



KLE Academy of Higher Education & Research Belagavi

[DEEMED-TO-BE-UNIVERSITY]

REACCREDITED AT THE 'A+' LEVEL BY NAAC (THIRD CYCLE), PLACED IN 'A+' CATEGORY BY MHRD (GoI)



Value Added Course on

Pharmaco vigilance & Drug Safety

Offered by

Dept. of Pharmacy Practice
KLE COLLEGE OF PHARMACY
Belagavi

JNMC Campus, Nehru Nagar Belagavi - 590010.

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Our B. Pharm Program has been accredited by NBA for a period of 6 years (from July 2019 to June 2025)



BELAGAVI

Preamble

Pharmacovigilance is the science of gathering, monitoring, researching, analyzing, and evaluating data from healthcare professionals and patients on the side effects of prescription drugs, biological products, herbal remedies, and traditional medicines in order to uncover new information about drug-related risks and shield patients from harm. Adverse Drug Reaction responses are of significant relevance to Pharmacovigilance & Drug Safety. The utilization of medications to treat illnesses and their prevalence has been around for a market for many years. The intensity and scope of an unfavorable reaction rely on a number of variables. As a result, drug safety, effectiveness, and cost containment are crucial. Pharmacovigilance is currently a highly important for participants.

Course Objective:

- The objective of this program is to train Participants about Identifying, Assessing, Reporting of ADR, Use of Software (VigiFlow) and its importance.
- **Course Outcome (CO)**
- **CO 1**: Search, Compile, Analyse and evaluate reports about adverse drug reactions in scientific literature and databases.
- **CO 2**: To Sensitize the participants with regard to the different methods of Causality assessment scales.
- **CO 3**: Improve participants to be better communicators with other health care professionals by providing them with relevant information about Adverse Drug Reaction.
- **CO 4**: To Experience hands on training by using VigiFlow software in reporting of AD

MODULES

Sl. no	Module	Resource Person	Duration (Hours)
1.	Pharmacovigilance and key Definitions	Faculty members from department of Pharmacy Practice	3
2.	Overview of approaches to signal detection	Faculty members from department of Pharmacy Practice	3
3.	Spontaneously reported drug-safety related Information	Faculty members from department of Pharmacy Practice	3
4.	Database that support signal detection	Faculty members from department of Pharmacy Practice	3
5.	Traditional methods of signal detection	Faculty members from department of Pharmacy Practice	4
6.	Hands on training on data entry into Vigiflow	Faculty members from department of Pharmacy Practice	4
7.	Software's – MedDRA, EUDRA, ORACLE ARGUS Safety Application	Faculty members from department of Pharmacy Practice	4
8	Overview to Advanced Excel	Resource Person	6

Syllabus content

- **Module 1: Pharmacovigilance and key definitions**

- It includes:

- Need for Pharmacovigilance after regulatory approval in different countries (India,UK, USA, Europe).
- Global regulatory Requirements and related guidelines in Pharmacovigilance.
- Taxonomy of drug safety signals .
- FDA regulations, CDSCO guidelines .

- **Outcome :**

- Participant will be able to understand about global regulatory requirements, drugsafety signals & Various regulatory approvals in different countries.

- **Module 2 : Overview of approaches to signal detection**

- Emergence of statistical data mining methods.
- Interpretation of data mining results within an integrated approach.
- Demonstration on signal detection.

- **Outcome :**

Participant can understand the importance of statistical data mining methods.

- **Module 3 : Spontaneously reported drug-safety related information**

- Data elements in Spontaneous reporting system.

- Different Methods of Causality assessment scales.
- Mechanisms for reporting.
- Limitations and challenges of spontaneous data.
- Reporting in special population

Outcome :

- Participants should be able to report ADRs by various Causality assessment scales.
- **Module 4: Database that support signal detection**
- Spontaneous reporting databases
- Data quality
- **Module 5: Traditional methods of signal detection**
- Case and case series review
- Case Narrative Writing
- Simple analyses of larger datasets

Outcome :

- Participants can compare various cases by reviewing them and can able to analyse the larger data easily.

Module 6: Hands on training on data entry into VigiFlow

Outcome :

Participant gets hands on experience on data entry into VigiFlow software (A web-based individual case safety report management system)

Module 7 : Software's – MedDRA, EUDRA, ORACLE - ARGUS Safety Application

Gaining knowledge about Processing, analyzing and reporting adverse event cases originating in pre and post market drugs, biologics, vaccines and devices by using above softwares



Module outcomes:

Student will be able to learn

MO 1: Processing , analyzing and reporting adverse event cases originating in pre and post market drugs, biologics, vaccines and devices by using above softwares

MODULE 8:

6 HOURS

Overview to Advanced Excel**Section One - Make a Start with Excel**

- What is a Spreadsheet?
- Excel Rows and Columns
- Enter Text and numbers in a cell
- Data Formatting - Font formatting, Number formatting, colour of a cell; centre text and numbers; Table formatting, Conditional formatting, Hide/Unhide; Sort / filter, paste special, Find and select
- Text Functions Using: Mid/Search/Left/Right Functions; Using Trim/Clean/Upper/Lower Functions; Using Substitute/Text Functions; Using Trim/Clean/Proper/Dollar Function
- Currency symbols in excel
- How to save your work in excel

Section Two - Excel Formulae

- The SUM Function
- How to multiply in excel
- Subtract and Divide
- Combine the Arithmetic Operators
- Formula Auditing
- The Average Function
- The Date & Time Function

Section Three - Microsoft spreadsheet Features

- Advanced Filters - Extracting Records with Advanced Filter; Using Formulas in Criteria
- Advanced Sorting - Sorting by Top to Bottom/Left to Right; Creating/Deleting Custom List; Sort by using Custom List
- How to Merge cells
- Data Import from Web, Text (Text to columns)
- Removing Duplicates
- How to use Auto fill in excel
- How to Sort data in excel
- Searching with MATCH and INDEX
- How to Create an Excel Template
- Data Forms in Excel
- Drop Down Lists in Excel
- Add your own Error Messages

- Array Formulas Intermediate Excel
- Frequency Distribution Intermediate Excel
- Hyperlinks in Excel

Section Four - Microsoft Excel Pivot Tables & Charts

- Excel Pivot Tables (Creating, Formatting Simple PivotTables), Creating / Modifying a PivotChart
- Create an excel chart
- Formatting Charts: Move and Resize your chart; Charts Styles and Layouts; Adding Chart Titles and Series Titles Legends / Labels
- Formatting / Renaming / Deleting Data Series; Changing the Order of Data Series; Chart Layout Panel in Excel
- Printing Charts
- Adding Data to a Chart;
- Create Pie chart in Excel
- Format Pie chart segments
- Create a 2D line Chart in Excel (Combo Charts – Secondary Axis)
- Format your Axis titles
- Predict the future with a Trendline chart
- Sparkline charts
- Section Five - Conditional Logic
- 'IF' Function
- Conditional Formatting in excel
- Statistical Functions:
- CountIF, Count IFS, SUMIF, SUMIFS, Averagelf, Averagelfs, Nested IF, IFERROR Statement, AND, OR, NOT; LARGER / SMALLER Functions (Colour coding & data rearrangement)
- Absolute Cell References

Section Six - Advanced Excel – Data Processing & LOOKUP Functions

- Reference other Worksheets
- LOOKUP Function: VLOOKUP/HLOOKUP Function in Excel; Index and Match; Creating Smooth User Interface Using Lookup; Nested VLookup; Reverse Lookup using Choose Function

Arrays Functions - Array Formulas, Use of the Array Formulas; Basic Examples of Arrays (Using ctrl+shift+enter); Array with if, len and mid functions formulas; Array with Lookup functions; Advanced Use of formulas with Array.

Module Outcomes: Upon completion of this module students will be able to:

1. Create & Edit worksheets
2. Process data sets using Outline, autofilter & pivot tables
3. Process data sets employing Excel Formulae & produce statistical results
4. Extract and modify data with search and replace, use conditional formatting to highlight specific data
5. Creates and format PivotTables & Charts

Validate data using LOOKUP features

Teaching Methodology

Activities, Learning Resources and Assessment

Suggested Class Room Activities

Presentations on selected

topicsQuizzes

Discussions

Assignments

Hands on training

Live case study

Problem Based Learning

Career Prospects

Pharmacovigilance Associate

Drug safety Associate

Pharmacovigilance Officer

Safety monitor

Safety scientist

- **Reference Books / websites**

- Textbook of Pharmacovigilance by SK GUPTA
- Fundamentals of Pharmacovigilance by Verma Sumit
- Current trends in Pharmacovigilance by Punjab S vikas & company
- Practical Aspects of signal detection in Pharmacovigilance
- CDSCO Website

Assessment

25% Formative assessment:

- 10% marks will be awarded on the basis of average of two assignments given in the course i.e. 05 Marks.
- 20% marks will be given on the basis of professional activity i.e. Quiz/discussion/short project/any innovative activity i.e. 10 Marks.
- 20% marks will be awarded on the basis of objective/subjective Test i.e. 10 Marks.

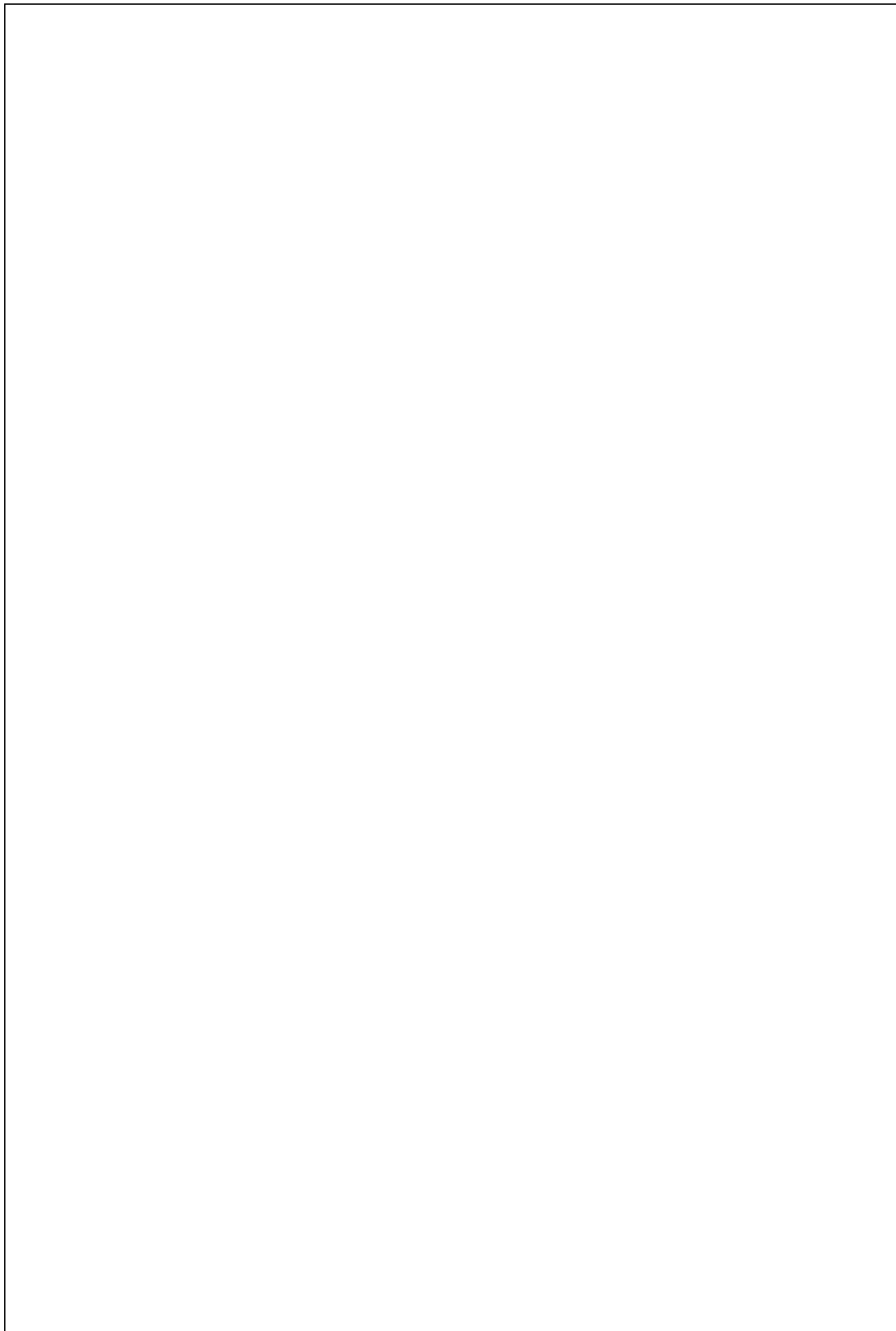
75% summative assessment:

End term exam of 25 marks will be conducted to award the 50% of the total exam score. Question paper will be set as per the university rules applied to other courses.

- **Eligibility:** Students of B Pharmacy, M Pharmacy, PharmD, BSc Nursing, MSC Nursing, BDS, MDS, MBBS, MSc Clinical Research and other allied sciences.
- **Duration:** 12 weeks
- **Fees/Charges:** The course is offered to the students without any fee

Added Benefits for the Participating Students

- Hands on Training in VigiFlow software
- Course completion certification to all Participants





Highlights of the Course

- **Overview of Pharmacovigilance & Drug Safety Reporting**
- **Signal detection & supporting tools – MedDRA, EUDRA, Oracle, ARGUS Safety Application**
- **Hands on training into VigiFlow**
- **Self-Directed Learning (SDL), Problem-Based Learning (PBL), Team-Based Learning (TBL)**