



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: 2015

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:

S.No	Date	Time	Resource Persons
1	05-07-2015	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr G Sada Siva Rao & Mrs Preeti
2	11-07-2015	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr G Sada Siva Rao & Mr D Nagarjuna Reddy
3	12-07-2015	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr V D C Sravan Kumar & Mrs Preeti
4	19-07-2015	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mrs Preeti & Mr V D C Sravan Kumar
5	26-07-2015	10.00 AM- 1.00 PM & 2.00-5.00 PM	Mr G Sada Siva Rao & Mr V D C Sravan Kumar

Person Incharge (Coordinator):

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

Coordinator**PRINCIPAL**