



**M.S**

**PHARMACEUTICAL TECHNOLOGY**

- Formulations & Formulation Development
- Industrial Pharmacy & Production of Synthetic Drugs
- Novel Drug Delivery Systems , Quality Control & Pre-Clinical GLP
- National, International Drugs enactments & Regulatory Affairs
- Pharmacokinetics & Bio- Pharmaceutics
- Calibrations , Qualifications & Validations

**- One year duration**

First Year

**MS**  
Pharmaceutical  
Technology

Second Year

- Good Manufacturing Practices (GMPs)
- GMP Audits (Internal & External)
- Quality Assurance & Good Documentation Practice
- Personality development

**- Six months duration**

**Project work**

- Project Draft Submission
- Dissertation (expository and written)
- Viva Examination

**- Six months duration**

## ABOUT YOUR COURSE

The primary goal of this program is to provide Pharma Education to professionals seeking career advancement in Pharmaceutical Industries. The program is designed to address all innovative and rapid changes affecting the Pharmaceutical Industry.

The course work emphasizes, but not limited to the areas of Formulation Development, Manufacturing, Packaging, Quality Control, Validation, Quality Assurance and Good Documentation Practice, GMPs, GLP, Stability Studies, Regulatory Submissions etc.,

**Seminars :** Seminars are conducted regularly to achieve the following objectives :

- a. To enable and specialise in National and International Regulatory Requirements.
- b. To create an aptitude for taking to original creative work in Regulatory Compliance.
- c. To create a capability for higher level consultancy work in Pharmaceutical Industry.

**Project Work :** Each student has to undertake a project work for Six months on any advanced topic to acquire the following:

- a. To achieve comprehension and exposition of an advanced topic in Validations, Qualifications, GMP Audits etc.
- b. To enable self study and collating material from different sources relating to a topic.

**Summarising :** To achieve our high targets as above, we have devised a **4 - dimensional strategy** as follows :

1. Teaching together with video and video based training by renowned experts on topics, classical and modern, pure and applied.
2. Participate in regular seminars.
3. Develop self study and independent thinking.
4. Acquire and improve skills of documentation.

ENTRY  
REQUIREMENTS

- a. Applicants must have successfully completed a Graduation in Pharmacy from any recognized University.
- b. Applicants must have a minimum of 6 months work experience in an approved industry and is presently working in any Pharmaceutical / Bio-Tech / Medical Devices / Blood and Blood Products / Cosmetics / Food or any other relevant Industry.
- c. Proficiency in English.

AWARD  
OF DEGREE

A student will be declared eligible for the award of the M.S. Degree if the following academic regulations are fulfilled:

- a. He has pursued the course of study for not less than 24 months and not more than 48 months.
- b. He has registered for and studied all the subjects.



## MS ACADEMIC REGULATIONS

### MARKS

|                                 |           |       |
|---------------------------------|-----------|-------|
| Course work                     | - 600+400 | Marks |
| Project (course + dissertation) | - 200     | Marks |
| Total                           | - 1200    | Marks |



## MS ACADEMIC REGULATIONS

### COURSE STRUCTURE

Duration of the Course

: 2 years



COURSE PATTERN

FIRST YEAR

- Internal Exam - I - 10 Marks  
(Group Discussion)
- Internal Exam - II - 15 Marks  
(Paper Presentation)
- Year End Exams - 75 Marks  
(Conducted by University)

SECOND YEAR

- Internal Exam - I (Group Discussion) - 10 Marks
- Internal Exam - II (Paper Presentation) - 15 Marks
- End Exams (Conducted by University) - 75 Marks
- Project - Draft Report Submission - 50 Marks
- Dissertation (expository and written) - 100 Marks
- Viva Examination 50 Marks

## MS PROJECT & PASS MARK

### PROJECT

Project shall be evaluated for 200 marks as under :

- a. Project - Draft Report Submission for 50 marks.
- c. Dissertation (expository and written) for 100 marks.
- d. Viva Examination for 50 marks.

**MS**  
**2 YEARS COURSE**

**Please refer the attached leaflet for  
Operational Guidelines, Test Dates  
& Nature of Internal and Semester  
End Examination.**

**ABOUT  
YOUR COURSE**

This course is intended to enrich the knowledge of working professionals with an understanding of the areas of cGMP (CFR21 parts related to finished formulations and APIs) GLP, Schedule-M, Patent Laws, Validations, Qualifications, Calibration Programme, Stability Program, Good Documentation Practice etc.



## I YEAR

| Code    | Subject Title                                                    |
|---------|------------------------------------------------------------------|
| PT 1011 | Formulations & Formulation Development                           |
| PT 1012 | Industrial Pharmacy & Production of Synthetic Drugs              |
| PT 1013 | Novel Drug Delivery Systems , Quality Control & Pre-Clinical GLP |
| PT 1014 | National, International Drugs enactments & Regulatory Affairs    |
| PT 1015 | Pharmacokinetics & Bio-Pharmaceutics                             |
| PT 1016 | Calibrations, Qualifications & Validations                       |

## II YEAR

|         |                                                 |
|---------|-------------------------------------------------|
| PT 2011 | Good Manufacturing Practices (GMPs)             |
| PT 2012 | GMP Audits (Internal & External)                |
| PT 2013 | Quality Assurance & Good Documentation Practice |
| PT 2014 | Personality Development                         |

## PROJECT WORK

|         |                                                                                       |
|---------|---------------------------------------------------------------------------------------|
| PT 2015 | Project draft submission<br>Dissertation (expository and written)<br>Viva Examination |
|---------|---------------------------------------------------------------------------------------|

## COURSE CONTENTS

Actual coverage in each subject will be decided by the instructor/ guest faculty / teacher concerned allowing a variation of upto 20% from the suggested contents.



## FORMULATIONS & FORMULATION DEVELOPMENT

### Brief Description :

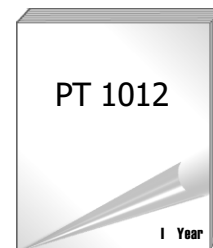
- Pre-Formulation Studies
- Incompatibilities encountered in drug multi-component combinations and /or Drug-excipient compatibility
- Pharmaceutical Formulation Additives, Containers and Closures
- Manufacturing and Quality control of Solid Dosage forms, Semi-Solid Dosage forms, Liquid Dosage forms, Sterile Dosage forms, Metered Dosage forms (Aerosols)
- Study of principles, Production techniques, Pilot batch studies, Scale-up Studies, Transfer of technology to commercial scale batches, stability conditions
- Storage and handling of In-Process and finished dosage forms, principles of stability studies as per ICH Guidelines.

## SUGGESTED REFERENCES

1. The Theory and Practice of Industrial Pharmacy by Lachman L & Liberman HA
2. The Science and Practice of Pharmacy by Remington.
3. US FDA Regulatory Affairs, Douglas J. Pisano, David Mantus
4. Pharma Journals

## INDUSTRIAL PHARMACY & PRODUCTION OF SYNTHETIC DRUGS

## SUGGESTED REFERENCES



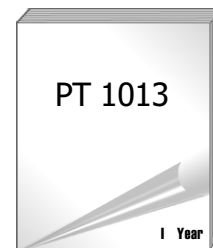
### **Brief Description :**

- Materials of construction, Operation, calibrations and maintenance of Pharmaceutical Manufacturing Equipment and Quality control equipments used in API and Pharmaceutical Formulations.
- Mechanical Unit Operations: Handling and Mixing of particulate Solids, Agitation and Mixing of Liquids, Size reduction, Separation, Crystallization, Filtration, Aseptic Processing.
- Production Management Including production organization, objectives and policies, layout of buildings, services, equipment and their maintenance, materials managements, handling and transportation, inventory management and control, production and planning, sales forecasting, budget and cost control.
- Detailed study of general manufacturing flow. General Mechanism involved in the synthesis of Active Pharmaceutical Ingredients. Structural interpretation of Active Pharmaceutical Ingredients. Detailed study of manufacturing process packaging and quality control of few active pharmaceutical ingredients.

1. The Theory and Practice of Industrial Pharmacy by Lachman L & Liberman HA
2. The Science and Practice of Pharmacy by Remington
3. Fine Chemicals, Drugs and Pharmaceuticals by Gowtham Malik, Small Business Publications.
4. Spectrometric identification of Organic Compounds, Silver Spein, Wiley Publications
5. ICH Harmonised Tripartite Guideline (Good Manufacturing Practice Guide for Active pharmaceutical ingredients ICH Q7A)

NOVEL DRUG  
DELIVERY  
SYSTEMS & ITS  
QUALITY  
CONTROL

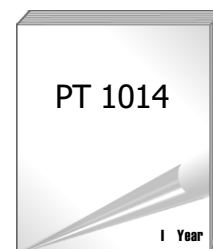
SUGGESTED  
REFERENCES



**Brief Description :**

- Introduction, Concepts, Physiochemical Properties to be considered, use of polymers in controlled release drug delivery systems.
- Design, fabrication, evaluation and applications of Controlled release oral, parenteral drug delivery systems, Implantable and transdermal therapeutic systems, Ocular and intraocular delivery systems, Bioadhesive drug delivery systems, Proteins and peptide drug delivery
- Principles of Drug Targeting
- Targeting to Lungs, Brain, Respiratory
- Liposomes, Niosomes, Microspheres, Nanoparticles, Resealed Erythrocytes and Monoclonal antibiotics.
- Formulation / Standardization / Expiration dating for VS, TS, BS.
- Analytical instrumentation ( HPLC,GC,IR,Dissolution Equipment)  
Pharmaceuticals quality control tests ( Tablets,Capsules)  
Pre-Clinical GLP

1. The theory and practice Industrial Pharmacy by Lachaman L & Liberman HA
2. The Science and Practice of Pharmacy by Remington.



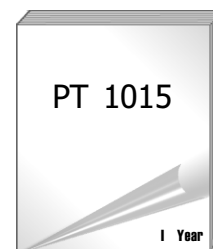
## NATIONAL, INTERNATIONAL DRUGS ENACTMENTS & REGULATORY AFFAIRS

### **Brief Description :**

- Drugs and Cosmetics Act 1940 & Rules 1945
- DMROA Act 1950 and Rules 1955
- NDPS Act 1985 and Rules 1986
- DPCO 1995
- The procedures prescribed for obtaining a licence / permit / approval for the API and Formulations
- Provisions related to actions prohibited under the statutory enactments and the penal actions for violation thereof
- Introduction to US - FDA, Canadian - HPFBI, European Union - EDQM, UK - MHRA, South African - MCC, Australian - TGA etc.,
- Introduction to NDA & ANDA submissions

## SUGGESTED REFERENCES

1. D & C Act 1940 and Rules 1945, Vijay Malik, Eastern Book Co, Delhi
2. D & C Act 1940 and Rules 1945, S.W. Deshpande, Vandana Publications, Mumbai
3. Drugs and Magic Remedies Act, S.W. Deshpande, Vandana Publications, Mumbai
4. Consumer Protection Act 1986, Gogia Law Agency, Hyderabad
5. Intellectual Property Law, Justice P.S. Narayana, Gogia Law Agency, Hyderabad



## BIO-PHARMACEUTICS & PHARMACOKINETICS

### **Brief Description :**

#### **Bio-Pharmaceutics**

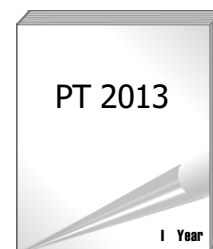
- Formulation factors affecting bio-availability of drugs in solid, semi solid, liquid oral and parenteral dosage forms
- Physicochemical properties affecting bio-availability, pH-partition theory, dissolution, surface area adsorption, complexation, polymorphism, techniques of enhancing dissolution rate.
- Drug transport mechanism and factors affecting absorption, distribution, bio-transformation and elimination.

#### **Pharmacokinetics**

- Basic concepts of Pharmacokinetics
- First order process, rate constants, half life, zero order process.
- Introduction and application of One compartment model, two compartment model and Non-compartment models.
- Organ Clearance, total clearance, renal clearance and excretion, hepatic clearance and elimination
- Design of bio-availability and bio-equivalence studies and the regulatory requirements involved.

## SUGGESTED REFERENCES

1. The Science and Practice of Pharmacy by Remington
2. Biopharmaceutics and Clinical Pharmacokinetics, 3<sup>rd</sup> Edition, Milo Gibaldi



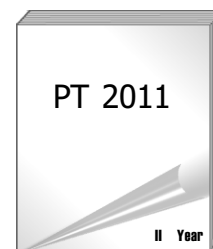
## CALIBRATIONS QUALIFICATIONS & VALIDATIONS

### **Brief Description :**

- Instrument Calibrations, Facility Qualification, Equipment Installation Qualification, Operational Qualification □ Performance Qualification,
- Validation Definitions, Master Plan
- Essential Pre Validation Activities, Protocol Preparation, Protocol Execution, Deviations and Change Controls, Summary and Certification, Ongoing Monitoring.
- Revalidation
- Cleaning Validation, Computer Validation, Analytical Method Validation □ Prospective Process Validation, Retrospective Process Validation, Concurrent Process Validation

## SUGGESTED REFERENCES

1. Calibration in Pharmaceutical Laboratory , Tony Kowalski
2. Process Validation and Quality Assurance, Carl B. Rifino
3. Process Validation for Solid Dosage Forms, Nash, R.A
4. Validation Terminology, Kenneth G. Chapman



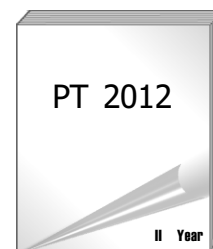
## GOOD MANUFACTURING PRACTICES (GMPs)

### **Brief Description :**

- GMP general considerations and definitions, Aim & objective of GMPs ,GMP requirements for activities of manufacturing / packaging / labeling, testing,
- Introduction to GMPs - TGA , GMPs - MHRA, GMPs - HPFBI, GMPs - MCC, GMPs - EDQM, etc.
- CFR 21 , Part 210 & 211.
- ICH Q7A GMPs for APIs
- D & C Rules 1945 Schedule - M

## SUGGESTED REFERENCES

1. How to Practice GMP, 1<sup>st</sup> Edition, P.P. Sharma
2. Good Laboratory Practice, Selier, Jurg P
3. The Gazette of India, Extraordinary, New Delhi
4. A Text Book of Forensic Pharmacy by Mithal
5. WHO Technical Report Series No. 908, 2003



## GMP AUDITS (INTERNAL & EXTERNAL)

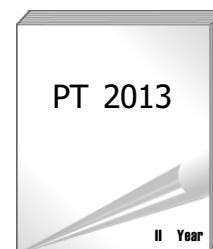
### **Brief Description :**

- GMP Compliance Audit, Definition and Definition Summary, Audit Policy, Internal Audits
- External Second Party Audits
- External Third Party Audits
- Preparation for Audit, Conducting Audit, Audit Analysis, Audit Report, Audit Follow-Up
- A Typical Internal (First Party) Audit Report
- External (Second Party) Audit Report
- Third Party Audit Report

## SUGGESTED REFERENCES

1. Quality Assurance of Pharmaceuticals, WHO, Vol - II
2. Good Pharmaceutical Manufacturing Practice Rational and Compliance, John Sharp

## QUALITY ASSURANCE & GOOD DOCUMENTATION PRACTICE



### Quality Assurance

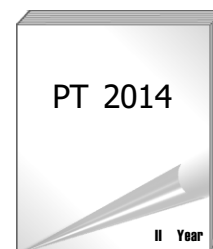
- Quality Assurance Activities in Specific Issues like Ware House Control, Raw Material Control, Product Containers / Closures / Packaging Material Control
- Manufacturing Control, Laboratory Controls, Facility Qualification, Validations, Stability and Calibration Programmes.
- Annual Product Reviews, Handling Summary Reports.
- Form 483's, FDA or Other Regulatory Warning Letters

### Good Documentation Practices

- Standard Operating Procedures (SOPs) Related to Ware House, Production, Packaging, Quality Control, Validation and Quality Assurance Departments
- Master Manufacturing Documents, Master Packaging Documents
- In-Process Control Documents
- Validation Summary Reports Document Review Forms
- Out of Specification Reports, Document Control

## SUGGESTED REFERENCES

1. Quality Assurance of Pharmaceuticals, WHO, Vol - I
2. FDA Regulatory Affairs, Douglas J. Pisano, David Mantus
3. Process Validation and Quality Assurance, Carl B. Refino
4. Good Pharmaceutical Manufacturing Practice Rational and Compliance, John Sharp



## PERSONALITY DEVELOPMENT

### **Brief Description :**

Introduction to Personality Development , Personality pattern.

Introducing oneself to others, Introducing others, Making enquiries, seeking information, Responding to enquiries, supplying information, Making, accepting, and refusing offers/invitations.

Self-Esteem meaning of Self-Esteem, Develop Self-Esteem face and expect reality.

Self improvement : Plan to improve long term goals, short term objectives.

Developing positive attitudes : Attitude and image, Learning attitudes .

Listening : Barriers to listening, Good listening skills.

Conflict : Types of conflict, values and benefits of conflict stages, Handling conflict adjustments.

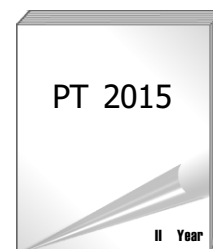
Self motivation: Sources of motivation.

Self Management : Efficient work habits.

Stress Management : Causes and Effects of stress.

## SUGGESTED REFERENCES

1. Personality Development, Elizabeth B. Hurlock, Tata McGraw Hill
2. Personal Development for Life and Work 8th Edition, Wallace & Masters.



## PROJECT WORK

### **Brief Description :**

- Required to carry out work-oriented program that is considered vital to the organization.
- Selection of the topic for Project Work will be in consultation with the Dept. Head/Guide, needs to be approved.
- Should submit a comprehensive Project report at the end of the Second Year.
- Project Work is evaluated on the basis of Project draft submission, Dissertation (expository and written) & Viva Examination.

## GLOSSARY



### **Quarantine**

The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.

### **Contamination**

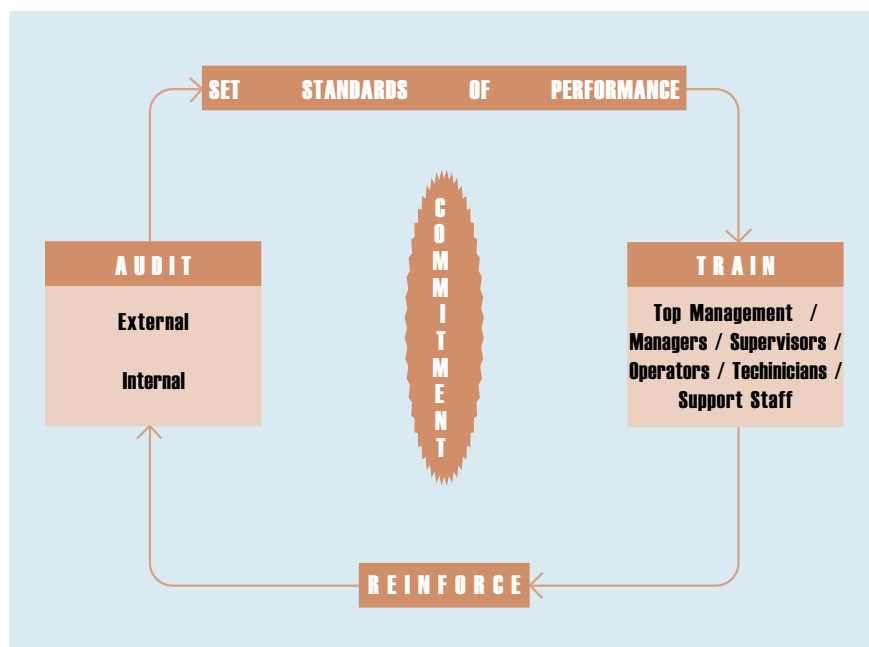
The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into or on to a starting material or intermediate during production, sampling, packaging or repackaging, storage or transport.

### **Cross-contamination**

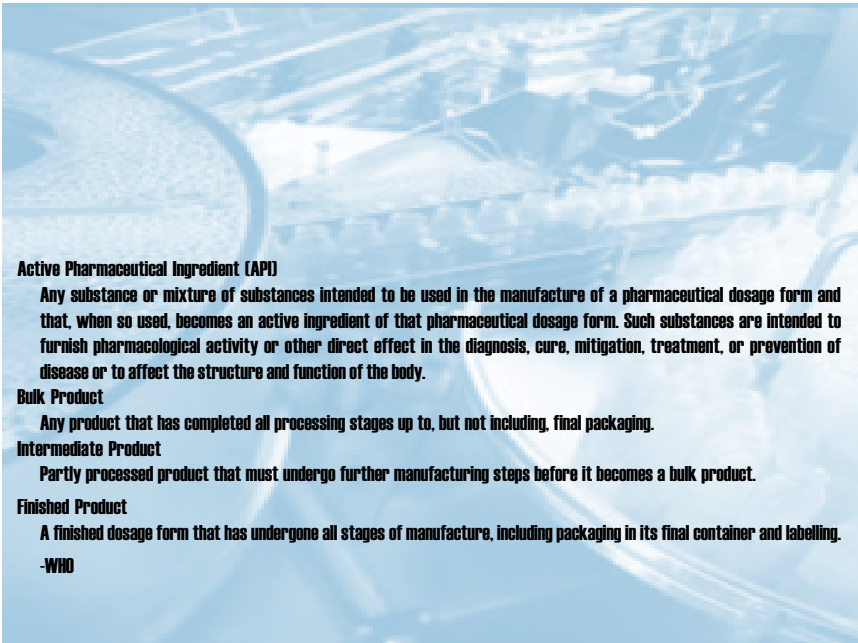
Contamination of a starting material, intermediate product or finished product with another starting material or product during production.

-WHO

GOOD  
MANUFACTURING  
PRACTICES



## GLOSSARY



### **Active Pharmaceutical Ingredient (API)**

Any substance or mixture of substances intended to be used in the manufacture of a pharmaceutical dosage form and that, when so used, becomes an active ingredient of that pharmaceutical dosage form. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure and function of the body.

### **Bulk Product**

Any product that has completed all processing stages up to, but not including, final packaging.

### **Intermediate Product**

Partly processed product that must undergo further manufacturing steps before it becomes a bulk product.

### **Finished Product**

A finished dosage form that has undergone all stages of manufacture, including packaging in its final container and labelling.

-WHO

## GLOSSARY

### **Worst Case**

A condition or set of conditions encompassing upper and lower processing limits and circumstances, within standard operating procedures, which pose the greatest chance of product or process failure when compared to ideal conditions. Such conditions do not necessarily induce product or process failure.

- PIC/S

### **In-process Control**

Checks performed during production in order to monitor and, if necessary, to 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.

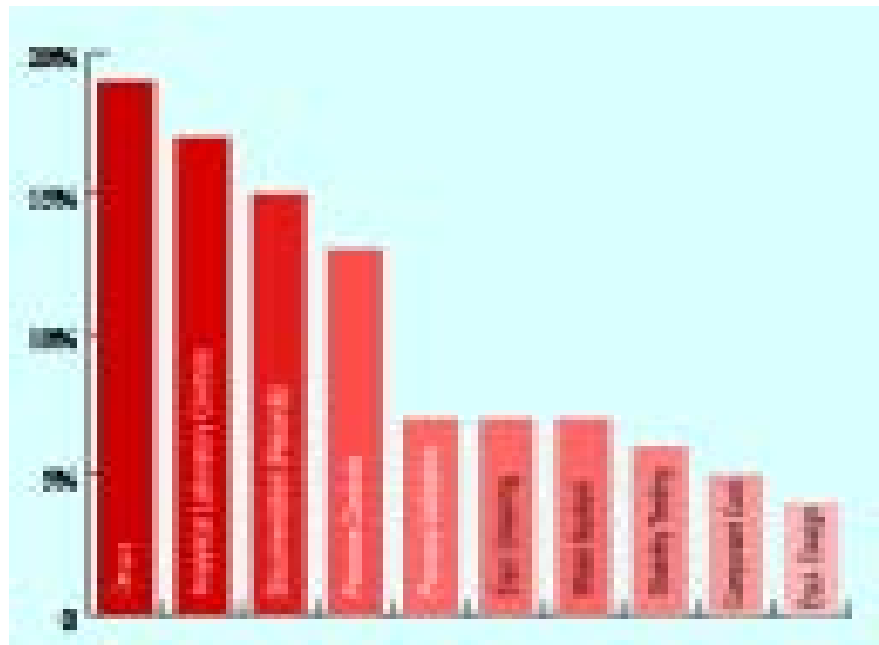
- WHO

### **Change Control**

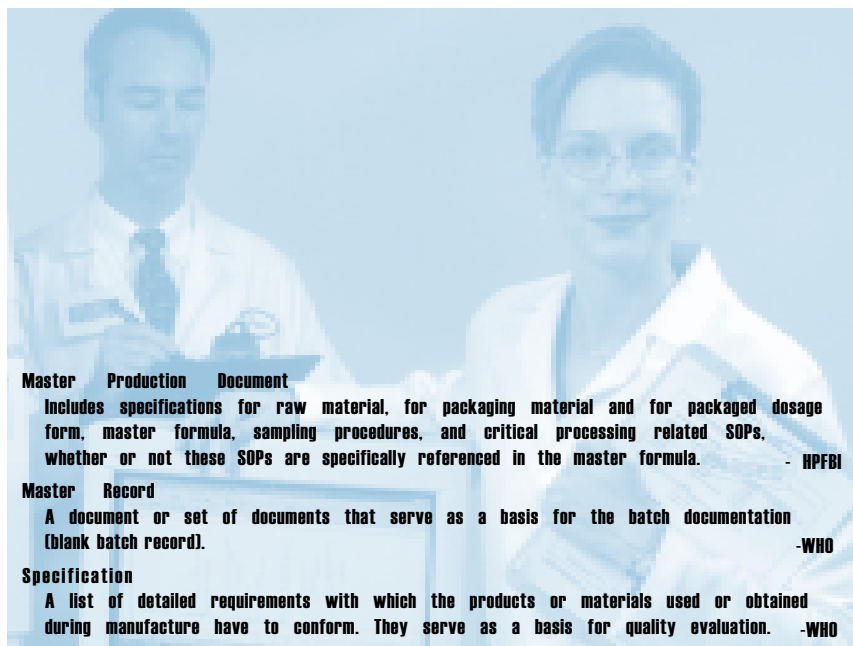
A written procedure to describe the actions to be taken if a change is proposed to facilities, materials, equipment and processes used in the fabrication, packaging and testing of drug products or any change that may affect product quality or support system operation.

- HPFI

MOST COMMON  
cGMP  
DEFICIENCIES



## GLOSSARY



**Master Production Document**

Includes specifications for raw material, for packaging material and for packaged dosage form, master formula, sampling procedures, and critical processing related SOPs, whether or not these SOPs are specifically referenced in the master formula. - HPFBI

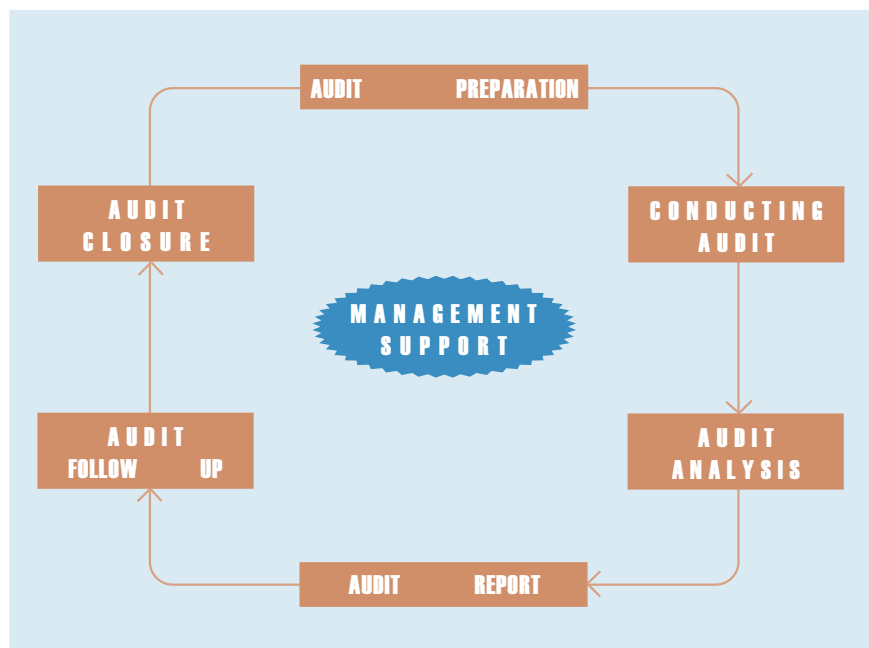
**Master Record**

A document or set of documents that serve as a basis for the batch documentation (blank batch record). -WHO

**Specification**

A list of detailed requirements with which the products or materials used or obtained during manufacture have to conform. They serve as a basis for quality evaluation. -WHO

GMP  
AUDIT SYSTEM



## GLOSSARY

### Calibration

The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established.

- WHO

### Installation Qualification

The documented act of demonstrating that processing equipment and ancillary systems are appropriately selected and correctly installed.

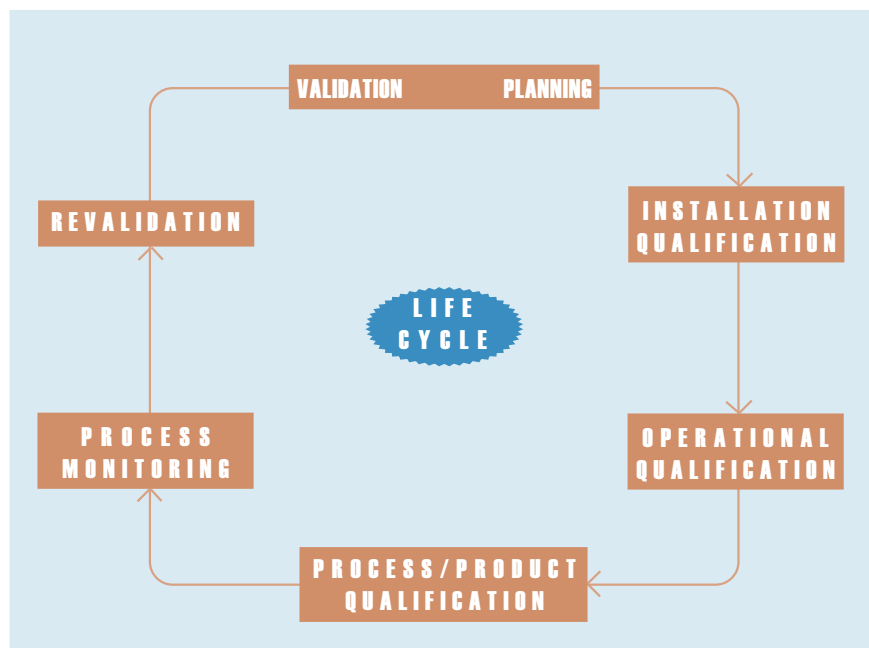
- HPFBI

### Operational Qualification

The documented act of demonstrating that process equipment and ancillary systems work correctly and operate consistently in accordance with established specifications.

- HPFBI

PROCESS  
VALIDATION



## GLOSSARY



**Critical Process Parameter**

A parameter which if not controlled will contribute to the variability of the end product.  
- HPFBI

**Standard Operating Procedure (SOP)**

An authorised written procedure giving instructions for performing operations not necessarily specific to a given product or material (e.g. equipment operation, maintenance and cleaning; validation; cleaning of premises and environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production documentation.  
-WHO

Good  
DOCUMENTATION

