MAHARANI LAKSHMI AMMANNI COLLEGE FOR WOMEN

(NAAC ACCREDIDATED B++)

UGC SPONSORED CAREER OPTED COURSE

Subject: Certificate Course in Clinical Biochemistry

COURSE STRUCTURE
CERTIFICATE COURSE IN CLINICAL BIOCHEMISTRY

PAPER NO.	TITLE OF THE PAPER	THEORY HRS	PRACTICAL HRS	TOTAL
MODULE I	**Clinical Biochemistry I** Biomolecules, Water as Biological Solvent, Acids, Bases, pH, Buffers	20	20	40
MODULE II	**Clinical Biochemistry II** Chemistry of Carbohydrates, Amino acids and Proteins, Lipids, Nucleic acids	35	20	55
MODULE III	**Clinical Biochemistry III** Plasma Proteins, Immunoglobulins, Hemoglobin, Principles of Electrophoresis	15	20	35
MODULE IV	**Clinical Biochemistry IV** Vitamins, Enzymes	30	0	30
	TOTAL	**100**	**60**	**160**

INTRODUCTION TO BIOMOLECULESS

Major Elements of the Human Body,
Major Biomolecules of the Human Body,
An overview of the Major Functions and Methods used in the separation and purification of Biomolecules,
Salt Fractionation , Chromatography, Gel Filtration, Electrophoresis, Ultra Centrifugation.

WATER AS BIOLOGICAL SOLVENT

Biomedical importance, Structure of water, Dipolar Nature and Hydrogen Bonds.
Dissociation of Water.

ACIDS, BASES, pH AND BUFFERS

Modern Concepts of Acids and Bases , Weak and Strong acids, Dissociation constant, Ionic product of water pH – Henderson – Hasselbalch Equation.

Buffers – Commonly used Buffers – Bicarbonate, Citrate, Acetate, Phosphate, Tris – Hcl Buffers.

Methods used in the determination of pH, Theory of indicators use of Glass Electrodes and Reference Electordes.

CLINICAL CORELATIONS

Buffers of Blood, pH of Blood

Methods of Expressing concentrations – Percentage weight and volume, Gram molecular weight, molar solutions, Equivalent weight, Normal solutions, Calculations involved in conversions of molar solutions.

Colligative Properties: Osmolarity, Osmolality, Osmometry.

CLINICAL CORELATIONS: Basis of oral rehydration Therapy. Glucose as osmotic Diuretic in Diabetes.

CHEMISTRY OF CARBOHYDRATES

Occurance, and General Importance, Definition, Classification with Examples.

MONOSACCHARIDES: Stereo Isomerism, Optical Isomerism, Principles of Polarimetry, Reactions Characteristic of Aldehyde and Ketone groups – Oxidation, Reduction, Hydrazone Formation, Sugar Acids, Sugar Alchols, Amino Sugars and Phosphorylated Sugars Formation of Furfurals, Methyl Glucosides, Mutarotation.

DISACCHARIDES: Sturcture, Properties and Biomedical Importance of Lactose, Maltose, Sucrose, Cellobiose, Isomaltose.

POLYSACCHARIDES: Homo and Heteropolysaccharides – Starch, Glylogen, Cellulose, Dextrins, Inulin Mucopolysaccharides – Heparin, Hyaluronic Acid, Chondroitin Sulphate, Dermatin Sulphate, Keratin Sulphate.

FUNCTIONS OF PROTEOGLYCANS:

CLINICAL CORELATION:

Inulin used to Determine GFR,
Mucopolysaccharides as Components of Blood Group substances.

Clinical Significance of Mucopolysaccharides – Role in Fertilisation, Cell to Cell communication and in Tumors.

CHEMISTRY OF AMINO ACIDS:

Amino Acids in Mammalian Proteins, Properties of Amino Acids, Standard and Derived Amino Acids – Hydroxy Proline, Hydroxy Lysine, Gamma Carboxy Glutamate, Gamma Amino Butric Acid, Beta Alanine.

CLINICAL CORELATIONS:

Amino Acids As Neurotransmitters – Catecholamines, Glutamate.

Derivatives of Amino Acids that Serve as Hormones – Thyroid and Medullary Hormone.
Oxytocin used to Induce Labour.

CHEMISTRY OF PROTEINS:

An outline of Protein Classification, Structural Organisation – Primary, Secondary, Tertiary, Quatenary levels, Methods to study the Protein Structure, Properties of Proteins.

CLINICAL CORELATIONS:

Alterations of Primary Structure can lead to Disorders - illustration using sickle cell Anaemia.
Prion Diseases
Applied Importance of Hcl in Digestion
Precipitation of Caesin.

PLASMA PROTEINS:

Functions, Electrophoretic Separation of Plasma Protein.

CLINICAL CORELATIONS:

Alterations in Diseased Conditions – Nephrotic syndrome, Liver Cirrhossis, Viral Hepatitis, malignancy, Multiple Myeloma.
Bence - Jones Proteins.

IMMUNOGLOBULINS:

Structure, Classification and Functions of Immunoglobulins.

CLINICAL CORELATIONS:

Monoclonal and Polyclonal Gamopathy.
Use of Antibodies in Clinical Chemistry.

HAEMOGLOBULINS:

Structure of Haemoglobin, Corelations between structure and Functions.

CLINICAL CORELATIONS:

Types of Anaemias.

PRINCIPLES OF ELECTROPHORESIS

Paper, Agarose, Gel, PAGE and Immunoeletrophoresis,

CHEMISTRY OF LIPIDS:

Overview of Functions of Body Lipids,
Definition, Classification,
Fatty Acids – Saturated, Unsaturated, Physical, Chemical Properties;
Optical, geometrical Isomerism, Triglycerides, Waxes, Phospholipids

containing Glycerol, and Sphingol, Sphingomyelins, Cerebrosides and Gangliosides.
Sterols including Cholesterol

CLINICAL CORELATIONS:

Intake of PUFA Protect against Heart Attacks Prostaglandins serve as local Hormones.

CHEMISTRY OF NUCLEIC ACIDS:

Structure of Purine and Pyrimidine Bases, Nucleosides, Nucleotides, Structure of DNA, RNA, Types of RNA.

CLINICAL CORELATIONS:

Lesch – Nyhan Syndrome.

VITAMINS:

Introduction and Classification
Fat soluble vitamins

Vitamin A – Chemistry, Dietary Sources, Carotenes, Digestion, Absorbtion, Transport, Storage, Biochemical Functions, Deficiency Diseases, hypervitaminosis A, Molecular mechanism of Vision.

Vitamin D – Chemistry, Dietary Sources, Provitamin D, Digestion, Absorbtion, Transport, Storage, Biochemical Functions, Deficiency Diseases – Rickets, Osteomalacia, Calcitol Formation. Hypervitaminosis D.

Vitamin E – Chemistry, Dietary Sources, Digestion, Absorbtion, Transport, Storage, Biochemical Function, Deficiency Diseases, Antioxidant Role.

Vitamin K – Chemistry, Dietary Sources, Digestion, Absorbtion, Transport, Storage, Biochemical Functions, Deficiency Syndromes. Antagonist of Vitamin K.

Vitamin BComplex: Sources, Chemistry, Daily Requirements, Coenzyme Functions, Deficiency Symptoms of B Complex Vitamins.

Vitamin C – Sources, Chemistry, Daily Requirements, Biochemical Functions, Deficiency Symptoms.

CLINCIAL CORELATIONS:

Folate Antagonists used as Theraputic Agents. For Combating Infections and Cancer. Wernicks Encephalopathy in Chronic Alcoholism. The Antituberculosis Drug INH Cause Deficiency of Peridoxiin.

Obstructive Jaundice can lead to Vitamin K Deficiency.

Newborn infants lack Vitamin K

Maize and Jowar Dependancy could be pellagragenic.

Too much of Raw egg white consumption is injurious to health.

Achylya gastrica causes pernicious Anaemia.
Vitamin E, Selenium, Vitamin C, Synergestically to inactivate free radicals.
Vitamin D Resistant Rickets.

ENZYMES:

Introduction, Protein Nature, Ribozymes, Mechanism of Action, Concept of active Site Enzyme Specificity, Classification Based on ICMB with Typical Examples Enzyme code No. Physical Factors affecting the rate of Enzyme Catalysed Reactions – pH, Temperature, Enzyme Concentration, Substrate Concentration, KM and its importance with Graphical Representation.

Enzyme inhibition
Reversible, Irreversible, Competitive, Non-Competitive, Un-Competitive, Illustration with graphical representation

Allosteric Enzymes
An overview of the mechanism of the regulation of enzyme activity-covalent modification, feed back inhibition.

Co-enzyme and Cofactors –concept of Holoenzymes,Proenzymes

Brief account of clinical enzymology
Clinical corelation:
Ethanol to treat, Methanol poisoning
Gout treatment by alopurinol,
use of glucose oxidase in the estimation of blood glucose

PRACTICALS

1. Preparation of standard solutions, Primary standard, Standardization of solution using indicators, Various types of titrations.
2. Determination of aminoacids concentration using formal titration.
3. Estimation of Urinary acid Ammonia and its Clinical significance
4. Free and combined acid in gastric juice and its Clinical significance
5. Qualitative test for Carbohydrates, Proteins and Lipids Microscopis examination of osazone.
6. Precipitation reactions of Proteins, Precipitation of Caesin at its Isoelectric pH. Heat Coagulation Test, Precipitation using Acid Reagent – Trichloroacetic Acid, Perchloric Acid, Precipitation using heavy metals – lead acetate, mercuric chloride.

Scheme For identification of unknown carbohydrates Proteins.

7. Reactions of Lipids – Solubility Test, Test ofr unsaturation, Test for Cholesterol, Libermann – Burchard Test, Saponification, Apperance of Cholesterol Crystals under Microscope.
8. Principles of Chromatography, Paper Chromatography – Separation of mixture of Amino Acids Verification of Beer – Lambert Law.
9. Estimation of Urinary Chlorides
10. Osmotic Fragility Test

LIST OF REFERENCES

1. Harper's illustrated Biochemistry 26th edition.
2. Fundamentals of Clinical Chemistry – Tietz.
3. Practical physiological Chemistry – Harold Varley 6th edition.

COURSE STRUCTURE
CERTIFICATE COURSE IN CLINICAL BIOCHEMISTRY

PAPER NO.	TITLE OF THE PAPER	THEORY HRS	PRACTICAL HRS	TOTAL
1	Hospital practice and patient care	10		10
2	Physiology and Biochemistry - I	20	10	30
3	Biochemistry – II (Chemistry of biological compounds & their determination)	20	10	30
4	Histopathology, Hematology and clinical pathology	30	20	50
5	Enzymology, Isotopic techniques and clinical biochemistry	20	20	50
TOTAL		=		160 Hrs

SYLLABUS

HOSPITAL PRACTICE AND PATIENTCARE

I Introduction to hospital :

Its set up and functions and the health team

Patient : As an individual, the reaction of patient and his family to illness.

- Qualities - Professional and Ethical behaviour expected
- Role and responsibilities of a lab technician in the health team

II Hospital and departmental procedures

III Communication : Interpersonal relations and communications

IV Records and reports :

V. Care of the patient

VIII First aid:

- Shock
- Hyperglycaemia, Hypoglycaemia
- Poison consumption
- Hazards in the department

Anemia: Definition, classification, major causes, Types of anemia-nutritional deficiency anaemia, Aplastic anemia, Hacmolytic anemia, sickle cell Anemia, effects of anaemia on body, treatment.

Blood Indices : Color index, MCH, MCV, MCHC

CSR and PCV: Determination, definition, values, variation factors affecting, significance.

Blood Volume: Normal value, determination of blood volume and regulation of blood volume, Body fluid, pH, normal values, variation and regulation.

Lymph- Lymphoid tissue, formation, circulation, composition and functions of lymph.

Practicals:

Study of microscope and its use
_____ of blood and study of Haemocytometer
haemoglobinometry
determination of specific gravity of blood
white blood cell count
red blood cell count
determination of blood groups
Leisbman's staining and differential WBC count
Determination of packed cell volume
Calculation of blood indices

FRAGILITY TEST FOR R.B.C.

Determination of bleeding time
Determination of clotting time
Blood pressure recording
Auscultation for heat sounds
Artificial respiration
Determination of vital capacity

BIOCHEMISTRY I

1. Chemistry of carbohydrates – structure classification and examples.
2. Chemistry of lipids – structure classification and examples
3. Chemistry of proteins – structure classification and examples
4. Chemistry of nucleic – structure classification and examples

(HISTOPATHOLOGY – HEMATOLOGY AND CLINICAL PATHOLOGY)

HISTOPHATOLOGY – II

1. Instrumentation:

   a) Tissue processor, b) knife sharpener, c) automatic slide stainer, d) microctome, knive freezing microtome; cryostat, f) Instruments for crossing, g) Electric saw.

2. Frozen section techniques: CO_2 freezing, cryostat and freezing microtome.
3. Techniques and principles of sections cutting and routine staining and special stains
4. Mounting – Techniques, various mountings
5. Use of microscope, polarisers

HAEMATOLOGY

Introduction

1. Blood collection
2. Anticoagulants used in haematology
3. Normal values in haemtalogy
4. Preparation of blood films
5. Stains used in haematology
6. Morphology of red cells
7. Morphology of leukocytes and platelets
8. Preparation of buffy coat smears
9. Laboratory methods used in the investigation of anaemias
   a. B12 and fotate assay
   b. Schilling test
   c. Serum iron and iron binding capacity
10. Laboratory methods used in investigation of haemolytic anaemias
   b. Osmotic fragility
   c. Investigation of G-6 PD deficiency
   d. Test for sickling
   e. Estimation of Hb-F, Hb-A2
   f. Plasma haemoglobin and haptoglobin, demonstration of haemosiderin in urine
   g. Haemoglobin electrophoresis
   h. Test for autoimmune hemolytic – anaemias
   i. Measurements of abnormal Hb pigments

Practical:

1. Enzymes: simple enzymatic reaction, demonstration of factors affecting enzyme action, determination of A, I, K, phosphates, I, D, H, SGOT, acid phosphates, analyze – salivary and pancreatic, determination of LDH isoenzymes.
2. Liver function tests, estimation of bilirubin total and conjugated, urobilinogen, urobilin and bile acids.
3. Gastric analysis, determination of free and total acid gastric stimulation, specimen collection.
4. Accuracy, precision and quality control. Demonstration and preparation of two methods. F. test and barrettes test.
5. Collection and measurements.
6. Automation, micro and ultra micro techniques
7. Lipids determination of serumplipids, cholestrol ester, triglyccerides on lipoprotein fractionation.
8. Analysis of calculi
9. Estimation of calcium, phosphorous and iron.

MAHARANI LAKSHMI AMMANNI COLLEGE FOR WOMEN Autonomous

DEPARTMENT OF MANAGEMENT STUDIES

CERTIFICATE COURSE IN FRENCH

SYLLABUS

Objective: To familiarize an international language and create avenues for better job and education opportunities.

Course Outcome: The course provides students with language proficiency, critical thinking and collaboration for job and education avenues.

Total Number Of Hours	Hours/Week	Internal Assessment Marks	End Semester Exam	Total Marks
50 Hours	2	50	50	100

Unit-1: Introduction to French language, its importance and role in business communication 2Hrs

Unit- 2: French alphabets and its pronunciations 2Hrs

Unit-3: Accents and orthographic signs. 2Hrs

Unit-4: Articles 2Hrs

Unit-5: Rules to form the plural, feminine. 2Hrs

Unit-6: Adjectives 2Hrs

Unit-7: Verbs: Irregular, regular, reflexive 2Hrs

Unit-8: Formation of Negative, Interrogative 2Hrs

Unit-9: Preposition 2Hrs

Unit -10: Conjunction 2Hrs

Unit-11: Numbers: cardinal and ordinal 2Hrs

Unit- 12: Days of the week, months of the year, seasons 2Hrs

Mid Term Exam 2Hrs

Unit-13: How to say Time 2Hrs

Unit-14: Adverbs 2Hrs

Unit-15: Pronouns 2Hrs

Unit-16: Compound verbs: the past tense, the future, the imperfect etc.	2Hrs
Unit-17: Comparative and Superlative degree	2Hrs
Unit-18: Short essay writing	2Hrs
Unit-19: Letter writing	2Hrs
Unit-20: Post card writing	2Hrs
Unit-21: Comprehension.	2Hrs
Unit-22: Simple translation from English to French and vice versa	2Hrs
Unit-23: Reading and conversation	2Hrs
Final Exam	2Hrs

Prescribed book:

COURS DE LANGUE ET DE CIVILISATION FRANÇAISES (Book-1) ALONG WITH C.D: ***G. MAUGER***

Microsoft Office Specialist

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NICT COMPUTER EDUCATION

Excel: Core Data Analysis, Manipulation, & Presentation; Learn - Practice - Certify

NICT COMPUTER EDUCATION

ADVANCED EXCEL

Objective: To understand how to customize the Excel workspace, the best practices for designing and managing worksheets and to perform statistical analysis.

Course Outcome: To familiarize students with data analysis and manipulation, sharing and collaborating information using Excel tools and techniques.

Total Number Of Hours	Hours/Week	Internal Assessment Marks	End Semester Exam	Total Marks
24 hours	2	30	70	100

Create Worksheets and Workbooks

1.1.1Create a workbook.

1.1.2 Import data from a delimited text file.

1.1.3 Add a worksheet to an existing workbook.

1.1.4 Copy and move a worksheet.

Navigate in Worksheets and Workbooks

1.2.1 Search for data within a workbook.

1.2.2 Navigate to a named cell, range, or workbook element.

1.2.3 Insert and remove hyperlinks.

Format Worksheets and Workbooks

1.3.1 Change worksheet tab color.

1.3.2 Rename a worksheet.

1.3.3 Change worksheet order.

1.3.4 Modify page setup.

1.3.5 Insert and delete columns or rows.

1.3.6 Change workbook themes.

1.3.7 Adjust row height and column width.

1.3.8 Insert headers and footers.

Customize Options and Views for Worksheets and Workbooks

1.4.1 Hide or unhide worksheets.

1.4.2 Hide or unhide columns and rows.

1.4.3 Customize the Quick Access toolbar.

1.4.4 Change workbook views.

1.4.5 Change window views.

1.4.6 Modify document properties.

1.4.7 Change magnification by using zoom tools.

1.4.8 Display formulas.

Configure Worksheets and Workbooks for Distribution

1.5.1 Set a print area.

1.5.2 Save workbooks in alternative file formats.

1.5.3 Print all or part of a workbook.

1.5.4 Set print scaling.

1.5.5 Display repeating row and column titles on multipage worksheets.

1.5.6 Inspect a workbook for hidden properties or personal information.

1.5.7 Inspect a workbook for accessibility issues.

1.5.8 Inspect a workbook for compatibility issues.

Insert Data in Cells and Ranges

2.1.1 Replace data.

2.1.2 Cut, copy, or paste data.

2.1.3 Paste data by using special paste options.

2.1.4 Fill cells by using Auto Fill.

2.1.5 Insert and delete cells.

Format Cells and Ranges

2.2.1 Merge cells.

2.2.2 Modify cell alignment and indentation.

2.2.3 Format cells by using Format Painter.

2.2.4 Wrap text within cells.

2.2.5 Apply number formats.

2.2.6 Apply cell formats.

2.2.7 Apply cell styles.

Summarize and Organize Data

2.3.1 Insert sparklines.

2.3.2 Outline data.

2.3.3 Insert subtotals.

2.3.4 Apply conditional formatting.

Create and Manage Tables

3.1.1 Create an Excel table from a cell range.

3.1.2 Convert a table to a cell range.

3.1.3 Add or remove table rows and columns.

Manage Table Styles and Options

3.2.1 Apply styles to tables.

3.2.2 Configure table style options.

3.2.3 Insert total rows.

Filter and Sort a table

3.3.1 Filter records.

3.3.2 Sort data by multiple columns.

3.3.3 Change sort order.

3.3.4 Remove duplicate records.

Summarize Data by using Functions

4.1.1 Insert references.

4.1.2 Perform calculations by using the SUM function.

4.1.3 Perform calculations by using MIN and MAX functions.

4.1.4 Perform calculations by using the COUNT function.

4.1.5 Perform calculations by using the AVERAGE function.

Perform Conditional Operations by using Functions

4.2.1 Perform logical operations by using the IF function.

4.2.2 Perform logical operations by using the SUMIF function.

4.2.3 Perform logical operations by using the AVERAGEIF function.

4.2.4 Perform statistical operations by using the COUNTIF function.

Format and Modify Text by using Functions

4.3.1 Format text by using RIGHT, LEFT, and MID functions.

4.3.2 Format text by using UPPER, LOWER, and PROPER functions.

4.3.3 Format text by using the CONCATENATE function.

Create Charts

5.1.1 Create a new chart.

5.1.2 Add additional data series.

5.1.3 Switch between rows and columns in source data.

5.1.4 Analyze data by using Quick Analysis.

Format Charts

5.2.1 Resize charts.

5.2.2 Add and modify chart elements.

5.2.3 Apply chart layouts and styles.

5.2.4 Move charts to a chart sheet.

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Insert and Format Objects

5.3.1 Insert text boxes and shapes.

5.3.2 Insert images.

5.3.3 Modify object properties.

5.3.4 Add alternative text to objects for accessibility.

Advanced Excel Expert Excel

Manage Workbook Options & Settings

1.1 Manage Workbooks.

1.2 Manage Workbook Review.

Apply Custom Data Formats & Layouts

2.1 Apply Custom Data Formats & Validation.

2.2 Apply Advanced Conditional Formatting & Filtering.

2.3 Create & Modify Custom Workbook Elements.

2.4 Prepare a Workbook for Internationalization.

Create Advanced Formulas

3.1 Apply Functions in Formulas.

3.2 Look up Data by using Functions.

3.3 Apply Advanced Date & Time Functions.

3.4 Perform Data Analysis & Business Intelligence.

3.5 Troubleshoot Formulas.

3.6 Define Named Ranges & Objects.

Create Advanced Charts & Tables

4.1 Create Advanced Charts.

4.2 Create & Manage Pivot Tables.

4.3 Create & Manage Pivot Charts.

4.4 Macros & Advance concepts of Macros.

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BANGALORE UNIVERSITY

CREATIVITY AND INNOVATION

B.Com/BBA/BHM/5 years Integrated Course in Commerce for VI Semester under Mrudukousalya.

Max Marks: 100 **Max time: 42 hrs.**

Objectives

1. To give an insight into creativity and innovation
2. To develop an appreciation for them among students, and
3. To enhance sensitivity to creativity and innovation

Module 1: Overview of Creativity — 10 Hours

Meaning and concept of creativity - Creativity Process- Nature and characteristics of creativity – Factors affecting creativity – understanding creativity from studying the profiles of most creative personalities.

Module 2: innovation Management — 20 Hours

Meaning and Importance – Difference with Creativity, Invention and Discovery – Process – Typology – Case Studies on Innovation business ideas like Red bus, Flip fart, Ola, Big Basket, methods and techniques – organizational Aspects – Economic Aspects like venture capital, angel investors – Evaluation of Effectiveness of Innovation – Legal Aspects like IPR, patent etc.

Pedagogy

The pedagogy needs to explore the following

- Videos on You tube
- Case studies
- Interaction with creative persons and Innovators
- Demonstration by students.

Module 3: Creativity and various Forms of Arts — 12 Hours

Understanding the forms and characteristics of Various Painting Traditions (cave paintings, Ajanta murals, Indian miniatures, Traditional & Folk Arts), Sculpture (Indian sculpture & Temple architecture), contemporary Art forms – Art & Architecture (Photography, Films, Graphic Animation and Digital Art), Performing Arts (Music, Dance and Theatre), and Poetry & Literature with examples.

References Books

- Vinnie Jauhari& Sudhanshu Bhushan, "Innovation Management". Oxford University Press,2014
- SholmoMaital, DVR Seshadri, "Innovation Management", Response Books 2007
- Indian Art by Partha Mitter
- Art of India pre-history to present by Frederick M. Asher
- Contemporary Indian Art and other realities by Yashodara Dalmia

Websites

- www.redbus.in
- www.olacabs.com
- www.flipkart.com
- www.bigbasket.com
- Performing Arts- Wikipedia
- Digital Art- Wikipedia
- Graphics and Animation - Wikipedia
- Browse Wikipedia as and when necessary

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4.7 PRINCIPLES OF EVENT MANAGEMENT

OBJECTIVE:
The objective is to provide students with a conceptual framework of Event Management, Event Services, Conducting Event and Managing Public Relations.

Unit: 1- INTRODUCTION TO EVENT MANAGEMENT **12 Hrs**
Event- Meaning- Why Event Management- Analysis of Event, Scope of Event, Decision Makers- Event Manager Technical Staff- Establishing of Policies & Procedure- Developing Record Keeping Systems.

Unit: 2-EVENT MANAGEMENT PROCEDURE **12 Hrs**
Principles for holding an Event, General Details, Permissions- Policies, Government and Local Authorities, - Phonographic Performance License, Utilities- Five Bridge Ambulance Catering, Electricity, Water Taxes Applicable.

Unit: 3-CONDUCT OF AN EVENT. **12 Hrs**
Preparing a Planning Schedule, Organizing Tables, Assigning Responsibility, Communication and Budget of Event- Checklist, Computer aided Event Management– Roles & Responsibilities of Event Managers for Different Events.

Unit: 4-PUBLIC RELATIONS **10 Hrs**
Introductions to Public Relations- Concept- Nature- Importance- Limitations- Media- Types of Media- Media Management, Public Relation Strategy & Planning. Brain Storming Sessions- Writings for Public Relations.

Unit: 5 CORPORATE EVENTS **10 Hrs**
Planning of Corporate Event, Job Responsibility of Corporate Events Organizer, Arrangements, Budgeting, Safety of Guests and Participants, Creating Blue Print, Need for Entertainment in Corporate Events And Reporting.

Skill Development

1. Preparation of Event Plan for Wedding, Annual general body Meeting of an MNC.
2. Preparing Budget for conduct of National level intercollegiate sports events.
3. Preparation of Event Plan for College day Celebrations
4. Preparation of Budget for Conducting inter collegiate Commerce Fest.

Book References

1. Event Entertainment and Production – Author: Mark Sonderm CSEP Publisher: Wiley & Sons, Inc.
2. Ghouse Basha – Advertising & Media Mgt, VBH.
3. Anne Stephen – Event Management, HPH.
4. K. Venkataramana, Event Management, SHBP.
5. Special Event Production – Doug Matthews – ISBN 978-0-7506-8523-8
6. The Complete Guide to successful Event Planning – Shannon Kilkenny
7. Human Resource Management for Events – Lynn Van der Wagen (Author)
8. Successful Team Manageemnt (Paperback) – Nick Hayed (Author)
9. Event Management & Public Relations by Savita Mohan – Enkay Publishing House
10. Event Management & Public Relations By Swarup K. Goyal – Adhyayan Publisher - 2009

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NON-CORE: V SEMESTER BCA - SOFTWARE TESTING

SYLLABUS

Unit 1: Introduction to Software Testing

Definition, Importance, Types of Software Testing, Testing Principles, Software Development Life Cycle, Software Testing Life Cycle, SDLC vs STLC, V Model of Testing

Unit 2: Types of Testing

Manual Testing, Automated Testing, Unit Testing, Integrated Testing, System Testing, Smoke and Sanity Testing, Regression Testing, Non-Functional Testing

Unit 3: Test Case Development

Test Scenario, Test Case Specifications, Test Case Design, Test Case Management Tools, Test Basis, Traceability Matrix, Types of Traceability Matrix, Creation of Test Data

Unit 4: Software Testing Techniques

Software Testing Techniques with Examples, Equivalence Partitioning & Boundary Value Analysis, Decision Table Testing, State Transition Diagram, Use Case Testing

Unit 5: Test Management Control

Estimation, Project Team, Test Plan, Test Deliverables, Project Monitoring, Test Report, Issue Management, Software Quality Assurance, Defect Management, Risk Management, Software Testing Metrics

Skills developed:

1. Software development lifecycle management skills
2. Testing tools and techniques
3. Project Management
4. Test Planning and Documentation
5. Test case development
6. Software Quality Assurance
7. Risk Management
8. Testing metrics
9. Defect Tracking
10. Automation
11. Professional Ethics and Code of conduct

Entrepreneurship Development

1. Training on Software Testing tools for Manual Testing
2. Training on Software Testing tools for Automation Testing

Employment Opportunities

1. Software Test Engineer
2. Automation Test Engineer

CLINICAL RESEARCH AND DATA MANAGEMENT

Syllabus of the theory papers

CDMT-01 -Preclinical and Clinical Research

Total Hours: 52

Unit – I **10 hours**

Drug Discovery process and Drug designing: Overview of Drug discovery process, Cost of Drug development, Protein Structure Prediction: Comparative and Homology modeling, The Critical Assessment of protein Structure Prediction (CASP), Superposition of proteins using different tools, RMSD, Presentation of protein conformations, Hydrophobicity factor, Shape complementary. Molecular Docking Studies: Structure-based De Novo Ligand design, Drug Discovery – QSAR, Different types of docking approaches (Structure-based, Ligand-based), Mode of interaction studies, Pharmacophore prediction based on the docking analysis.

Unit – II **13 hours**

Preclinical studies: Preclinical drug development, Guidelines for animal studies , Types of Pre-clinical trials, Pharmacokinetics: Overview, Routes of Drug Administration, Absorption (Bioavailability, Active and Passive Diffusion), Distribution (Modes of Distribution), Metabolism (First Pass Effect, Second Pass Effect, Half Life of Drugs, Biotransformation, Importance of CYP families in Metabolism), Excretion (Clearance Rate, Modes of Excretion) and Pharmacodynamics (PD): Receptor Activation, Commonly Targeted Receptors, Signaling Mechanism and Drug Action, Dose Response Curve, Action of Agonist and Antagonist, Efficacy and Toxicity (LD 50, ED 50)

Unit – III **07 hours**

Human Anatomy and Physiology: Introduction to Human anatomy and Physiology and related disorders: Integumentary system, Muscular system, Skeletal system, Circulatory system, Nervous system, Lymphatic system, Respiratory system , Digestive system and Endocrine system.

Unit – IV **09 hours**

Clinical research: Scope of Clinical Research, Good Clinical Practices (GCP), History of clinical research, Nuremberg code, Belmonte report, Thalidomide disaster, Types of clinical trials, clinical trials Phases, Special Clinical Trials, Medical Devices Trials, Un-anticipated risk in clinical research. Investigator Brochure, Informed Consent Form, Sponsor Monitor and Investigator responsibility, SOP in Clinical Trials, Clinical Trial Monitoring, Role of CRA, QA and QC in Clinical Trials, CRF Design.

Unit – V **10 hours**

Study Population and Design: Overview of study design, Issues on generalization. Practical aspects: recruitment (case method example). Selection of the Questions, Types of questions, adverse

effects.Study design:Natural history, frequent errors. Types of studies: Experimental, uncontrolled, RCTs, other designs – equivalence, non-inferiority, observational, retrospective, sample size, bias and confounding. Experimental Design - issues of uncontrolled studies: before and after comparison in a single group, temporal variation of disease, staff, equipment and environment, , learning and psychological effect.. Experimental Design – Randomized Clinical Trials: parallel-group design, stratified parallel group design, parallel group randomized block design, complete cross-over design, simultaneous treatments design, factorial design. Types of randomization: simple , blocked, stratified and Adaptive, Blindness:– unblinded, Single Blind, Double-blind and Triple blind trials, .Dichotomous response variables, Sample size: sample size for repeated measures, equivalency of interventional studies , Estimating sample size parameters, fraud and misconduct.

Unit – VI **05 hours**

Genomics and Personalized Medicine: NGS techniques: Illumina (Solexa) sequencing, Roche 454 sequencing, Ion torrent: Proton / PGM sequencing, SOLiD sequencing, PacBio sequencing and Fourth generation sequencing, Purpose of DNA and RNA sequencing, Cost and speed of each platform; discussions on relative extent of uses, advantages and applications of sequencing in personalized in medicine and Biomarker development.

References

1. A.R.Leach, Molecular Modelling Principles and Application, Longman, 1996.
2. J.M.Haile, Molecular Dynamics Simulation Elementary Methods, John Wiley and Sons,1997.
3. Satya Prakash Gupta, QSAR and Molecular Modeling, Springer - Anamaya Publishers,2008
4. Laurence Brunton, Bruce A Chabner, BjornKnollman (12th Edition): Pharmacological Basis of Therapeutics.
5. Laurence Brunton, Bruce A Chabner, BjornKnollman (2nd Edition): Goodman and Gilman Manual of Pharmacology and Therapeutics
6. Gregory Bock, Dalia Cohen, Jamie Goode, Novartis and J. Craig Venter (2001) From Genome to Therapy: Integrating New Technologies with Drug Development - No. 229.
7. Susanna Wu-Pong, YongyutRojanasakul, and Joseph Robinson (2006): Biopharmaceutical Drug Design and Development.
8. Herbert A Kirst, Wu-KuangYeh, Milton J (2001): Enzyme technologies for pharmaceutical and biotechnological applications.
9. Xinkun Wang, Next-Generation Sequencing Data Analysis

CDMT-02: CLINICAL DATA MANAGEMENT

Total Hours: 52

Unit I **11 hours**

Data Collection and Reporting: Recruitment of Study Participants: strategies and Sources, monitoring, problems, reasons for participation, reducing dropout rates. Participant Adherence: Considerations before participant enrolment, maintaining good participant adherence, adherence monitoring, special populations. Assessing and Reporting Adverse Events: determinants of adverse effects, reporting adverse events. Data collection and quality control: problems in data collection, minimizing poor quality data, training, pre-testing, techniques to reduce variability, data entry, quality monitoring.

Unit II **12 hours**

Clinical Research Site Management: Preparation of protocol, Audits and Inspection of Trial sites, Budgeting of Clinical trials, Multicentric Clinical Trials. Study management: Monitoring process, Coordinating protocol implementation, Internal and external reporting; Performance Measures: timesheet, clinical monitor, Clinical Trial Management. Quality Assurance and Clinical Data Management plan, Data management standardsin clinical research, and Monitoring Database audits, QA group, clinical monitoring . Data privacy, Data Capture: Optical Mark Recognition, electronic data capture, Optical Character Recognition; Data validation, Data presentation, data storage and archival, Handling missing data: imputations and challenges, adjusting for baseline variables. Good Clinical Data Management Practices, Data Management Plan, CRF designing. Serious adverse event data reconciliation,Database closure, Design and analysis of surveys, CDISC standards, Dataset preparation for analysis.

Unit III **07 hours**

Pharmacovigilance: Adverse Event Reporting System And Form, Diagnosis And Managements Of ADRs, Medical Evaluation Of AE Quality System In PV, Expedited Reporting Criteria, PSUR & PBRER, PV Database And Signal Detection,Risk Assessments & Managements.

Unit IV **11 hours**

Guidelines of Medical Coding: Introduction to Physiology and Anatomical Coding, Medical terminology, Professional guidelines for medical coding: ICD -International Classification of diseases, CPT -Current Procedural terminology, Standardization of medical terms, MedRA and other coding dictionaries.

Unit V . **11 hours**

Regulatory Affairs : Historical Perspective, Ethical Issues, ICH-GCP Guidelines I and II, Schedule Y, ICMR guidelines for biomedical research, Regulatory Issues in US, Australia, Japan and Europe (UK), Regulatory Issues in India.

REFERENCE BOOKS

1. A manager's guide to the design and conduct of clinical trials by Phillip I. Good
2. Clinical Trials: Design, Conduct and Analysis by Curtis L. Meinert
3. Clinical Trials: A Practical Guide to Design, Analysis, and Reporting By Duolao Wang, Ameet Bakhai
4. Fundamentals of Clinical Trials By Lawrence M. Friedman, Curt D. Furberg, David DeMets
5. Management of data in clinical trials by Eleanor McFadden
6. Principle and Practice of Clinical Research by John I. Gallin, Frederick P Ognibene
7. Clinical Data Management By Richard K. Rondel, Sheila A. Varley, Colin F. Webb
8. Principles and Practice of Clinical Research By John A Gallin
9. Understanding Oracle Clinical by Safari Books online

CDMT-03: BIOSTATISTICS AND DATA ANALYSIS

Total hours: 52

Unit I **18 hours**

Fundamentals of Biostatistics: Data classification, data distribution, descriptive methods for categorical data, descriptive methods for continuous data. Statistical Tests (note: only basics of statistical tests will be covered), estimation of parameters, comparison of population, proportions, comparison of population means, correlation and regression. Sample Size: dichotomous response variables (two independent samples, paired dichotomous response).Sample size for continuous response variables (two independent samples).Sample size for repeated measures, Sample size for equivalency of interventional studies, Estimating sample size parameters. Survival Analysis: Estimation of the survival curve (Kaplan-Meier estimate).Comparison of two survival curves, covariate adjusted analysis, use of survival analysis in clinical research. Other Issues in Data Analysis Poor quality or missing data, Intention-to-treat analysis, Competing events, Covariate adjustment. Other Issues in Data Analysis 2: subgroup analyses, comparison of multiple variables, use of cut points, meta-analysis of multiple studies. Probability and Normal Distributions, Estimation, Hypothesis Testing, Anova

Unit II **07 hours**

Statistics for clinical trials: Types of data in clinical trials, Computer System Validation: 21 CFR 11, CTM system, Systems Software Validation Issues: auto encoder, User Acceptance Test, SDLC; Oracle Clinical, workflow, Intelligent Character Recognition; Basic Clinical Research tools and Resources for Data Management and Analysis SAS CLINICAL: Introduction to SAS in CDM, components of SAS, Different data types, Base/SAS, SAS/STAT, SAS/GRAPH, SAS/ACCESS, SAS Procedures, SAS Macros, Brief Introduction to SQL, SAS/SQL, SAS Enterprise Guide 4.1

Unit III **13 hours**

Case Study using SAS: TLG (Tables listings and Graphs) of clinical trials in SAS, Tables in clinical trials, Screening failures, Subject disposition, Subject disposition by visits, Premature discontinuation from study medication, Subject disposition by center, Protocol deviation, Demographics and baseline characteristics, Medical and surgical history, Gynecological history, Screening Pap smear, mammography and serum pregnancy test results

Unit IV **14 hours**

NGS data analysis: Downloading the genome sequence, Quality Check & Filtering, Read assembly, Gene prediction, Gene annotation, Advance annotation and analysis, Diseases variant identification, Haplogroup identification, Binding site identification, pathway analysis.

REFERENCE BOOKS

1. Analysis of Clinical Trials Using SAS: A Practical Guide By Alex Dmitrienko, Geert Molenberghs, Christy Chuang-Stein, Walter W. Offen
2. Fundamentals of clinical trials by Lawrence M. Friedman, Curt Furberg, David L. DeMets
3. Medical Statistics: A Textbook for the Health Sciences By Michael J. Campbell, David Machin, Stephen J. Walters
4. Professional SAS Programmer's Pocket Reference by Rick Aster
5. Practical Guide to Clinical Data Management, Second Edition by Susanne Prokscha
6. support.sas.com/documentation/onlinedoc/91pdf
7. Xinkun Wang, Next-Generation Sequencing Data Analysis

CDME: Syllabus of the Elective theory papers

(Choose from any one of the following)

CDME-01- MEDICAL WRITING

Total Hours : 52

Unit I **08 hours**

Introduction & Scope- Origin of technical documentation: ICH guidelines, Basic report writing review Clarity: basic principles of clarity Communication cycle. CTD Triangle: Information on the CTDe of medical writing: The medical literature and Clinical Writing; Scope of clinical writing, Examples of Medical Writing, Required skills, Primary employers; Spectrum of jobs/engagement of clinical writers.

Unit II **10 hours**

Scientific publishing - Scientific Article: Principal parts and content, The medical literature and the scientific publication process, Title, abstract, keywords, introduction, Objectives. Material, methods, results, discussion. Technical Issues in Medical Writing: Tables: Advantages; characteristics of a good table, Figures: Types of Figures, Copyright,Permissions Citations: Referencing; citation-parts; Publication practices and authorship; Scientific Integrity, Misconduct in research; Ethics of authorship, Plagiarism and other forms of misconduct in research, In-text citation styles (APA, MLA), Mendelay and other open access software to formalize citations.

Unit III **12 hours**

Data acquisition, Basic report writing review Clarity: Managing and Sharing Data, Data ownership, Ethical and Data Acquisition Issues. Data Management Concerns, Privacy and Confidentiality. Regulatory writing: Definition of terms: laws, regulation, guidelines, Role of Regulatory Affairs in the Drug Development, The Investigational New Drug (IND) Application as the Platform for Drug Development, Regulatory Environment in India. Regulatory bodies-National and international. Selected regulations and guidance for drug studies (FDA).

Unit IV **10 hours**

Medico-Marketing Writing- Standard Operating Procedures-SOP - Developing Effective Standard Operating Procedures, How to Write Standard Operating Procedures,Writing for Biotech Industry/Pharmaceutical Industry, Pharmaceutical Marketing, Writing An Effective Case Study For A Medical Device, Advertising drugs; Legal considerations. Writing- Vetting of advertisements, Truthful presentation, Essentials for public advertising, Professional advertisement essentials. Minimum requirements.

Unit V **06 hours**

Common technical document (CTD)- India Safety Writing-Safety (MSDS)- industry perspective SAFETY NARRATIVES - Clinical Trials . Other issues: consistency, tracking, delivery Medico-Marketing Writing, Origin of technical documentation, ICH guidelines.

Unit VI **06 hours**

Interpersonal Skills: Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, importance of team work, resolution of conflicts, multi-tasking, training the team members, knowledge of project management

Reference Books

1. Clinician's Guide to Medical Writing by Robert B Taylor
2. Independent Medical Coding: The Comprehensive Guidebook for Career Success By Donna Avila-Weil, Rhonda Regan
3. The Complete Guide to Medical Writing By Mark C. Stuart
4. Dr. S.S. Khanka, Enterpreneurial development", S.Chand publications

CDME-02: SCIENTIST - CLINICAL RESEARCH & DRUG DEVELOPMENT

Total hours:52

Unit I **10 hours**

Basics of Clinical Pharmacology

Pharmacokinetics and Pharmacodynamics and its clinical applications. Rational Prescribing. Adverse Drug Effects, Toxicology and Drug Interactions.PK-PD study, significance in clinical research.BA-BE study, significance in clinical research. Route of drug administrations, advantage & disadvantages. First Human Dose, Drug Designing and Formulation.

Unit II **10 hours**

Clinical Development

Definitions & Terminologies, History in Clinical Research, Regulations and Ethics in Clinical Research.IND, NDA& ANDA processes, requirements & guidelines. Clinical trial Preparation, Clinical Research Monitoring, Patient recruitment and retention, Adverse Event and Serious Adverse Event Reporting, Agreement and Clinical Trial Budget, Error Fraud and Misconduct QA/QC,Compliance Audit and Inspection, Project and Vendor Management, Finance Management of Clinical Trials.

Unit III **10 hours**

Clinical Evaluation

Scope, Definitions, General principles of clinical evaluation, Source of data/document used in clinical evaluation (stage1), Appraisal of clinical data (Stage2), Analysis of clinical data (stage3).The Clinical Evaluation Report and the role of the notified body in assessment of clinical evaluation data-Examination of design dossier, Evaluation as part of the quality system procedure and Notified body specific procedure and expertise.

Data Science

Study Setup and CRF Designing for a clinical trial, Creating Reports and Transferring data. Clinical data analysis and reporting using software, Understanding and reviewing statistical analysis plan. Creating Analysis Datasets.

Unit IV **10 hours**

Clinical Evaluation /Reporting and documentation

Scope, Definitions, General principles of clinical evaluation, Source of data/document used in clinical evaluation (stage1), Appraisal of clinical data (Stage2), Analysis of clinical data (stage3).The Clinical Evaluation Report and the role of the notified body in assessment of clinical evaluation data-Examination of design dossier, Evaluation as part of the quality system procedure and Notified body specific procedure and expertise. Data Science - Study Setup and CRF Designing for a clinical trial, Creating Reports and Transferring data. Clinical data analysis and reporting using software, Understanding and reviewing statistical analysis plan. Creating Analysis Datasets.

Unit V **06 hours**

Safety and Security at workplace

Different types of occupational health hazards, knowledge of chemical substances, characteristics & safety measures, use of safety gears, masks, gloves & accessories, evacuation procedures for workers & visitors. Health, safety & security issues – types (illness, fire accidents), company policies and procedures, When and how to report, summon medical assistance & emergency services

Unit VI **06 hours**

Interpersonal Skills

Understand work output requirements, company rules, guidelines & policies related to the process flow, identifying and reporting issues requiring intervention, delivery of quality work on time & report any anticipated reasons for the delay, importance of team work, resolution of conflicts, multi-tasking, training the team members, knowledge of project management

References:

1. WHO expert Committee on specification for Pharmaceutical Preparation WHO-GENEVA, 2005 edition.
2. ICMR guidelines-2008, ICMR -New Delhi, 2006 edition.
3. Clinical Research Fundamental and Practice-Vishal Bansal Para Medical Publisher, 2010 edition
4.Pharmacovigilance for Beginners-Dr. S Gunasakaran and R. Salhesh Kumar Tatamani Magalir Co-operative press, 2010 edition.
5. Essentials of clinical Research-Dr. Ravindra B Ghooi amd Sachin C. Itkar Niral Prakashan 2010 edition
6. Basic methods of Medical Research, Aitbs Publishers, India, 2013 edition.
7. Clinical Research quality system manual, Nancy J Stark. 2009

Syllabus of the practical paper

CDMP01: PRECLINICAL STUDIES AND MEDICAL WRITING

1. Sketching of a molecule, preparation of small molecule, Preparation of protein and docking
2. Building a 3D structure of a protein,Pharmacophore mapping
3. Cytotoxic assay
4. Proliferation assay
5. Isolation of genomic DNA from Blood and Agarose gel Electrophoresis.
6. PCR
7. Genome sequencing
8.2D gel electrophoresis
9. Flowcytometry
10. HPLC
11. Animal Handling, Blood with drawal from rat through tail vane puncture, Blood with drawal from rat by retro-orbital puncture
12. Administration of Drugs by oral route, Intravenous injection, Intramuscular injection
13.Abstract writing ,Writing of Introduction in a manuscript ,Writing of Materials and Methods in a manuscript , Writing of Results in a manuscript, Discussion in a manuscript, Writing of conclusion in a manuscript , Referencing(endnote format)
14. Using of Microsoft word , Using of Microsoft excel(incorporating formulae, graphs)
15. SOP writing
16. Protocol writing
17. Management of open clinica
18. eCRF design
19. Randomization, study set up
20. Subject profile preparation

CDMP02: SAS AND DATA ANALYSIS

1. Introduction to SAS
2. Running SAS programs
3. Descriptive information and statistics
4. An overview of statistical tests in SAS
5. Exploring data with graphics
6. using where with SAS procedures
7. Missing values in SAS
8. SAS options
9. Overview of SAS syntax of SAS procedures
10. Common error messages in SAS
11. Inputting raw data into SAS
12. Reading dates into SAS and using date variables
13. Creating and recoding variables
14. Using SAS functions for making/recoding variables
15. Subsetting variables and observations
16. Labeling data, variables and values
17. Using Proc Sort and the BY statement
18. SAS Functions
19. Gene annotation
20. Pathway analysis.