GUJARAT TECHNOLOGICAL UNIVERSITY

GRADUATE SCHOOL OF PHARMACY

offered

Certificate Course

in

Pharmaceutical Quality Systems and Audit Compliance

Graduate School of Pharmacy, Gujarat Technological University,
K-6, Near Polytechnic campus, Gandhinagar -382028
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Background

The Gujarat Technological University (GTU) has established its Constituent PG School named Graduate School of Pharmacy (GSP) in 2017 at GTU Gandhinagar Campus. Currently, GSP is running M.Pharm courses in Pharmaceutical Regulatory Affairs (PRA), Pharmaceutical Quality Assurance (PQA) and Pharmaceutics. The GTU has developed the advance research facilities at the Graduate School of Pharmacy to cater the need of Students, Faculties, Research Scholars and Industries.

Introduction about the course:

This course deals with the various aspects of quality and quality systems like TQM (total quality management), Six Sigma, and Six system Inspection models with regards to pharmaceutical Industry. Other quality standards like ISO 9001:2015, WHO-GMP, 21 CFR part 21, ICH Q10 and NABL accreditation will also be covered.

This certificate course deals with the understanding and process for auditing in pharmaceutical industries. This also covers the methodology involved in the auditing process of different in pharmaceutical industries.

Auditing is a critical function within a pharmaceutical company. It provides management with information about how effectively the company controls the quality of their processes and products. Auditors must perform their jobs competently to ensure their company's compliance with pharmaceutical regulations and other quality standards. This 'Pharmaceutical Audit Compliance and Quality Systems certificate course' is specifically designed to address the knowledge and challenges of GMP auditing for the pharmaceutical industry and present the basic competencies required to effectively perform the auditor's assigned responsibilities.

Course Highlights:

- Assignments for all the course modules for continuous evaluation and guidance.
- Interactive or online live sessions on all key areas of the course giving all flexibility to the participants.
- Online classes for all the modules will be conducted on the weekends. Moreover, a doubt clearing session will also be scheduled before the examination.
- All the efforts are made by GTU-GSP faculty members to make the entire course modules easily understandable.
- At the end of each course modules, the trainers shall obtain feedback from the participants using specially designed questionnaires.
- All learning and training delivery initiatives shall be conducted in English.

Eligibility:

Any Life sciences graduate/B Pharm/ M. Pharm, MSc in science disciplines/ any diploma /degree holders. Working professionals of any of the following industry types Drugs or Food manufacturing, Medical Device, Ayurveda, Pharmaceutical Industry Regulation, Clinical

Research, Homeopathic or Ayurveda Medicine Manufacturing, Cosmetic Manufacturing, Biotechnology or any related industry are highly encouraged to apply for the certification.

Program Structure:

Duration: 03 Months

No. of Seats: 30

Theory: 03 Hours lecture on Saturday

Credit: 02

Mode: Being an e-course, the program will be based on a combination of weekly online lectures, Interactive discussion and e-submission of assignments.

Course Fees:

Rs. 10000/- for Indian nationals and 200 USD for overseas professionals. This covers the certification registration fee and examination fee.

Re- Examination:

In case the participant is not able to pass the certification exam in first attempt/exam notification, he/she will have to re- register for the next scheduled examination by submitting re- registration form along with the re- registration fee of Rs. 1500/- (50 USD). However, the participants will be given sufficient flexibility in scheduling their "First" certification exam.

Program syllabus (Brief Outline):

Module	Content	Hrs (Approx.)
1	Introduction to Quality: Evolution of Quality, Definition of Quality, Dimensions of Quality, Quality as a Strategic Decision: Meaning of strategy and strategic quality management, mission and vision statements, quality policy, Quality objectives, strategic planning and implementation, McKinsey 7s model, Competitive analysis, Management commitment to quality Customer Focus	3

2	Pharmaceutical quality Management: Basics of Quality Management, Total Quality Management (TQM), Principles of Six sigma, ISO 9001:2015,	4
3	Pharmaceutical Quality Management – ICH Q10, Knowledge management, Quality Metrics, Operational Excellence and Quality Management Review	3
4	NABL certification and accreditation, CFR-21 part 11, WHO-GMP requirements	4
5	Six System Inspection model: Quality Management system, Production system, Facility and Equipment system, Laboratory control system, Materials system, Packaging and labelling system. Concept of self-inspection. Quality systems: Change Management/ Change control. Deviations, Out of Specifications (OOS), Out of Trend (OOT), Complaints - evaluation and handling, Investigation and determination of root cause, Corrective & Preventive Actions (CAPA), Returns and Recalls, Vendor Qualification, Annual Product Reviews, Batch Review and Batch Release. Concept of IPQC, area clearance/ Line clearance.	5
6	Introduction: Objectives, Management of audit, Responsibilities, Planning process, information gathering, administration, Classifications of deficiencies	2
7	Auditing of vendors and production department: Bulk Pharmaceutical Chemicals and packaging material Vendor audit, Warehouse and weighing, Dry Production: Granulation, tableting, coating, capsules, sterile production and packaging	3
8	Auditing of Microbiological laboratory: Auditing the manufacturing process, Product and process information,	3

	General areas of interest in the building raw materials, Water, Packaging materials	
9	Auditing of Quality Assurance and engineering department: Quality Assurance Maintenance, Critical systems: HVAC, Water, Water for Injection systems, ETP	3
Total Hours		30

Expected Course Outcomes:

After completion of course, the attendee shall be able to

CO1	Understand the Quality Systems aspects in a pharmaceutical industry
CO2	To appreciate the importance of documentation
CO3	To understand the scope of quality certifications applicable to Pharmaceutical industries
CO4	To understand the importance of compliance auditing and the methodology of auditing
CO5	To understand audit process, checklist for auditing and reporting

Evaluation:

Through different modes like submission of assignments, Mid-course and end course examination.

Certification:

Certificate will be awarded to successful students who will attend at least 80% of scheduled activities and qualify the examination.

Carrer Opponurities:

The certified participants can work in following industries:

- Pharmaceutical Manufacturing Organizations
- Contract Research Organizations (CRO)
- Consulting firms for Pharmaceutical compliance
- Pharmaceutical R&D Organizations

Placement Assistance & Corporate Relations:

The Institute has partnered with many organizations for providing with placement assistance to its participants. Besides, GTU has a robust Industry Institute Interaction Cell (IIIC) comprised of senior level Human Resources professionals and Talent Acquisition experts which maintains close links with business and industry. This cell is continuously engaged in promoting the employability of our participants and encouraging the concerned Human Resources department and Hiring Managers to recruit/hire our participants for their vacant positions. The efforts of our placement cell also include helping with professional resume writing & interview skills.

The GTU's Industry Institute Interaction Cell (IIIC) actively recommends our students and training participants for various job requirements and specialized roles to Human Resource, Talent Acquisition as well as the heads of various departments in Pharmaceutical, Healthcare and Food industries on regular basis.