THE BIOSCIENTIST—
A TEAM PLAYER IN THE PHARMACEUTICAL INDUSTRY

by

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Definitions: Bioscience
Scope of bioscience
Pharmaceutical industry

Bio scientist in the foundation of the pharmaceutical industry

Pharmaceutical industry divisions/departments

Opportunities/Relevance

Conclusion
What is Bioscience?
This is a course that aims for students to develop an understanding of the complexity and diversity of life processes through the study of a range of modules. Modules include:

- Molecular biotechnology
- Immunology
- Cell biology
- Biochemistry
- Applied biology
- Microbiology
- Botany
- Zoology
- Development biology
SCOPE OF BIOSCIENCE

Bioscience courses can take you in a wide range of directions, and the beautiful thing about it is that it’s not static. The constant updates to research methods and technology found in the biosciences allow us to learn throughout our careers.

Skills developed are:

- Computer skills
- Analytical skills
- Independent learning skills
- Creative skills
- Applying what you have learnt in a practical situation
- Determination, patience, self-confidence, persistence, self-discipline

Affords you an understanding of how science works.
The pharmaceutical industry develops, and markets drug or pharmaceuticals licensed for use as medications.

It’s into perfecting the purification of organic compounds from coal tar and other mineral sources and also established rudimentary methods in organic chemical synthesis.

It is also involved in the purification of biological materials.

The pharm company is allowed to deal in generics or brand medications and medical devices.
It is subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs.

For instance, in Nigeria, we have regulatory bodies like; NAFDAC, SON, NESREA, PSN, PCN, ministry of health(both at the state and federal levels), LASEPA etc. others include international bodies like WHO qualifications.
The pharm industry traces it roots to two sources – the local apothecaries distributing botanical drugs such as morphine and quine the large scale manufacture in the 1800s by the multinational corporations including; Merck, Hoffman la Roche, Burroughs– Wellcome (now GlaxoSmithKline), Abbott laboratories, Eli lilly and Upjohn (now part of Pfizer).

Alexander Fleming penicillin (a professor of bacteriology)

Robert Koch BCG (bovis bacille calmette Guerin) discovered by a microbiologist.

They also helped in application of drugs like;

- Insulin
- Adrenalin (epinephrine)
- Immunotherapy and chemotherapy in cancer
- Kidney transplant
- Faecal transplant
- Genetic engineering
What did they do?

- Produced antibiotics
- Worked on toxins in form of chemicals to kill target substances and cells that cause harm to the living systems
- Used the knowledge of genetics, immunology to identify causes and proffer solutions.
- Used technology to produce large quantities of potential drug for medical purposes.
MICROBIOLOGY

- This is the study of micro-organisms such as bacteria, protozoa parasites, viruses and fungi.

- The study helps us to explore how micro-organisms cause infectious diseases, become drug resistant, contribute to our health, assist us to absorb food.

- It also assists us to know their natural habitat and how well to multiply them.
**BIOTECHNOLOGY**

- This is the science which combines biology with technology.
- It uses living systems and organisms to develop or make useful products or any technological application.
- It uses biological systems, living organisms or derivatives thereof to make or modify products or processes for specific use.
- Since it’s the applied knowledge of biology, it seeks to duplicate or change the function of a living cell so it will work in a more predictable and controllable way.
- It uses advances in genetics research to develop products for human diseases and conditions.
Biochemistry is the study of chemical processes and chemical transformations in living organisms.

- Some others study DNAs, proteins, enzymes, carbohydrates, and cell biology that is, the molecular aspect of life.
- They focus on planning and conducting research experiments, mainly for developing new products.
- They also study the origin, formation, function, deficiency, symptoms of chemical reactions in living organisms.
APPLIED BIOLOGY

Is the understanding of how organisms work from subcellular to whole organisms.

- It involves the use of living organisms (mostly microbes) to produce useful products.

- It also includes traditional processes like brewing, cheese making and modern developments such as genetic engineering which can lead to new drugs against cancer and other diseases.
GENERAL DIVISIONS/DEPARTMENTS IN A PHARM. INDUSTRY.

1. Medical department
2. Research and development department
3. Quality control department
4. Production and packing department
5. Purchasing department
6. Warehousing department
7. Engineering and Technical department
8. Marketing and sales department
9. Finance department
10. Human resources
11. Corporate affairs department
12. Information technology department
13. Corporate strategy and business development
DISTRIBUTION OF DEPARTMENTS IN THE PHARM. INDUSTRY

- Bioscience related depts: 46%
- Non-Bioscience related depts: 54%
DIVISIONS IN PHARM INDUSTRY

<table>
<thead>
<tr>
<th>Departments</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fundamental depts</td>
<td>46.4%</td>
</tr>
<tr>
<td>Pharm. related depts</td>
<td>28.6%</td>
</tr>
<tr>
<td>Bioscience related depts</td>
<td>25%</td>
</tr>
</tbody>
</table>
The charts above confirm the analysis of research & development personnel record, drawn at a symposium held at the royal society in 1979 on ‘biological education, training and employment’ of Beecham group.
THE BIO-SCIENTIST: RELEVANCE AND OPPORTUNITIES IN THE PHARM INDUSTRY

Warehouses
The raw material warehouse is nearer to the production and the quality control while the finished goods warehouse is usually nearer the company’s outlet for easy and efficient transportation.

Duties include:
- Receiving of goods
- Quarantining
- Allocating space for goods
- Providing proper storage conditions
- Stock keeping
SAFETY DATA SHEET

1. Identification

Product identifier: PHENOL, CRYSTALS

Other means of identification

Product No.: 4056, 2858, 2862, 0605, 0273, 0028

Recommended use and restriction on use

Recommended use: Not available.
Restrictions on use: Not known.

Manufacturer/Importer/Supplier/Distributor information

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Avantor Performance Materials, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td>3477 Corporate Parkway, Suite 200</td>
</tr>
<tr>
<td></td>
<td>Center Valley, PA 18034</td>
</tr>
<tr>
<td>Telephone:</td>
<td>Customer Service: 855-282-6867</td>
</tr>
<tr>
<td>Fax:</td>
<td></td>
</tr>
<tr>
<td>Contact Person:</td>
<td>Environmental Health &amp; Safety</td>
</tr>
<tr>
<td>e-mail:</td>
<td><a href="mailto:info@avantormaterials.com">info@avantormaterials.com</a></td>
</tr>
</tbody>
</table>

Emergency telephone number:

24 Hour Emergency: 908-859-2151
Chemtrec: 800-424-9300

2. Hazard(s) identification

Hazard classification

Health hazards

- Acute toxicity (Oral) Category 3
- Acute toxicity (Dermal) Category 3
- Acute toxicity (Inhalation – vapor) Category 3
- Skin corrosion/irritation Category 1B
- Serious eye damage/eye irritation Category 1
- Germ cell mutagenicity Category 2
- Specific target organ toxicity – repeated exposure Category 2

Environmental hazards

Acute hazards to the aquatic environment Category 1

Label elements

Hazard Symbols:
SAFETY DATA SHEET  cont.

7. Handling and storage

Precautions for safe handling: Use personal protective equipment as required. Avoid contact with eyes, skin, and clothing. Do not breathe dust or vapor. Do not taste or swallow.

- Do not eat, drink or smoke when using the product. Use only with adequate ventilation. Wash hands thoroughly after handling. See Section 8 of the MSDS for Personal Protective Equipment.

Conditions for safe storage, including any incompatibilities:

- Do not store in metal containers. Keep in a cool, well-ventilated place. Store in a dry place.

8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

<table>
<thead>
<tr>
<th>Chemical identity</th>
<th>Type</th>
<th>Exposure Limit values</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHENOL</td>
<td>TWA</td>
<td>5 ppm</td>
<td>US. ACGIH Threshold Limit Values (2011)</td>
</tr>
<tr>
<td></td>
<td>REL</td>
<td>5 ppm 19 mg/m3</td>
<td>US. NIOSH: Pocket Guide to Chemical Hazards (2010)</td>
</tr>
<tr>
<td></td>
<td>Ceil_Time</td>
<td>15.6 ppm 60 mg/m3</td>
<td>US. NIOSH: Pocket Guide to Chemical Hazards (2010)</td>
</tr>
<tr>
<td></td>
<td>PEL</td>
<td>5 ppm 19 mg/m3</td>
<td>US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000) (2006)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>5 ppm 19 mg/m3</td>
<td>US. OSHA Table Z-1-A (29 CFR 1910.1000) (1989)</td>
</tr>
</tbody>
</table>

Biological limit values

<table>
<thead>
<tr>
<th>Chemical identity</th>
<th>Exposure Limit values</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHENOL (Phenol with hydrolysis: Sampling time: End of shift.)</td>
<td>250mg/g Creatinine in urine</td>
<td>ACGIH BEL (2011)</td>
</tr>
</tbody>
</table>

Appropriate engineering controls: No data available.

Individual protection measures, such as personal protective equipment

General information: Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An eye wash and safety shower must be available in the immediate work area. Use explosion-proof ventilation equipment.

Eye/face protection: Wear safety glasses with side shields (or goggles) and a face shield.

Skin protection

Hand protection: Chemical resistant gloves

Other: Wear suitable protective clothing and gloves.

Respiratory protection: In case of inadequate ventilation use suitable respirator.

Hygiene measures: Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing to remove contaminants. Discard contaminated footwear that cannot be cleaned. Provide eyewash station and safety shower.
Production/packaging department
Depending on the nature of product, it’s into activities such as:
- Granulation, compression, coating, homogenization, etc
- Filling, tubing, counting, labelling, cartoning, wrapping, etc

Purchasing department
- Sourcing for pharmaceutical raw materials
- Sourcing for pharm packing materials
- Sourcing for all other departments’ needs
- Pricing of such materials.
Research and development

- Potential drug discovery or design.
- Update and line extension of existing drugs.
- Formulation of generic products.
- Initiate and conduct accelerated stability studies in preparation for new product registration.

Quality control/assurance department

- It carries out both quantitative and qualification testing to determine whether products can be released into the market as per specification.
They must contain the same active ingredients as the original formulation.

This suggest that there may be a slight modification in the formulation in respect to other substance called ‘excipients’ in the formulation. Excipients are other components apart from the active ingredient. They serve in different capacity ranging from bulking agent, buffers, preservatives, disintegrates, binders, stabilizing agent, solvents thickeners and so on.
Generics however in spite of any form of modification must be within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetics and pharmacodynamics properties.

In most cases, generic products are available once the patent protections afforded to the original developer have expired.
Perform analysis on the following:

- Raw materials (bulks, excipients, water)
- Blends and intermediate products
- In process
- Finished products
- Samples under Stability testing
- Lab support (method development, working standards and reference standards)
The department is further divided into two;
- The chemical section
- The microbiological section

It is in these sections that analysis such as;
- Assay/bioassay
- Description
- Identification
- Limit of impurities

Others depend on dosage forms (tablets, powders, syrups, suspensions, etc) includes;
- Disintegration, dissolution rate, hardness/friability, uniformity of dosage units, water content, microbial limits.
- pH, antimicrobial preservative content, extractables, alcohol content, particle size, redispersibility, viscosity/specific gravity, reconstitution time, and microbial limit test etc are performed.
Judging from the above listed analyses, it is fundamental that new analytical procedures as well as validation of such procedure must be developed.

Existing procedures available through pharmacopoeias be performed.

It therefore means a good bio–scientist with interest in quality control must be vast in the use of laboratory equipment.
Equipment used in QC include;
- High performance liquid chromatography
- Gas chromatography
- Thin layer chromatography
- UV/VIS spectrophotometer
- Infra-red spectrophotometer
- Atomic absorption spectrophotometer
- Autoclaves
- Weighing balances
- pH meter
- Melting point apparatus
- Laminar flow
- Distillation rate apparatus
Another place for a biological science graduate in a pharmaceutical industry is sales of pharmaceutical products as medical reps. They talk with pharmacists, hospital personnel, physicians, patient advocacy groups, retirement homes etc.

Promote new products and treatment to present update information in these areas to the medical world

Raise public awareness regarding health issues.
CONCLUSION

- The Bioscientist is an indispensable partner in a wide range of industries – the water treatment and engineering industry, the food and beverage industry, the breweries and so many others; apart from the pharmaceutical industries.

- The ground is yet to be broken as far as the relevance of the bioscientist is concerned. Discoveries of strains and species and better understanding of the living systems to solve problems in science, medicine and health are yet to be made.
CONCLUSION cont.

- No module of Bioscience is independent of the other, they are interwoven, the botanist discovers the plant, the zoologist the animals, the applied biologist establishes the field of application while the biotechnologist enhances the use in relevance to technological application.

- The whole world is waiting on the pharmaceutical industry for help in this areas.

- If almost 50% of the employees in a pharmaceutical industry are bio scientists, it means therefore, that the world is looking up to the bio scientists.

- Together we can do it.
Thank you