



# HINDU COLLEGE OF PHARMACY, GUNTUR

## Department of Pharmacy Practice

### CERTIFICATE COURSE

**Title: The Importance of Pharmacovigilance – Safety monitoring of medicinal products**

**Code: VACPP01**

**Year of Introduction: 2017**

#### **About the course (Description):**

This certificate program will provide the fundamental skills you need to do your job. Topics include, but are not limited to:

- Premarketing clinical safety and pharmacovigilance
- Postmarketing drug safety and pharmacovigilance
- Risk management strategies
- How to prepare for a safety inspection
- Signal detection and data mining
- Understand pharmacovigilance practices – both in India and worldwide

#### **CONTENTS:**

**No. of Hrs. 30**

- **Session 1**
  - Introduction
  - Spontaneous reporting
  - pharmacovigilance practices – both in India and worldwide
- **Session 2**
  - Clinical Trials - Patients Safety and Pharmacovigilance.
  - Clinical Trials – Phases and Legal Requirements  
(Guidelines and laws governing Pharmacovigilance)
- **Session 3**
  - Signal identification
  - Event Monitoring
  - Data processing
- **Session 4**
  - Causality assessment of ADR
  - Individual Case Safety Reports
  - Periodic Safety Update Reports
- **Session 5**
  - Case studies & Answers for Exercise based Questions

#### **Course Outcomes:**

Good Laboratory Practice guidelines helped the students in gaining the skills of design, Standard operating procedures, conduct, performance, monitoring, auditing, recording, analyses, reporting, storage and retention of records and materials of Pre-clinical trials.

**SCHEDULE:**

<b>S.No</b>	<b>Date</b>	<b>Time</b>	<b>Resource Persons</b>
1	05-03-2017	10.00 AM- 1.00 PM & 2.00-5.00 PM	Dr J Krishna Pavan & Dr N Naveena
2	11-03-2017	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr G Sada Siva Rao & Mr D Nagarjuna Reddy
3	12-03-2017	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr V D C Sravan Kumar & Dr G V Srujana
4	19-03-2017	10.00 AM- 1.00 PM & 2.00-5.00 PM	Dr J Krishna Pavan & Mr V D C Sravan Kumar
5	26-03-2017	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr G Sada Siva Rao & Dr N Naveena

**Person Incharge (Coordinator):**

<b>Name</b>	<b>Address</b>	<b>e-mail</b>	<b>Phone No.</b>
Mr P Seetaramaiah	Director & HOD Dept. of Pharmacy Practice, HCOP, Guntur	hcopharmacypractice@gmail.com	9849546292

**Coordinator****PRINCIPAL**