Enclosure - IV

(1)

Course of Study for Quality Assurance

QA- MPY 201

ADVANCED QUALITY ASSURANCE TECHNIQUES-I

(Regulatory guidelines for pharmaceutical Quality management)

Study of concepts of cGMP & Related documents of following :

1.0 Personnel :

- Qualification, Experience and Training
- Key persons and their responsibilities
- Personnel hygien and clothing
- Legal aspects and consultants

2.0 Building and facilities

- Principal areas in a manufacturing facility, Surround area
- Building Management System
- Plumbing and drainage system
- Sewage, refuge and disposal of waste
- Washing and toilet facilities
- Sanitation and maintenance of sanitation
- Water System / HVAC
- Requirements in facility to handlew special category molecules like, immunosupressants, steroids, harmones, potent molecules,etc.
- Environmental control / safety and health requirement

3.0 Equipment

- Design, site, Location, construction
- Equipment identification and Logs
- Cleaning, Operation and maintenance of equipment.
- Equipment qualification

4.0 Materials

- Qualification of vendors
- Purchasing, RM/PM/Int/Bulk and Finish Products
- Rejected, returned and recovered products. Reagents and culture media
- Reference and working standards
- Miscellaneous materials, waste materials

5.0 Quality Management

- Concept of QA, QC & cGMP
- Key activities in quality management function as per cGMP guidelines.
- Risk based approach to quality management system.

6.0 Current Good Laboratory practice

- Introduction and general provisions of cGLP
- Organisation and Personnel
- Facilities
- Equipment
- Testing facility Operation
- Test and control articles
- Protocol for conduct of a non clinical laboratory study
- Records and reports
- Disqualification of Testing Facilitation
- Ref. 21 CFR part 58
- Out of specification results- handling and having CAPA (Corrective and preventive action) plan in place.

7.0 cGMP Guidelines for biological Poducts

RECOMMENDED BOOKS

1. Pharmaceutical Quality Assurance M.A. Potdar, Niral Prakashan, Pune
2. International regulatory guidelines on GMP by USA, Australia, S. Africa and WHO
3. Good manufacturing Practices, S.H. Wills & J.R.Stoker, Marcel dekker Inc.
4. Current Good Manufacturing Practices for Pharmaceuticals by Prof. M.A. Potdar BS Publications, Hyderabad.

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ADVANCED QUALITY ASSURANCE TECHNIQUES-II

(Pharmaceutical Manufacturing and Quality Control)

1.0 Manufacturing Operations and Control

- Sanitation of manufacturing premises
- Control of mix ups and cross contaminations
- Processing of intermeditates and bulk products
- Packaging and labelling operations
- I.P.Q.C.
- Release of finished products
- Process deviations
- Charge in of components
- Time limitation on production
- Drug poduct Inspection
- Expiration Dating
- Calculation on Yield.

2.0 Out Sourcing

- Out sourcing of Mfg and Planning Operations
- Out sourcing analytical services
- Out sourcing other services
- Confidentiality agreements

3.0 Post Operational Activities

- Distribution
- Recalled, Returned & recovered products
- Product Complaints
- Annual product Quality renew

4.0 Sterile Pharmaceutical Activities

- Manufacturing and Quality Control Aspects of sterile pharmaceutical poducts

5.0 Inspection, Test, and Measurement

- The terminology of Inspection
- Conformance to specification and fitness for use
- Disposition of Nonconforming product

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- The terminology of Inspection
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- Inspection planning
- Seriousness classification
- Automated Inspection
- How much inspection is necessary ?
- Inspection Accuracy
- Errors of Measurement

6.0 Inspection and test sampling plans

- The concept of acceptance sampling
- Economics of Inspections
- Sampling Risks: The operating characteristic curve
- Analysis of some rule of thumb sampling plans
- Evaluation of parameters affecting acceptance sampling plans
- Quality indices for acceptance sampling plans
- Types of sampling and Multiple sampling
- Characteristics of a good acceptance plan

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ADVANCED QUALITY ASSURANCE TECHNIQUES-III

(Pharmaceutical Validation)

1. **Introduction to Pharmaceutical Validation :**
   - Definition , Manufacturing Process Model
   - Government regulation, scope of Validation
   - Advantage of Validation
   - Organisation for Validation
   - Validation Master plan
   - URS, D.Q., IQ, OQ & P.Q. of Facilities.
   - Regulatory requirements for validation

2. **Calibration Master plan**

3. **Validation Of Equipment:**
   - Concept of URS, DQ , IQ , OQ & PQ
   - Validation of following equipment
   - Dry Powder Mixers
   - Fluid Bed and Tray dryers.
   - Rapid Mixer Granulators
   - Lyophilizer
   - Film Coating Machine
   - Tablet Compression M/c.
   - Dry Heat Sterilizers / Tunnels
   - Autoclaves
   - Capsule filling machines.
   - Validation of Integrated lines by media fill test
   - Validation of existing equipment

4. **Vendor Certification :**
5. **Utilities Validation :**
   - Validation of Pharmaceutical Water System & pure steam
   - Validation of HVAC system

6. **Cleaning Validation:**
   - Cleaning of Equipment
   - Cleaning of Facilities

7. **Analytical Method Validation :**
   - General principles of analytical method validation
   - Validation of following analytical Instruments
     i. HPLC
     ii. Dissolution test apparatus
     iii. U.V./ Visible spectrophotometers

8. **Process Validation :**
    - Prospective, Concurrent , retrospective & revalidation
    - Process capability and statistacal evaluation of process validation data
    - Process validation of following formulation
        i. Coated tablets
        ii. Capsules
        iii. Parenterals (Injectable)
        iv. Ointments / Creams
    - Liquid Orals
    - Regulatory requirements for validation

9. **Computer System Validation :**
    - ERP system/s used in Pharmaceutical Industry

Recommended Books :

1. Pharmaceutical Process Validation, Second Edition, Ira R.Berry & Robert Nash, Marcel Dekker Inc.
2. Validation of Pharmaceutical Process (Sterile Products), F.J. Carleton and J.P. Agalloco, Marcel Dekker Inc.
3. Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan, Pune
4. Current Good Manufacturing Practices, M.A. Potdar, BS Publication, Hyderabad.
5. USFDA Guidelines

QA- MPY 204
ADVANCED QUALITY ASSURANCE TECHNIQUE –IV
(Quality Planning and Analysis)

1. **Basic concepts of Quality**
   - Quality defined
   - The quality function
   - Managing for quality
   - Perspective on Quality – Internal versus External

2. **Quality Improvement and Cost Reduction**
   - Sporadic and chronic quality problems
   - Need for quality improvement & cost reduction.
   - Causes of poor quality and high cost.
   - Provide a remedy and prove its effectiveness for improving quality.
   - Resistance to change
   - Institute Controls to hold the Gains.

3. **Control of Quality**
   - Definition of control
   - Self control
   - The control subject for quality
   - Units of measure
   - Setting a Goal for the Control subject
   - The Sensor
   - Measuring Actual performance
   - Interpreting the difference between Actual performance and the goal.
   - Taking action on the difference
   - Continuous process regulation

4. **Developing a quality culture**
   - Technology and culture
   - Theories of Motivation
   - Create and Maintain Awareness of Quality
   - Provide Evidence of management and empowerment
   - Provide recognition and rewards
   - Time to change the culture

5. **Manufacture**
   - Importance of manufacturing planning for quality
   - Initial planning for quality
   - Concept of controllability, self-control
   - Defining quality responsibilities on the Factory floor

- Self Inspection
- Automated manufacturing
- Overall review of manufacturing planning
- Process quality audits
- Quality and production floor culture

6. **Statistical Process control**
   - Definition and Importance of SPC
   - Quality measurement in manufacturing
   - Statistical control charts- general
   - Advantages of statistical control
   - Process capability
   - Estimating Inherent or potential capability from a control chart analysis
   - Measuring process performance
   - Special process control and quality improvement
   - Pursuit of decreased process variability
   - The Loss function

7. **Quality Assurance General Concepts**
   - Definition of quality assurance
   - Concept of quality assurance
   - Quality audit- The concept
   - Subject matter of audits
   - Structuring the audit programme
   - Planning and performing audits of activities
   - Human relations in auditing
   - Audit reporting
   - Essential ingredients of a quality audit programme
   - Quality surveys
   - Product audit
   - Sampling for product audit
   - Reporting the results of product audit

Recommended books

1) Quality planning and Analysis by J.M.Juran and F.M. Gryna
   Publisher – Tata McGraw Hill – India
2) Improving Quality through planned experimentation
   By Moen :Tata McGraw Hill- India.
3) Statistical Quality Control by Grant – Publisher Tata McGraw Hill- India
4) Pharmaceutical Quality System : Oliver

QA- MPY 205
QUALITY ASSURANCE TECHNIQUES –I
(Practical) (16 hrs/week)

1. Designing of following key documents.
   - Site master file
   - SOP on SOP
   - Mpcr/bpcr (For sterile and non sterile products)
   - Change contract format
   - Product complaint document
   - Internal audit document
   - Product recall document
   - IPQC Document
   - Material receipt, sampling, dispensing and storage documents
2. Experiment and documentation on Dissolution Test
3. I.P.Q.C. Tests for Tablets/ Capsules/ Inj/Liquids/Ointments.
4. Validation of analytical method
5. Validation of following equipment
   - + Autoclave
   - + Hot air oven
   - + Membrane filter
   - + Powder Mixer (Dry)
   - + Tablet Compression Machine
6. Validation of a processing area
7. Validation of analytical instruments
8. Cleaning validation of one mixing equipment

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