THE ROLE OF A CHEMIST IN THE PHARMACEUTICAL INDUSTRY

BY

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INTRODUCTION

- The targets of the pharmaceutical industries are the lives of human beings and animals.

- In view of this, what are produced and marketed must guarantee the safety and wellness of the users of the products.

- The industry is highly regulated; hence the need for qualified and trainable professionals to fit into the key areas of operations in the industry.

INTRODUCTION

Most pharmaceutical industries are divided into various departments for smooth running of their operations. These are:

- Administrative/Human Resources
- Finance
- Procurement
- Sales and Marketing
- Warehousing/Logistics
- Technical
- Engineering

N.B. Quality Assurance, Quality Control, Research and Development (R & D) and Manufacturing all fall under the Technical section of the industry.

INTRODUCTION

- The chemist plays a key role in the Technical section of the pharmaceutical industry.
- In this sector, you find chemists occupying positions such as
- Laboratory Analyst
- Quality Assurance Manager
- Quality Control Manager
- Production Chemist
- Therefore, this presentation will be centered on job functions of chemist in quality assurance, quality control and production section of the industry.

DEFINITIONS

- **QUALITY ASSURANCE:** This consists of all the arrangements made with a view to ensuring that medicinal products are of the quality required for their intended use.
- **QUALITY CONTROL:** Is that part of GMP (Good Manufacturing Practice) concerned with sampling, making specifications and testing with the organized system, documentation and release procedures, which ensure that the necessary and relevant tests are actually carried out and that only materials and products with satisfactory quality are released for use and for sale or supply.

DEFINITIONS

- **GOOD MANUFACTURING PRACTICE(GMP):** Is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their use and as required by marketing authorization.

- **GOOD LABORATORY PRACTICE(GLP):** are the organisational processes, facilities, staff and conditions which ensure that laboratory operations/analyses are performed, monitored, and recorded in accordance with regulatory, safety and health requirements.

DEFINITIONS

- **VALIDATION**: The action of proving that any material, process, procedure, activity, system, equipment or mechanisms used in manufacture or control can, will and does achieve the desired and intended results.
- **QUALIFICATION:** Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results.

N.B*: The meaning of the word "validation" is sometimes extended to incorporate the concept of qualification.*

DEFINITIONS

- **CALIBRATION** - The process of verifying the capability and performance of an item of measuring and test equipment compared to traceable measurement standards.
- **IN-PROCESS CONTROL –** Checks performed during production in order to monitor and, if necessary, adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

CHEMIST'S ROLE IN QUALITY CONTROL

- Ensure GLP
- Availability of procedures for all activities in the laboratories – procedures for testing of RM, PM, intermediate and FP.
- Qualification(IQ, OQ, PQ) of all equipment used in conducting various quality control activities.
- Regular/Scheduled calibration of equipment
- Verification of compendia procedures for product analysis.
- Validation of internally developed/in-house method for both material and product analysis.
- Methods are available for reagent preparation.

CHEMIST'S ROLE IN QUALITY CONTROL

- Maintain and Keep an up-to-date inventory of all chemicals and reagents.

- Adequate storage of all chemicals and reagents.

- Development of Vendor and Purchasing Specifications for RM and PM which are to be used by the Procurement department in its dealing with suppliers

CHEMIST'S ROLE IN SAMPLING AND SAMPLE MANAGEMENT

- Sampling of starting and packaging materials is an activity that resides with Quality Control which the chemist/analyst belongs to.

- This is done in accordance with the written procedure and samples taken should be representative of the batches of materials or product.

CHEMIST'S ROLE IN SAMPLING AND SAMPLE MANAGEMENT

- Sampling of materials is carried out as specified in the procedure e.g. using **n plan** for starting materials **(n = 1 + √N).** N is the number of sampling units in the consignment. The value of n is obtained by simple rounding.
- P plan can be used for other materials apart from starting materials. **p = 0.4√N**
- N is the number of sampling units.
- p are obtained by rounding up to the next highest integer.

CHEMIST'S ROLE IN SAMPLING AND SAMPLE MANAGEMENT

When sample of material is taken, each sample container should bear a label indicating the following:

- The name of the sampled material
- The batch or lot number
- The number of the container from which the sample has been taken
- The number of the sample
- The signature of the person who took the sample
- The date of sampling

CHEMIST'S ROLE IN SAMPLING AND SAMPLE MANAGEMENT

It is mandatory for a chemist/analyst to retain samples of materials.

- Retention samples should be representative of batch of materials or products from which they are taken.
- Retention sample from each batch of finished products should be retained till one year after the expiry date

CHEMIST'S ROLE IN SAMPLING AND SAMPLE MANAGEMENT

- Retention samples of materials and products should be of the size sufficient to permit at least two full re-examination.

- Finished products should be kept in their final packaging and stored under the recommended conditions.

CHEMIST'S ROLE IN IN-PROCESS CONTROL

Chemists play an active role in production process. The various stages of production are monitored by the quality personnel such as:

- Verification and confirmation of the status of materials and equipment before commencement of production.
- Dispensing of materials and compounding processes.
- The following IPC checks are performed:
- Weight variation
- Hardness
- Friability
- DT
- Leakage test – for blister-packed solid products
- pH
- Viscosity
- Wt./ml

CHEMIST'S ROLE IN PRODUCT ANALYSIS

- As chemist/analyst in Quality Control, you will be responsible for product analysis using the approved procedure specified in the product monograph.

- The analysis could be performed by wet chemistry or instrumental analysis depending on the specified method.

CHEMIST'S ROLE IN PRODUCT ANALYSIS

For liquid product, the following tests are carried out as specified in the product monograph:

- Identity test for active ingredients
- Colour determination
- pH determination
- Weight per mL
- Determination of preservatives
- Potency test

CHEMIST'S ROLE IN PRODUCT ANALYSIS

For solid dosage form – Tablet

- Identity test for active ingredients
- Hardness, Friability test
- Dimension
- Weight variation/content uniformity
- Disintegration time
- Dissolution time
- Visual defects(chipping, coating defects)

CHEMIST'S ROLE IN VENDOR AUDIT/APPROVAL

This is a teamwork. Chemist in the company of other scientists(Biochemist, Pharmacist, etc.) performs this role:

- Audit new and old suppliers and write report.
- Make recommendation to management for vendor approval/disapproval.
- Carryout periodic vendor performance appraisal.

CHEMIST'S ROLE IN RELEASE/APPROVAL OF MATERIAL AND PRODUCT

- Chemist who heads the QC Laboratory has the responsibility for release/rejection of materials/products based on the outcome of the analysis.

- That is, the recommendation of the analyst will guide the HOD in the release/approval/rejection of an item.

CHEMIST'S ROLE IN ANALYTICAL METHOD VALIDATION

It is the responsibility of chemist/chemistry-related professional in QC to ensure all internally generated methods of analysis are validated.

- The purpose of analytical method validation is to ensure that the procedure under consideration is capable of giving reproducible and reliable results.
- AMV is carried out with a written and approved protocol stating the analytical characteristics to be measured.
- Analytical Characteristics measured are:

Accuracy, Precision, Repeatability, Reproducibility, Ruggedness or Robustness, Linearity and Range of the method, Specificity, Selectivity and Interference, Limit of detection, Limit of quantitation.

N.B: Methods generated in-house are validated, while compendia methods are only verified.

CHEMIST'S ROLE IN ANALYST VALIDATION

- Analyst that works in your laboratory and upon whose results you base your decision for approval/rejection of items must be validated.
- To validate your analyst, the chemist draws up a protocol, performs an analysis using the prescribed and approved procedure and equipment under the recommended condition.
- The result obtained is documented and its record kept.
- The same sample already analyzed by you, is now given to the analyst for analysis using same method and equipment. If the result obtained is in agreement with the expected outcome, the analyst is now said to be validated on the procedure.

CHEMIST'S ROLE IN PROCESS VALIDATION

This is establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

- Process Validation is a team work that involves chemist, pharmacist, other chemistry-related professional and an engineer.
- The team will follow a written and approved protocol to validate the process – e.g. manufacturing process of a particular product.
- It is always the responsibility of the quality head who might be a chemist, to ensure all manufacturing and control processes are validated.
- A re-validation may be triggered from the result of analysis.

CHEMIST'S ROLE IN PROCESS VALIDATION

Types of process validation are stated below:

- **Prospective validation** – Validation conducted prior to the distribution of either a new product, or product made under a revised manufacturing process, where the revisions may affect the product's characteristics.
- **Retrospective validation** – Validation of a process for a product already in distribution based upon accumulated product, testing and control data.

CHEMIST'S ROLE IN EQUIPMENT QUALIFICATION

- Equipment in QC, Production and Engineering departments that are key to GMP must be qualified. There must be documented evidences that the equipment have passed IQ, OQ and PQ.

N.B:

- IQ – Installation Qualification
- OQ – Operational Qualification
- PQ – Performance Qualification

CHEMIST'S ROLE IN STABILITY STUDIES

- This is a function of the quality department which the chemists, microbiologists and other chemistry – related professionals belong to. You are to carryout the stability study of the product pre and post registration with the regulatory body (NAFDAC). This study is used to determine the shelf-life of the product and its storage condition.
- For the stability studies, the world has been partitioned into zones by ICH(International Committee on Harmonization) based on climatic conditions in each zone. ICH is now called International Council on Harmonization.

CHEMIST'S ROLE IN STABILITY STUDIES

LONG TIME TESTING CONDITIONS			
ZONE	**TYPE OF CLIMATE**	**TEMP.**	**HUMIDITY**
Zone I	Temperate zone	21 ± 2°C	45%RH ± 5%RH
Zone II	Mediterranean/Subtropical zone	25 ± 2°C	60%RH ± 5%RH
Zone III	Hot dry zone	30 ± 2°C	35%RH ± 5%RH
Zone IV	Hot humid/tropical zone	30 ± 2°C	65%RH ± 5%RH
Zone IVb	Hot /Higher humidity	30 ± 2°C	75%RH ± 5%RH

CHEMIST'S ROLE IN STABILITY STUDIES

ACCELERATED AND INTERMEDIATE TESTING CONDITIONS		
CLIMATIC ZONE	**TEMP°C**	**HUMIDITY**
Accelerated Ambient	40 ± 2°C	75%RH ± 5%RH
Accelerated Refrigerated	25 ± 2°C	60%RH ± 5%RH
Accelerated Frozen	5 ± 2°C	No Humidity

CHEMIST'S ROLE IN STABILITY STUDIES

The purpose of the study is to determine the shelf-life and appropriate storage condition of the product.

- To conduct the stability study, an approved SOP must be in place.
- A written and approved protocol must be followed for the study. – The protocol will call out the product to be placed on stability, reason for the study, condition of study, period of study(number of months/year), sample withdrawal schedule, etc.

- After each sample withdrawal, test is carried out and

CHEMIST'S ROLE IN R & D

- Chemists are deeply involved in improving the existing products or developing new ones.

- **R & D** in a pharmaceutical company involves teamwork, and chemists are always part of this team. Chemists will be expected to run trials of new formulations at the laboratory level and put them under stability studies.

CHEMIST'S ROLE IN WATER ANALYSIS

The analyst/chemist has it as his/her duty to carryout daily the analysis of the water produced in the factory. The water produced falls into 2 categories, namely : Potable and Purified Water.

Potable water is used for drinking while **Purified water is for manufacturing purposes.**

Purified water is obtained by any of the following methods:

- Distillation
- Ion-exchange
- Reverse osmosis

CHEMIST'S ROLE IN WATER ANALYSIS

- The chemist/analyst performs both physical and chemical tests on the water and gives recommendation as to its suitability for use.

- Please take note: In some organizations, water regeneration is given as a duty to the chemist.

CHEMIST'S ROLE IN WASTE WATER ANALYSIS

- The environment around us must not suffer from the effluent discharges resulting from the operations of the company.

- For this reason, the waste water from the manufacturing and laboratory washings are monitored to ensure the company complies with the environmental law.

- It is the duty of the chemist/analyst in Quality Control section to analyse the effluent using the approved procedure to ensure its compliance with the requirements of environmental law.

CHEMIST'S ROLE IN PEST CONTROL

- Recommendation /Approval of chemicals to be used in pest control exercise and ensuring that no banned chemicals are used.

- To supervise the pest control activity within the company.

- Ensure the contractor issues a pest control certificate at the completion of the exercise.

CHEMIST'S ROLE IN DOCUMENTATION

It is part of regulatory requirements that the chemist or chemistry-related professional who heads the QC department maintains the following documents:

- Specifications
- Sampling procedures
- Test procedures and records(including test worksheet and/or laboratory notebooks)
- Test reports and/or quality certificates
- Data from environmental monitoring
- Validation records of test methods
- Procedures for, and records of calibration of instruments
- Procedures for, and records of the maintenance of equipment

CHEMIST'S ROLE IN COMPLAINTS HANDLING

- Customer Complaints received by the company are always passed to the QC head/Chemist for investigation.
- The complaints are recorded and investigated to ascertain its genuineness. The cause of the complaint and who is responsible for the complaint - whether the company or customer, are determined.
- Investigation Report of the complaint is then generated.

CONCLUSION

- In this short presentation, we have seen some of the job functions of a chemist in a pharmaceutical industry.

- The products of the company are for human or animal consumption, and any neglect on the part of the chemists can either make or mar the company and the general public as a whole.

CONCLUSION

- Therefore, the quality and safety of our products can only be guaranteed if we as chemists conscientiously play our part and ensure nothing goes wrong in the exercise of our duties.

- I appeal to you as upcoming chemists, please you are to be honest with what you do, and when you find yourself out there as chemists in the industry, ensure you do what your job role entails diligently, judiciously and excellently.

References:

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Thank you