

### Attendance & Examination:

- ◆ 80 % attendance required during the course.
- ◆ The participants shall be evaluated from total marks 100 out of which External (GTU level) 60 marks and Internal (Institute level) 40 marks.
- ◆ Minimum passing marks are 40% in both External and Internal individually.

### Sessions & Course Duration

- ◆ Course Duration: 45 Hrs
- ◆ Sessions will be taken on online mode.
- ◆ Sessions on Saturday & Sunday
- ◆ Approx. Weeks 12 to 15 Weeks

### Course Fee

Student / Faculty / Pharma professional: INR1000/- &

Overseas Professional : 50 USD

### Bank Details for Payment

Bank Name: Union Bank of India

Account No.: 356702010017281

IFSC Code: UBIN0535672

Branch: Anand, Gujarat

### Registration Link

<https://forms.gle/SmaDuSFdbitRbzTt9>

**Last Date of Registration: 31/07/2023**

**Starting Date of Course: 05/08/2023**

### Patron

Smt. Jyotsanaben Patel

Hon. Seceretary, SRKSM

### Convener

Dr. Tejal R. Gandhi

Principal

Anand Pharmacy College

### Course Co-ordinators

Dr. Anita Mehta

Head, Pharm D Program

Dr. Akshay Shah

Professor & Head,

Department of Pharmacy Practice

### Course Co-coordinators

Dr. Juliet Joy Joseph

Dr. Arshi Panchal

### For any Query Contact:

Dr. Akshay Shah

Course Co-ordinator

(M) 9824163108

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After Successful completion of 1<sup>st</sup> Batch  
GUJARAT TECHNOLOGICAL  
UNIVERSITY

CENTRE FOR CONTINUING  
EDUCATION (GTU-CCE)

LAUNCHES

A SHORT TERM CERTIFICATE  
COURSE ON

**PHARMACOVIGILANCE (Batch-2)**



Organized By



**ANAND PHARMACY COLLEGE**

Managed By

Shri Ramkrishna Seva Mandal

Opp- Towan Hall, Anand- 388 001

## About Trust

**Shri Ramkrishna Seva Mandal (SRKSM)** is a registered body under the Societies Act and was established as a public trust in the year 1954. The trust was setup under the leadership of Late Shri Gordhanbhai Patel, popularly and respectfully known as “Vakil Saheb”. And with whole hearted cooperation of the prominent citizens and leading industrialist of the area, as multi- dimensional experiment, advertising various socio- economic problems and its implications. At present, Shri Ramkrishna Seva Mandal is managing about 27 academic institutes from K G School to Post Graduate Schools of excellence by effectively and efficiently maintaining pace with the ever- changing needs of modern educational environment. The Hon. Secretary, Smt. Jyotsnaben K Patel is a source of inspiration by itself and her ever readiness to help by providing dynamic leadership acts as a stimulating force of growth & development.

## About Institute

Anand Pharmacy College is one of the leading institute of Gujarat, established in 1998 under the aegis of Shri RamKrishna Seva Mandal. The institute is conducting All India Council for Technical Education (AICTE), New Delhi, approved courses since 1998. The institute is accredited by NAAC Third cycle with ‘A<sup>+</sup>’ grade (CGPA 3.38). Anand Pharmacy College offers B. Pharm, Pharm. D, M. Pharm in Pharmaceutics, Pharmacology, Regulatory Affairs, Pharmaceutical Quality Assurance & Pharmaceutical Technology and Ph.D. programs. Anand Pharmacy College has Adverse Drug Reactions Monitoring Centre approved by Indian Pharmacopoeia Commission (IPC), National Coordination Centre (NCC) - Pharmacovigilance Programme of India (PvPI), Ghaziabad.

## About Gujarat Technological University

Gujarat Technological University is a premier academic & research institution which has driven new ways of thinking since its 2007 founding, established by the Government of Gujarat vide Gujarat Act NO. 20 of 2007. Today, GTU is an intellectual destination that draws inspired scholars to its campus, keeping GTU at the nexus of ideas that challenge and change the world. GTU is a State University with 486 affiliated colleges in its fold operating across the state of Gujarat through its Five zones at Ahmedabad, Gandhinagar, Vallabh Vidyanagar, Rajkot and Surat. The University caters to the fields of Engineering, Architecture, Management, Pharmacy and Computer Science. The University has about 4,00,000, students enrolled in a large number of Diploma, Under Graduate, Post Graduate programs along with the robust Doctoral program.

## Course Objective

This course is anticipated to focus on

- ◆ Safe drug use, protecting patients, and ultimately safeguarding public health
- ◆ Support more ADR reports from the public and healthcare professionals.
- ◆ A fundamental comprehension of the Pharmacovigilance and Regulatory Services Concept.
- ◆ Acquire a working knowledge of the fundamentals of drug safety.
- ◆ Recognize the goals of active pharmacovigilance.
- ◆ To comprehend how administrative and operational procedures use pharmacovigilance
- ◆ Recognize the major obstacles to pharmacovigilance.
- ◆ Become familiar with the advantages and drawbacks of pharmacovigilance in the medical field.
- ◆ Aspects of essential Pharmacovigilance actions that are practical and adhere to international standards, such as medical evaluation, casualty assessment, expectedness assessment, case narratives, MedDRA, case processing, compilation of safety report, etc.

## Course Outcomes

- ◆ Understand the need for pharmacovigilance, basic terminology, classification of adverse drug reactions (ADRs), describe pharmacovigilance techniques, and manage risk.
- ◆ Explain different pharmacovigilance programmes, how to set up a pharmacovigilance center, the international regulatory organizations for pharmacovigilance, and communication in pharmacovigilance.
- ◆ Development of various reports, use of trustworthy information sources, statistical techniques, and software for pharmacovigilance.

## Topics at a Glance

- ◆ History, General overview of Pharmacovigilance
- ◆ Adverse Drug Reactions and Safety Reports
- ◆ Management Systems and Drug Dictionaries in Pharmacovigilance
- ◆ Methodologies in Pharmacovigilance
- ◆ Seriousness & Expectedness & Causality Assessment Criteria
- ◆ Aggregate Safety Reports
- ◆ Pharmacovigilance Programme in India (PvPI)
- ◆ Pharmacovigilance Regulations in Various Countries
- ◆ Software usage in Pharmacovigilance
- ◆ Communication in pharmacovigilance

## Eligibility of Participant

- ◆ B. Pharm/M. Pharm/Pharm D/Ph. D pursuing or completed.
- ◆ Graduate degree in life sciences such as Biochemistry, Biotechnology, Botany, Zoology, and Genetics
- ◆ Graduation degree in Medicine such as MBBS, BDS, BPT, BAMS, BHMS, Nursing
- ◆ Working person in Pharmaceutical industry, IT Industry and CRO.