A TECHNICAL REPORT

ON

STUDENT INDUSTRIAL WORK EXPERIENCE SCHEME

(S.I.W.E.S)

UNDERTAKEN AT

NALIS PHARMACEUTICALS LIMITED, OWERRI, IMO STATE

BY

OBI CHIAMAKA LILIAN.

MATRIC NUMBER: 16/MHS07/024.

COLLEGE OF MEDICINE AND HEALTH SCIENCES

DEPARTMENT OF PHARMACOLOGY AND THERAPEUTICS.

AFE BABALOLA UNIVERSITY

FROM

MAY– AUGUST 2019.

IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF BACHELOR OF SCIENCE (B.sc).

TABLE OF CONTENTS

Acknowledgement

Dedication

Abstract

CHAPTER ONE

- Introduction to SIWES

CHAPTER TWO

- History of NALIS
- Vision of the establishment
- Mission of the establishment
- Philosophy
- Various departments and functions
- List of products
- Organogram

CHAPTER 3

INTRODUCTION TO MANUFACTURING PLANT

- Production department
- Biochemistry department
- Microbiology department

CHAPTER 4

- Problems encountered during the program
- Conclusion

ACKNOWLEDGEMENTS

I thank God Almighty for the grace he has given me to partake in the industrial training program. To my parents for their support, and encouragement throughout the training period, also my lecturers, fellow IT students, and all the staff of Nalis who contributed in one way or another to the success of my training.

DEDICATION

This report is dedicated to my heavenly father for strength and provision to continue throughout the period of the training and also to my parents for their love and support.

ABSTRACT

This report is a summary of the experience I was able to gather during my SIWES program at NALIS pharmaceuticals limited.

It contains a summary of the personnel, departments in the company, drugs produced, the production methods, the equipment used, tests carried out and other useful information I obtained during my training.

CHAPTER ONE

INTRODUCTION

The student industrial work experience scheme [SIWES] is the acceptable skill training program which forms part of the approval minimum academic standard in the various degree programs for all Nigerian tertiary institutions.

It is an effort to bridge the gap existing between theory and practical of Science, Engineering and Technology, Agriculture, Management and all other professional education program in Nigerian tertiary institutions.

It is aimed at exposing students to machine and equipment professional work methods and way of safe guarding other organization. The scheme is a tripartite program involving the polytechnics, Universities and Colleges of Education all going into the industries [employers of labor].

BACKGROUND OF SIWES

Student Industrial Work Experience Scheme [SIWES] was established by Industrial Training Fund [ITF] in the year 1973 to solve problems of lack of adequate practical skills in industries by Nigerian graduates of tertiary institutions. The Industrial Training Fund solely funded the scheme during its formative years but as financial involvement became unbearable to fund, it withdrew from the scheme in 1978.

OBJECTIVES OF SIWES

- Provide an avenue for students in Nigerian schools to acquire industrial skill and experience in their course of study.
- Prepare students for the work situation they are likely to face after graduation.
- Expose students to work method and techniques in handling equipment and machinery that may not be available in the Universities.
- Provide students opportunities to apply their theoretical knowledge and acquire work practice.
- Make transitions from school to the world of work easier and this enhances student contact for later placement after graduation.
- Enlist and strengthen employer involvement in the entire educational process of prepare students for employment in Industries and Commerce.
- To help students on contacts for job placements.
- Provide students with an opportunity to apply their knowledge in real work situation thereby bridging the gap between theory and practice.

CHAPTER TWO

HISTORY OF NALIS

NALIS pharmaceuticals limited was founded in 2011. From a small marketer and distributor of pharmaceutical products, Nalis has grown to become a progressive pharmaceutical company engaged in importation, distribution, marketing and manufacturing of a broad array of brand and generic pharmaceutical products. Product development has continually expanded both on existing and new product lines.

The company situates at Nekede-Naze industrial cluster, Nekede, Owerri, Imo state.

MISSION STATEMENT

To be amongst the leading global Pharmaceutical companies that deliver quality and innovative pharmaceutical products.

VISION STATEMENT

To be one of the most preferred indigenous healthcare companies in Nigeria by 2025.

PHILOSOPHY

The corporate philosophy at Nalis Pharma is in serving customers with Qualitative, Effective, and Well on Time deliveries of products. The stakeholders of the Company lay a great importance in the realization of the mentioned principles, thereby effecting a positive synergy to the entire Value Chain ultimately benefitting the customer.

VARIOUS DEPARTMENTS AND FUNCTIONS

1) Regulatory Affairs
   - Oversight of full product lifecycle
   - Ensuring product development program is compliant
   - Ensuring product marketing program is compliant
   - Ensuring post-marketing product is compliant.

2) Production

   - Production of goods that are used by the company.

3) Quality Assurance and Control

   - Monitoring incoming raw materials
   - Monitoring stored raw materials
   - Analysis on varying products and raw materials
   - Analysis on packaging materials e.g. inner cartons, dosage caps
   - Analysis for indices of quality of stored products.

4) Warehousing and logistic

   - Outgoing of finished goods to the market.

5) Accounts

   - Track all revenue and expenditures
   - Making payments and keeping bills paid
   - Making sure everyone gets paid
   - Preparing financial reports
   - To avoid errors, fraud and theft.

6) Procurement

   - Procuring materials
   - Evaluating price.

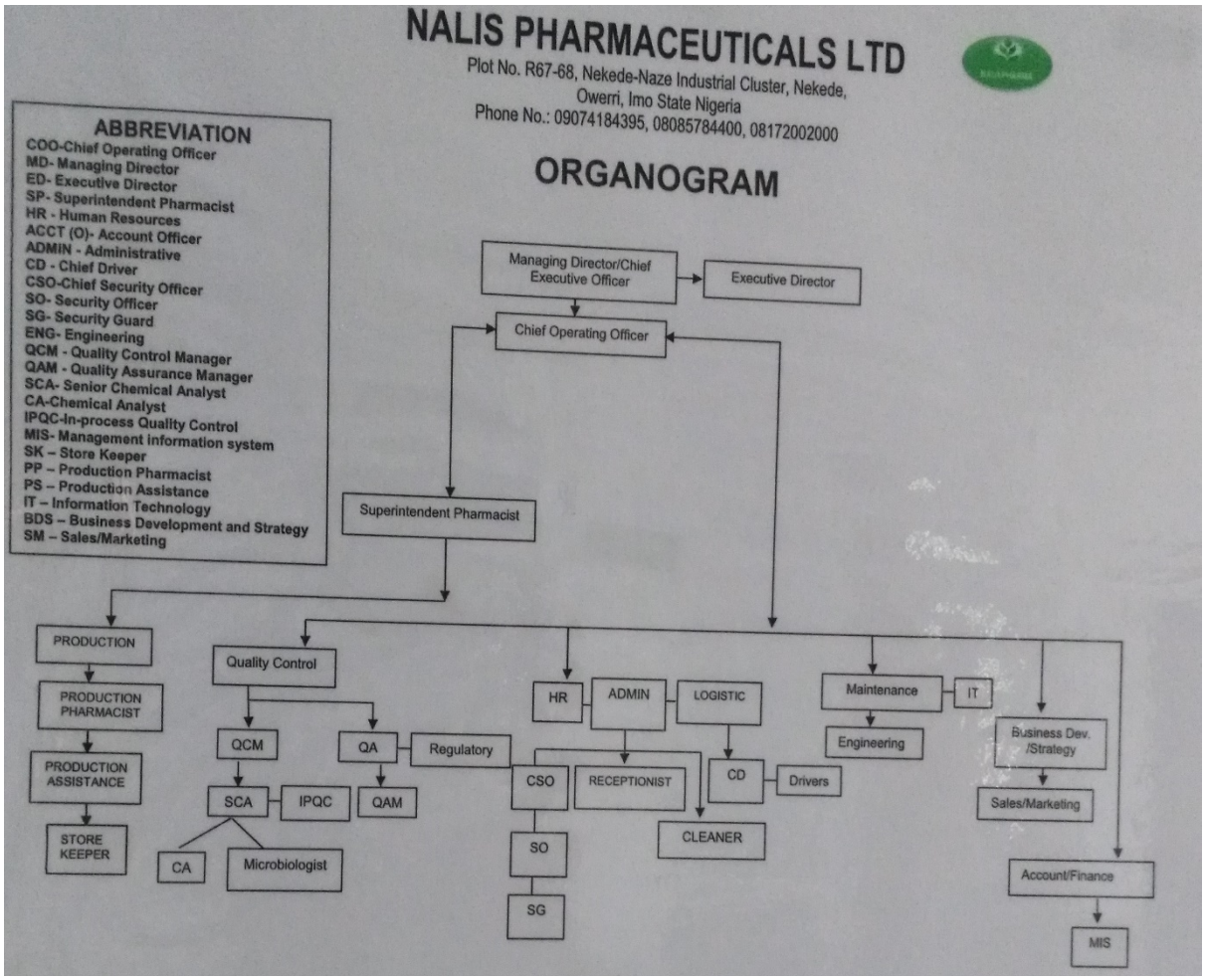
7) Engineering

   - Machine installation
   - Maintenance of machines.

LIST OF PRODUCTS

- Ribufen suspension
- Nalotrim suspension
- Nalovite
- Cosine expectorant
- Nalis vitamin C
- Prytune syrup
- Prytune expectorant
- Tcare3
- Morlyn expectorant
- Nalolyn expectorant.

ORGANOGRAM



CHAPTER 3

INTRODUCTION TO MANUFACTURING PLANT

PRODUCTION DEPARTMENT

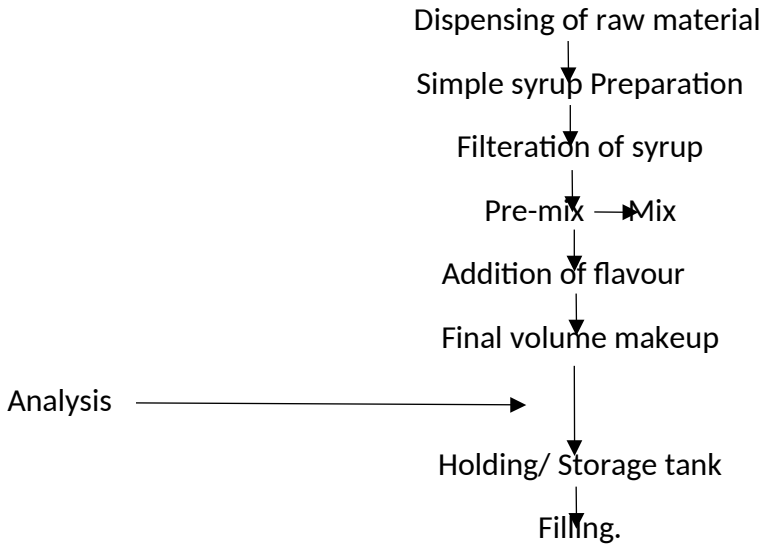
In this department I was introduced to the various equipment used in production, which are;

- Sugar Mixing Tank- Used to dissolve sugar to form smooth, agglomerate-free and homogenous syrup
- Double Filter- Removes particles that were not well dissolved in the mixing tank to give a homogenous mixture
- Liquid Drug Mixing Tank- Used to mix dissimilar liquids to give a consistent, smooth, agglomerate-free mixture
- Holding Tank- A storage tank that provides a safe environment so its content would not interact with the environment or insides of the tank i.e. to prevent contamination before it will be used.
- Transfer Pipe- For transportation of the mixed drug from one place to another
- Bottle Washing Machine- Used to wash and sterilize the bottles where the drug would be filled.
- Bottle Filling and Sealing Machine- Used to fill the bottles with the drug and also for sealing the bottles
- Bottle Labelling Machine- For labelling the filled and sealed bottles

I was involved in the production of various drugs such as (Nalovite, Tcare3)-Blood tonics, (Prytune syrup, Prytune expectorant, Cosine syrup, Morlyn expectorant, Nalolyn expectorant) -Cough syrups, (Ribufen) –Analgesic, (Nalotrim) –Antibiotic, Nalis vitamin C.

Before production starts, the Quality Control department have to make sure that water and all the other raw materials are suitable for production and also that all the equipment are properly calibrated, because for any preparation we need quality water and quality raw materials. They ensure that the water is properly de-ionized, because some of the raw materials to be used for production are positively and negatively charged and if there are still ions in the water, they will form complexes by binding. If binding is not prevented, the potency of the drugs produced would be diminished.

PROCESS FLOW CHART FOR SYRUP PRODUCTION



After the mixing process, bulk samples of the drug would be taken to the Quality control lab for assay to ensure that the drug complies with the pharmacopoeia standards, if it complies, the go ahead would be given for the filling, capping and labelling stages of production.

BIOCHEMISTRY DEPARTMENT

In the Biochemistry department I was introduced to various laboratory equipment and their principles such as;

- Ultra violet spectrophotometer- used to measure the rate of light absorbance of a substance which in this case is a liquid drug
- Viscometer- used to check the resistance of a substance to deformation at a given rate
- Refractometer- used for checking the refractive index of a substance
- PH meter- used to check the degree of acidity or alkalinity of a substance
- Automatic water titrator- used to check the moisture content in a liquid
- Colorimeter- used for checking color absorbance
- Magnetic stirrer- used to stir/mix a substance
- Vacuum drying oven- used to check loss on drying
- Box resistance furnace- used for heating materials above 1000 degree celsius, also used to determine the percentage of sulphate ash in raw materials
- Fume hood chamber- used to extract excess discharge of acid.

UV SPECTROPHOTOMETER

AUTOMATIC POLARIMETER

VACCUM DRYING OVEN

In this department, I observed as the Biochemist carried out assays on the raw materials and on bulk samples of the finished products following the Pharmacopeia standard.

Assay Methods;

1) For the Active Pharmaceutical Ingredients present in Cosine Syrup

- Diphenyhydramine- 0.20g of the sample is dissolved in 20ml of acetic acid and 10ml of mercury acetate solution. Then titrate with 0.1mol perchloric acid using 0.05ml of crystal violet as an indicator. 1ml of 0.1mol perchloric acid used is equivalent to 29.18ml/g of Diphenyhydramine HCL.
  Specification
  98.0 - 101.0% for raw material
  90.0 - 110.0% for finished product.

- Ammonium Chloride- 1.00g of the sample is dissolved in 20ml of water, a mixture of 5ml of aldehyde solution previously neutralized with phenolphthalein solution and 20ml of water is added. Titrate slowly after 1-2mins with 1mol of sodium hydroxide using further 0.2ml of the same indicator. 1ml of 1mol of sodium hydroxide is equivalent to 53.49ml of ammonium chloride.
  Specification
  39.0-100.5% for raw material
  94.0- 106.0% for finished product.

2) For the Active Pharmaceutical Ingredient present in Prytune Syrup

- Chlorpheniramine Maleate- 0.150g of the sample is dissolved in 25ml of acetic acid. Titrate with 0.1mol perchloric acid, determine the endpoint potentiometrically. 1ml of 0.1mol perchloric acid is equivalent to to 19.54mg of Chlorpheniramine maleate.
  Specification
  98.0- 101.0% for raw material
  90.0- 110.0% for finished product.

3) For the Active Pharmaceutical Ingredient present in Nalovite

- Vitamin B12- 5ml of sample dissolved in 500ml of water, then 25ml of the mixture in 200ml of water
- Vitamin B2- 5ml of sample is dissolved in 150ml of water, then 2ml of acetic acid is added, then poured into 1000ml of water. 3.5ml of sodium acetate is added to 10ml of the initial mixture, then it is diluted to 50ml.

MICROBIOLOGY DEPARTMENT

In this department, I was introduced to various laboratory equipment and their principles such as;

- Incubator- used to determine the rate at which microorganisms grow within a certain temperature within a specified time
- Colony counter- used to determine the number of microbial colonies found in a prepared medium
- Laminar airflow chamber- used for sterilization using Ultra Violet light
- Static passive box- used for passing sterilized materials
- Autoclave- used for destruction of bio hazardous microbes, also used for sterilization

INCUBATOR

LAMINAR AIR FLOW CABINET

STATIC PASSIVE BOX

After the introduction to the equipment, I was thought how to clean laboratory work surface and equipment properly;

First with warm water+ little detergent using a soft clean rag, then with warm water alone, then disinfecting the areas with Isopropyl alcohol (IPA).

After this I was thought how to prepare Media. Media is used in carrying out microbiological analysis which is done to check for the presence of microorganisms in the drugs/ finished products.

Types of Media

- PSA- Pseudomonas Agar Base
- MCA- Mac Conkey Agar without salt
- SDA- Sabouraud Dextrose Agar
- MSA- Mannitol Salt Agar Base
- NA- Nutrient Agar
- SSA- Salmonella Shigella Agar
- PW- Peptone Water.

Procedure for Analysis

All the media to be used will be weighed using a weighing balance and put in conical flasks, then the flasks would be covered properly with foil and wrapped with tape to prevent contamination and evaporation. Then they would be placed in the autoclave, so they can dissolve properly. Also the petri dishes together with the pipette and pipette tips will be placed in the autoclave for sterilization. Then the conical flasks containing the media along with the petri dishes, pipette and pipette tips will be taken to the laminar airflow where the media will be poured into the petri dishes. This is done in the laminar airflow to avoid

contamination. The pipette will be used to carry the drug to be analyzed and the drug will be put in the petri dishes, then the various media will be poured. Then the petri dishes will be passed through the Static Passive Box to the incubation chamber, and they will be placed in the incubators for the required time. After this process they will be brought out and observed to see if microorganisms are present in the finished product, i.e. the drug.

If microorganisms are absent, the go ahead for the filling and packaging will be given.

I also observed microbiological analysis of the air of various sections of the industry, of raw water, and also of raw materials.

CHAPTER 4

PROBLEMS ENCOUNTERED DURING THE PROGRAM

- Distance
- Bad road
- No pay

CONCLUSION

Aside from the minor challenges faced, I have to say my SIWES was very successful because I worked in a pharmaceutical company therefore I was able to learn a lot related to my field of study.

I was opportune to take part in the production of various drugs, therefore I was able to learn the basic processes involved in the production of drugs in syrup form. I was able to learn the Active Ingredients of various pharmaceutical preparations, the quantities required, percentage at which they would achieve their curative/ therapeutic effects, and also their adverse effects, and all these are in line with pharmacology.

So I'm really grateful for this opportunity because I gained so much, both in the practical and theoretical aspect, I also met a lot of people who impacted me in more ways than one.