A TECHNICAL REPORT ON STUDENT INDUSTRIAL WORK EXPERIENCE SCHEME UNDERTAKEN AT DRUGFIELD PHARMACEUTICALS LIMITED-LYNSON CHEMICAL AVENUE, KM 38, LAGOS-ABEOKUTA EXPRSSWAY, SANGO OTTA, OGUN STATE, NIGERIA.

BY

ONIKOYI FOLASADE

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COLLEGE OF MEDICINE AND HEALTH SCIENCE

DEPARTMENT OF PHARMACOLOGY

AFE BABALOLA UNIVERSITY

ADO EKITI, NIGERIA.

REPORT OVERVIEW

I, ONIKOYI FOLASADE, hereby submit this report in fulfillment of my industrial training. It aimed to show the knowledge gathered during the student industrial work experience scheme period.It gives a detailed account of useful information pertaining to the training received at DRUGFIELD PHARMACEUTICALS LIMITED. Though the content of this work has been summarized, it covers the knowledge garnered during the extensive period of the programme.

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CHAPTER ONE

1.0 HISTORY OF DRUGFIELD

Drugfield Pharmaceuticals Limited, a wholly indigenous Nigerian company, was founded in 1991 and commenced production in 1993 as a drug manufacturing outfit after approval and due recognition of relevant agencies and bodies including the National Agency for Food and Drug Administration and control (NAFDAC) and Pharmacists Council of Nigeria (PCN).

From an initial product dosage form of dermatological antibiotic and antifungal preparations, our facility now houses additional dosage form manufacturing areas for antibiotic dry syrups, capsules, tablets, ointments, creams, gels, powders, eye/ear drops, small and large volume liquid injectable preparations , nasal drops amongst others. In all modesty, we pride ourselves as the largest product portfolio carrier in the industry with over 140 registered product range.

The completion in 2012 of our ultra modern current Good Manufacturing Practices (cGMP) compliant manufacturing facility for the production of intravenous infusion products (large volume parenteral), creams and gels as well as sterile ophthalmic has enhanced our competence to respond to global operational demands and acceptance.

Our recognition by Regulatory Agencies and International Certification as evidenced by the NIS, with a strong, virile, committed, competent and dedicated professionals and staff.

1.1 VISION/MANDATE

To become the leading Pharmaceutical multi-dosage form manufacturer in Nigeria.

1.2 MISSION

To improve quality of life through manufacture, distribution and sale of quality, safe and effective medicines.

1.3 SLOGAN

Excellent products from a sure source.

1.4 LIST OF PRODUCTS

The different products manufactured by the company are listed under these categories:

- Creams, Lotions, Solutions, and Gels.
- Ointments.
- Tablets and Capsules.
- Syrups and Powders.
- Oral Suspensions.
- Injectable .
- Large Volume Parenteral (Intravenous Fluids).
- Powders for tropical application.
- Eye, Ear and Nasal drops.

CHAPTER 2

2.1 QUALITY ASSURANCE/CONTROL DEPARTMENT

Quality Assurance is a way of preventing mistakes or defects in manufactured products and avoiding problems when delivering solutions or services to customers. Quality assurance is applied to physical products in pre-production to verify what will be made meets specifications and requirements.

Goals of Quality Assurance Department:

- Continuous and consistent development, implementation and maintenance of quality assurance management system.
- Staff training and compliance with the requirements of the quality assurance management.
- Developing and making arrangements for enhancing the quality of provided products.
- Organizing and conducting internal audit of the quality assurance management system.
- Control over equipment and production process.
- Investigation of customer claims.

2.2 Regulatory Affairs Department

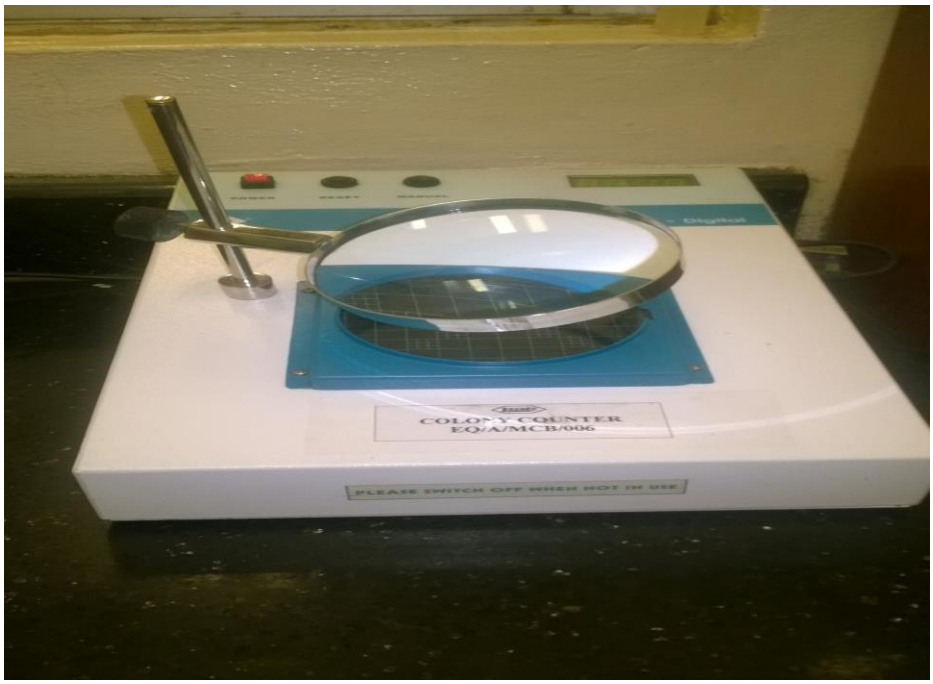
- Oversight of full product lifecycle.
- Ensuring product development program is compliant.
- Ensuring product marketing program is compliant.
- Ensuring post-marketing product is compliant

Regulatory Affairs (RA), also called Government Affairs, is a profession within regulated industries, such as pharmaceuticals, medical devices, energy, and banking. Regulatory Affairs also has a very specific meaning within the healthcare industries (pharmaceuticals, medical devices, Biologics and functional foods). Most companies, whether they are major multinational pharmaceutical corporations or small, innovative biotechnology companies, have specialist departments of Regulatory Affairs professionals. The success of regulatory strategy is less dependent on the regulations than on how they are interpreted, applied, and communicated within companies and to outside constituents. Regulatory Affairs plays a crucial role in the pharmaceutical industry and is involved in all stages of drug development and also after drug approval and marketing. The drug development process is a lengthy, complex and extremely costly albeit necessary process. Pharmaceutical companies use all the data accumulated during discovery and development stages in order to register the drug and thus market the drug.

2.2MICROBIOLOGY DEPARTMENT

In the microbiology section of the company, there are specific assays carried out to ensure that reliable products are produced for the consumer's consumption. Some of the equipment used in the microbiology department includes the microscopes, incubators, autoclaves, laminar air

flow hood, colony counter and quite a few others. Here are some documented diagrams of some of them:


COLONY COUNTER
EQ/A/MCB/006
PLEASE SWITCH OFF WHEN NOT IN USE

The assays carried out in the microbiology laboratory are enumerated below:

- Environmental monitoring.
- Sterility Test.
- Finger Prints.
- Sampling of raw materials.
- Water Analysis.
- Backwashing Analysis.
- Gross Contamination Test.
- Microbial limit Test.

- ENVIRONMENTAL MONITORING.

AIM: To ensure that every areas used for manufacture are cleaned and free from contamination.

PROCEDURE:

- Sterilize the following by autoclave at 121℃ for 15 minutes and transfer to the laminar air flow hood: petri dishes, Trypton Soy Agar (TSA), Saboraud Dextrose Agar (SDA).
- Label the petri dishes accordingly.
- Pour about 18-20 ml molten agar and allow to solidify.
- Expose to designated spots for 30 minutes.
- Collect and incubate at 37℃ (TSA) for 48 hours and 30℃ (SDA) for 72 hours.
- Record the result every 24 hours.

- STERILITY TEST.
  AIM: To ensure that the products are sterile.

  PROCEDURE:
  - Set and wrap up the sterility test kit stored with aluminum foil.
  - Wrap the filter cutter, forceps.
  - Prepare Fluid Thioglycollate Medium (FTM) and Trypton Soy Broth (TSB).
  - Dispense each into screw capped test tubes or into screw capped conical flasks.
  - Get enough distilled water.
  - Prepare enough Bacto-peptone.
  - Sterilize all materials and reagents in the autoclave at 121℃ for 15 minutes.
  - Bring out to cool in the laminar air flow room.
  - In the laminar air flow room, swab all samples and transfer into the Pyrex cup.
  - Open the tap and let the sample flow out of the collecting flask.
  - Wash the sample finally with peptone, allow this to drain.
  - For control, the filter paper is only washed with peptone.
  - Transfer each filter paper by means of a sterile forceps on the filter cutter which will divide it into two halves.
  - Inoculate each medium (FTM and TSB) in separate test tubes with each half of the filter paper.

  Then incubate FTM at 37℃ and TSB at 25℃ for 14 days while observing it everyday.

- FINGER PRINTS.

AIM: To know the condition of the personnel fingers on handling the manufacturing or filling of the products.

SCOPE: To ensure that personnel adhere to good hygiene.

MEDIA:
TSA- Trypton Soy Agar.
SDA- Saboraud Dextrose Agar.

PROCEDURE:

- Prepare, sterilize and pour TSA and SDA agar plates.
- Take the plates to designated places and have each of the pour medium as control.
- Take fingerprints of the personnel involved.
- Incubate TSA at 37℃ for 24-48 hours and SDA at 20℃ for 72-120 hours.

- SAMPLING OF RAW MATERIALS.

SAMPLING OF NON-STERILE RAW MATERIALS.

- Put on nose mask and hand gloves.
- Label dry sterilized bottles to take the samples.
- Use a sterile spatula to take samples randomly into the bottles.

SAMPLING OF STERILE RAW MATERIALS.

- Take the following materials into the UV lock: scissor, forceps, dry sterile bottle or container.
- Allow the above materials to stay in the UV lock for at least 24 hours.
- Collect samples into sterile bottles or containers.
- Take the samples to the laminar air flow room.

- WATER ANALYSIS

PURPOSE: To provide a detailed analysis for comprehensive microbial analysis of water.

PROCEDURE

SAMPLING COLLECTION

- Water samples are collected on weekly basis.
- Samples are collected from different sources: Borehole, Treated, Purified, Reserved, Osmosis and Distilled water.
- Sterilize the reagents and glassware in the autoclave at 121℃ for 15 minutes.

- To collect the sample, sterilize the water source with cotton wool moistened in 70% ethanol, open the tap and allow to run for 1 minute.
- Collect the water sample aseptically into the sterilized bottle.

- GROSS CONTAMINATION TEST.

PURPOSE: To ensure the product is free from contaminant.

SCOPE: To ensure that the product is free from microorganism.

DEFINITION:

TSA- Tryptone Soy Agar.

SDA- Saboraud Dextrose Agar.

PROCEDURE:

- Pour the sterilized molten agar medium into petri dishes and allow to solidify.
- Label the poured plates accordingly.
- Streak the ointment/cream on the surface of the molten agar and incubate at 37℃ (TSA) for 48 hours and (SDA) at 25℃ for 168 hours.

- MICROBIAL LIMIT TEST.
  PURPOSE: To ascertain the quality of the products or materials microbiologically for the fitness of consumption before being used for production or released into the market.
  DEFINITION:
  PCA- Plate Count Agar.
  SDA- Saboraud Dextrose Agar.
  PROCEDURE:
  Sterilize the followings by autoclaving at 121℃ for 15 minutes. Petri dishes, PCA, Test tubes with 9ml lactose broth.
  METHOD: Serial dilution and pour plate method.
  - Set up a series of 3 test tube each containing 9ml of diluents (lactose broth) label $10^{-1,}$ 10^{-2}, 10^{-3} and 8 Petri dishes, two plates for each dilution and two plates for control.
  - Transfer 1ml from sample into tube 10^{-1} and 1ml into each of the two plates.

- Transfer 1ml sample from 10^{-1} to tube 2 and 1ml to each of the two plates, this gives a dilution of 10^{-2}.
- Repeat the process for tube 3 (10^{-3}).
- Pour molten PCA to four plates (10^{-1},10^{-2} 10^{-3} and control) and SDA to four plates (10^{-1},10^{-2},10^{-3} and control).
- Pour at 37℃ for PCA and 30℃ for SDA for 168 hours.

2.3 CHEMICAL LABORATORY

EQUIPMENT USED IN THE CHEMICAL LAB

A spectrophotometer

A viscometer

The assays I worked on with an analyst involved:

- Assay of mutrovite syrup to determine the ascorbic acid content.
- Assay of Neurogesic Extra Ointment to determine the acid value content.
- Assay of Neurogesic Extra Ointment to determine the weight per ml.
- Assay of Vistulent Eye Drops to determine the specific gravity.

TITLE: ASSAY OF MUTROVITE SYRUP.

AIM: TO DETERMINE THE ASCORBIC ACID CONTENT.

METHOD: TITRIMERTRY.

PROCEDURE:

1. Weigh 5ml of sample in duplicate into a mixture of 100ml of distilled water and 25ml of 2NH2SO4 into a 250ml conical flask.

2. Mix the solution properly, add 3ml of starch solution.

3. Titrate immediately with 0.1N iodine solution.

Calculation: $\frac{\text{Titre value x factor of iodine x 8.806 x SG}}{\text{Weight of sample}}$

TITLE: ASSAY OF NEUROGESIC EXTRA GREASLESS OINTMENT.

AIM: To determine the acid value content.

PROCESS:

1. Weigh 2g of Neurogesic Greaseless Ointment into a conical flask.

2. Add 50ml of equal volumes of ethanol and ether that has been neutralized with 0.1M Potassium Hydroxide using 0.5ml of phenolphthalein solution as indicator.

3. As the ointment completely dissolves, titrate with 0.1M Potassium Hydroxide, shake constantly until pink color persists for 15 seconds.

Calculation: $\frac{\text{Titre value x 5.61 x factor of 0.1M koH}}{\text{Weight of sample}}$

TITLE: ASSAY OF NEUROGESIC EXTRA OINTMENT

AIM: TO DETERMINE THE WEIGHT PER ML

PROCEDURE:

Weight of empty crucible W1= 29.4304

Weight of crucible + water W2= 59.8150

Weight of crucible + sample= 61.3431

W3-W1 =61.3431 -29.4304 = 31.9127 =1.05

W2-W1 59.8150-29.4304 = 30.3846

TITLE: ASSAY OF VISTULENT EYE DROPS.

AIM: TO DETERMINE THE SPECIFIC GRAVITY.

PROCEDURE:

Weight of SG bottle W1= 22.1284

Weight of SG bottle + Water W2= 47.3618

Weight of SG bottle + sample W3= 53.7300

W3-W1 =31.6016 =1.25

W2-W1 25.1284

2.4 Conclusion

In conclusion, the program was a success because I accumulated knowledge from various fields and was able to fuse them together for the enhancement of my study In school. In addition, SIWES has been successful in aiding students socially and academically, thereby equipping students for the challenges ahead, thereby, boosting the moral and intellectual capability of students.