

**GUJARAT TECHNOLOGICAL UNIVERSITY**

**GRADUATE SCHOOL OF PHARMACY**

**offered**

**Certificate Course**

**in**

**Pharmacovigilance and Medical Writing**



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

Website: <https://www.gsp.gtu.ac.in>

Contact: +91 7069007910

# **Certificate Course in Pharmacovigilance and Medical Writing**

## **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:**

Pharmacovigilance is a discipline which pertains to the safety of drugs available in the market as well as those which are still in the development phase. Pharmacovigilance is one of the fastest growing area of the health science industry. Different regulatory bodies like USFDA & EMA are boosting the adoption rate of Pharmacovigilance system by pharmaceutical companies. Several countries including like India is in the process of implementing stringent regulations for adoption of Pharmacovigilance. A Pharmacovigilance centre or department in any industry takes the lead in monitoring the side effects of drugs as marketed drugs may possess risks that have not been fully identified & assessed during clinical trials. The Pharmacovigilance team invokes greater responsibilities for a drug safety mechanism to prevent/ treat the adverse side effects caused by a drug or device depending on its drug-dose & intake.

The term “Medical Writing “is a very broad, it is a very different from scientific writing. It mainly involves writing associated with clinical trials, regulatory submissions, Pharmacovigilance and medico marketing. Medical writing is a dominant profession involved in all stages of product development in the pharmaceutical and biotech industry having a significant role in the success or failure of new products, inventions and devices. Professionals with medical writing skills work in the pharma-biotech and clinical research industry, healthcare organizations, media or as freelance entrepreneurs.

The combination of Pharmacovigilance and Medical Writing is a different type of program which provides knowledge and training to the participants in the area of drug safety and medical writing. It also provides training regarding how to write regulatory documents and scientific writing.

## **Course Highlights:**

- Comprehensive eLearning course which mainly focuses on Pharmacovigilance and medical writing industry
- Well-structured course, intelligently put together under guidance of industry and academic experts from same field
- Online eLearning course starting from lectures, online materials, weekly evaluation and end term evaluation

## **Eligibility:**

The minimum eligibility criteria for certificate course in Pharmacovigilance and Medical Writing include either of the following:

- Graduation degree in Pharmacy/Pharmaceutical Sciences
- Graduate degree in life sciences such as Biochemistry, Biotechnology, Botany, Zoology, and Genetics
- Graduation degree in Medicine such as MBBS, BDS, BPT, BAMS, BHMS
- Graduation degree in Nursing
- Students in the final year of the courses as above are also eligible to apply
- PG Students/ Research Scholars in the field as mentioned above are also eligible.
- Candidates with work experience in Pharmacovigilance and Medical Writing industry are also be eligible for this program.

## **Program Structure:**

Duration: 03 Months

No. of Seats: 15

Theory: 03 Hours lecture on each 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:** 10,000/-

## **Program syllabus (Brief Outline):**

**Module 1: Pharmacovigilance – I:** General Introduction of Clinical Research; Epidemiology and Evidence Based Medicine

**Module 2: Pharmacovigilance – II:** Pharmacovigilance System

**Module 3: Pharmacovigilance – III:** Principles of Pharmacovigilance, Pharmacovigilance and Selected System Organ Classes

**Module 4: Pharmacovigilance – IV:** Pharmacovigilance Regulations and Guidelines worldwide

**Module 5: Pharmacovigilance – V:** Global Pharmacovigilance and Safety Standards

**Module 6: Pharmacovigilance – VI:** Case Study

**Module 7: Medical Writing – I:** Basics of Good Medical Writing; Writing Tips and Computer Skills

**Module 8: Medical Writing – II:** Introduction to important documents

**Module 9: Medical Writing – III:** Overview of the Regulatory, Marketing and Drug Promotion Process

**Module 10: Medical Writing – IV:** Publication Writing and Managing the Review Process

**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 will qualify the examination.

**Carrer Opponurities:** Pharmacovigilance and Medical Writing professionals play a very vital role in monitoring the safety of drugs that are available in the market. Pharmacovigilance teams enter safety data in various databases and try to identify any trend in adverse event reports for each product that are reported by consumers and physicians. Pharmacovigilance professionals and medical writer can work in healthcare industry as:

- Drug Safety Associate
- Drug Safety Executive
- Drug Safety Coordinator
- Drug Safety Scientist
- Medical Writer
- Regulatory Writer