COURSE NAME:	Food Safety & Quality Management
TOTAL DURATION:	45 Hrs
MODE OF DELIVERY	PHYSICAL CLASSROOM TRAINING AT RESPECTIVE COLLEGES
TRAINER TO STUDENT RATIO:	1:50
TOTAL MARKS:	75

Table 1	
OVERALL COURSE OBJECTIVE:	● Analyze and integrate quality systems in food and drug manufacturing, emphasizing their significance in ensuring safety and compliance. ● Develop and implement effective documentation practices for regulatory compliance and quality assurance in life-saving drug production. ● Critically assess and optimize warehouse management processes, including vendor qualification, material procurement, and inventory control. ● Design and oversee production workflows, with a focus on validating processes for pharmaceutical products, tablets, capsules and other food products. ● Evaluate and validate facility, equipment, and engineering requirements, applying advanced laboratory testing and specification methodologies.
LEARNING OUTCOME:	● Evaluate and design comprehensive process flows for quality management and risk mitigation in food and pharmaceutical industries. ● Develop and validate industry-specific procedures for laboratory testing, equipment calibration, and

	compliance with quality standards. ● Apply advanced documentation and data integrity practices to ensure accurate and regulatory-compliant record-keeping. ● Formulate and execute robust validation protocols for manufacturing processes, laboratory equipment, and quality systems. ● Analyze and optimize warehouse and operational management strategies to enhance efficiency and adherence to industry standards.

TABLE 2: MODULE WISE COURSE CONTENT AND OUTCOME				
SL. NO	MODULE NAME	MODULE CONTENT	MODULE LEARNING OUTCOME	DURATION (HRS)
1	Food Quality Regulations, Standards, and Compliance in India	● Food Quality Regulations and Guidelines in India ● Quality Certifications (ISO, FSSAI, FDA) ● Government Regulations and Roles of Departments in Food Industries	• Evaluate the regulatory frameworks governing food quality in India. • Assess the roles and responsibilities of various departments in food industries for maintaining	10

			compliance. • Critique the standards and certifications (ISO, FSSAI, FDA) and their impact on food safety.	
2	Quality Management Systems and Documentation	•Good Documentation Practices & Data Integrity Assurance •Change Control Processes •Deviation Management Practices	• Design effective documentation systems adhering to Good Documentation Practices. • Develop change control and deviation management procedures for maintaining quality integrity. • Analyze case studies to ensure compliance with data integrity requirements.	8
3	Auditing, Qualification, and Validation	•Conducting Self-Inspection and Quality Audits •Qualification and Validation of Equipment	• Formulate robust auditing methodologies to identify gaps in quality systems. • Evaluate qualification and	10

		•Out-of-Specifications (OOS) Handling	validation protocols for equipment in compliance with industry standards. • Interpret OOS results and propose effective resolutions.	
4	Root Cause Analysis, CAPA, and Risk Management	• Root Cause Analysis and Investigations • Corrective and Preventive Actions (CAPA) • Quality Risk Management	• Conduct root cause analyses for non-conformances. • Plan and implement CAPA processes to prevent quality issues. • Develop risk management strategies to mitigate quality risks effectively.	9
5	Complaint Management and Product Recall Procedures	• Complaint Handling Processes • Product Recall Log Preparation and Reporting	• Design efficient systems for complaint handling and resolution. • Evaluate product recall strategies to minimize risks to public health.	8

			• Create detailed product recall logs and reports for regulatory compliance.	

TABLE 3: OVERALL COURSE LEARNING OUTCOME ASSESSMENT CRITERIA AND USE CASES			
LEARNING OUTCOME	**ASSESSMENT CRITERIA**	**PERFORMANCE CRITERIA**	**USE CASES**
Role and responsibilities in QA and QC in the Food industries	● Analyze various regulations and guidelines governing QA and QC departments in food industries and their impact on product quality. ● Critique the effectiveness of current quality control processes in sample case studies. ● Design a strategic plan for quality control measures based on regulatory requirements. ● Demonstrate the ability to differentiate roles and responsibilities within QA and QC departments through role-play or simulation exercises.	● Demonstrate the knowledge of rules and regulations in quality dept	Quality Department and its control for product quality
Requirement in the industries for	● Evaluate real-world examples of non-compliance in	● Demonstrate the importance of drug	Prepare Standard operating

good manufacturing and testing regulations	manufacturing practices and propose corrective strategies. ● Develop a detailed Standard Operating Procedure (SOP) for a specific quality system. ● Justify the inclusion of specific quality checkpoints in drug preparation using GMP principles. ● Critique existing SOPs for adherence to GMP regulations through peer review exercises.	preparation through good manufacturing practices	procedure for Quality system
Batch record, validation procedure writing skills	● Create a comprehensive batch manufacturing record for a simulated product. ● Evaluate batch records for completeness, accuracy, and compliance with industry standards. ● Analyze common errors in batch documentation and propose solutions to improve quality assurance. ● Demonstrate the ability to draft detailed validation procedures through practical exercises.	● Prepare comprehensive batch records	Prepare and document Batch records
Preparation of URS, IQ,	● Design a detailed User Requirement Specification	● Identify and create	Prepare Validation

OQ, PQ documents	(URS) for specific equipment or utilities. ● Develop Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) documents based on given scenarios. ● Analyze validation requirements to ensure compliance with regulatory standards. ● Defend validation strategies during simulated audits or presentations.	validation strategies as per intended use and compliance.	protocol and report for equipment/ utilities
Process flow for Change management Process flow for Deviation management Process flow for RCA and CAPA Process flow of Complaints & Recall	● Design process flow diagrams for change control, deviation management, root cause analysis (RCA), and corrective and preventive action (CAPA). ● Develop methodologies for managing complaints and product recalls based on given scenarios. ● Evaluate the efficiency of process flows for compliance with GxP requirements. ● Propose improvements to	● Design, develop, define the various process flow as per GxP requirements and to develop methodologies inline the required regulations	Process flow chart for quality attributes

	existing process flow systems based on case studies.		
HACCP flow as per regulations	● Define critical control points and hazards for a given food production process. ● Develop a Hazard Analysis and Critical Control Points (HACCP) plan tailored to specific scenarios. ● Justify the steps included in a HACCP plan based on regulatory requirements. ● Evaluate a sample HACCP plan for its effectiveness in ensuring food safety compliance.	● Define, develop the HACCP for food industries	HACCP documents
Perform Internal audit	• Identify non-conformances in a simulated or real-world quality system during an internal audit. • Prepare an internal audit report that highlights findings, root causes, and corrective actions. • Evaluate the effectiveness of audit processes and propose enhancements for ensuring compliance. • Demonstrate proficiency in conducting internal audits through role-play or mock	Identify and resolve GXP issues while ensuring compliance	Identify non-conformance in the system and write Internal audit report

	exercises.		

TABLE 4: LIST OF FINAL PROJECTS THAT COMPREHENSIVELY COVER ALL THE LEARNING OUTCOME	
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

TABLE 5: COURSE ASSESSMENT RUBRICS (TOTAL MARKS: 75)				
ASSESSMENT CRITERIA	**DESCRIBE THE CRITERIA OF THE BELOW CATEGORY PERFORMANCE**			**TOTAL MARKS**
	FAIR	**GOOD**	**EXCELLENT**	
Multiple Choice Question	15	20	25	25
Project Report I	5	7	10	10
Project Report II	5	7	10	10
Project Report III	5	7	10	10
Project Report IV	5	7	10	10
Project Report V	5	7	10	10

Category	**Assessment Criteria**	**Performance Levels**	**Weightage (Marks)**
Practical Skills Proficiency	Demonstrates ability to perform job-specific tasks effectively, using relevant to quality documentation and awareness of quality importance in the	Fair, Good, Excellent	10

Category	Assessment Criteria	Performance Levels	Weightage (Marks)
	industry.		
Technical Knowledge Application	Applies theoretical concepts to practical scenarios with accuracy and relevance during manufacturing or testing of drugs	Fair, Good, Excellent	15
Project Execution	Completes assigned projects or use cases demonstrating innovation, thoroughness, and skill application relevant to industry standards.	Fair, Good, Excellent	40
Communication and Reporting	Clearly presents findings, solutions, or project outcomes using professional communication and documentation standards (e.g., reports, presentations).	Fair, Good, Excellent	10

Performance Levels Description

Level	Description
Fair (50%-64%)	Basic performance; demonstrates minimal skill application and understanding; needs significant improvement to meet industry standards.
Good (65%-79%)	Competent performance; meets expectations with minor gaps; capable of performing job tasks independently with occasional guidance.
Excellent (80%-100%)	Outstanding performance; exceeds expectations with exceptional skill application and problem-solving; ready for professional industry roles.