### Name of Institute: INDUS UNIVERSITY- IISHLS (Institute of science Humanities and liberal studies)

### Name of Faculty: Dr. Anokhi shah

**Fundamentals of Pharmacovigilance and safety reporting**

Course code: UCR0501

Course name:B.SC CLINICAL RESEARCH AND HEALTHCARE MANAGEMENT

Pre-requisites: Basic understanding and knowledge of clinical research

Credit points: 3 credits

Offered Semester:

**Course Coordinator**

Full Name:Dr. Anokhi shah

Department with siting location: 4thfloor Bhawar building, class 11

Telephone: 9974702063

### Email:anokhishah.cr@indusuni.ac.in

Consultation times:Monday to Friday 3 to 4 pm

**Course Lecturer**

Full name:Dr.Anokhi shah

Department with siting location: 4thfloor Bhawar building, class 11

Telephone: 9974702063

Email:Anokhishah.cr@indusuni.ac.in

Consultation times: Monday to Friday 3 to 4 pm

Students will be contacted throughout the Session via Mail with important information relating to this Course.

# Course Objectives

By participating in and understanding all facets of this Course a student will:

1 To learn about Fundamentals of Pharmacovigilance and safety reporting

Course Outcomes (CO)

After successful completion of course, student will able to understand,

* The main purpose of this course is to educate students all about drug safety, the need and importance of Pharmacovigilance
* To understand the scope of drug safety reporting
* The regulatory requirement for Pharmacovigilance
* To understand signal detection and management process

Course Outline

(Key in topics to be dealt)

**Course Content:**

**Unit 1 Pharmacovigilance**

Definitions, Overview and Scope, Importance, History: Pre Thalidomide era, Thalidomide Disaster and Post Thalidomide Era; Pharmacovigilance; Drugs withdrawn from the Market; WHO Drug monitoring

Programme and Uppsala Monitoring centre. Pharmacovigilance Regulations in India and national PV policy and programme.

Pharmacovigilance Methods:Passive Surveillance, Active Surveillance and Stimulated Reporting. PMS Methodologies - Observational studies, Case studies, Cohort studies,

**Unit 2 Adverse drug reaction reporting and Signal Detection**

Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment,

Signal Detection: Signal generation, Sources and methods of Signal Detection, Automated quantitative Signal Detection.UMCsignalling Process. PV data base softwares(Aris, Argus etc for case report Management

**Unit 3 Benefit Risk Assessment**

Actual v/s perceived Risk and benefits, Factors affecting benefit risk balance; Methods of Risk Minimization, Pharmacovigilance Planning. Pharmacovigilance Planning Guidelines.

**UNIT 4: Global Safety Monitoring Systems**

Introduction to Drug Safety Guidelines ICH, WHO etc.PV in Europe, US, India, China, Australia, Japan. Regulations and guidelines of these countries .US FDA medwatch, Uk Yellow card System.) Sources of Individual Case Safety Reports, format and content and compilation of PSURS world-wide.. Data entry terminology MEDRA, WHO ART , WHO DD

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# Method of delivery

1. Face to face lectures
2. PPT/Video presentation/
3. Class activities
4. Article presentation
5. Seminar presentation

# Study time

3 hours/week

# Blooms Taxonomyand Knowledge retention(For reference)

(Blooms taxonomy has been given for reference)



Figure 1: Blooms Taxonomy



Figure 2: Knowledge retention

# Graduate Qualities and Capabilities covered

(Qualities graduates harness crediting this Course)

|  |  |
| --- | --- |
| **General Graduate Qualities** | **Specific Department of \_\_\_\_\_\_Graduate Capabilities** |
| **Informed**  Have a sound knowledge of an area of study or profession and understand its current issues, locally and internationally. Know how to apply this knowledge. Understand how an area of study has developed and how it relates to other areas. | **1 Professional knowledge, grounding & awareness:**  Student will be able to learn regarding different application of clinical Data management, startup phase and process of data Management. |
| **Independent learners**  Engage with new ideas and ways of thinking and critically analyze issues. Seek to extend knowledge through ongoing research, enquiry and reflection. Find and evaluate information, using a variety of sources and technologies. Acknowledge the work and ideas of others. | **2 Information literacy, gathering & processing**  Student will be able to learn and create  Different CRF designing and application could be done in different phases of trial. |
| **Problem solvers**  Take on challenges and opportunities. Apply creative, logical and critical thinking skills to respond effectively. Make and implement decisions. Be flexible, thorough, innovative and aim for high standards. | **4 Problem solving skills**  Student will be able to learn problem solving skill by solving queries in project and can use easy software Handling. |
| **Effective communicators**  Articulate ideas and convey them effectively using a range of media. Work collaboratively and engage with people in different settings. Recognize how culture can shape communication. | **5 Written communication** |
| **6 Oral communication** |
| **7 Teamwork**  Students can learn in industry with practical approach and in team work with user department and in collaboration with different stakeholders. |
| **Responsible**  Understand how decisions can affect others and make ethically informed choices. Appreciate and respect diversity. Act with integrity as part of local, national, global and professional communities. | **10 Sustainability, societal & environmental impact**  Students can understand importance of data and application finally in drug research  In the Pharmaceutical industry. |

# Practical work:

Document preparation

Case studies in clinical trials

# Lecture/tutorial times

(Give lecture times in the format below)

3 Lectures/week

# Attendance Requirements

The University norms states that it is the responsibility of students to attend all lectures, tutorials, seminars and practical work as stipulated in the Course outline. Minimum attendance requirement as per university norms is compulsory for being eligible for mid and end semester examinations.

# Details of referencing system to be used in written work

An Introduction to Pharmacovigilance by Patrick Waller

# Text books

1. Recommended text: An Introduction to Pharmacovigilance by Patrick Waller (2010)
2. References: Targeted Regulatory Writing Techniques: Clinical Documents for Drugs and Biologics by Linda Fossatti Wood and MaryAnn Foote

# **Additional Materials**

Notes and PPT assessment guidelines

Your final course mark will be calculated from the following:

**Assessment guidelines**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject : Fundamentals of Pharmacovigilance and Safety Reporting | | | | | | | | | |
| Program : B.Sc-Clinical Research and Healthcare Management | | | Subject Code :UCR0501 | | | Semester : V | | | |
|  | | | | | | | | | |
| Teaching Scheme | | | Examination Evaluation Scheme | | | | | |  |
| Lecture | Tutorial | Practical | Credits | University Theory Examination | University Practical Examination | Continuous Internal Evaluation (CIE)- Theory | Continuous Internal Evaluation (CIE) - Practical | Total | |
| 3 | 0 | 0 | 3 | 40 |  | 60 |  | 100 | |

# Mid sem exam 40 marks Attendance 05 marks Presentation 05 marks Assignment 1 05 marks Assignment 2 05 marks Final exam 40 marks

# SUPPLEMENTARY ASSESSMENT

Students who receive an overall mark less than 40% in mid semester or end semester will be considered for supplementary assessment in the respective components (i.e mid semester or end semester) of semester concerned. Students must make themselves available during the supplementary examination period to take up the respective components (mid semester or end semester) and need to obtain the required minimum 50% marks to clear the concerned components.

# Practical Work Report/Laboratory Report:

A report on the practical work is due the subsequent week after completion of the class by each group.

# Late Work

Late assignments will not be accepted without supporting documentation. Late submission of the reports will result in a deduction of -% of the maximum mark per calendar day

# Format

All assignments must be presented in a neat, legible format with all information sources correctly referenced. **Assignment material handed in throughout the session that is not neat and legible will not be marked and will be returned to the student.**

# Retention of Written Work

Written assessment work will be retained by the Course coordinator/lecturer for two weeks after marking to be collected by the students.

# University and Faculty Policies

Students should make themselves aware of the University and/or Faculty Policies regarding plagiarism, special consideration, supplementary examinations and other educational issues and student matters.

**Plagi**a**rism** - Plagiarism is not acceptable and may result in the imposition of severe penalties. Plagiarism is the use of another person’s work, or idea, as if it is his or her own - if you have any doubts at all on what constitutes plagiarism, please consult your Course coordinator or lecturer. Plagiarism will be penalized severely.

***Do not copy the work of other students.***

***Do not share your work with other students (except where required for a group activity or assessment)***

***.***

# Course schedule(subject to change)

**(Mention quiz, assignment submission, breaksetc.as well in the table under the Teaching Learning Activity Column)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Week #** | **Topic & contents** | | | **CO Addressed** | | **Teaching Learning Activity (TLA)** |
|  | Weeks 1 | Definitions, Overview and Scope, Importance, History: Pre Thalidomide era, Thalidomide Disaster and Post Thalidomide Era | | | Presentation material | | PPT/Notes |
| Weeks 2 | Pharmacovigilance; Drugs withdrawn from the Market; WHO Drug monitoring | | | Presentation material | | PPT/Notes |
| Week 3 | Definitions and classification of ADRs Detection and reporting, Causality assessment, Severity and seriousness assessment, | | | Presentation material | | PPT/Notes |
| Week 4 | Signal Detection: Signal generation, | | | Presentation material | | PPT/Notes |
| Week 5 | ources and methods of Signal Detection, Automated quantitative Signal Detection | | | Presentation material | | PPT/Notes |
|  | | |  | | | | |
|  | Week 6 | Actual v/s perceived Risk and benefits, | | Presentation material | | PPT/Notes | |
| Week 7 | Factors affecting benefit risk balance; Methods of Risk Minimization, Pharmacovigilance Planning. Pharmacovigilance Planning Guidelines. | | Presentation material | | PPT/Notes | |
| Week 8 | Introduction to Drug Safety Guidelines | | Presentation material | | PPT/Notes | |
| Week 9 | PV in Europe, US, India, China, Australia, Japan. Regulations and guidelines of these countries | | Presentation material | | PPT/Notes | |
|  | Week 10 | US FDA medwatch, Uk Yellow card System.) Sources of Individual Case Safety Reports | | Presentation material | | PPT/Notes | |
| Week 11 | format and content and compilation of PSURS world-wide.. Data entry terminology MEDRA, | | Presentation material | | PPT/Notes | |
|  | Week 12 | WHO ART , WHO DD | | Presentation material | | PPT/Notes | |