KLE
EMPOWERING PROFESSIONALS

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

Drug Regulatory Affairs

KLE COLLEGE OF PHARMACY
TRUTH, LOVE, SERVICE, SACRIFICE
BELAGAVI

Offered by

Dept. of Quality Assurance
KLE COLLEGE OF PHARMACY
Belagavi

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

Preamble:

Pharmaceutical Regulatory Affairs is an emerging specialised discipline which is vital in successfully delivering a safe and effective product to the market. It is the key player in drug development and their approval by taking into account the global laws and regulations. It also plays an important role in bringing about new policy implementation and research. Helps in developing writing skills to fill dossier for various products across the globe with due consideration of the respective legalities.

Course Objective:

This course is designed to impart fundamental knowledge on cGMP in pharmaceutical industries and to understand elementary knowledge about the regulatory requirements and registration procedures for marketing the products in various countries. Upon gaining knowledge the students can become expert in regulatory writing and submission to agencies. This course prepares the students for basic regulatory requirements in India of PMB for manufacture, import, registration, export, sale, marketing authorization and intellectual property rights.

Course Outcomes:

Upon completion of this course, participants will be able to:

CO1: Able to understand the key elements of current Good Manufacturing Practices.

CO2: Shall be able to know the Regulatory registration requirements.

CO3: Able to know the concepts of IPR.

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Modules:

Module 1: Introduction to ICH and WHO Guidelines, Audits and Drug product development

Sr No	Value added Topic	Duration
1.	Q series guidelines for product development	02 Hours
2.	cGMP guidelines 2.1. Premises 2.2 Personal 2.3 Equipment 2.4 Sanitation 2.5 Materials 2.6 Manufacturing operations 2.7 Validations 2.8 QC systems 2.9 QMS 2.10 Documentation	02 Hour
3.	Types of audits and regulatory compliance 3.1 Internal audit 3.2 Contractor audits 3.3 Supplier quality audits 3.4 product-specific quality audits 3.5 QSIT (Quality System Inspection Technique) audits	1.5 Hours
4.	Phases of clinical trials and GCP 4.1 Human / Clinical pharmacology (Phase I) 4.2 Therapeutic exploratory trials (Phase II) 4.3 Therapeutic confirmatory trials (Phase III) 4.4 Special studies – Bio-availability / Bio-equivalence (Phase IV).	1.5 Hour
	Total Hours	**06 Hours**

Upon completion of this module students will able to

- **MO1:** Discuss the concepts of international regulatory requirements.
- **MO2:** Describe the concepts of audits and clinical regulatory compliance.

Module 2: Regulatory requirements for product approvals.

Sr No	Value added Topic	Duration
1.	Investigational New drug Application (IND) New Drug Application (NDA) Abbreviated New Drug Application (ANDA),	02 Hour
2.	Hatch-Waxman act and amendments Code of Federal Regulations (CFR)	1.5 Hour
3.	Drug product performance – *in-vitro* Bioequivalence and Drug Product Assessment – *in-vivo* Post marketing surveillance,	1.5 Hour
4.	Pharmaceutical Labeling, Scale up Post approval changes	01 Hours
	Total Hours	**06 Hours**

Upon completion of this module students will able to

- **MO1:** Describe the Requirements of different drug applications.
- **MO2:** Explain the concepts of product approval requirements.

Module 3: Regulatory Filing systems in different countries

Sr No	Value added Topic	Duration
1.	EU – ASMF (Active Substance Master Files) CEP (Compliance of European Pharmacopoeia) EU – DMF (Drug Master File) US – DMF application.	2 Hour
2.	Various types of DMF CTD –Module 1,2,3,4.	2 Hour
3.	Quality Overall Summary (QOS), Laws and Act	1 Hour
4.	Orange Book, Purple Book	1 Hour
	Total Hours	**06 Hours**

Upon completion of this module students will able to

- **MO1:** Analyze various documents for regulatory filings.
- **MO2:** Interpret the regulatory laws and acts.

Module 4: Registration procedures in various countries

Sr No	Value added Topic	Duration

1.	Introduction, structure, and application process 1.1 India (CDSCO Central Drug Standards Control Organization), 1.2 US (FDA- Food and Drug Administration), 1.3 UK (MHRA- Medicines and Health Products Regulatory Agency), 1.4 Australia (TGA- Therapeutics Goods Administration), 1.5 Canada (HPFB- Health Products and Food Branch), 1.6 Japan (MHLW- Ministry of Health and Labour Welfare)	06 Hour
	Total Hours	**06 Hours**

Upon completion of this module students will able to

- **MO1:** Discuss the process of drug product registration in major regulatory authorities.

Module 5: Overview to Advanced Excel

Sr No	Value added Topic	Duration
1.	**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	06 Hour

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 / Lables
- 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, AverageIf, AverageIfs, Nested IF, IFERROR Statement, AND, OR, NOT; LARGER / SMALLER Functions (Colour coding & data rearrangement)
- Absolute Cell References

	Section Five - 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.	
	Total Hours	**06 Hours**

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 feature

Total Course Duration: 30 Hours

TEACHING METHODOLOGY & EVALUATION

- **Professional Activities, Learning Resources and Assessment**
- **Suggested Class Room Activities**
    - MCQ's, Case studies, Problem based learning, Assignment, Group Discussions, Quizzes, Seminars
- ***25% Formative assessment:***
- 10% marks will be awarded on the basis of an average of two assignments given in the course (05 Marks).
- 20% marks will be given on the basis of professional activities Quiz/discussion (10 Marks).
- 20% marks will be awarded on the basis of an objective type examination (10 Marks).

***75% summative assessment*:**

- End term exam of 75 marks will be conducted to award 75% of the total exam score. Exam Score: 40% passing criterion will be based on Formative assessment plus Summative assessment scores.
- Attendance: 80% attendance is compulsory to complete this course.

ELIGIBILITY & OTHER RELEVANT INFORMATION

- **Eligibility: Students pursuing B. Pharm final year and post graduation**
- **Duration:** 20hrs of lectures spread over 3 Months
- **Fees/Charges:** The course is offered to the students with a nominal registration fee.
- **Added Benefits for the Participating Students:**
    - Enriched knowledge of Pharmaceutical product development and Tech transfer.
    - Nurturing the technical skills in designing the scale-up parameters for production.
    - Enhanced Patent and market research skills.
    - Enhanced employability skills.

CAREER OPPORTUNITIES

- Regulatory Affairs Officer
- Senior Regulatory Associate
- Senior Executive Regulatory Affairs
- Assistant Manager of Regulatory Affairs
- Manager of Regulatory Affairs
- Drug Safety Specialist

Recommended Books and E-References:

1. Generic Drug Product Development, Solid Oral Dosage forms, Leon Shargel and Isader Kaufer, Marcel Dekker series, Vol.143.

2. The Pharmaceutical Regulatory Process, Edited by Ira R. Berry and Robert P. Martin, Drugs and the Pharmaceutical Sciences, Vol.185, Informa Health care Publishers.

3. New Drug Approval Process: Accelerating Global Registrations by Richard A Guarino, MD, Drugs and the Pharmaceutical Sciences, Vol.190.

4. Guidebook for drug regulatory submissions. By Sandy Weinberg, John Wiley & Sons. Inc.

5. FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics. Edited By Douglas J. Pisano, David Mantus.

6. Clinical Trials and Human Research: A Practical Guide to Regulatory Compliance By Fay A. Rozovsky and Rodney K. Adams

7. www.ich.org/
8. www.fda.gov/
9. https://european-union.europa.eu/index_en
10. www.cdsco.nic.in
11. https://www.tga.gov.au/tga-basics
12. https://www.canada.ca/
13. www.mhlw.go.jp

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Since 1968
Alchemizing Pharma Education

Highlights of the Course

- Concepts of Innovator, Generic Drugs & Drug Development Process
- Phases of Clinical Trials before Drug Product Commercialization.
- Regulatory aspects of Product Filing, Registration & Approval
- Post-approval Regulatory Norms for Actives & Drug Products.
- Submission of global documents in CTD/ eCTD formats