ख्वाजा मुईनुद्दीन चिश्ती भाषा विश्वविद्यालय, लखनऊ, उत्तर प्रदेश (भारत)
Khwaja Moinuddin Chishti Language University, Lucknow, U.P. (India)
U.P. STATE GOVERNMENT UNIVERSITY,
(Recognised Under Section 2(f) & 12(B) of the UGC Act, 1956 & B.Tech. Approved by (AICTE)

FACULTY OF ENGINEERING & TECHNOLOGY

KHWAJA MOINUDDIN CHISHTI LANGUAGE UNIVERSITY, LUCKNOW, UTTAR PRADESH

B.TECH. BIOTECHNOLOGY

Curriculum Structure

SECOND YEAR
(III & IV Semesters)

SEMESTER- III

Subject – Biostatistics

Course Outcome (CO): -	
CO 1:	Students will be able to solve Problems in Engineering domain related to Measures of Central tendency and Dispersion.
CO 2:	Students will be able to analyse and solve problems related to Correlation and Regression and Chi-Square Test, T-Test.
CO 3:	Students will be able to analyse and solve problems related to ANOVA and Statistical Quality control Chart.
CO 4:	Students will be able to learn principles of experimental design & types of statistical quality control.

Course Content:

Unit I

Data and classification: Data type, Classification and summarization of data, Diagrams and graphs, Measures of central tendency, Measures of dispersion, Moments, Skewness, Kurtosis.

Unit II

Probability and Distributions: Definitions of probability, Additive law of probability, Conditional probability, Multiplicative law of probability, Binomial distribution, Poisson distribution, Normal distribution.

Unit III

Correlation, Regression and Tests: Correlation, Karl Prearson's coefficient of correlation, Rank Correlation, Lines of regression.

Unit IV

Tests of Hypothesis and ANOVA: Hypothesis tests, Student's t-test, Chi-square test, F-test, One way and two-way analysis of variance.

Unit V

Design and Quality control: Principles of experimental design and analysis, completely randomized design, Randomized block design, Latin square design, Statistical quality control, Types of quality control, Control chart for variables, Control chart for attributes.

Text Books:

1. S.P Gupta, Statistical Methods, Sultan Chand and Sons Publishers.
2. Georgr W. and William G., Statistical Methods, IBH Publication.
3. Ipsen J et al., Introduction to Biostatistics, Harper and Row Publication.
4. BS Grewal, Higher Engineering Mathematics, Khanna Publisher, 2005.
3. PSS Sundar Rao, An Introduction to Biostatistics, Prentice Hall.
4. Zar J, Biostatistics, Prentice Hall, London.

Subject – Analytical Techniques

Course Outcome (CO): -	
CO 1:	Master various light spectroscopy and microscopy techniques, including fluorescence, confocal, and atomic force microscopy for detailed analysis of biological samples.
CO 2:	Apply chromatography methods, such as HPLC, GC, and ion-exchange, along with ultracentrifugation and electrophoresis for effective separation and analysis of biomolecules.
CO 3:	Utilize advanced spectroscopy techniques like NMR, X-ray crystallography, and mass spectrometry for structural and compositional analysis of proteins and metabolites.
CO 4:	Employ PCR, real-time PCR, and other high-throughput techniques, including SPR and BLI, for detailed transcriptomic, proteomic, and metabolomic analyses.

Course Content:

Unit 1: Light spectroscopy and Microscopy-Absorption, IR, Scattering (Raman and Rayleigh), Resonance Raman, Fluorescence (steady-state and time resolved), Confocal microscopy, multi-photon microscopy, Atomic Force Microscopy.

Unit 2: Chromatography-Ion-Exchange, Affinity, Hydrophobic, Size exclusion, FPLC, HPLC, GC. Ultracentrifugation, Electrophoresis.

Unit 3: Solution- and solid-state NMR spectroscopy, X-ray crystallography, Mass spectroscopy-MALDI, LC-MS, GC-MS, MS-MS, MALDI-Mass imaging.

Unit 4: Proteomics, MS and NMR based Metabolomics, DNA and RNA sequencing for genomics.

Unit 5: PCR for transcriptomic, Real time PCR, Droplet PCR, Calorimetry, Surface Plasmon Resonance (SPR), Bio-layer interferometry (BLI), High content screening.

Practical

1. Measurement of IR and Raman spectra of small molecules
2. Measurement of excitation and emission spectra of a fluorophore and their wavelengths for maximum excitation and emission
3. Purification of a compound from a mixture using HPLC

4. Protein purification using affinity, ion-exchange and gel filtration chromatography
5. Analysis of NMR spectra and structure determination of a bio-active compound like cyclosporine.
6. Analysis of SPR and ITC data and calculation of binding affinities.
7. Demonstration of analysis of genomics data.

Text Books/References:

1. Biophysical Chemistry, Vol II by Charles R. Canter and Paul R. Shimmel.
2. Protein Purification: Principles and Practice by Robert K. Scopes (Narosa).
3. Principles of Fluorescence Spectroscopy by Joseph R. Lakowicz.
4. Infrared Spectroscopy Fundamentals and Applications by Barbar Stuart.
5. Raman Spectroscopy for Chemical Analysis by RICHARD L. McCREERY.
6. NMR spectroscopy by Harald Gunther (John Wiley).
7. Mass Spectrometry Basics by Christopher G. Herbert and Robert W. Johnstone.
8. Chromatographic methods by A Braithwaite and F. J. Smith (Kluwer Academic Publishers).

Subject – Biochemistry

Course Outcome (CO): -	
CO 1:	Understand the role of biological buffers, pH, and amino acid properties in biochemistry, including the pK and pI values of proteins.
CO 2:	Analyze peptide bonds, protein structures, stability, and folding, and apply protein methodology to study native protein structures.
CO 3:	Explore enzyme kinetics, nucleic acids, lipids, membranes, and carbohydrates to grasp their biochemical functions and interactions.
CO 4:	Learn about metabolic pathways, including glucose metabolism, the citric acid cycle, and integration of metabolism, along with the biochemical basis of diseases like diabetes.

Course Content:

Unit 1: Introduction to biological buffers and its importance in biochemistry, pH, water, basics of amino acids, pK and pI values of amino acids, pK values of the ionizable groups of proteins.

Unit 2: Peptide bond, peptide, protein structures, protein stability and folding, native structure of protein, protein methodology.

Unit 3: Enzymes and kinetics, nucleotide, biochemistry of nucleic acids, lipids and membrane, carbohydrates

Unit 4: Introduction to metabolism. Glucose metabolism, citric acid cycle, electron transport chain, amino acid and lipid metabolism, haemoglobins.

Unit 5: Regulation and integration of metabolic pathways and the biochemical basis of human diseases (e.g. diabetes). Biochemical techniques.

Practical

1. Estimate quality and quantity of the carbohydrates.
2. Analyse quality and quantity of the lipids.
3. Analyse quality and quantity of the DNA, RNA.
4. Estimate quality and quantity of the proteins.
5. Estimate lysozyme enzymatic activity.
6. Estimate quantity of sugar from given sample.

Text Books/References:

1. Principles of Biochemistry by David L. Nelson and Michael M. Cox
2. Biochemistry by Geoffrey Zubey
3. Biochemistry. 5th edition. Berg JM, Tymoczko JL, Stryer L. New York: W H Freeman; 2002.
4. Essentials of Glycobiology [Internet]. 3rd edition. Varki A, Cummings RD, Esko JD, et al., editors. Cold Spring Harbor (NY): Cold Spring Harbor Laboratory Press; 20152017.
5. Basic Neurochemistry: Molecular, Cellular and Medical Aspects. 6th edition. Siegel GJ, Agranoff BW, Albers RW, et al, editors. Philadelphia: Lippincott-Raven; 1999.

Subject – Microbiology

Course Outcome (CO): -	
CO 1:	Understand the historical context and significance of microbes in agriculture, health, medicine, and industry, along with prokaryotic and eukaryotic cell structures.
CO 2:	Explore microbial diversity, taxonomy, and growth, including viruses and various growth media and culture methods.
CO 3:	Analyze microbial metabolism processes, including respiration, fermentation, photosynthesis, and nitrogen fixation, to understand microbial energy and nutrient processing.
CO 4:	Apply knowledge of microbial molecular biology, genetics, and ecology to study microbial interactions, pathogenicity, and growth control in food and industrial applications.

Course Contents:

Unit 1: Introduction to Microbiology (History and Scope- Role of Microbes in agriculture, public health, medicine and industry). Organization of Prokaryotic and Eukaryotic Cell Structure and Function.

Unit 2: Diversity of the Microbial World- (Microbial Evolution, Taxonomy, Microbial Diversity), The Viruses, Microbial Nutrition and Growth (Types of growth media, Mathematical Expression of growth phases, culture methods).

Unit 3: Microbial Metabolism (Aerobic & anaerobic respiration, fermentation, Entner-Duodruffs pathway, photosynthesis, nitrogen fixation).

Unit 4: Microbial Molecular Biology and Genetics (Genome and gene structure, Replication, Expression, Regulation of gene expression (operon system), transformation conjugation and transduction)).

Unit 5: Microbial Ecology (Microbes from Marine, Freshwater and Terrestrial Environments) Microbial Interactions (Symbiotic, non-symbiotic), Pathogenic Microbes. Control of microbial growth – (Effect of heat, Sterilization, disinfectants, therapeutic agents, antimicrobial resistance). Applications in Food and Industrial Microbiology.

Practical

1. Microbial Good Lab Practices and Biosafety
2. Media preparation, sterilization and disinfection
3. Microscopic examination of different groups of microorganisms
4. Total count and viable count determination
5. Microbial simple and differential staining methods
6. Isolation of pure culture and its preservation
7. Microbial Growth Curve Determination
8. Effect of physical and chemical environment on growth
9. Biochemical tests for microbial identification
10. Antibiotic Sensitivity of Microorganisms

Text Books/References:

1. Prescott's Microbiology by Willey, Sherwood and Woolverton.
2. Brock Biology of Microorganisms by Madigan, Martinko, Stahl and Clark.
3. General Microbiology by Stanier, Ingraham, Wheelis and Painter.
4. Microbiology, M. Pelczar, E. Chan, N. Kreig, 5th ed, MGH.

Subject – Cell & Molecular Biology

Course Outcome (CO): -	
CO 1:	Analyze cell structure, organelles, and the cell cycle, including cell division and regulation, and understand cell-cell junctions and the processes of mitosis and meiosis.
CO 2:	Examine gametogenesis, fertilization, embryogenesis, and early developmental stages, focusing on morphogen gradients, differentiation, asymmetric cell division, and tissue development.
CO 3:	Study early asymmetric divisions, symmetry generation, organogenesis, metamorphosis, sex determination, and the role of apoptosis in organ development across animal and plant systems.
CO 4:	Explore morphogen gradients, axis patterning, stem cells, and model organisms to understand developmental processes and plant fertilization, seed formation, and differentiation.

Course Content:

Unit 1: Microscopy- Visualizing cells and tissues; Integrating cells into tissues (animals and plants); Structure of cell and cell organelles, Details of the cell cycle, cell division and regulation; Cell-Cell junctions; Mitosis and Meiosis.

Unit 2: Gametogenesis (plants and animals), fertilization and embryogenesis, morphogen gradients, differentiation, asymmetric cell division, cell fate and lineage determination, Developmental embryonic stages, zygotic division, incomplete division and consequences; Ecto, meso and endodermal development, neural plate and tube formation.

Unit 3: Early asymmetric division and generation of symmetry in developing embryo in animals and plants; organogenesis and morphogenesis, metamorphosis, animal life cycle, sex determination and role of apoptosis in organ development.

Unit 4: Role of morphogens and their gradient in axis patterning and determination. Concept of anteroposterior, dorso-ventral, and medio-lateral axis formation. Stem cells, pluripotency, and iPS cells. Model organisms like *Drosophila melangoster, C. elegans, G. gallus, Xenopus. Arabidoposis*, etc.

Unit 5: Introduction to plant fertilization, ovule and egg, and support cells; Root and shoot development, seed formation (monocot/dicot) and germination; flowering and nonflowering plants; Cellular differentiation and senescence; Meristematic tissue, development of root and leaf and floral tissues.

Practical

1. Understanding components of different kinds of microscopes.
2. Visualization of mitochondria, plastids, and other intracellular structures.
3. Study of the life cycle of *Drosophila melanogaster*.
4. Study of different stages of chick embryos.
5. In situ hybridization of *Drosophila* embryos to study the cellularization process.
6. Observation of developmental mutants in Drosophila and *C. elegans*
7. Study of mitosis in onion root tips
8. Totipotency: Analysis of Growth and Subculture

Text Books/References:

1. Molecular Biology of the Cell: Bruce Alberts, Alexander Johnson, Julian Lewis, Martin Raff, Keith Roberts, Peter Walte; 6th edition New York: Garland Science; 2008.
2. Cell and Molecular Biology-Concepts and Experiments; Gerald Karp et al. John Wiley; 8th edition; 2015.
3. Plant Development: The Cellular Basis (1990 edition) by R. F. Lyndon (PublisherSpringer)
4. Topics in Plant Physiology 3. Series editors M. Black and J. Chapman; Unwin Hyman Ltd, 1990.
5. Plant growth and Development: a molecular approach: DE. Fosket; Academic Press 1994.
6. Developmental Biology (12th Edition) by Michael J.F. Barresi and Scott F. Gilbert (Publisher- Sinauer Associates Inc; 2019).
7. Molecular Cell Biology. 4th edition. Lodish H, Berk A, Zipursky SL, et al. New York: W. H. Freeman; 2000.

SEMESTER IV

Subject – rDNA Technology

Course Outcome (CO): -	
CO 1:	Understand and apply recombinant DNA technology, including the use of cloning and expression vectors for genetic manipulation in bacterial hosts.
CO 2:	Utilize restriction enzymes, ligases, and PCR-based methods for DNA modification, gene identification, and amplification in recombinant DNA projects.
CO 3:	Perform restriction digestion analysis, prepare competent cells, and transform recombinant DNA into bacterial hosts for cloning and expression purposes.
CO 4:	Screen and analyze recombinant bacterial colonies through colony PCR, restriction digestion, sequencing, and evaluate the expression of recombinant DNA in appropriate hosts.

Course Content:

Unit 1: Introduction to recombinant DNA technology and its uses, Vectors: cloning, expression, and promoter less vectors, Cloning and expression of bacterial host strain.

Unit 2: Restriction enzymes, Ligase, other important DNA modifying enzymes (e.g. CIAP) and their use in recombinant DNA technology. Tools for gene Identification and Isolation including PCR based methods. Amplification of DNA using PCR.

Unit 3: Selection of restriction sites (Restriction digestion analysis of target DNA) for cloning of an amplified DNA into selected vector (cloning/expression), Preparation of bacterial competent cells, Transformation of ligated (recombinant) DNA in selected host (e.g. Bacterial host).

Unit 4: Screening of recombinant bacterial colonies using colony PCR, restriction digestion analysis of the recombinant DNA, sequencing of the recombinant DNA and expression of the recombinant DNA (expression construct) into a suitable host.

Unit 5: Purification and selected characterization (spectroscopic) of the purified recombinant proteins. Discuss possible troubleshoots. Genomic and cDNA library Site directed mutagenesis RNA isolation and RT-PCR.

Practical

1. Preparation of competent cells.
2. Transformation of the selected plasmid (high copy number).
3. Isolation of the plasmid from bacterial culture (alkali lysis methods).

4. Restriction digestion of the plasmids and analysis using DNA gel and extraction of plasmid DNA from the gel using glass wool methods.
5. PCR amplification and ligation
6. Selection of transformed E. coli and validation of cloning
7. RNA isolation and RT PCR and their analysis.

Text Books/References:

1. Principles of Gene Manipulation and Genomics, Primrose & Twyman.
2. Winnacker, Ernst L. (1987). From genes to clones: introduction to gene technology [Gene und Klone] (in German), Horst Ibelgaufts (trans.), Weinheim, New York: VCH, ISBN 0-89573-614-4.
3. Modern Genetic Analysis. Griffiths AJF, Gelbart WM, Miller JH, et al. New York: W. H. Freeman; 1999.
4. Molecular Cloning - Sambrook Russel - Vol. 1, 2, 3.
5. Molecular Biology of the Cell. 4th edition. Alberts B, Johnson A, Lewis J, et al. New York: Garland Science; 2002.

Subject – Good Manufacturing and Laboratory Practice

Course Outcome (CO): -	
CO 1:	Apply Good Manufacturing and Laboratory Practices (GLP and GMP) and understand their role in regulatory approval, ethical considerations, and quality control in pharmaceutical manufacturing.
CO 2:	Navigate ICH guidelines, national and international regulatory authorities, and pharmaceutical laws to ensure compliance in product design and development.
CO 3:	Implement Quality by Design (QBD) principles and Design of Experiment (DOE) methodologies in biotech product development to enhance process efficiency and product quality.
CO 4:	Analyze case studies and simulations to understand the drug development and approval process, including clinical studies, GMP, formulation, production management, and marketing.

Course Content:

Unit 1: Introduction to Good Manufacturing and Laboratory Practice, Requirement of GLP and GMP compliance for regulatory approval, Ethics in manufacturing and control.

Unit 2: Introduction to ICH guidelines and their usage, National and international regulatory authorities and their function, Pharmaceutical Jurisprudence and Laws related to Product design.

Unit 3: Principles of quality by design (QBD) Introduction to the concept of Design of Experiment (DOE) Application of QBD principles in Biotech product development.

Unit 4: Case studies: Example of QBD and DOE in Process Development, Example of DOE in analytical development.

Unit 5: Drug Development & Approval Process, Regulation of Clinical and Preclinical Studies, Good Manufacturing Practices, Formulation Production Management, Authorization and marketing of drugs. Computer simulation on process design.

Practical

1. Standard Operating Procedures.
2. Preparation of Standard Solution and Buffers.
3. Demo and Maintenance of Internal and External Audit.
4. Calibration of Instruments: PH meter, colorimeter, spectrophotometer, water bath, Distillation assembly, Burette, Pipette etc.
5. Use of Microsoft word, Excel. (For Data entry, calculation and graphical representation).

Text Books/References:

1. cGMP starter guide: Principles in Good Manufacturing Practices for Beginners, Emmet P. Tobin, Createspace Independent Publishing Platform, April 2016.
2. Good Manufacturing Practices for Pharmaceuticals: GMP in Practice, B Cooper, Createspace Independent Publishing Platform, July 2017.
3. Sarwar Beg and Md Saquib Hasnain, Pharmaceutical Quality by design: Principles and application, Academic press, March 2019.
4. Ron S. Kenett, Shelemyahu Zacks, Daniele Amberti, Modern Industrial Statistics: with applications in R, MINITAB and JMP, 2nd Edition, Wiley, January 2014.
5. N Politis S, Colombo P, Colombo G, M Rekkas D.Design of experiments (DoE) in pharmaceutical development, Drug Dev Ind Pharm. 2017 Jun;43(6):889-901. doi: 10.1080/03639045.2017.1291672.
6. Andrew Teasdale, David Elder, Raymond W. Nims, ICH quality guidelines- An implementation guide, Dec 2017.
7. Gajendra Singh, Gaurav Agarwal an Vipul Gupta, Drug regulatory affairs, CBS publication, 2005.

8. Marc P. Mathieu, New Drug Development: A regulatory overview, Nov 2000.

Subject – Immunology & Immuno-technology

Course Outcome (CO): -	
CO 1:	Identify and describe immune cell types, lymphoid organs, and the mechanisms of humoral and cell-mediated immunity, including pro-inflammatory and anti-inflammatory cytokines.
CO 2:	Explain the components and processes of the innate and adaptive immune systems, including antibody structure, diversity generation, and major histocompatibility complex.
CO 3:	Understand antigen presentation, B and T cell maturation and activation, and the roles of T cell subtypes and co-stimulatory molecules in immune responses.
CO 4:	Apply immunological techniques for diagnostics and research, including ELISA, flow cytometry, and immuno-blotting, and explore advanced topics like antibody design, vaccine production, and immunotherapy.

Course Content:

Unit 1: Immune cell types, Hematopoiesis, B and T lymphocytes, NK cells, Lymphoid organs (primary and secondary), Features of introduction to inflammation, Humoral immunity/Cell-mediated immunity, Pro-inflammatory and anti-inflammatory cytokines.

Unit 2: Innate Immune system, cell polarization/activation (classical/alternate), Adaptive immune system, Antibody structure, Generation of antibody diversity , (Somatic hyper mutation), Major histocompatibility complex.

Unit 3: Antigen presentation, APCs, Germinal center, Plasma Cells, BCR signaling, B-cell maturation/activation, T-cell development, negative/positive selection, TCR rearrangement, co-stimulatory molecules. T cell subtypes: Th1, Th2, Th17, Tregs etc.

Unit 4: Vaccines, memory B and T cell responses, active immunization, passive immunization. Immunity without infection (autoimmunity, hypersensitivity, host vs graft reaction). Immune checkpoints: PD1, CTLA4, TIM3 etc. Design of recombinant antibodies, Commercial production of polyclonal and monoclonal antibodies, Antibodies in diagnostics, Immuno-therapy in cancer, checkpoint therapy, Vaccine production, Plant immunology.

Unit 5: Immunological techniques: Immuno-diffusion assay, ELISA, Immuno-blotting, ELISPOT assay, Immuno-Histochemistry, Flow Cytometry, FACS sorting, Immuno-precipitation.

Practical

1. Western blotting
2. Isolation and microscopic visualization of T-cells and B-cells
3. Use a commercially available immune diagnostic strip tests
4. Immuno-precipitation of a protein from cell lysate using antibody
5. Determination of binding affinity of antigen-antibody complex
6. Demonstration of ELISA
7. Demonstration of FACS

Text Books/References:

1. Kuby Immunology by Thomas J. Kindt, Barbara A. Osborne, Richard Goldsby.
2. Principles of Microbiology and Immunology by Harper and Row.
3. Introduction to Medical Immunology by Gabriel Virella.