



DEPARTMENT OF BIOLOGICAL SCIENCE  
COLLEGE OF SCIENCE & TECHNOLOGY  
COVENANT UNIVERSITY

# TOWN-GOWN INTERACTION

COMPENDIUM

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# COMMERCIALIZATION AND BIOLOGICAL SCIENCES

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## 1. Introduction

Biological sciences and act of laboratory research output have evolved greatly over the years. In the last few decades, research output has shaped most industrial product and its acceptability with new and novel improvement. New technologies and inventions in several fields of biological science have aid industrial products with innovative, cheap, and affordable for many people. Use and application of biotechnology have come with great cost but it has provide solution to many human endeavours and challenges. It is highly imperative to commercialize biological products in order to have more funds for further research and inventions. Product development and its commercialization depend on various competing factors such as societal acceptability, availability and application of new technologies, partnership, intellectual property, and advertisement among others.

Identification of research problem and providing solution through biotechnological applications is seemingly a herculean task and to make the product acceptable with the current demand of the society. Searching for research update and relevant literature is a challenging factor in biological research and application of appropriate tools and technique require amount of time for product development which is the critical step that must be followed with precise and accurate biological techniques.

Therefore, development and commercializing biological products is an extensive workflow that require specific influences of the several fields of biological sciences, knowing psychology of consumers choice, their feel and perspective coupled with selection between different alternatives. For a biological scientist's product to stay relevant, he has to tap into the psychology of how consumers Feel, feel, reason, and select between different alternatives.

This step is quite imperative because the importance of customer/consumer can't be overemphasized.

Consumers are humans, hence they all feel, think and act. Therefore they can digest the content of a comprehensive advert. Hence commercialization allows us to see that our thousands of man hours in the laboratory had not been in vain, and our product/service would soon be available to the people we created it for (Plate 1).



**Plate 1:** Workflow from laboratory to commerce

However, the unique place of commercialization in product development scheme has to be well identified (Plate 2).



**Plate 2:** Product development scheme

## 2. Knowing the consumer

Consumers are more interested in the experience the producers have to deliver and not the details of the journey to the current status or aspirations of the company (Plate 3).



**Plate 3:** Sell the experience and not the method behind it (Source: MMXIV Sheep Hyken)

The consumers are not only relevant for patronage but also are potential marketers of purchased products (Plate 4). It is then vital to note that they deserve some rewards for doing the job of marketing on behalf of the company. This strategy works because people tend to repeat behaviour for which they have been rewarded.



**Plate 5:** Customers are potential marketers

Generally speaking, consumers are the victims of commercialized mass culture today as a result of hyped commercials (Plate 6).



**Plate 6:** Hyped commercials

It's not just about differentiation, it is business-critical. Studies have shown that after a positive customer experience 69% would recommend the company to others and 50% would use the business more frequently. On the other hand, after a negative experience 58% will never use the company again. 49% will tell friends not to use the business. 34% would take revenge by posting a review online or sharing a poor experience on social media. Therefore if one wants to sell more, it is vital to know why customers buy. When a prospect reaches out to make enquiries, the prospect is motivated to find out if their need can be met. On the other hand, when a producer contacts a prospect, he must determine first whether they recognize that they have a need, and only then can the producer address whether their offering can address the needs of the prospect (Plate 7).

## The Six Stages of Purchase Behavior in the Transtheoretical Model

f o r m a



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### Plate 7: How customers buy

A producer has to be consistent and appropriate. To stay precisely relevant, four (4) fundamental questions must be answered:

1. A brand audit and a gap analysis can help you determine the consistency. How well does your brand reinforce the desired messages?
2. In terms of the appropriateness, how well does your brand articulates your desired positioning of your brand?
3. How coherent and consistent is your life science brand?
4. How well do your messages resonate with your audiences?

Invention is a discovery of a new concept whereas Innovation is a profitable Invention. As horizon of understanding and knowledge expands, our invention-driven mind learns innovation capabilities.

### **3. Failure rates of new products**

Studies have shown that Out of 11000 new products introduced by 77 companies, only 56% are present 5 years later. Only 8% of new product concepts offered by 112 leading companies reached the market. Out of that 83% failed to meet marketing objectives. A significant aspect of your role involves communication, including written, presentations, customer interactions, finding new strategic collaborations with a combination of commercial experience.

Our attitude defines our general approach to life and the way we do things, and it is a function of the results that will ensue.

Attitude [Thoughts + Feelings + Actions] = Results.

### **4. Conclusion**

The following are characteristics of Biological sciences majors:

1. Interests in multiple areas of science
2. Conducting research in the laboratory or field
3. Desire to learn about living organisms
4. Desire for intellectual growth
5. Precision and attention to details
6. Inquisitive
7. Critical thinking and problem solving
8. Proficiency in experimental design
9. Understand various biological processes
10. Record, analyze, and summarize data
11. Oral and written communication skills

Biological Sciences employment opportunities exist almost every area in Nigeria in the medical, dental, veterinary, ecological, genetic organizations, public health, research,

teaching, administration, sales, service, and manufacturing government agencies, educational institutions, private business, and industry. Many entry level biological science jobs accept a Bachelor's degree.

# **CAREER DEVELOPMENT & ADVANCEMENT: “FIGHTING THE ODDS”**

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## **1. Introduction**

### SCOPE

1. Understanding career development
2. Understanding career advancement
3. What are the odds we must fight?
4. Why do you need to fight?
5. How do we fight and win?

Career Development is the lifelong process of managing, learning, work, leisure, and transitions in order to move toward a personally determined and evolving preferred future.

- **Lifelong:** Career development is not summed up in a single decision. It's a continuous process of alignment and re-alignment.
- **Managing:** Career development will happen whether it is managed or not. The question is the extent to which you want to influence your career direction versus leaving it to chance.
- **Learning, work, leisure, and transitions:** Career development is the mechanism by which learning (formal and informal), work (paid and unpaid) and the transitions between are navigated.
- **Personally determined:** Career development is about intentionality. Done well, it ensures that the decisions we make about learning and work are grounded in knowledge of self (personal interests, attributes, values and skills), and knowledge of

educational/labour market realities (conditions, finances, prospects, entry requirements, progression and pathways).

- Evolving preferred future: Career development recognizes that both we and our labour market change over time. What we want and what is possible are not static. Hence, we need to be very vigilant.

## **2. Personal development**

The following steps are required for personal development towards attainment of a desired career:

1. Self: One must get accustomed to one's self by understanding one's personality, interests and values. These are keys to making the right career decisions.
2. Strengths: You must know how to use your talents, skills, and personal qualities.
3. Horizons: One must make time to explore the world of work, training and learning.
4. Network: Ability to identify the relevant contacts to a specific career path.

Career Advancement simply put is growth climbing the career ladder moving up to the next level.

## **3. Conclusion**

The odds we must persistently fight in our career journey include:

1. Self: The most challenging and most important odd the fight is one's self through self-control, self-discipline, self-assessment/ appraisal, and maintenance of character
2. Time: Respect time, master time, avoid time wasters.
3. Environment: Toxic workplace, unhealthy competition amongst staff, strives, envy, etc.
4. Negative organizational norms & values which are deemed uncivil behaviour such as bullying, sexual harassment, etc.

# **DEVELOPING YOUR MOST INDISPENSABLE ASSETS: ATTITUDE & VISION**

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## **1. Introduction**

The objectives of this study include:

1. To know the two valuable & indispensable assets: vision & attitude in their life.
2. To understand how these 2 assets guide and tailor their future aspirations.
3. To know how to develop positive attitude their vision.
4. To know the career option in biological science.
5. To learn from my experience in achieving my goal

- **Vision**

A vision is a Goal, a desired result and description of something in future. No career exists without a goal and no goal exists without a carrier. If you must become what you desire in life your attitude must be right from onset of your career.

- **Attitude**

Attitude is a settled way of thinking or feeling about something. A predisposition or tendency to respond positively or negative towards a certain idea, object, person or situation.

### **Types of attitude**

1. Positive attitude: A person who possesses a socially acceptable behavior has a positive attitude. He is someone who explores good things in others and will not go

after negativity. A positive person sees opportunity in all challenges and is ready to explore every situation for better and good

2. Negative attitude: An attitude is negative when it is not inclined towards positive element. A person with a negative attitude is likely to complain about change rather than adapter. They might blame their failure on others and doubt the credibility of others. They have a tendency of feeling others are inferior hence suffering from self-styled superiority complex.

There is a very thin line between personality trait and attitude. Personality is more rigid and somewhat permanent while attitude is subject to change with different situation experience in life. An attitude is learned and acquired.

Every attitude has 3 components which are describable by the “ABC model of attitude”

A- Affective (emotional/feelings)

B- Behavioural (visual/ reaction)

C- Cognitive (belief/ informational).

Out of the 3 components of attitude, only the behavioural component can be directly observed. Without developing positive attitude, a vision can't be fulfilled. You must have a right attitude to get to right altitude in life. The engine of success is attitude. For a goal to be achieved, attitude of 100 %, brilliance of 88 %, intelligence of 115 % and hard work of 98 % is required.

The following are required for development of positive attitudes; you need to:

1. build yourself self esteem
2. stop being a victim

3. find an objective you want to achieve
4. find mentor / inspiration
5. stay away from Negative influence
6. stay focus on what you can

## **2. Careers in Biological Sciences**

Career for the biological science typically breakdown into 5 groups and exist in private industries, health care, education, government agencies , research field etc. A general biological science degree can be sufficient for entry into many of the career options. However more specialized study is often required for career advancement.

Career options:

1. Molecular Biology.
2. Biotechnology
3. Environmental Science
4. Human biology
5. Academics
6. Microbiology
7. Research Scientist (Life Scientist)
8. Research scientist (Medical)

A biological scientists can function as a:

1. Bioinformatician
2. Biomedical Engineer

3. Biotechnology Laboratory Technician
4. Biotechnology Research Associate
5. Clinical Research Associate
6. Crime Lab Technician
7. Quality Control Analyst
8. Quality Control Engineer
9. Senior Research Scientist
10. Validation Technician
11. Biotechnology / Pharmaceutical Sales

Biotechnology is combining knowledge about life and living organisms with modern technology to create new systems, devices, materials, food...that could improve human life and help preserve environment. Most biotechnology products are associated with agriculture, food industry and medicine, and logically - careers in those fields are most popular.

A Laboratory Scientist functions in scientific laboratory where different kind of researches are performed, a laboratory assistant's main duties include sampling, and measuring, collecting and analyzing investigated data. Maintenance of laboratory equipment such as centrifuges, titrators, pipetting machine is also one of the tasks. Laboratory tests and strict methodology are very important especially when hazardous material is under investigation. Besides using typical lab equipment in work – computational analysis of given data is also important. High quality laboratory work is necessary for later research and development stages.

Greenhouse and Field Technician is involved in modern agricultural research which deals with new, genetically modified plants. As a greenhouse and field technician, you'll be in charge for planting seeds, pollinating plants, applying fertilizers and pesticides. Special

attention to the problems that may arise (pest, disease) is extremely important as those are genetically modified organisms. Basic knowledge of equipment used in everyday work as well as computer knowledge is also very important for this position.

Forensic DNA Analyst is associated with crime laboratories where DNA analysis is performed to solve legal issues. Urine, saliva, blood, semen, hair...those are the samples that could be used for DNA analysis. After sample collection, DNA is extracted and analyzed using couple methods (PCR, electrophoresis). Final results are further compared with the already known DNA profiles. Methodology is strict: properly collected and stored evidence, documentation on technical laboratory details and well written final reports are essential for successful prosecution. Depending on the laboratory size, employees could be more or less specialized.

Clinical research associate (CRA) monitors clinical trials on a new drug. After preclinical studies (when tested on animals) are finished, drug is entering clinical trials where (depending on the study phase) smaller or larger group of people will be evaluated for possible adverse effects. CRA is included both in study design and in writing reports using given results. Close monitoring is especially important to make sure that protocol is not violated. Clinical data is collected, summarized and analyzed to help made final conclusion on a drug effect.

Bioinformatics Specialist is involved in combining biology and computers. Data derived from various studies (DNA associated experiments, for example) is gathered in the computers. Software is in charge for data organization, manipulation and final analysis. Data mining is useful way to collect lot of publically available and jet relevant data that could be used in different experimental stages (for comparison or quick information extraction) or to help

merge data from different sources. Programming skills are necessary for software and database manufacture and maintenance.

A Production Engineer role can be obtained in any Biotechnology Product based company (like Cosmetics/FMCG, Pharmaceutical firms, Food industry etc). Role of a production engineer involves mapping process parameters to keep the line of production progressive (which is crucial for any large scale production company, especially pharmaceuticals).

To become a quality assurance (QA) engineer in a biotechnology company, you need to have specialization/professional experience in Microbiology/Aseptic compliance. Role of a QA engineer is to ensure contamination free and standardized product formation. Controlling the level of toxins, microbial contamination, proportions of various constituents is what comes under the role of a QA engineer.

Companies like McKinsey, IBM, Evalueserve, Wipro, TCS, Deloitte etc hire biotechnology consultants for market research, knowledge process outsourcing, Audits, R&D etc.

Biotechnology is a growing industry in United States and other developed countries offering excellent pay and benefits. Many positions are available for people with a background in biological science with good laboratory and computer science skills. Biotechnology, however, is no new science. It has been around for years right from the 1970's when the recombinant DNA was discovered.

The biotechnology industry has experienced steady growth over the past decade, which is expected to continue. The increase in employment will mostly be in the area of bio-pharmaceuticals, which is by far the largest sector of the biotechnology industry. The growth of bio-pharmaceuticals is driven by the high amount of research devoted to this sector. As much as 90% of the money invested in biotechnology research is in the pharmaceutical sector.

### **3. Conclusion**

Biological science students have a bright future and many opportunities are available to explore.

# UNVEILING THE ROLE OF CELLULAR NUTRITION FOR SOUND HEALTH

Seun Biobaku

(Health Officer, Neolife International, Ogun State, Nigeria)

## 1. Introduction

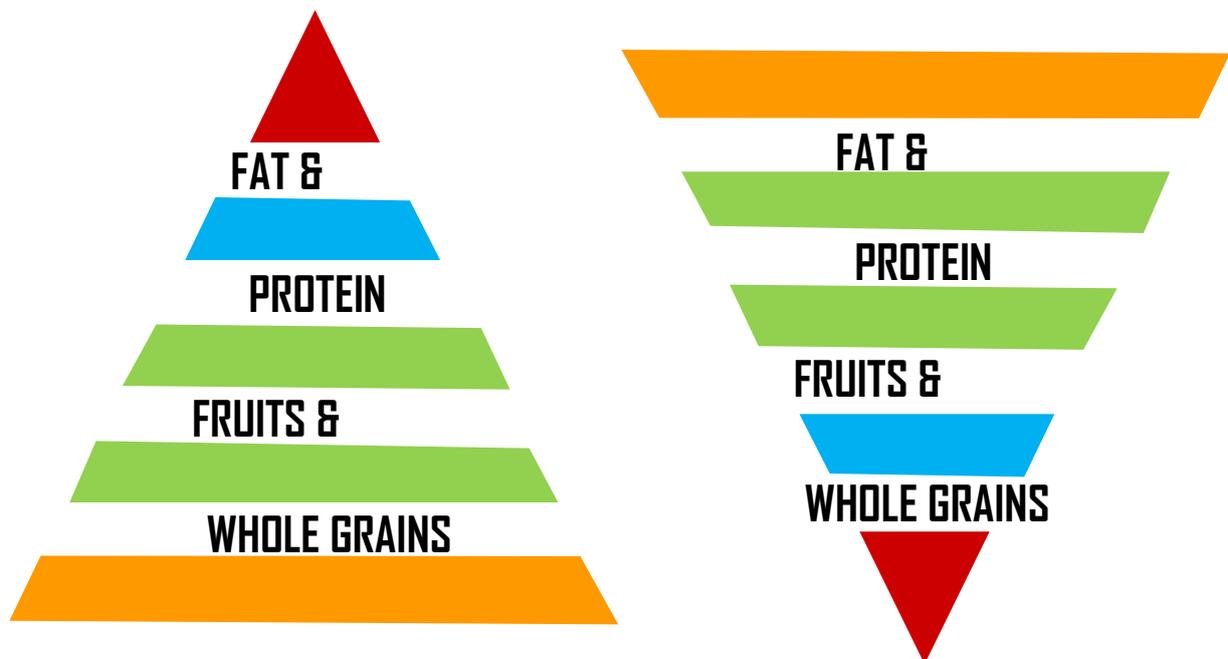
There are four main components that guarantees your sound health

1. Your diets
2. How do you handle the changes that occurs in your body as you are ageing?
3. Your cells are starving: you need to feed your cells
4. The impact of stress on our health.

Components of life include:

- Diet and exercise
- Good diet and exercise contributes up to 60% of our wellbeing.

Below is the general feeding habits as opposed to the recommendation of World Health Organization.

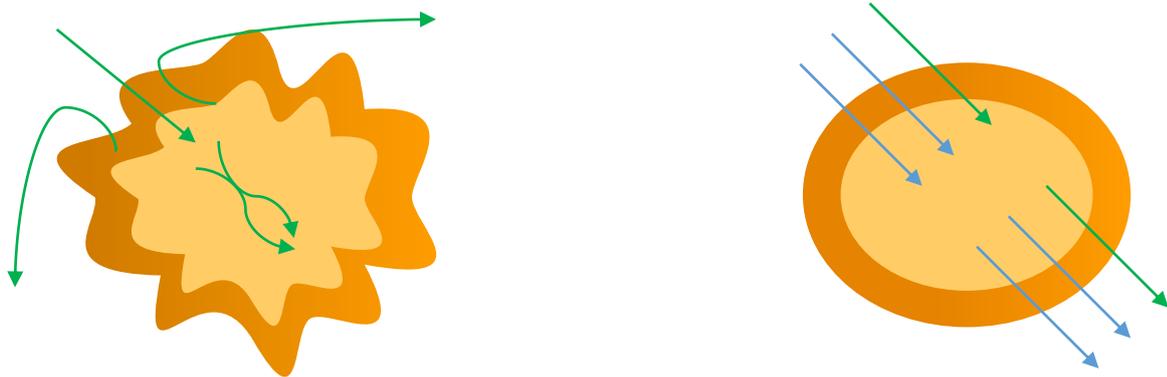


**Figure1:** Common diet versus WHO-recommended diet

Below are factors that mitigate against the common diet:

1. 70% Of the people only feed the belly and not the cells
2. Diet changes as we age, some foods automatically becomes a poison as we grow.
3. We either eating to die or diet we can't be neutral.
4. 65% of health crisis today emanates from diet crisis.

As we grow older, the tissues and organs of the body becomes old, and this brings about changes in our entire health frame work. This changes that occur are most of the time termed sickness or disease by the doctors, while to us in the faith, we call it affliction of the devil.



**Figure 2:** A. Unhealthy cell as a result of poor diet

B. Healthy cell due to recommended diet

At the end of the day it is the cells that bear the outcome of our diet and unhealthy diet may lead to malformed cells as seen in Figure 2 A, thereby resulting in sickness and disease.

Life is segmented into three (3) zones namely:

1. Active/vibrant zone;0-25yrs
2. Tired zone;26-51yrs(we lose 10,000 cells on a daily basis)
3. Weak/dead zone;52-75yrs(we lose almost 50,000 cells on a daily basis)



**Figure 3:** Hierarchy of life

Stress is any weight you allow on one's mind or body that is beyond your strength to carry. According to WHO projects of 2011, stress will account for one out of every four deaths by the year 2020

Negative impacts of stress human health include:

1. It drains the blood and weakens the blood viscosity
2. It weakens the body immune system
3. It makes you look older than your age

## **2. Case study**

CANCER is cell just like any other cells, because is living: everything living grows

Our treatments

- i) Cellular starvation: every cells requires glucose to grow. Glucose and carbohydrate are withdrawn from the diet. Cellular starvation helps to curtail and minimizes the spread of cancer cells.

Below is a recommended diet review to achieve cellular starvation:

- Carbohydrates > 2%

- Lipids and sterols > 10%
  - Cruciferous, Flavonoidss and Carotenoids= 60 %
  - Protein > 28%
- ii) Cancer degeneration and detoxification: ones cellular starvation has being successfully achieved .Cancer degeneration and detoxification are carried out by phyto-defence and beta-guard supplement based in nature and backed by science.
- This treatment therapy has generated a lot of testimonies today to the glory of God

### **3. Conclusion**

Medicine alone cannot guaranteed 100% health care, diet and personal regulation of health in conjunction with stringent regulation by Nutritionist may guarantee healthier life and longevity.

# **THE QUEST FOR EXCELLENCE: OPPORTUNITIES FOR A CAREER IN QUALITY MANAGEMENT**

William E. Onwuka (MBA, ASQ-CMQ/OE, CPGP, CHA, MIPAN)

(Principal Consultant, Fine Spectra Consult Limited, Lagos)

## **1. Introduction**

The paper is aimed at the following:

1. To create awareness of quality and its impact in organizational excellence
2. To identify the different approaches to quality
3. State careers available within the quality framework and related fields
4. List insights to building a successful career.
  - The quality challenge

In today's global competitive marketplace the demands of customers are for ever increasing. The supply chain also faces tremendous volatility. Quality is uniformity of the product characteristics or delivery of a service around a nominal or target value. It is conformance to set standard and fully stated requirements. It is fitness of an innovation, product service, or idea for the intended purpose.

Quality can also be termed as Satisfying customer expectations and understanding their needs and future requirements. It's the Degree to which a set of inherent characteristics of an object fulfils requirements. Quality performance aims at a standard of zero defects. Competition means there's no such thing as a permanent quality level. Continuous improvement is necessary if one is to stay competitive. It is a collective responsibility.

Quality is required by the following categories:

- ◆ Parents
- ◆ Students

- ◆ Academic and Non-Academic staff
- ◆ Industry
- ◆ Shareholders/Management
- ◆ NUC
- ◆ Staff
- ◆ Vendors
- ◆ Government

The quality goals include:

1. Customer Satisfaction: Consistently meet and exceed customers' expectation
2. Compliance: Comply with statutory and regulatory requirements
3. Sustainability: Sustained Success

The focus to stay relevant are to:

- Lower Costs-less reworks
- Productivity improves
- Capture Market share with better quality and lower price
- Stay in Business
- Provide More Jobs

Quality control tools include:

- ◆ Flowcharts
- ◆ Histograms
- ◆ Pareto Charts
- ◆ Scatter diagrams
- ◆ Run charts
- ◆ Cause and effect diagrams
- ◆ Check lists

- ◆ Affinity diagrams

A part of quality management focused on fulfilling quality requirement. The activities or techniques used to achieve and maintain the product quality, process and service. Finding & eliminating causes of quality problems through tools & equipment so that customer's requirements are continually met.

Quality control jobs include:

- ◆ QC Analyst – testing and evaluation of samples
- ◆ QC Officer – responsible for documentation, and sampling
- ◆ QC Manager – Coordinating QC activities

Public Analyst – Official declaration of product quality (often works independently).

## **2. Quality assurance system**

A part of quality management focused on providing confidence that quality requirements will be fulfilled. Quality assurance (QA) is the prevention of quality problems through planned and systematic activities including documentation. It is a complete system to assure the quality of products or services.

Quality assurance jobs include QA Officer Documentation Officer, QA Manager, and Validation Manager. Quality management system is a set of Set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve quality objectives.

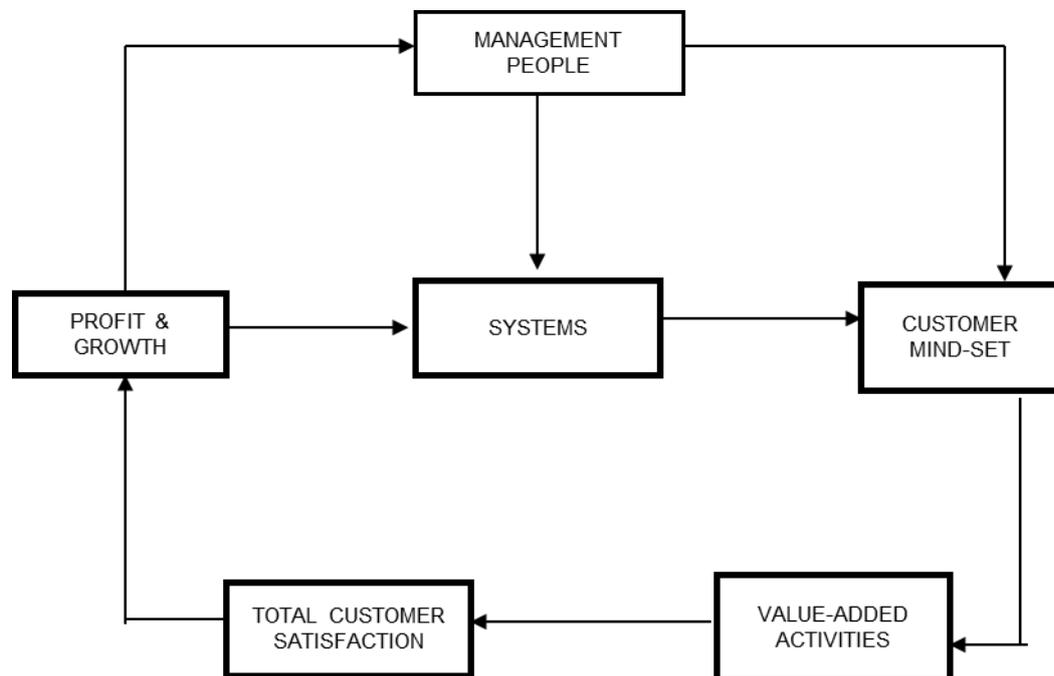
Seven (7) principles of quality management are:

1. Customer focus
2. Leadership
3. Engagement of People
4. Process Approach

5. Improvement
6. Evidence-based Decision Making
7. Relationship Management

Quality management jobs include Quality Manager Compliance Manager, Internal Auditor, and Lead Auditor.

### 3. Total quality management



**Figure 1:** Total quality management chart

Total quality management jobs include TQM Manager, Director of Quality, and Consultants.

The following are selected business excellence models:

- Malcolm Baldrige Award – USA
- Deming Prize – Japan
- European Quality Foundation – Europe

Business excellence models framework include:

1. Leadership
2. Strategic quality planning
3. Human resource development
4. Process management
5. Customer and market focus
6. People satisfaction
7. Quality and business results
8. Impact on society

Business excellence model jobs include Quality Manager, Assessors, and Consultants.

- Six-sigma

A six-sigma initiative is a way to stress continual innovation and improvement in products, services, processes and behaviour.

It seeks to eliminate waste and to mistake proof the processes that create value for customers.

A six-sigma level of performance means that there will be only 3.4 defects, or less per million opportunities for error. A systematic approach to identifying and eliminating waste through continuous improvement, flowing the product at the pull of the customer in pursuit of perfection. Also known as the Toyota system.

The eight (8) wastes include:

1. Overproduction
2. Waiting
3. Transportation
4. Non-Value-Added-Processing

5. Excess Inventory.
6. Defects
7. Excess Motion
8. Underutilized People

Sustainability is defined as sustained success. It is a result of the ability of the organization to achieve and maintain its objectives in the long term. The sustained success of an organization is demonstrated by its ability to satisfy needs and expectations of its customers and other interested parties over the long term and in a balanced way. The following companies have maintained sustained success since their dates of inception as stated below:

- ◆ 1812 Citicorp
- ◆ 1837 Procter & Gamble
- ◆ 1847 Philip Morris
- ◆ 1850 American Express
- ◆ 1886 Johnson & Johnson
- ◆ 1891 Merck
- ◆ 1892 General Electric
- ◆ 1901 Nordstrom
- ◆ 1902 3M
- ◆ 1903 Ford
- ◆ 1911 IBM
- ◆ 1915 Boeing

- ◆ 1923 Walt Disney
- ◆ 1927 Marriott
- ◆ 1928 Motorola
- ◆ 1938 Hewlett-Packard
- ◆ 1945 Sony
- ◆ 1945 Wal-Mart

Changes have occurred over the times, but a sustainable organization evolves with the trends of time. Changes occur as a result of the following:

- Customer expectations
- Technological change
- Global competition
- Market fragmentation
- Workforce changes

Benefits and exposures career in quality include:

1. Learn valuable management strategies, and the mechanics of how companies operate.
2. Do you love the idea of business travel, getting away from the office, and getting the guided tour of some interesting organizations?
3. Increase your earning potential, and professional marketability to potential employers or within your current organization.
4. Seamless transition between diverse industries, or positions.
5. Follow your entrepreneurial spirit, and start your own consulting, or auditing business.

Quality control specialists are needed in the following areas:

- ◆ Federal, provincial/state and municipal government departments
- ◆ Manufacturing companies (including automotive, mechanical, electronics, etc.)
- ◆ Food production and distribution companies
- ◆ Oil, gas and mining companies
- ◆ Construction companies
- ◆ Energy and utility companies
- ◆ Pharmaceutical companies
- ◆ Educational institutions & hospitals
- ◆ Self-employment (as a consultant)

#### **4. Skills needed to become a quality professional**

1. Construction companies
2. Energy and utility companies
3. Pharmaceutical companies
4. Educational institutions & hospitals
5. Self-employment (as a consultant)
6. Strategic orientation
7. Versatile and quick to learn
8. Integrity and tactful (auditors)
9. Analytical
10. Good statistical capability (Six-sigma etc)

11. Food Safety Management – ISO 22000 / HACCP
12. Environmental Management System – ISO 14001
13. Medical Laboratories QMS – ISO 15189
14. Occupational Health & safety Management – OHSAS18001

## **5. Conclusion**

### The 10 Commandments of Career Success

1. Have a Vision
2. Know your product
3. Identify your customer
4. Develop your road map
5. Build your case
6. Commanding the hunt
7. Sell your product
8. Network for Net worth
9. Be organization (Record keeping)
10. Be power focused

## Food Safety and Pharmaceuticals Quality Assurance: Prospects for the 21<sup>st</sup> Century

William E. Onwuka (MBA, ASQ-CMQ/OE, CPGP, CHA, MIPAN)

(Principal Consultant, Fine Spectra Consult Limited, Lagos)

### **Outline:**

- Key Stakeholders (End users, National Regulators & Standard Bodies, WTO, FAO etc.)
- Quality & Food Safety Challenge
- Food safety
- Pharmaceutical quality assurance ( GMP, QA, QMS etc.)
- The GMP interface
- Traceability requirements
- Personnel Competency
- Summary

Stake holder's expectations include:

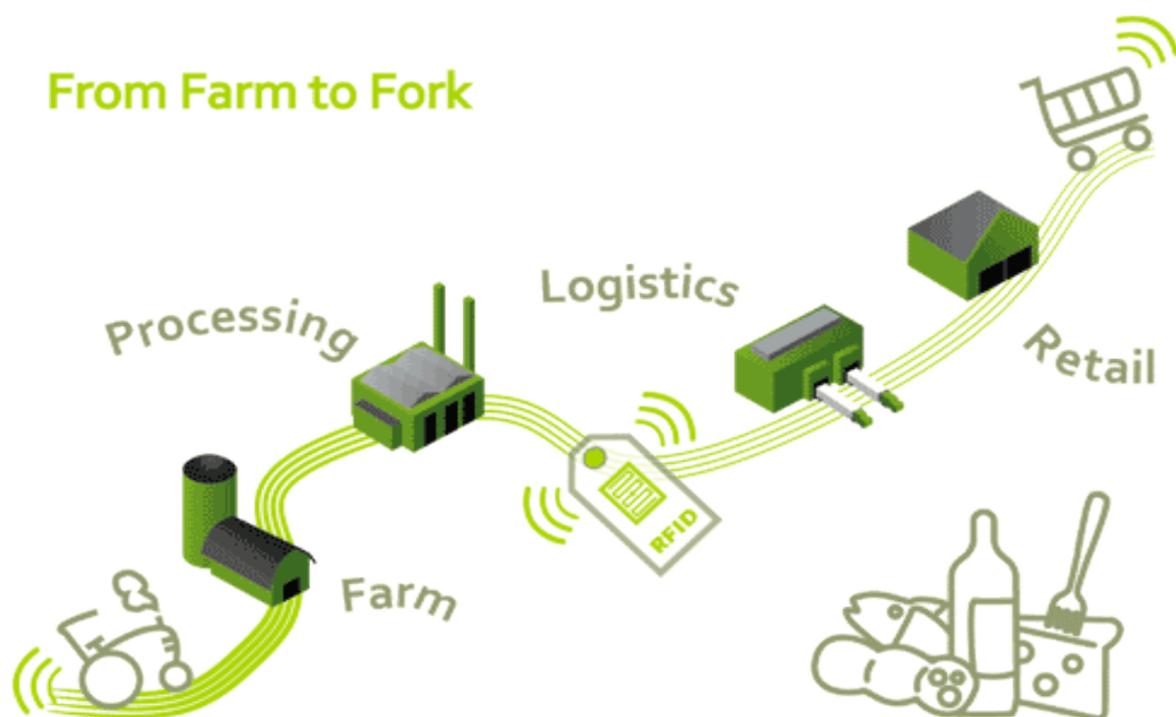
- End users – pleasant taste, appealing, energy and safe
- Regulators – meets quality standard and processes in a sanitary environment using validated systems (GMP)
- Standards body – meets national requirements for physio-chemical and microbiological
- MDAs – compliance with national policies and guidelines
- WTO – compliance with WTO's Agreement on the Application of Sanitary and Phytosanitary Measures for food safety in international trade.
- **FAO** – ensuring global food sustainability

### **Food Safety & Quality Challenge**

- Access to sufficient amounts of safe and nutritious food is key to sustaining life and promoting good health.
- Unsafe food containing harmful bacteria, viruses, parasites or chemical substances, causes more than 200 diseases – ranging from diarrhoea to cancers.
- An estimated 600 million – almost 1 in 10 people in the world – fall ill after eating contaminated food and 420 000 die every year, resulting in the loss of 33 million healthy life years (DALYs).
- Children under 5 years of age carry 40% of the foodborne disease burden, with 125 000 deaths every year.
- Diarrhoeal diseases are the most common illnesses resulting from the consumption of contaminated food, causing 550 million people to fall ill and 230 000 deaths every year. Food safety, nutrition and food security are inextricably linked.

- Unsafe food creates a vicious cycle of disease and malnutrition, particularly affecting infants, young children, elderly and the sick.
- Foodborne diseases impede socioeconomic development by straining health care systems, and harming national economies, tourism and trade.
- Food supply chains now cross multiple national borders. Good collaboration between governments, producers and consumers helps ensure food safety
- 10% of drugs sold in developing nations are considered fake –WHO Report

Food safety is a scientific discipline describing handling, preparation, and storage of food in ways that prevent foodborne illness. This includes a number of routines that should be followed to avoid potentially severe health hazards. Food Safety often overlaps with food defense to prevent harm to consumers (Figure 1).



**Figure 1:** Production chain

In considering industry to market practices, food safety considerations include the origins of food including the practices relating to food labeling, food hygiene, food additives and pesticide residues, as well as policies on biotechnology and food and guidelines for the management of governmental import and export inspection and certification systems for foods.

### **The HACCP approach**

The HACCP approach is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, Procurement and handling, to manufacturing, distribution and consumption of the finished products.

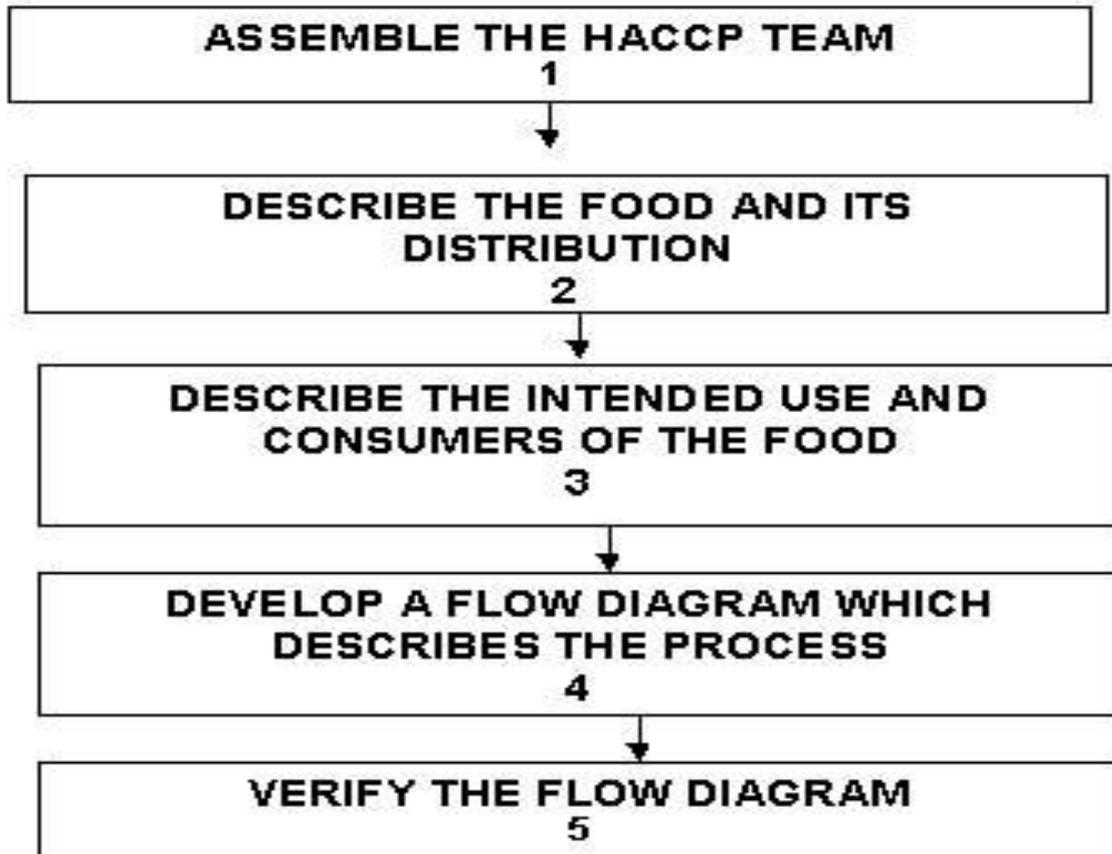
Prerequisites include:

The production of safe food products requires that the HACCP system be built upon a solid foundation of pre-requisite programs:

cGMP as an important factor;

- Facilities – Locations, Constructions, Sanitary design
- Suppliers control
- Specifications for all raw materials
- Production equipment
- Personnel Hygiene
- Trainings
- Documented Procedure for core activities
- Receiving, Storage, and Shipping
- Effective Pest Control Program etc.

## FIVE PRELIMINARY STEPS



**Figure 2:** Flow chart of HACCP

There are seven (7) principles of HACCP, they include:

- Conduct a hazard analysis
- Determine the Critical Control Points(CCPs)
- Establish Critical Limits
- Establish Monitoring Procedures
- Establish Corrective Actions
- Establish Verification Procedures
- Establish Record Keeping and Documentation Procedures

## **THE FOOD MANAGEMENT SYSTEM**

- An international approach
- Certification provides some credence

### **ISO 22000:2018 (Figure 3)**

- Section 1 – Scope
- Section 2 – Normative Reference
- Section 3 – Terms & Definitions
- Section 4 – Context of the organization
- Section 5 – Leadership
- Section 6 - Planning
- Section 7 – Support
- Section 8 – Operations
- Section 9 – Performance evaluation of the food safety management system
- Section 10 - Improvement



**Figure 3:** Food safety certification

Topical issues on food safety include:

- Food additives and colorants
- Pesticides residues
- Genetically modified organisms
- Food Fraud
- Biodefence

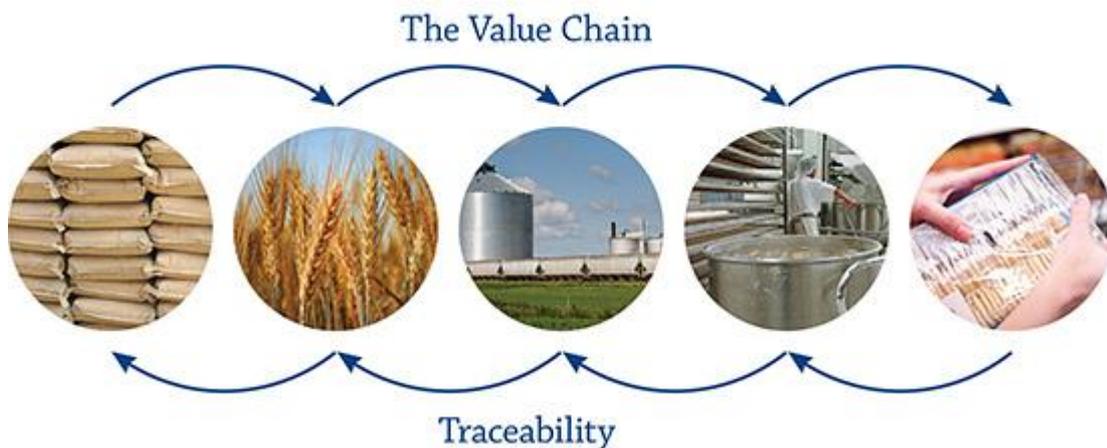
#### **Food traceability**

- Traceability is the ability to track any food through all stages of production, processing and distribution (including importation and at retail). Traceability should mean that movements can be traced one step backwards and one step forward at any point in the supply chain.
- Extends to being able to identify the source of all food inputs such as:

- raw materials
- additives
- other ingredients
- Packaging.

### Why is traceability important?

Traceability enables corrective actions (such as a product recall) to be implemented quickly and effectively when something goes wrong. Traceability allows food businesses to target the product(s) affected by a food safety problem, minimising disruption to trade and any potential public health risks (Figure 4).



**Figure 4:** Traceability flowchart

A concrete case: dioxin contamination in potato peels occurred in 2004. Below are details;

Date: In autumn 2004

Country: Holland

Contaminate: Dioxin.

Area of inspection – Milk farm

- Primary source of contamination: Clay used in food processing to separate high quality potatoes from lower quality ones.
- Secondary Source of contamination: Clay had contaminated potato peels used for feeding animals
- Risk exposure: Over 200 farms spread across The Netherlands, Belgium, France and Germany.
- Lesson learnt: A stitch in time saves nigh

### **What is Pharmaceutical Quality Assurance?**

- **Quality assurance** is a wide concept that covers all aspects that collectively or individually impact the **quality** of the product. ...
- **Quality assurance** is a good practice in the manufacture of **pharmaceutical** products, as it is the process of vouching for integrity of products to meet the standard for the proposed use.

# Three Stages of Quality Assurance

Procedures are just words on a page. It doesn't mean it's happening.  
Effective Quality Assurance requires evidence to ensure the Quality Management System is in place, in use and in control.

**In Place**  
Procedurally

- ✓ Compliant SOPs
- ✓ Operational SOPs
- ✓ SME/QA Approved
- ✓ Effective Training



**In Use**  
Behaviorally

- ✓ SOPs Respected
- ✓ SOPs Followed
- ✓ GDP Record Keeping
- ✓ Accessible Data Source



**In Control**  
Measurably

- ✓ Performance Metrics
- ✓ Self-Detection/ Correction
- ✓ Risk Communication
- ✓ Controlled Improvement

## Enablers of Quality Assurance

- Quality System Ownership
- Management Responsibility and Oversight
- Business Integration

### The regulatory challenge

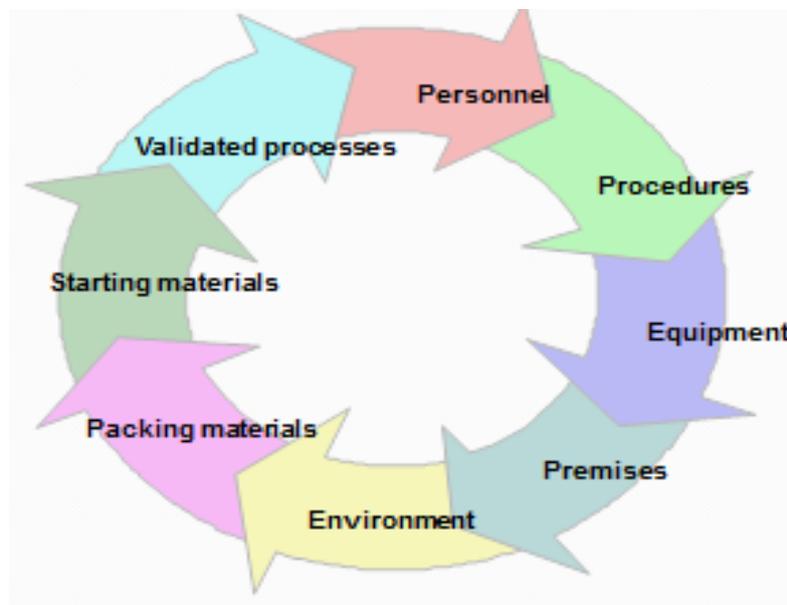
NAFDAC's Regulatory and Control functions cover the Manufacture, Importation, Exportation, Sale, Advertisement and Distribution of Food, Cosmetics, Medical Devices, Packaged Water, Chemicals and Drugs (Decree 15 of 1993).

### What is GMP?

- GMP is an aspect of quality assurance which aims to ensure that products are consistently manufactured and controlled to a quality appropriate for their use and market authorization.
- Use of adequate materials, facilities, equipment and instrumentation, performed and supervised by qualified well-trained staff in accordance with rational and well defined written processes and procedures to produce (world-class) products.

## Why Comply with GMP in Nigeria?

- Compliance ensures products consistent reliability
- It is consistently and pragmatically being enforced by NAFDAC and SON
- Compliance helps companies achieve improvement in all areas of production
- It builds confidence amongst workers
- It supports audits



**Figure 5:** Factors contributing to quality products

The 10 golden rules of GMP include:

1. Get the facility design right from the start
2. Validate processes
3. Write good procedures and follow them
4. Identify who does what

5. Keep good records
6. Train and develop staff
7. Practice good hygiene
8. Maintain facilities and equipment
9. Build quality into the whole product lifecycle
10. Perform regular audits

### **Other Quality Programs**

- Quality Control
- Quality Assurance
- Quality Management System (ISO 9001)
- Pharmacovigilance
- Total Quality Management/Operational excellence

Career opportunities include:

- Documentation Officers
- Microbiologists/Chemists/Analysts
- Validation Officers
- In-process control officers
- Process Improvement Personnel
- Regulatory Affairs Officers
- QC/QA Manager

- Lean Six-Sigma Specialist
- Quality Management Consultant
- Integrated Management Systems Managers/Auditors/Trainers
- Food Safety
- Occupational Health & Safety
- Information System Management
- Business Continuity Management
- Systems Certification Auditors/Assessors

Personnel competencies in these specializations include;

- Post Graduate Diploma/M.Sc (Quality Management/Food Safety )
- Certified Manager of Quality & Organizational Excellence – ASQ/CQI
- ISO 9001/ISO 22000 Lead Implementers and ISO 9001 Lead Auditor – Training providers
- HACCP Certification
- Lean Six Sigma Certification
- Business Process Analysts

## **Conclusion**

"Food safety involves everybody in the food chain." (Mike Johanns). Hence, manufacturing failures emerge from the line; quality failures emerge from the boardroom.

