system (QMS) (Manning, 2018). The implementation of GMP should be able to change the overall organization of processing units, as well as managers and food handlers’ behavior and knowledge on the quality and safety of products manufactured. This was proven by the work of (Dias *et al.*, 2012) on implementation of GMP in small-scale production of mozzarella cheese in Brazil which showed that the average percentage of conformity after the implementation of GMP was significantly increased from 32% to 66%. Food safety incidents have undoubtedly contributed to a loss of trust of consumers and have created misperception on the subject, although among experts there is a broad consensus that the food supply has never been safer (Motarjemi and Lelieveld, 2014). The intensification of farming using additives (such as pesticides) and

preservatives to improve taste, appearance and shelf-life, and assessing new technologies that will in future impact agricultural production (such as genetically modified foods, nanotechnology, animal cloning) are all subjects that contribute to this burden of mistrust (Bokulich *et al.*, 2016). Hence, the challenges we face must not be underestimated. The rapid pace of change in science and technology, changes in legislation and the current socioeconomic and socio demographic realities have all had a marked impact on our food choices (Motarjemi and Lelieveld, 2014). Today, globalization makes it possible to have greater varieties of foods, brought to us from all corners of the world. As a result, food can now be sourced practically anywhere, sometimes subject to different quality standards and means of preparation. This equates to additional risk and requires careful management at all levels across the food chain (Bouxin, 2014). Manufacturers and regulators alike have recognized their responsibilities, and are well aware just how vulnerable and unpredictable contamination can be if appropriate food safety measures are not firmly embedded in a manufacturer's food safety management system. Regaining the trust of consumers and developing an international consensus among stakeholders on the acceptable level of risks and the safety measures for effectively addressing these risks remains a key challenge (Manning, 2018).

Basic Principles of Good Manufacturing Practice

Good manufacturing practices (GMPs) guidelines are not prescriptive instructions on how to manufacture products. They are a series of general principles that must be observed during manufacturing. When a company is setting up its quality program and manufacturing process, there may be many ways it can fulfill GMP requirements. It is the company's responsibility to determine the most effective and efficient quality process that both meets business and regulatory needs (Manning, 2018).

The ten basic principles of good manufacturing practices as listed by Hoffmann, S. A. (2010) include:

- i. Writing detailed systematic procedures that provide a roadmap for controlled and consistent performance.
- ii. Carefully following written procedures to prevent contaminations, mix-ups and errors.
- iii. Promptly and accurately documenting work for compliance and traceability.
- iv. Proving that systems do what they are designed to do by validating work.
- v. Integrating productivity, product quality, employee safety into the design and construction of facilities and equipment.
- vi. Properly maintaining facilities and equipment.
- vii. Clearly defining, developing and demonstrating job competence.
- viii. Protecting products against contamination by making cleanliness a daily habit.
- ix. Building quality into product by systematically controlling components and products related processes such as manufacturing, packaging, labelling, testing, distribution and marketing.
- x. Conducting planned and periodic audit.

The Food Industry

The food system is a complex, concentrated, and dynamic chain of activities that begins with the production of raw agricultural commodities on farms, estates, fields and gardens. The system moves to value-added processed and manufactured products and then to retail food stores and food service establishments (restaurants and institutions) where they are merchandised, prepared, and sold to consumers (Erisham and Niranjana, 2009).

Each sector of the food system is unique in size, scope, and diversity, has evolved, and adapted to changes in demographics and lifestyles, science and technology, and consumer demands. The larger the food industry gets, the more concentrated and diversified food safety, sanitary practices become, and it has taken on a new importance in protecting public health (Isara *et al.*, 2010). Customers have higher expectations of quality and safety of processed food products; hence, the food industry faces an unprecedented level of scrutiny (Brody, 2016). In the current era of emphasis on food safety and security, high-volume food processing and preparation operations have increased the need for improved sanitary practices from processing to consumption. In order to comprehend the role of sanitation and food safety in the food industry, it is important to understand how food can become contaminated or unsafe (Erisham and Niranjana, 2009).

Food Contamination: Sources and Classification

Codex Alimentarius defines "contaminant" as substances not intentionally added to the food, but found inside as a result of the production process, farming practices, treatment, packaging, transport or storage of food, or result of environmental contamination. Foreign substances such as insect fragments, animal hair, etc. are not included in this definition (Vita *et al.*, 2014). Food contaminants become hazards if they pose risk to the human health or cause injuries or illnesses.

The sources of food contamination can be broadly categorized into three main groups namely microbial, chemical and physical contamination.

Microbial contamination: Microorganisms resulting in food spoilage and food poisoning such as *Pseudomonas* spp., *Listeria monocytogenes*, *Clostridium botulinum*.

The vast majority of outbreaks of food-related illness are due to pathogenic microorganisms, rather than to chemical or physical contaminants. Microorganisms are

generally undetectable by the unaided human senses and they are capable of rapid growth under favorable storage conditions, hence, much time and effort are spent in controlling and/or eliminating them (Isara *et al.*, 2010). Microorganisms in food may ultimately be destroyed by cooking, but they may have already produced toxins, making it vital to prevent contamination through the use of appropriate hygienic practices (Kamala and Kumar, 2018). Although not a direct food safety concern, increased levels of spoilage organisms will usually mean a reduction in the length of time that the food remains fit for consumption. This can affect product quality and thus influence the consumer's perception of the product (Bokulich *et al.*, 2016). Manipulation of growth factors such as temperature, pH, humidity, provides the basis for the control of microorganisms during food processing operations. Prevention of microorganisms to the food chain through early actions such as addressing the microbiological quality of water and maintaining the storage and transport systems clean pay much in the long term for the food industry (Erisham and Niranjana 2009).

Chemical contamination: Pesticide residues, cleaning agents.

The chemicals may enter the food chain as residues of pesticides, antibiotics, preservatives, and chemicals used for cleaning and sanitization of the food processing plants or even as intentional additives used with profit as main motivation. The use of chemicals in the food industry are governed by food regulations and good practices, which when ignored could end up in food safety problems such as recent incidence of melamine in milk products. The chemical hazards are one of the main causes of food contamination that are associated with foodborne disease outbreaks (Rather *et al.*, 2017).

Physical contamination: Glass fragments, metal particles, plastic, hair.

The physical entities that can impair the safety of foods include solid particles of material from soil, glass, metals etc. entering

food from the environment and process equipment. Attention to prevent the entry of these materials during handling practices forms the key to ensure food safety from physical factors (Kamala and Kumar 2018). A good food manufacturing system need to establish adequate checks and measures to prevent the problems arising due to entry of microbial, chemical and physical contaminants right along the food chain.

Good Manufacturing Practices (GMP)

Prerequisite Programs

Every food facility should develop Good Manufacturing Practices (GMPs) tailored to that specific operation. All employees (including nonproduction personnel, such as those in management or maintenance) as well as visitors to the facility must follow good manufacturing practices (GMPs) requirements. The activities addressed by GMPs and HACCP prerequisite programs for most food processing plants are essentially similar regardless of the nature of their end products (Eresha and Niranjana, 2009).

A successful Hazard analysis and critical control point (HACCP) system is not achievable without well-conceived, well written, and properly implemented and monitored Standard Operating Procedure and good manufacturing practices (GMP) (Schmidt and Newslow, 2013). Amoa-Awua *et al.*, (2007) Implemented GMP as a prerequisite program, before HACCP in their attempt to manage hazard, aflatoxins and enteric pathogens in the production of an indigenous fermented maize product in Ghana and it was successful.

Key Areas Covered by GMP Prerequisite Programmes

Since the activities required a good manufacturing practice GMP or HACCP prerequisite programmes by most food processing plants are similar, it is possible to compile a generic list of basic food safety control.

A generic list of basic food safety control (Erisham and Niranjana, 2009).

- i. Plant environment and facilities

- ii. Production equipment and machinery
- iii. Raw materials and ingredients
- iv. Quality assurance
- v. Storage and delivery
- vi. Employee training and personal hygiene
- vii. Cleaning and sanitation
- viii. Pest control
- ix. Record keeping and traceability

Application of GMP Prerequisite Programs in the Food Industry

The prerequisite programs include the Good manufacturing practice (GMP) activities required by food industry, and should, therefore, be applicable to food plants that operate without HACCP systems. There are as described below;

Premises and Facilities

This programme is mainly implemented during the design and construction stages of a food processing plant to ensure the facilities are not a source of contamination (Erisha and Niranjana, 2009). The building and surroundings including the outside property, roadways, building design and construction, product flow, sanitary facilities, and water/steam/ice quality should be designed, constructed and maintained in a manner to prevent conditions that may result in the contamination of food (Gawai and Sreeja, 2019).

Transportation and Storage

All ingredients, raw material, packaging material or other incoming material and finished product should be handled, stored and transported in a sanitary manner and at appropriate temperatures to avoid contamination, rapid proliferation of microorganisms, spoilage or damage (Soman and Raman, 2016).

Receiving location: A location which is well separated from food processing areas should be used for receiving raw materials, ingredients, packaging materials, and non food materials. Receiving materials should not be kept long at the receiving location and should soon be transferred to designated storage areas (McAvoy, 2014).

Sanitary conditions of transport vehicles should be monitored and also quality and safety of raw materials should be verified to ensure they are suitable for their intended use. Records of verification of received materials should be maintained (Kamala and Kumar, 2018). Clearly labeled storage areas for different materials (dry products, chemicals, packaging and raw materials and finished products) need to be demarcated (McAvoy, 2014).

Personnel Training, Hygiene and Practices

This prerequisite program addresses the activities by accomplishing designated tasks. It is essential that the employees should not contribute to or be a source of contamination or cross-contamination of foods (Eresham and Niranjana, 2009). Both contract and permanent employees should:

- i. Wear lab coat
- ii. Wash hands thoroughly and sanitize before starting work, after each absence from work station, after using toilet facilities, and at any time after handling contaminated materials.
- iii. Remove all unsecured jewelry and other objects, which may fall into or otherwise contaminate food. If any hand jewelry cannot be removed, it should be covered by material that can be maintained in an intact, clean and sanitary condition.
- iv. Not smoke, eat or drink in food handling areas.
- v. Maintain gloves in an intact, clean, and sanitary condition, if they are necessary in food handling.
- vi. Store clothing and other personal belongings in areas other than where food is exposed or equipment/utensils are washed.
- vii. Maintain adequate personal hygiene. Other personnel practices such as personal hygiene, hand washing, personal items, garments and work wears should be given serious attention. (Omar, 2002).

Sanitation and Pest Control

This prerequisite program should address all ongoing and periodic activities and operations that are directed at maintaining the environment, facilities, structures, and equipment in a food plant under sanitary conditions. All plants should have a written, effective and safe sanitation and pest control program (Eresham and Niranjana, 2009). The program should specify:

- i. The name of a contact person at the plant responsible for pest control
- ii. The name and address of any extermination company used
- iii. A list of all chemicals and methods used for their application.
- iv. A map of bait locations.
- v. Procedures and frequency of inspection.
- vi. A pest survey and

Control report form (United States Food and Drug Administration U. S. F. D. A. 2017)

Equipment Performance and Maintenance

This prerequisite program addresses the activities directed at design, construction, installation, performance, maintenance, and use of equipment in a food plant. (Nielsen, 2010). Storage equipment, monitoring and measuring equipment should be given special importance.

Storage equipments such as freezers and storage tanks need to be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device to monitor the temperature fluctuations. Regular cleaning schedules for storage equipment need to be established and practiced to prevent food contaminations arising from accumulating contaminants (De Mesquita, 2014). All measuring equipment which has a direct effect on the production process, safety and quality of the products should be regularly calibrated against a national standard and records need to be maintained (Keener, 2019).

Raw Material Control and Control of Manufacturing

This prerequisite program addresses the activities directed at Control of incoming raw materials and other ingredients. Control of food manufacturing operations essential to produce a safe food. Proper functioning of controlled purchasing ensures that purchased goods are conforming to specified requirements (Isara *et al.*, 2010). All reasonable precautions are taken to ensure that production procedures do not contribute contamination from any source by carefully monitoring the physical factors such as time, temperature, humidity, moisture, pH, pressure. Manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration are controlled to ensure that mechanical breakdowns, time delays, temperature fluctuations and other factors do not contribute to the decomposition or contamination of food (Keener, 2019).

Customer Complaint, Traceability and Recall Program

This prerequisite program addresses the activities directed at Handling customer complaints, the procedures to be followed for conducting a recall of a food that has reached the market place, Identifying and tracing all raw materials, ingredients, and products. Ensure the company has a written procedure to handle customer complaints. This procedure should include receiving of complaints, recording, investigation and management involvement to implement corrective actions to prevent its recurrence and responsibilities need to be clearly documented. All raw materials and ingredients used for the production and products at any stage, including intermediate, semi-finished, prefinished, finished, recycled, reworked, pre-packaged, and packaged should be identified and recorded (Nahla, 2012).

Traceability

A procedure need to be developed to enable the identification of processing history of products produced from the plant at any

stage to get details of raw materials, ingredients, processing aids, packaging materials, and the processing and storage equipment used for the production of a particular food (Wallace and Mortimore, 2016).

Recall Procedure

Ensure the company has a written product recall procedure in operation. The recall procedure needs to provide the precise method of notifying all distribution networks and retailers involved, including contact names and telephone numbers. The procedure needs to specify halting the transit of products at any stage in the distribution chain. All recalled material at whatever stage of the distribution chain should be quarantined and clearly labelled (Clute, 2009).

A recall program should contain at a minimum, the following elements:

- i. Documentation identifying the product coding system and product designation.
- ii. Records of finished product distribution, kept for a period of time that exceeds the shelf life of the product.
- iii. The step by step procedure, to follow in the event of a recall, including the extent and depth of the recall.
- iv. A current list and addresses of people that will take part in any recall activities.
- v. Means of notifying the affected customers, retailers, wholesalers.
- vi. Control measures for the returned recall product.
- vii. Means of assessing the progress and efficacy of the recall.
- viii. Means of coordinating recall with regulatory agencies (Clute, 2009).

CONCLUSION

Good Manufacturing Practice (GMP) is a collection of activities with guidelines that provide minimum requirements expected of a manufacturer to ensure that harm does not get to the consuming public.

The food industry is a vast and complex system with dynamic chain of activities ranging from the procurement of raw materials from the farm, fields, and gardens to the manufacture of enhanced products for consumers from diverse location and lifestyle. The use of technological approach such as animal cloning, and genetically modified foods as well as food safety incidents such as foodborne disease outbreaks contribute to mistrust and misconception about the food industry. Good manufacturing practice prerequisite programs provide a comprehensive coverage of the requirements of a food plant and is enforced in Nigeria by the National Agency for Food and Drug Administration (NAFDAC). The application of Good Manufacturing Practice becomes the legal and ethical responsibility of any food industry in order to produce safe and quality food for its consumers.

REFERENCES

- Amoa-Awua, W. K., Ngunjiri, P., Anlobe, J., Kpodo, K., Halm, M., Hayford, A. E. and Jakobsen, M. (2007). The effect of applying GMP and HACCP to traditional food processing at a semi-commercial kenkey production plant in Ghana. *Food Control* 18(11): 1449-1457.
- Bokulich, N. A., Lewis, Z. T., Boundy-Mills, K., and Mills, D. A. (2016). A new perspective on microbial landscapes within food production. *Current Opinion in Biotechnology* 37:182-189.
- Bouxin, A. (2014). Management of Safety in the Feed Chain. In *Food Safety Management*. Academic Press P .23-43.
- Brody, H. (2016). Professional medical organizations and commercial conflicts of interest: ethical issues. *Annals of Family Medicine* 8(4): 354-358.
- Clute, M. (2009). Food industry quality control systems, CRC Press, Taylor & Francis Group, Florida, USA.

RECOMMENDATIONS

1. Timely reviews of GMP in the food industry should be done at regular intervals for better efficiency.
2. Food safety regulatory and enforcement agencies should ensure implementation of food safety policies in the food industry.
3. Significant changes to product and production procedure should be reflected in the GMP prerequisite programs and well communicated to personnel involved. Personnel should be re-trained whenever such changes occur.
4. The food industry should have a well-detailed plan and budget sufficient to set up the food business.
5. Further studies should be carried out on the applicability of Good Manufacturing Practices in the food industry to create more awareness in the Food industries in Nigeria.

- De Mesquita, E. D. F. M. (2014). Sanitary aspects of brazilian shellfish farming: the key problem eliana de fátima marques de mesquita. *Medical and Applied Malacology Crossing Boundaries: Integrative Approaches to Malacology*, 30.
- Dias, M. A. C., Sant'Ana, A. S., Cruz, A. G., José de Assis, F. F., de Oliveira, C. A. F. and Bona, E. (2012). On the implementation of good manufacturing practices in a small processing unity of mozzarella cheese in Brazil. *Food Control* 24(1-2): 199-205.
- Erisham, M. and Niranjan, R. (2009). GMP and HACCP; A handbook for small and medium scale food processing enterprises. The Ceylon chamber of commerce (CCC) in collaboration with the Sri-lanka food processors association. P .1-51.
- Gawai, K. M., and Sreeja, V. (2019). Quality and Safety Management in the dairy industry. *Engineering Practices for Milk Products: Dairyceuticals, Novel Technologies, and Quality* (1)1: 205.

- Hoffmann, S. A. (2010). Getting to risk-based food safety regulatory management: lessons from federal environmental policy. Taylor M. R. (Ed.) In *Toward Safer Food*. p. 19-38.
- Isara, A. R., Isah, E. C., Lofor, P. V. O., and Ojide, C. K. (2010). Food contamination in fast food restaurants in Benin City, Edo State, Nigeria: Implications for food hygiene and safety. *Public Health* 124(8): 467-471.
- Kamala, K., and Kumar, V. P. (2018). Food Products and Food Contamination. In *Microbial Contamination and Food Degradation*. Academic Press. P.1-19.
- Keener, K. M. (2019). Food regulations. In *Handbook of Farm, Dairy and Food Machinery Engineering* Kutz, M. (Ed.) Academic Press. P.15-44.
- Mahmood, A., and Akhtar, S. (2018). TTP'S Safe Havens in Afghanistan: A Constant Threat to Pakistan's Internal Security. *South Asian Studies*, 33, 2.
- Manning, L. (2018). *Food and Drink-Good Manufacturing Practice: A Guide to its Responsible Management*. John Wiley & Sons. P.17-31
- McAvoy, S. A. (2014). Global regulations of food colors. *The Manufacturing Confectioner* 94(9): 77-86.
- Moldenhauer, J. (2018). *Disinfection and Decontamination: A Practical Handbook*. CRC Press. P.22.
- Motarjemi, Y., and Lelieveld, H. (2014). Fundamentals in management of food safety in the industrial setting: challenges and outlook of the 21st century. In *Food safety management* (pp. 1-20). Academic Press.
- Moore, I. (2009). *Manufacturing Cosmetic Ingredients according to Good Manufacturing Practice Principles*. In *Global Regulatory Issues for the Cosmetics Industry* William Andrew Publishing (2): 79-92.
- Nahla S. B. (2012) handling, packaging and storage. In: *promising pharmaceuticals*. Purusotam B. (Ed.). BoD-books on demand P.63
- National Agency for Food and Drug Administration and Control NAFDAC (2016). Good manufacturing practices guideline for pharmaceutical products: drug evaluation and research. Retrieved 22 January 2020.
- Nielsen, S. S. (2010). United States government regulations and international standards related to food analysis. *Food Analysis* P.15-33.
- Omarjee, J. H., Germishuizen, W. A., Chetty, R. and Stubbings, D. (2018). Plasma fractionation in South Africa: challenges and successes in meeting international standards. *Annals of Blood*, 3, 1.
- Ramakrishna, S., Tian, L. and Wang, C. (2015). Quality management systems for medical device manufacture. *Medical Devices: Regulations, Standards and Practices* (3)103: 49-64
- Rather, I. A., Koh, W. Y., Paek, W. K. and Lim, J. (2017) the Sources of Chemical Contaminants in Food and Their Health Implications. *Frontal of Pharmacology* 8: 830.
- Schmidt, R. H. and Newslow, D. (2013). *Hazard Analysis Critical Control Points (HACCP)-Prerequisite Programs*. The Food Science and Human Nutrition Department, the University of Florida. p. 1-2.
- Soman, R. and Raman, M. (2016). HACCP system-hazard analysis and assessment based on ISO 22000: 2005 methodology. *Food Control* 69: 191-195.
- United States Food and Drug Administration (2017). Facts about the Current Good Manufacturing Practices (CGMPs) Current Good Manufacturing Practices (CGMPs). Retrieved 14 January 2020

- Vita, D. S., Rosa, P., and Giuseppe, A. (2014). Effect of gamma irradiation on aflatoxins and ochratoxin, a reduction in almond samples. *Journal of Food Research* 3(4): 113-120.
- Wallace, C. A. & Mortimore, S. E. (2016). HACCP. *Handbook of Hygiene Control in the Food Industry*. Woodhead Publishing P. 25-42.
- Warier, N., and Mehta, P. (2016). Comparative study of generic drug registration requirements for dossier submission in African Region- Kenya, Ghana, Nigeria, and Botswana. *Applied Clinical Research, Clinical Trials and Regulatory Affairs* 3(2): 71-81.
- World Health Organization (2007). WHO good manufacturing practices: Main principles for pharmaceutical products". *Quality Assurance of Pharmaceuticals: A compendium of guidelines and related materials - Good Manufacturing Practices and Inspection*, WHO Press 1(2): 17-18.