COURSE NAME	Good Manufacturing Practices - Quality Assurance
TOTAL DURATION:	45HRS
MODE OF DELIVERY	PHYSICAL CLASSROOM TRAINING AT RESPECTIVE COLLEGES
TRAINER TO STUDENT RATIO:	1:50
TOTAL MARKS:	75

TABLE 1	
OVERALL COURSE OBJECTIVE:	• Conceptualise concept of quality system and its importance in the manufacturing of drug substances, Drug Products, Biologics, Medical devices, and clinical studies. • Provide Good Documentation skills required in formulating life-saving drugs • Warehouse management – material procurement, vendor qualification and vendor assessment • Production/ Operation management – Process involved in tablet, capsule, manufacturing steps. • Live Online demonstration of manufacturing process flow from Industry • QC Laboratory testing and specification requirements • Facility, Equipment and Engineering requirements in pharmaceutical industry • Validation of Process and Lab Equipment and its importance
LEARNING OUTCOME:	• Identify the process flow of drug quality requirements in the pharmaceutical and medical devices. • Develop Process flow of product quality and risk management in the drug manufacturing. • Execute Validation activities • Create Data integrity controls • Draft Good Documentation practices • Explore Qualification and Validation requirements • Perform Warehouse and operation management

TABLE 2: MODULE WISE COURSE CONTENT AND

OUTCOME				
SL.NO	**MODULE NAME**	**MODULE CONTENT**	**MODULE LEARNING OUTCOME**	**DURATION (HRS)**
1	Good Manufacturing Practices and its Regulations	Detailed knowledge about Quality control and assurance for the testing and release of food and drugs	Role and responsibilities in QA and QC in the Food, drug, and medical devices industries	4
2	Functions of pharmaceutical industries (Quality, Production, Engineering, RA, R&D)	Exploring various dept in pharmaceutical industries and its roles and responsibilities	Requirement in the industries for good manufacturing and testing regulations as per Indian, US, EU GMP	4
3	Good Documentation Practices & Data Integrity Assurance	Importance of Data integrity and documentation in pharmaceutical industries	Batch record, validation procedure writing skills	4
4	Conducting and Facing Self-Inspection and Quality Audits	Auditing methodology and procedures and skills to find trouble shooting	Perform Internal audit	4
5	Qualification and Validation	Execution of equipment validation	Preparation of URS, IQ, OQ, PQ documents	4
6	Change Control	Initiating Change control for any technical changes	Process flow for Change management	4
7	Deviation Management	Develop Deviation report for any non-conformances	Process flow for Deviation management	4
8	Out of specifications	Exploring the failure results and handling of failed data	Process flow for OOS	4
9	Root causes and investigations and CAPA	Perform Root cause analysis	Process flow for RCA and CAPA	4
10	Quality Risk	Perform Risk	QRM process flow	4

	Management	Management	as per ICH Q9	
11	Market Return and Retention sample Management	Prepare Complaint log and report	Requirement testing of market samples and retention	3
12	Complaint Handling & Product Recall	Prepare Product recall log and report	Process flow of Complaints & Recall	2

TABLE 3: OVERALL COURSE LEARNING OUTCOME ASSESSMENT CRITERIA AND USECASES		
LEARNING OUTCOME	**ASSESSMENT CRITERIA**	**USECASES**
Role and responsibilities in QA and QC in the Food, drug and medical devices industries	Multiple Choice Question	Quality Department and its control for product quality and drug safety
Requirement in the industries for good manufacturing and testing regulations as per Indian, US, EU GMP	Project Report I	Prepare Standard operating procedure for Quality system
Batch record, validation procedure writing skills	Multiple Choice Question	Prepare and document Batch records
Perform Internal audit	Multiple Choice Question	Identify non-conformance in the system and write Internal audit report
Preparation of URS, IQ, OQ, PQ documents	Project Report II	Prepare Validation protocol and report for equipment/utilities
Process flow for Change management. Process flow for Deviation management. Process flow for OOS. Process flow for RCA and CAPA Process flow of Complaints & Recall	Project Report III	Process flow chart for quality attributes
QRM process flow as per ICH Q9	Project Report IV	QRM Process flow as per ICH Q9
Requirement testing of market and retention samples	Multiple Choice Question	Requirement on QC Testing

TABLE 4: LIST OF FINAL PROJECTS	
SL.NO	**FINAL PROJECT**
Project Report I	Standard operating procedure for Quality system
Project Report II	Prepare Validation protocol and report for equipment/utilities
Project Report III	Process flow chart for quality attributes
Project Report IV	Quality Risk Management as per Process flow
Project Report V	Prepare Internal Audit report