

MGM INSTITUTE OF HEALTH SCIENCES

Accredited by NAAC with 'A' Grade (Deemed University u/s 3 of UGC Act, 1956) Sector-01, Kamothe, Navi Mumbai - 410 209 Tel 022-27432471, 022-27432994, Fax 022 - 27431094 E-mail : registrar@mgmuhs.com ; Website : www.mgmuhs.com

# CHOICE BASED CREDIT SYSTEM (CBCS)

(With effect from 2018-19 Batches)

Curriculum for M.Sc. Allied Health Sciences M.Sc. Molecular Biology

Dr. Shashank D. Dalvi Vice Chancellor MGM Institute of Health Sciences Navi Mumbai - 410209

Approved in BOM – 53/2018, Resolution No. 4.5.3, dated 19/05/2018and amended upto BOM-57/2019, Dated 26/04/2019

### DIRECTOR'S MESSAGE

Dear Students,

Greetings!!!!!

I take this opportunity to welcome you on behalf of MGM family to the Masters Degree at MGM School of Biomedical Sciences (MGM SBS).

MGM School of Biomedical Sciences (MGM SBS) established in the year 2007, the MGM School of Biomedical Sciences envisaged building a progressive learning community and is committed to pursuit of excellence in higher education, total development of personality and shaping the students into sensitive, self-reliant citizens of the country imbued with the ideals of secularism and a scientific aptitude. We set global standards to make our students scientifically as well as ethically stronger. The college adopts the national qualification frame work for the post-graduate programs which has adopted Credit Base Choice System (CBCS) so that, we construct a value based system of education that encourages critical thinking and creativity, a research platform as opposed to rote learning.

The P.G (M.Sc.) courses offered are; Medical Anatomy, Medical Physiology, Medical Biochemistry, Medical Microbiology, Medical Pharmacology, Biotechnology, Genetics, Molecular Biology, Masters in Hospital administration and Biostatistics, M.Sc. Cardiac Care Technology, M.Sc. Medical Radiology and Imaging Technology, M. Optometry. Over time, the program has evolved, to meet the challenges of the ever changing field of biomedical education system.

With Best Wishes,

Director MGM School of Biomedical Sciences

### ABOUT MGM SCHOOL OF BIOMEDICAL SCIENCES

#### Mission

To improve the quality of life, both at individual and community levels by imparting quality medical education to tomorrow's doctors and medical scientists and by advancing knowledge in all fields of health sciences though meaningful and ethical research.

### Vision

By the year 2020, MGM Institute of Health Sciences aims to be top-ranking Centre of Excellence in Medical Education and Research. Students graduating from the Institute will have the required skills to deliver quality health care to all sections of the society with compassion and benevolence, without prejudice or discrimination, at an affordable cost. As a research Centre, it shall focus on finding better, safer and affordable ways of diagnosing, treating and preventing diseases. In doing so, it will maintain the highest ethical standards.

### About – School of Biomedical Sciences

MGM School of Biomedical Sciences is formed under the aegis of MGM IHS with the vision of offering basic Allied Science and Medical courses for students who aspire to pursue their career in the Allied Health Sciences, teaching as well as research.

School of Biomedical Sciences is dedicated to the providing the highest quality education in basic medical sciences by offering a dynamic study environment with well equipped labs. The school encompasses 21 courses each with its own distinct, specialized body of knowledge and skill. This includes 7 UG courses and 14 PG courses. The college at its growing years started with mere 100 students has recorded exponential growth and is now a full-fledged educational and research institution with the student strength reaching approximately 581 at present.

Our consistent theme throughout is to encourage students to become engaged, be active learners and to promote medical research so that ultimately they acquire knowledge, skills, and understanding so as to provide well qualified and trained professionals in Allied Health Sciences to improve the quality of life.

As there is increased need to deliver high quality, timely and easily accessible patient care system the collaborative efforts among physicians, nurses and allied health providers become ever more essential for an effective patient care. Thus the role of allied health professionals in ever-evolving medical system is very important in providing high-quality patient care.

Last but by no means least, School of Biomedical Sciences envisions to continuously grow and reform. Reformations are essential to any growing institution as it fulfills our bold aspirations of providing the best for the students, for us to serve long into the future and to get ourselves updated to changing and evolving trends in the health care systems

#### **INTRODUCTION**

To keep pace with the worldwide education and research scenario in the field of biological science, MGM Institute of Health Sciences has started M.Sc. Molecular Biology course which is designed to enrich the students with wide knowledge and understanding of the advance techniques in molecular biology and its applications. The primary objective of this program is to provide job oriented and research driven education.

#### VISION

- Academic excellence & development of excellent intellectual system for rich technology talent pool
- Research & development driven education
- Student involvement inresearch projects
- Advance education and training

#### MISSION

• Generation of research& technology talent pool in the area of molecular biology

#### SALIENT FEATURES

- Very strong infrastructure e.g. classroom, conference and seminar room well equipped library, computer and internet facility, hostel, hospital, hygienic canteen etc.
- Excellent teaching staff highly experienced faculty, expert and professionals from various organizations.
- Support from state of the art MGMIHS OMICS Research Center: A highly equipped laboratory for advanced life sciences - proteomics, genomics computational biology etc. (This centre is providing unique and exploratory platform for discovery research).
- Frequent guest lecturers (by external faculty)/seminar/symposium/ workshops.
- Opportunity for students for their involvement in major research projects of institute.
- Provision of project work on applied aspects of molecular biology and opportunity to implement their novel ideas in research.

### NAME OF THE DEGREE

Master of Science in Molecular Biology: M.Sc. (Molecular Biology)

#### **OBJECTIVES**

The students of M.sc. Molecular Biology course (2 years) should be able to

- Deep knowledge and understanding of molecular biology and its applications
- Understand key implications of proteomics, Genomics and related aspects.
- Research driven education
- Read and analyze the primary research literature, critically assess scientific experiments and evaluate the impact of a scientific discovery.
- Be primed and able to conduct quality research in latest molecular biology based research topics.

#### **ADMISSION REQUIREMENTS**

- Citizenship: Indian nationals can apply under the General category. Foreign nationals or NRI or Indian nationals supported by NRI relatives can apply under the Foreign/NRI category.
- Qualification: Candidates with 50% marks in B.Sc. Molecular Biology/ Biotechnology/ Microbiology/ / Biochemistry/Genetics /Botany/Zoology /B.Sc. Nursing/MBBS/BDS) or any equivalent degree in life sciences of any recognized university.
- Total Seats=20

### **DURATION OF STUDY**

The duration of the study for M.Sc. Molecular Biology will be of four semesters spread over two years.

#### Program pattern

- First Semester: July
- Second Semester: January
- Third Semester: July
- Fourth Semester: January

	Se	emester I				
Syllabus Ref. No.	Subject	Credits	Teaching hours	Ν	Marks	
	Theory			Internal Assessment	Semester Exam	Total
MB 101 T	Cell Biology	4	4	20	80	100
MB 102 T	Molecular Immunology	4	4	20	80	100
MB 103 T	Molecular Enzymology	4	4	20	80	100
MB 104 T	Metabolic Engineering	4	4	20	80	100
	Practical					
MB 101 P	Cell Biology	2	4	10	40	50
MB 102 P	Molecular Immunology	2	4	10	40	50
MB 103 P	Molecular Enzymology	2	4	10	40	50
MB 104 P	Metabolic Engineering	2	4	10	40	50
	Total	24	32	120	480	600

	Semeste	r II				
Syllabus Ref. No.	Subject	Credits	Teaching hours	Ι	Marks	
	Theory			Internal Assessment	Semester Exam	Total
MB105 T	Gene and Protein Science	4	4	20	80	100
MB106 T	Bioinformatics & Computational biology	4	4	20	80	100
MB 107 T	DNA Recombinant Technology	4	4	20	80	100
CC 001 T	Research Methodology and Biostatistics (Core Course)	4	4	20	80	100
	Practical					
MB 105 P	Gene and Protein Science	2	4	10	40	50
MB 106 P	Bioinformatics & Computational biology	2	4	10	40	50
MB 107 P	DNA Recombinant Technology	2	4	10	40	50
CC 001 P	Research Methodology and Biostatistics (Core Course)	2	4	10	40	50
	Total	24	32	120	480	600

	Sen	nester III				
Syllabus Ref. No.	Subject	Credits	Teaching hours	Γ	Marks	
	Theory			Internal Assessment	Semester Exam	Total
MB 108 T	Genomics	4	4	20	80	100
MB 109 T	Proteomics	4	4	20	80	100
	Core Elective course**	4	4	20	80	100
MB 110 T	Nanobiotechnology					
MB 111 T	Molecular Diagnostics					
MB 112 T	Drug discovery					
MB 113	Dissertation/Project Proposal*	6	12	50	-	50
	Practical					
MB 108 P	Genomics	2	4	10	40	50
MB 109 P	Proteomics	2	4	10	40	50
MB110 P MB111 P MB112 P	Core Elective Practical Nanobiotechnology Molecular diagnostics Drug discovery	1	2	10	40	50
MB 114	Seminar*	1	2	50	0	50
	Total	24	36	190	360	550

	Sen	nester IV				
Syllabus Ref. No.	Subject	Credits	Teaching hours	I	Marks	
	Theory			Internal Assessment	Semester Exam	Total
**	General Elective	4	4	100	-	100
GE 001 T	Analytical Instrumentation					
GE002 T	Bioethics, Biosafety, IPR & Technology transfer					
GE003 T	Quality Assurance & Quality Control					
MB 113	Dissertation / Project*	18	36	50	200	200
	Practical					
MB 115 P	Educational Tour / Field Work/Industrial Visit/Hospital Visit*	2	0	50	-	50
	Total	24	40	200	200	400

### \*(a) *Dissertation / Project* Course commences in III Semester

(b) *Educational Tours / Field Works/Hospital Visit/Industrial Visit* Course may be carried out in any Semester or all Semestersbut evaluated and Grade Points are to be added in 4<sup>th</sup> Semester.

(Elective): Any one subject is to be chosen from the following (Subjects offered may change from time to time depending on the availability of expertise)

\*\*Elective courses may or may not have practical and/or field work.

▲ Multidisciplinary / Interdisciplinary

#### EDUCATIONAL/INDUSTRIAL TOUR:

Industrial visit has its own importance in building a career of a student which is pursuing a professional degree. Objections of industrial visit are to provide students an insight regarding internal working of reputed hospitals and labs. Industrial visits provides students an opportunity to learn practically thoughts interactions, working methods and employment practices as theoretical knowledge is not enough for making a competent and skilful professionals.

# **M.Sc. MOLECULAR BIOLOGY**

# **SEMESTER I**

### MB 101T: CELL BIOLOGY (THEORY) -60hrs

UNIT	ΤΟΡΙΟ
1	Overview of Cell biology Universal features of cells Diversity of genomes Visualization of cell, its fine structure and molecules
2	The cell membrane and its structure Transport across membrane, Ion channels Receptor mediated endocytosis
3	Cellular components and function, protein sorting Vesicular traffic inside the cells Mitochondria and chloroplast and its genetic system
4	Cell signaling, receptor, ligands, signaling pathways Signal transduction mechanisms Cytoskeleton of cells, cytoskeleton filaments, molecular motors
5	Cell cycle, regulation of cell division, cell cycle checkpoints. Cell division- Mitosis, meiosis and the mechanism of cell division
6	Germ cells, Stem cells, Cancer cells
7	Apoptosis: Mechanism, Pathways, Markers

### Reference Books:

- 1. Cell and Molecular biology, Gerald Karp, John Wiley and sons Inc.
- 2. Cell Biology by C.B. Powar.
- 3. Cell and Molecular Biology; DeRobertis; Lippincott Williams & Wilkins 8tEdition (2001).
- 4. Molecular Biology of the Cell and the Hypercell with CDROM; Alberts, Bray; Garland Publishing 1<sup>st</sup> Edition (1999).

5. Molecular Biology of the Cell with CDROM Alberts, Bruce; Johnson, Alexander; Lewis, Julian 4th Edition (2005).

6. Molecular Cell Biology, H. Lodish, A. Berk, S. L. Zipursky, W. H. Preeman and Company.

### MB 102T: MOLECULAR IMMUNOLOGY(THEORY) - 60 hrs

UNIT	TOPIC
1	The origin of immunology: Innate and acquired immunity; humoral and cell mediated immunity. Primary and secondary lymphoid organ: antigen, B cell, T cell subsets and macrophages.
2	Molecular basis of Immunology: Structure of antibody, Molecular basis of antibody diversity, polyclonal and monoclonal antibody, complement, antigen-antibody reactions.
3	Major Histocompatibility complex (MHC): Class I & II antigens their functions
4	Immune response and tolerance: Regulation of immune response, immune tolerance; hyper sensitivity, autoimmunity;
5	Immunity to Infection : Bacteria, viral, fungal and parasitic infections (with examples from each group); Hypersensitivity Type I-IV; Autoimmunity; Types of autoimmune diseases; Mechanism and role of CD4+ T cells; MHC and TCR in autoimmunity;
6	Immunological basis of graft rejection; Clinical transplantation and immunosuppressive therapy; Tumor immunology
7	Primary immunodeficiency, Acquired or secondary immune deficiencies, immune modulators and immune enhancers
8	Antibody engineering

- 1. Immunology, An introduction by Ian R Tzard, Thomson publisher.
- 2. Immunology, Gordan Reeve and Ian Todd.
- 3. Essential Immunology: Ivan Roitt.
- 4. Kuby, Immunology: Gold by, Kindt and Osborne.
- 5. Immunology: Roitt, Brostoff, Mole.
- 6. Introductory Immunology : Huw Davies

# MB 103T: MOLECULAR ENZYMOLOGY(THEORY)-60 hrs

UNIT	TOPIC			
1	Classification and nomenclature of enzyme, Extracellular and intracellular enzyme, Inducible and			
	constitutive enzyme, properties of enzymes as catalytic power, enzyme specificity, cofactors,			
	isoenzymes, multi enzyme complex and multi functional enzyme.			
2	Enzyme techniques- enzyme assays, analysis of enzyme assays, Expression of the enzyme			
	activity (International Unit), specific activity of enzyme, Coupled reaction, Isolation and			
	purification of enzyme, concept of fold purification and yield, Importance of pure enzymes,			
	chemical modification of enzyme, molecular techniques in enzymes, immobilization of enzymes.			
3	Factors affecting the rate of enzymes catalyzed reactions, Study of enzyme kinetics, Plots for			
	enzyme kinetics: Michelis-Menten, Lineweaver-Burke plot and Eddie Hofstee plot. Use of initial			
	velocity, Determination of rate constant for enzyme catalyzed reactions, inhibition and exchange			
	studies to differentiate between multi substrate reaction mechanisms. Methods of examining			
	enzyme-complex, Use of substrate analogs, kinetics of various types of inhibitionand kinetics of			
	enzyme inhibition.			
4	Allosteric enzymes, sigmodial kinetics (Cooperativity phenomenon. Hill and Scatchard plots) and			
	their physiological significance. Symmetric and sequential modes for action of allosteric enzymes			
	and their significance. K class and V class allosteric enzymes.			
5	Active site of enzymes: Basic concept, conformation of active site, mapping of active site by			
	different methods. Lysozyme and chyrnotrypsin as models.			
6	Enzyme engineering: Basic concept for designing a new enzyme in reference to therapeutic			
	enzyme, Immobilization of enzymes, designer enzymes, biosensor enzymes, enzyme			
	crystallization and X-ray crystallography, Flexibility & conformational mobility of enzymes.			
7	Clinical Enzymology: End point and kinetic methods for determination of enzyme activity, SI			
	units. Application of $K_m$ to Diagnostic enzymology serum enzymes in health and disease,			
	Isoenzymes.			

### Reference Books:

- 1. Biochemistry- Stryer, Berg, 6thEdition, W.H.Freeman and Co., 2007.
- 2. Lehninger' Principles of biochemistry-Nelson, Cox, 4<sup>th</sup>Edn., W.H.Freeman and Co., 2005.
- 3. Harper's Principles of Biochemistry-Murray, Gardener, Mayes, Rodwell, 27<sup>th</sup>
  - N Edn. McGraw Hill Education, 2006.
- 4. Biochemistry-Zubay; G, 3rdEdn. Pearson Education P.Ltd, 2003.
- 5. Fundamentals of Enzymology by Nicholas Price, Oxford University Press.
- 6. Enzyme Structure and Mechanism byAlan Fersht, W. H. Freeman.

7.Enzymes: Biochemistry, Biotechnology, Clinical Chemistry by Trevor Palmer, Horwood Publishing.

8. Enzyme Assays: A Practical Approach by Michael J. Danson, Oxford University Press

# MB 104 T: METABOLIC ENGINEERING(THEORY)-60 hrs

UNIT	TOPIC
1	Introduction to metabolic engineering, Coordination of metabolic reactions: Feedback inhibition, Multigene networks, methods for metabolic characterization: Genome, Transcriptome, Proteome, Metabolome, Fluxome.
2	Different model of cellular reaction, Stochiometry of cellular reactions, Reaction rates, Dynamic mass balance.
	Regulation of metabolic pathways: Regulation of Enzymatic Activity, Regulation of Enzyme concentration, metabolic pathway manipulation.
3	Metabolic flux analysis: Over determined and undetermined systems, Sensitivity analysis, Metabolite Balancing, Tracer Experiments, MS and NMR in labelling measurement, Applications of metabolic flux analysis.
4	Metabolic control analysis (MCA): Determination of Flux control coefficients, MCA of Linear and Branched pathways.
	Metabolic design: Gene amplification, Gene-disruption, Randomized and targeted strain development.
5	Metabolic Engineering in Practice: Actual examples from research and industrial biotechnology

# Reference Books:

1. Metabolic Engineering: Principles and Methodologies byGregory N. Stephanopoulos, Aristos Aristidou , Jens C. O. Nielsen.

2.Pathway Analysis and Optimization in Metabolic Engineering byByNéstor V. Torres By Eberhard O. Voit,Cambridge University Press.

# MB101P: CELL BIOLOGY (PRACTICAL) (60 Hrs.)

1	Microscopy:
	i. Simple, Compound, inverted and fluorescence
	ii. Cell count using haemocytometer
	iii. WBC- Differential counting
	iv. RBC- Osmotic fragility
	v. Preparation of microbial, animal and plant cells for microscopic examination & staining by
	Giemsa
2	Genetic apparatus:
	i. Cell viability assay
	ii. Mitosis & meiosis
3	Buccal smear of exfoliated epithelial cells
4	Osmosis, exosmosis and endosmosis
5	Fixation of cells & different fixatives
6	Dremanation of monomulan colla
6	Preparation of mononuclear cells

# MB 102P: MOLECULAR IMMUNOLOGY (PRACTICAL) (60 Hrs.)

1	Practical based on antigen – antibody interactions -
	Widal,
	VDRL,
	Blood grouping,
	CRP,
	Titre determination.
2	Radial Immunodiffusion, double diffusion
3	Immuno electrophoresis.

# MB103 P: MOLECULAR ENZYMOLOGY (PRACTICAL) (60 Hrs.)

1	$K_m$ and $V_{max}$ value of Transaminase and Amylase.
2	Determination of K cat
3	Determination of specific activity
4	Enzyme purification by gel chromatography
5	Enzyme immobilization
6	Rapid zymogram of enzyme.

# MB 104 P: METABOLIC ENGINEERING (PRACTICAL) (60 Hrs.)

1	Modulation of metabolic enzyme
2	Statin inhibition of HMG CoA reductase& its interpretation
3	Modification of metabolic network
4	Demonstration of cell signalling

# SEMESTER II

#### MB105 T:GENE AND PROTEIN SCIENCE(THEORY)-60hrs

UNIT	TOPIC	
1	The biochemical basis of inheritance, DNA as the genetic material, concept of gene organization, diversity of genomes.	
2	Denaturation and renaturation of DNA, T <sub>m</sub> , and complexity of DNA& Cot curves.	
3	Centraldogma, Genetic code, Gene expression – concept of operon and related elements in the unit, regulatory and structural gene.	
4	Extra chromosomal DNA and its functions, DNA isolation and estimation.	
5	Protein chemistry, amino acid composition, solubility of proteins, Isoelectric pH and proteomes.	
6	Protein Structure, Overview: Primary,Secondary, Tertiary and Quarternary structure, Primary structure Peptide bond conformation – Ramchandran Plot, Secondary Structure- Importance of alpha helix in protein structure & stability. Beta sheet structures in different proteins,Bonds& forces involved in tertiary and quarternary structure Contribution of tertiary and quarternary structures to protein architecture (Fibrous & Globular proteins, silk fibroin, Myoglobin, lysozyme), Protein motifs and their contribution to Protein architecture	
7	Protein denaturation and folding, Role of molecular chaperones	
8	Basic of protein estimation, isolation, purification special reference to various chromatographic methods and characterization	

### Reference Books:

- 1. Molecular Biology; David Freifelder, Narosa Publishing House, 2<sup>nd</sup>edition (2004).
- 2. Principles of Gene Manipulations; S. B. Primrose, R. M. Twyman, R. W. old, Blackwell Science, 6<sup>th</sup>Edition (2003).
- 3. Gene IX; Benjamin Lewin; Oxford Univ. Press, 8<sup>th</sup>edition (2004).
- 4. Advanced Molecular Biology; R. M. Twyman, 1\*Edition, (2003).
- Instant Notes on Molecular Biology; P.C. Turner, A. G. Mclennan, A. D. Bates & M. R. H. White, 2<sup>nd</sup>Edition (2002)

6. Structure and Mechanism in Protein Science: A Guide to Enzyme Catalysis and Protein Folding by Alan Fersht.

- 7. Lehninger' Principles of biochemistry-Nelson, Cox, 4th Edn., W.H.Freeman and Co., 2005.
- 8. Harper's Principles of Biochemistry-Murray, Gardener, Mayes, Rodwell, 27th N Edn.McGraw Hill Education, 2006.
- 9. Biochemistry-Zubay; G, 3rdEdn. Pearson Education P.Ltd, 2003.

### MB106 T: BIOINFORMATICS & COMPUTATIONAL BIOLOGY (THEORY)- 60 hrs

UNIT	ТОРІС	
1	Introduction to Genomic data and Data Organization: Sequence Data Banks – Introduction to sequence date banks –Protein sequence data bank. NBFR-PIR, SWISSPROT, Signal peptide data bank, Nucleic acid sequence data bank –GenBank, EMBL nucleotide sequence data bank, AIDS virus sequence data bank, Structural databanks – protein Data Bank (PDB), The Cambridge Structural Database (CSD) : Genome data bank – Metabolic pathway data : Microbial and Cellular Data Banks.	
2	Sequence analysis: Analysis Tools for Sequence Data Banks; Pair wise alignment - NEEDLEMAN and Wunsch algorithm, Smith Waterman, BLAST, FASTA algorithms to analyze sequence data: Sequence patterns motifs and profiles.	
3	Secondary Structure prediction (Proteins)s; prediction algorithms; Chao-Fasman algorithm, Hidden-Markov model, Neural Networking. Tertiary Structure predictions; prediction algorithms; Chao-Fasman algorithm, Hidden-Markov model, Neural Networking	
4	Cluster analysis; Phylogenetic clustering by simple matching coefficients; Sequence Comparison; Sequencepattern; Regular expression based pattern; Theory of profiles and their use in sequence analysis; Markovmodels; Concept of HMMS; Baum-Welch algorithm; Use of profile HMM for protein family classification;Pattern recognition methods, Neighbor Joining	
5	Applications in Biotechnology: Primer Designing, Phylogenetic Tree Analysis with Mammalian and Bacterial 9-10 specific genes, development of specific case studies	
6	Protein classifications, Fold libraries, Protein structure prediction: Fold recognition (threading), Protein structure predictions: Comparative modeling (Homology), Advanced topics: Protein folding, Protein ligand interactions, Molecular Modeling & Dynamics, Drug Designing	
7	Goals of a Microarray experiment; Normalization of Microarray data; Detecting differential gene expression;Principal component analysis; Clustering of microarray data; Structure determination by X-raycrystallography; NMR spectroscopy; PDB (Protein Data Bank) and NDB (Nucleic Acid Data Bank); Fileformats for storage and dissemination of molecular structure	
8	Probabilistic models and machine learning: Gene annotation and evolution	
9	Horizons-The Future: Protein Structure, The Future: Haplotype Mapping	

### Reference Books:

- 1. Introduction to Bioinformatics Teresa Atwood and David J.Parry, Pearson smith publication (2003).
- 2. Sequence structure and Database Des Higgins, Willice Taylor, Oxford press (2003).
- 3. Bioinformatics: Sequence and Genome analysis by David W. Mount CBS Publishers & Distributors, 2004 reprint.
- 4. Discovering Genomics, Proteomics and Bioinformatics, Campbell, ISBN: 788131715598, Pearson Education.
- 5. Bioinformatics: Databases, Tools, and Algorithms, OrpitaBosu, Simminder Kaur,

Thukral, ISBN: 9780195676839, Oxford University Press.

### MB107 T: DNA RECOMBINANT TECHNOLOGY(THEORY)-60 hrs

UNIT	TOPIC	
1	Introduction to recombinant DNA technology : Past, Present and future	
2	Vectors in DNA recombinant technology, Bacteriophage derived vectors in recombinant DNA, Lambda vectors, cosmids, Phagemids/M13 vectors, Yeast vectors.	
3	Enzymes used in DNA recombinant Technology, RE, DNA polymerases, Reverse Transcriptase, Polynucleotide Kinase, Terminal Transferase, Alkaline Phosphatase, S1-Nuclease, Bal-31, DNA Ligase.	
4	Introduction to cloning, Overview of Cloning, Purification and Separation of Nucleic Acids – cutting and joining DNA and vectors Design of Cloning and expression vectors, The construction of cDNA and genomic libraries, The labeling of DNA with radionucleotides, The screening of libraries: Oligonucleotide, cDNA and antibody probes	
5	Transformation and Transfect ion Membrane Fusion, Electroporation Gene-Gun and Micro- injection	
6	Restriction mapping; Chromosome walking and chromosomal localization of genes, RFLP and other uses of cloned sequences, micro cloning; DNA fingerprinting	
7	Restriction modification systems in Bacteria; F factor and conjugation, Transformation; Viruses: Generalized and Specialized transduction	
8	Recombinant DNA products applications: Insulin, antigen vaccine, growth hormones	

- 1. Essential molecular biology by T. A. Brown, Oxford university press.
- 2. Recombinant DNA: Watson et. al.
- 3. Molecular Biology Lab fax I & II: T. A. Brown.
- 4. Gene Cloning and DNA analysis: An introduction, (2006) 5/e. T. A. Brown,Black Well Publishing Company.
- 5. Principles of Gene Manipulation; S. B. Primrose, R. M. Twyman& R. W. old;Blackwell Science, 6<sup>th</sup>Edition (2001).
- 6. Molecular Cloning lab manual; Joseph Sambrook, David W. Russell, cold SpringHarbor Laboratory Press, 3<sup>rd</sup>Edition (2001)

# CC 001 T: BIOSTATISTICS & RESEARCH METHODOLOGY(THEORY)-60 hrs

Teaching Objective	The course is intended to give an overview of research and statistical models commonly used in medical and bio-medical sciences. The goal is to impart an intuitive understanding and working knowledge of research designs and statistical analysis. The strategy would be to simplify, analyse the treatment of statistical inference and to focus primarily on how to specify and interpret the outcome of research.
Learning Outcomes Student will be able to understand statistical models, research design the understating of background theory of various commonly used st techniques as well as analysis interpretation & reporting of results of statistical software.	

Sr. No.	Topics	Hrs. Alloted 60 Hrs.
А	Research Methodology:	
1	Scientific Methods of Research: Definition of Research, Assumptions, Operations and Aims of Scientific Research. Research Process, Significance and Criteria of Good Research, Research Methods versus Methodology, Different Steps in Writing Report, Technique of Interpretation, Precaution in interpretation, Significance of Report Writing, Layout of the Research Report	
2	Research Designs: Observational Studies: Descriptive, explanatory, and exploratory, Experimental Studies: Pre-test design, post-test design, Follow-up or longitudinal design, Cohort Studies, Case Control Studies, Cross sectional studies, Intervention studies, Panel Studies.	
3	Sampling Designs: Census and Sample Survey, Implications of a Sample Design, Steps in Sampling Design Criteria of Selecting a Sampling Procedure, Characteristics of a Good Sample Design, Different Types of Sample Designs (Probability sampling and non probability sampling), How to Select a Random Sample?, Systematic sampling, Stratified sampling, Cluster sampling, Area sampling, Multi-stage sampling, Sampling with probability proportional to size, Sequential sampling.	
4	Measurement in research: Measurement Scales, Sources of Error in Measurement, Tests of Sound Measurement, Technique of Developing Measurement Tools, Scaling Meaning of Scaling, Scale Classification Bases, Important Scaling Techniques, Scale Construction Techniques, Possible sources of error in measurement, Tests of sound measurement	5
5	Methods of Data Collection: Types of data, Collection of Primary Data, Observation Method, Interview Method, Collection of Primary Data	
6	Sampling Fundamentals : Need and importance for Sampling, Central LimitTheorem, Sampling Theory, Concept of Standard Error, Estimation, Estimatingthe Population Mean Estimating Population Proportion, Sample Size and itsDetermination, Determination of Sample Size through the Approach Based on	

	Precision Rate and Confidence Level.	
В	Biostatistics	
7	Data Presentation: Types of numerical data: Nominal, Ordinal, Ranked, Discrete and continuous. Tables: Frequency distributions, Relative frequency, Graph: Bar charts, Histograms, Frequency polygons, one way scatter plots, Box plots, two way scatter plots, line graphs	
8	Measures of Central Tendency and Dispersion: Mean, Median, Mode Range, Inter quartile range, variance and Standard Deviation, Coefficient of variation, grouped mean and grouped standard deviation (including merits and demerits).	3
9	Testing of Hypotheses: Definition, Basic Concepts, Procedure for HypothesisTesting, Measuring the Power of a Hypothesis Test, Normal distribution, datatransformation Important Parametric Tests, Hypothesis Testing of Means,Hypothesis Testing for Differences between Means, Hypothesis Testing forComparing Two Related Samples, Hypothesis Testing of Proportions,Hypothesis Testing for Difference between Proportions, Hypothesis Testing forComparing a Variance to Some Hypothesized Population Variance, Testing theEquality of Variances of Two Normal Populations.	6
10	Chi-square Test: Chi-square as a Non-parametric Test, Conditions for the Application Chi-square test, Steps Involved in Applying Chi-square Test, Alternative Formula, Yates' Correction, and Coefficient by Contingency.	2
11	Measures of Relationship: Need and meaning, Correlation and Simple Regression Analysis	2
12	Analysis of Variance and Covariance: Analysis of Variance (ANOVA):Concept and technique of ANOVA, One-way ANOVA, Two-way ANOVA, ANOVA in Latin-Square Design Analysis of Co-variance (ANOCOVA), ANOCOVA Technique.	4
13	Nonparametric or Distribution-free Tests: Important Nonparametric or Distribution-free Test Sign test, Wilcoxon signed-Rank Test, Wilcoxon Rank Sum Test: Mann-Whitney U test Kruskal Walli's test, Friedman's test, and Spearman Correlation test.	3
14	Vital Health Statistics: Measurement of Population: rate, crude rate, specific rate, Measurement of fertility: specific fertility rate, Total fertility rate, Reproduction rate, Gross Reproduction Rate, Net Reproduction Rate, Measures related to mortality: Crude Death Rate (CDR), Age-specific death Rate, Infant and child mortality rate, Measures related to morbidity.	4
15	Computer Application Use of Computer in data analysis and research, Use of Software and Statistical package. Introduction to SPSS. Importing data from excel, access, tab and comma separated files. Entering data, labeling a variable, coding and recoding a categorical and continuous variable. Converting data from string to numeric variables, sorting & filtering, merging, appending data sets. Frequencies, descriptive statistics, cross tabulations. Diagrammatic presentation include histogram, bar chart, pie chart, scatter diagram, box plot, line chart. Parametric test of hypothesis-one sample, Independent and paired sample t test, one way	3

ANOVA& post HOC test. Testing for normality, Chi-square test with measures	
of association. Pearson correlation. Non parametric test.	

### MB 105 P: GENE AND PROTEIN SCIENCE (PRACTICAL) (60 Hrs.)

1	DNA isolation, Spectrophotometric assessment of purity (260 : 280 ratio)
2	Tm of DNA,
3	Electrophoresis of DNA, DNA damage study
4	Protein isolation, estimation and preservation
5	Dialysis of protein, Molecular weight determination of proteins by SDS PAGE
6	Protein characterization

#### MB 106 P: BIOINFORMATICS & COMPUTATIONAL BIOLOGY (PRACTICAL) (60 Hrs.)

1	Study of structure of proteins using PDB, PROSITE, CATH, SCOP
2	Multiple alignment and Phylogenetic tree
3	Compare DNA/ Protein sequences using BLAST
	- Orthologs
	- Paralogs/ Homologs
4	Find the motifs in DNA sequences
5	Understanding structure function using of KEGG database
6	Docking studies using Argus Lab.
7	Programmes related to graphics and animation, RASMOL, MOLMOL, MX VRML etc.

Note: Any 5 Practical from each subject is mandatory.

# MB107 P: DNA RECOMBINANT TECHNOLOGY (PRACTICAL) (60 Hrs.)

1	Extraction of genomic DNA
2	Restriction digestion
3	DNA Ligation
4	Bacterial transformation
	- Plasmid extraction & electrophoresis
5	Bacterial conjugation

### C 001 P:BIOSTATISTICS & RESEARCH METHODOLOGY (PRACTICAL) (60 Hrs.)

Sr. No.	Topics	Hours allotted 60hrs
A	Research Methodology	
1	Sampling Designs	4 hrs
2	Measurement in research	5 hrs
3	Methods of Data Collection	3 hrs
4	Sampling Fundamentals	3 hrs
B	Biostatistics	
5	Data Presentation	4 hrs
6	Measures of Central Tendency and Dispersion	4 hrs
7	Testing of Hypotheses	12 hrs
8	Chi\-square Test	2 hrs
9	Measures of Relationship	3 hrs
10	Analysis of Variance and Covariance	4 hrs
11	Nonparametric or Distribution-free Tests	4 hrs
12	Vital Health Statistics: Measurement of Population	6 hrs
13	Computer Application Using Statistical Software	6 hrs

# **SEMESTER III**

### MB 108T: GENOMICS - 60 hrs

UNIT	TOPIC	
1	Introduction to genomics, Complete genomes The "omics" revolution, Early sequencing efforts, DNA sequencing technology developed.	
2	Structural genomics, Functional genomics, Epigenomics, Metagenomics, Pharmacogenomics	
3	Gene evolution and the human genome, human genome project, the content of human nuclear genome, tandemly repeated DNA, interspersed genome-wide repeats, human mitochondrial genome, genome evolution-acquisition of new genes (gene duplication, from other species, transposable elements), Non-coding DNA	
4	Mapping genomes, DNA markers for genetic mapping, physicalmapping, restrictionmapping, Fluorescent <i>in situ</i> hybridization(FISH), Sequence tagged site (STS) mapping, sequencing pipelines and databases, discovery of molecular biomarker (Northern blot, Gene expression, SAGE, DNA Microarray).	
5	Overview of regulation of genome activity, genome rearrangements, gene silencing by modification of histones and DNA, RNA in gene regulation, regulation of genome Activity During Development: Vulva development in <i>Caenorhabditiselegans</i> , Development in <i>Drosophila melanogaster</i> .	
6	Genomic medicine, synthetic biology and bioengineering	

- 1. Essential molecular biology by T. A. Brown, Oxford university press.
- 2. Molecular Biology Lab fax I & II: T. A. Brown.
- 3. Gene Cloning and DNA analysis: An introduction, (2006) 5/e. T. A. Brown, Black Well Publishing Company.
- 4. Principles of Gene Manipulation; S. B. Primrose, R. M. Twyman& R. W. old; Blackwell Science, 6<sup>th</sup> Edition (2001).
- 5. Molecular Cloning lab manual; Joseph Sambrook, David W. Russell, cold Spring Harbor Laboratory Press, 3<sup>rd</sup> Edition (2001)
- 6. Genomics: Fundamentals and applications by: SupratimChoudhuri, David B. Carlson
- 7. Introduction to Genomics Third edi.by Arthur M. Lesk

### MB 109 T: PROTEOMICS- 60 hrs

UNIT	TOPIC
1	Introduction to proteomics, Immunoproteomics, Nutriproteomics, scope of proteomics, limitations of proteomics studies.
2	Proteomes and complexity, Post-translational modificationsPhosphorylation, Ubiquitination, Structure- function relationship of proteins, protein domains within a protein with independent function, Protein bindingsites& protein subunits in large protein molecules, Effect of protein modification & cleavage eg: caspases, mammalian cytochrome C, importance of 3D- structure of proteins on its functions; eg: reverse transcriptase.
3	Protein-ligand interactions, protein binding to small molecules &ions,oxygen bindingeg: Hemoglobin, Calcium activation of troponin, modification of enzymes by binding to cofactors and coenzymes, Protein- receptor, Protein- Nucleic acid interaction, G protein receptor interaction and activation, histone binding to DNA, Prions allosteric changes in protein conformation due to ligand binding
4	Methods of studying proteins and current proteomic technologiesprotein detection with immunoassays, identifying proteins that are post-translationallymodified, mass spectrometry and protein profiling proteinchips, reverse-phased protein microarrays, Ab-microarray, Tissue – microarray.
5	Practical applications of proteomics, biomarkers, current research methodologies protein engineering, basic concepts for designing a new protein, energy status of protein molecule, protein crystallization, X-Ray Crystallography for determination of protein structure
6	Emerging trends in proteomics, Human plasma proteome, proteome informatics.

- 1. Introduction to Proteomics: Principles and Applications by Nawin C. Mishra, Günter Blobel, Wiley publisher.
- 2. Principles of Proteomics by Richard Twyman, Garland science/BIOS Scientific publisher.
- 3. Principles and techniques of biochemistry and molecular biology by Wilson and Walker, Cambridge University Press.
- 4. Tools and techniques of biotechnology, MousumiDebnath, Pointer Publishers, 1<sup>st</sup> edition.
- 5. Proteomics: Theory and Practice, Gomase VS and Chikhale NJ, Himalaya Publication House.

### **CORE ELECTIVE COURSES**

# MB110T: NANOBIOTECHNOLOGY (Theory) - 60 hrs

UNIT	ТОРІС
1	History of nanotechnology and nanobiotechnology
2	Introduction to nanoparticles, nanotoxicology and ethics of nanotechnology and nanobiotechnology
3.	Introduction to Nanotechnology and nanobiotechnology Characteristic scale for quantum phenomena, nanoparticles, nano-clusters, nanotubes, nanowires and nanodots. Nano-biointerface issues in the functionalization of devices.
4.	Various biological systems for synthesis of nanoparticles, Mechanism of synthesis of Nanoparticles in biological system. Purification of nanoparticles, Interaction between nanomaterials biological system, protein and DNA based nano structure, nanoself assembly.
5	Nanofabrication as material characterization, study of size, shape, & stability of nanoparticle, Nanolithography, X-ray, diffractions, UV-Spectrum, SEM/TEM, AFM, Scanning tunneling microscope.
6	Nanofluidics and surfaces: liquid structure near solid-liquid interfaces
7	Electro kinetic effects (electrophoresis, electro osmotic effect, electro viscous effect), surface reconstruction, dangling bonds and surface states
8	Biosensors: Nanoparticles preparation and uses in medicine.
9	Applications of Nanotechnology to Medicine and Diagnostics
10	Applications of Biosensors for diagnosis of genetic disorders, LOC (Lab on Chip)
11	Application of Nanotechnology for Cancer therapy

- 1. Nanotechnology- Basic science and emerging technologies (2005), by WillsonKannangava Smith, Simmons, Raguse, Oversease Press.
- 2. Biotechnanotechnology by David Goodsell, Wiley-Liss publisher.
- 3. Nanotechnology- Principles and practices by S. K. Kulkarni, Capital Publishing Co.

# MB 111T: MOLECULAR DIAGNOSTICS(THEORY)- 60 hrs

UNIT	TOPIC
1	Introduction: Application of Nucleic acid analysis techniques in Diagnostics
2	Size analysis of nucleic acids- Direct analysis of nucleic acids for diagnosis of Rotaviral diarrhea, HPV for cervical cancer, Dystrophin gene for muscular dystrophy.DNA probe based diagnosis of diseases, Preparation of DNA probes, labels for DNA probes, oligonucleotide probes, DNA probes assays & applications.
3	Detection of Genetic diseases.Extraction of Nucleic acid from clinical samples, Prenatal diagnosis of genetic diseases,RFLPARMS PCR for detection of mutation
4	Detection of Genetic variance.SNP detection by different methods (simple and high throughput methods) - RFLP, Taqman Assay, Mass spectroscopy, Temperature Gradient Capillary electrophoresis (TGCE)Single Stranded Conformational Polymorphism (SSCP), Multiplex PCR
5	DNA based technology in diagnosis of Cancer; Comparative Genomic Hybridization (CGH) & Human Genome Project

- 1. Fundamentals of Molecular Diagnostics byDavid E. Bruns, W.B. Saunders Company.
- Principles and techniques of biochemistry and molecular biology, Wilson and Walker, Cambridge University Press, 6<sup>th</sup> edition.
- 3. Tools and techniques of biotechnology, MousumiDebnath, Pointer Publishers, 1<sup>st</sup> edition
- 4. Molecular Diagnostics: Fundamentals, Methods and Clinical Applications byLela Buckingham.

### MB 112T: DRUG DISCOVERY (Theory) - 60 hrs

UNIT	TOPIC
1	Introduction to drug discovery, Pharmaceuticalindustry and drug development process,standard
	Drug Discovery Model, Small molecule drugs, Biologicals
2	Molecular Interactions in Proteins and Enzymes, Discovery, Innovation and Emerging
	Technologies, Examples of druggability, Issues in the pharmaceutical industry.
3	Right target, Overview on target validation, Systems Approaches in Drug
	Discovery, Chemical Genetics, Target selection and biomarkers, Protein modelling strategies.
4	The right drugs, <i>Insilico</i> drug design, Structural biology for drug design, Bioanalytical Techniques,
	High throughput screening, High content screening, Re-purposing drugs, Fragment-based drug
	design, Whole animal imaging, Gene therapy, Molecular Toxicology in Preclinical Studies.
5.	Getting drugs to market, Financing and protecting drug discovery, Designing Clinical Trials,
	Current therapeutic challenges inInfection,Cardiovascular disease, Cancer, Inflammation and
	COPD, Neurodegenerative diseases
6	Regulatory process, FDA drug regulatory process policy and economic considerations in drug
	development

### **Reference Books:**

- 1. Drug discovery and development (II edi.) by Raymond G. Hill, Humphrey P. Rang
- 2. Basic principles of drug discovery and development by: Benjamin Blass
- 3. Successful drug discovery by: Janos Fischer, David P.Rotella

# MB 113 : Dissertation & Project Proposal (Theory) \*

\*The Dissertation work will begin from 3rd Semester, and will continue through the 4th Semester.

## MB108P: GENOMICS (PRACTICAL) (60 Hrs.)

1	Endonuclease digestion of nuclei, (RFLP)
2	Western blotting
3	Elisa reader based assay
4	Polymerase Chain Reaction (PCR)
5	Demonstration on Northern & Southern blotting

# MB109P: PROTEOMICS (PRACTICAL) (60 Hrs.)

1	Protein crystallization method
2	2- D gel electrophoresis of proteins
3	Measurement of glycosylation in protein
4	Chemical modification of proteins in vitro& functional studies.
5	Immobilization of proteins.
6	Demonstration of Antibody Microarray.

# **CORE ELECTIVE COURSES (Practical)**

# MB110P: NANOBIOTECHNOLOGY (30 Hrs.)

	NANOBIOTECHNOLOGY
1	Synthesis of Nanoparticles, using biological system and others
	a. Plant mediated,
	b. Microorganism mediated
2	Purification of nanoparticle using sucrose density gradient
3	Toxicity study of silver nanoparticle
4	Effect of nanoparticles on human lymphocytes
5	Anti bacterial activity of nanoparticle

# MB111P:MOLECULAR DIAGNOSTICS (30 Hrs.)

	MOLECULAR DIAGNOSTICS
1	Demonstration on use of DNA probes for diagnosis of diseases
2	Demonstration of SNP analysis by RFLP
3	Demonstration of SNP analysis by Taqman assay.

# MB112P: DRUG DISCOVERY (30 Hrs.)

	DRUG DISCOVERY
1	Disease and Drug target identification and bioassay : Obesity, pancreatic lipase and development of natural substrate based assay for pancreatic lipase
2	Preparation of molecule and extract library : preparation of plant extracts (sequential extract) and TLC profiling
3	High throughput screening and selection: Lipase inhibition assay 96 well format system and selection
4	Druggability: IC 50 of lipase inhibitor, reversibility/irreversibility, Ki.
5	Invitro-toxicity assay: MTT

### MB114 : SEMINAR

For seminar/presentation there will be a maximum of 50marks. Seminar / presentations will be evaluated by the teachers of the dept. The marks obtained in the same will be kept confidentially with the Head of the Dept. and will be submitted along with the internal assessment marks.

# **SEMESTER IV**

### **GENERAL ELECTIVE**

#### GE 001 T:ANALYTICAL INSTRUMENTATION (60 Hrs.)

UNIT	TOPIC
1	Basic Techniques, Methods of cell disintegration; bioassays dialysis, ultra filtration and other membrane techniques.
2	Spectroscopy Techniques, UV, Visible and Raman Spectroscopy; Theory and application of Fluorescence; MS, NMR, PMR& ESR.
3	Chromatography Techniques, TLC; Chromatographic methods for macromolecule separation - Gel permeation, Ion exchange, Hydrophobic, Reverse-phase and Affinity chromatography; HPLC & HPTLC.
4	Electrophoretic Techniques, Polyacrylamide gel electrophoresis; Capillary electrophoresis; 2DElectrophoresis; Disc gel electrophoresis; Gradient electrophoresis; &Immunoelectrophoresis.
5	Centrifugation, Basic principles: RCF, Sedimentation coefficient etc; Types of centrifuge, High speed & Ultracentrifuges; Preparative centrifugation; Differential & density gradient centrifugation; Applications (Isolation of cell components); Analytical centrifugation; Determination of molecular weight by sedimentation velocity & sedimentation equilibrium methods.
6	Radioactivity, Radioactive & stable isotopes; Pattern and rate of radioactive decay; Units of radioactivity; Measurement of radioactivity; Geiger-Muller counter; Solid & Liquid scintillation counters (Basic principle, instrumentation & technique); Brief idea of radiation dosimetry; Autoradiography; Applications of isotopes: Radiotracer techniques; Isotope dilution technique; Metabolic studies; Clinical application; Radioimmunoassay.
7	Flow Cytometer

- 1. Principles and techniques of biochemistry and molecular biology by Wilson and Walker, Cambridge University Press.
- 2. Tools and techniques of biotechnology, MousumiDebnath, Pointer Publishers, 1<sup>st</sup> edition
- 3. Fundamentals of Molecular Diagnostics byDavid E. Bruns, W.B. Saunders Company.
- 4. Molecular Diagnostics: Fundamentals, Methods and Clinical Applications byLela Buckingham.
- 5. Physical biochemistry- applications to biochemistry and molecular biology, David Freifelder, Freeman and Co., 2<sup>nd</sup> edition.

# GE 002 T : BIOETHICS, BIOSAFETY, IPR & TECHNOLOGY TRANSFER (60 Hrs.)

UNIT	TOPIC
1	Introduction to bioethics -Development of an interdisciplinary field, Medical ethics, Purpose and
	scope.
2	Biosafety
	Introduction; Historical Background; Introduction to Biological Safety Cabinets; Primary
	Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms;
	Recommended Biosafety Levels for Infectious Agents and Infected Animals; Biosafety guidelines
	- Government of India; Definition of GMOs & LMOs
3	History and Evolution of IPR, basic Principles and Acquisition of Intellectual Property Rights,
	Basic Principles of Patent Law, Patent Application procedure, drafting of a Patent specification,
	understanding Copyright Law, Trade Mark, Design, Rights, International Background of
	Intellectual Property.
4	Requirement of patentable novelty, invention step and prior art, Budapest treaty, biodiversity,
	biotechnology and the Law-Objective, Structure of Gene/molecular Techniques, Commercial
	Potential of Biotech Inventions, Patenting Biotechnology Inventions-Objective, Microorganisms,
	Moral Issues in Patenting Biotechnological inventions. Traditional Knowledge, Plant Varieties
	Protection, Bio-Prospecting and Bio-Piracy, need for a Sui-Generis regime, Digital Library, Indian patent system as POST Trips effect.
5	
5	Patent Protection. Database and Data Protection-Objective, International conventions on IPR,
	WIPO Treaty, disputes under Intellectual Property Rights, Jurisdictional Issues, and Right & protection, infringement and violation, remedies against infringement, Case studies.
6	
6	Discovery and bioprocess innovation, Patent claims and rights, and patent transfer, Introduction to
	technology transfer, transfer process and law.

### Reference Books:

1.Biotechnology, Biosafety and Biodiversity bySivramiahShantharam& J.F. Montgomery

2.Intellectual property rights byNeerajPandey ,KhushdeepDharni,PHI Learning private limited

3. Intellactual property law handbookby B.L Wadehra, Universal Law publishing Co.Pvt. Ltd.

# GE003 T : QUALITY ASSURANCE & QUALITY CONTROL (60 Hrs.)

UNIT	TOPIC
1	Introduction to Quality assurance and quality control, Quality Assurance and Quality Control in pharmaceutical and healthcare industries.
2	Qualification and Validation Quality Assurance and Quality Control- Possible Problems and Fixes.
3	Types of Quality Testing (models, types, procedures etc.) Quality Testing Tools and Techniques, Quality Certifications, Govt. Regulations, ICH Guidelines and ISO 9000
4	Total Quality Management and GMP, Quality Risk Management, Assessing Quality Concerns at Different Work Units or Areas Setting up Quality Control Checks, Inspections and Audits.
5	Documentation, Good Documentation Practices, SOPs, Protocols, etc. Addressing Internal and External Quality Issues – Complying with Govt. regulations
6	Case Studies

- 1. Biotechnology operations: Principles and practices- Michael J Roy [CRC PRESS]
- 2. Biotechnology: Quality Assurance and validation Kenneth E. Avis, Carmen M Wagner, Vincent L. WD.
- 3. Quality operations procedures for pharmaceuticals API and Biotechnology Syed ImtiazHaider, Erfan Syed Asif [CRC PRESS].

### **MB113:** Dissertation/Project\*

- 1. Dissertation/Project work should be carried out as an individual Dissertation and actual bench work.
- 2. The students will carry independent project work under the supervision of the staff of Department on an advanced topic assigned to him/her. Inhouse projects are encouraged. Students may be allowed to carry out the project work in other Departmental laboratories /Research institutes /Industries as per the availability of Infrastructure.
- 3. Co guides from the other institutions may be allowed.
- 4. The Dissertation/Project work will begin from 3rd Semester, and will continue through the 4th Semester.
- 5. The Dissertation/Project report (also work book shall be presented at the time of presentation and viva voce) will be submitted at the end of the 4th Semester and evaluated.
- 6. Five copies of the project report shall be submitted to the Director, SBS.
- 7. For the conduct of the End Semester Examination and evaluation of Dissertation/Project work the University will appoint External Examiners.
- 8. Since the dissertation is by research, Dissertation/Project work carries a total of 250 marks and evaluation will be carried out by both internal and external evaluators.
- 9. The student has to defend his/her Dissertation/Project Work in a seminar which will be evaluated by a internal and external experts appointed by the University.
- 10. The assignment of marks for Project/Dissertation is as follows:

Part I-

Topic Selection, Review of Literature, Novelty of works-50 marks

Part-II-

- a. Continuous Internal Assessment, Novelty, Overall Lab Work Culture 100 Marks
- b. Dissertation/Project work book: 50 Marks
- c. Viva-Voce: 50 Marks
- d. However, a student in 4th semester will have to opt for general elective course from other related disciplines in addition to his Dissertation/Project work in the parent department.

#### **References Book**

Mentioned in each subject separately

#### MB 115 P: EDUCATIONAL TOUR /FIELD WORK/HOSPITAL VISIT /INDUSTRIAL VISIT

#### MONITORING LEARNING PROGRESS

It is essential to monitor the learning progress of each candidate through continuous appraisal and regular assessment. It not only also helps teachers to evaluate students, but also students to evaluate themselves. The monitoring be done by the staff of the department based on participation of students in various teaching / learning activities. It may be structured and assessment be done using checklists that assess various aspects. Model Checklists are attached

The learning out comes to be assessed should include:

i) **Journal Review Meeting (Journal Club):** The ability to do literature search, in depth study, presentation skills, and use of audio- visual aids are to be assessed. The assessment is made by faculty members and peers attending the meeting using a checklist (see Model Checklist – I)

ii) **Seminars / Symposia**: The topics should be assigned to the student well in advance to facilitate in depth study. The ability to do literature search, in depth study, presentation skills and use of audio- visual aids are to be assessed using a checklist (see Model Checklist-II )

iii) **Teaching skills**: Candidates should be encouraged to teach undergraduate medical students and paramedical students, if any. This performance should be based on assessment by the faculty members of the department and from feedback from the undergraduate students (See Model checklist III,)

iv) **Work diary / Log Book-** Every candidate shall maintain a work diary and record his/her participation in the training programmes conducted by the department such as journal, reviews, seminars, etc. Special mention may be made of the presentations by the candidate as well as details of experiments or laboratory procedures, if any conducted by the candidate.

v) **Records**: Records, log books and marks obtained in tests will be maintained by the Head of the Department.

# Checklist - I

# **Model Checklist for Evaluation of Journal Review Presentations**

Name of the student:

Date:\_\_\_\_\_

Name of the Faculty/ Observer:\_\_\_\_\_

S No.	Items for observation during presentation		Below average	Average	Good	Very Good
		0	1	2	3	4
1	Article chosen was					
2	Extent of understanding of scope & objectives of the paper by the candidate					
3	Whether cross- references have been consulted					
4	Whether other relevant references have been Consulted					
5	Ability to respond to questions on the paper /subject					
5	Audio-visuals aids used					
7	Ability to defend the paper					
3	Clarity of presentation					
)	Any other observation					
	Total score 34/50		I	<u> </u>		

# Checklist - II Model Checklist for Evaluation of the Seminar Presentations Name of the student:

Date:\_\_\_\_\_

Name of the Faculty/ Observer:

S No.	Items for observation during presentation		Below average	Average	Good	Very Good
		0	1	2	3	4
1	Article chosen was					
2	Extent of understanding of scope & objectives of the paper by the candidate					
3	Whether cross- references have been consulted					
4	Whether other relevant references have been Consulted					
5	Ability to respond to questions on the paper /subject					
6	Audio-visuals aids used					
7	Ability to defend the paper					
8	Clarity of presentation					
9	Any other observation					
	Total score		1	1		

# **Checklist - III** Model Checklist for Evaluation of Teaching Skill

 Name of the student:
 \_\_\_\_\_\_\_\_

 Name of the Faculty/ Observer:
 \_\_\_\_\_\_\_\_

S. No.		Strong Point	Weak point
1	Communication of the purpose of the talk		
2	Evokes audience interest in the subject		
3	The introduction		
4	The sequence of ideas		
5	The use of practical examples and /or		
	illustrations		
6	Speaking style (enjoyable, monotonous, etc.,		
	specify)		
7	Summary of the main points at the end		
8	Ask questions		
9	Answer questions asked by the audience		
10	Rapport of speaker with his audience		
11	Effectiveness of the talk		
12	Uses of AV aids appropriately		

### Checklist - IV

## **Model Check list for Dissertation / Project Work Presentations**

Name of the student:\_\_\_\_\_ Date:\_\_\_\_\_

Name of the faculty/ Observer:\_\_\_\_\_

S No.	Points to be covered		Below average	Average	Good	Very Good
		0	1	2	3	4
1	Interest shown in selecting topic					
2	Appropriate review					
3	Discussion with guide and other faculty					
4	Quality of protocol					
5	Preparation of proforma					
	Total score					

Checklist - V

# Continuous Evaluation of dissertation / project work by Guide/

### **Co-Guide**

Name of the student:\_\_\_\_\_ Date:\_\_\_\_\_

Name of the faculty/ Observer:\_\_\_\_\_

S No.	Points to be covered		Below average	Average	Good	Very Good
		0	1	2	3	4
1	Interest shown in selecting topic					
2	Appropriate review					
3	Discussion with guide and other faculty					
4	Quality of protocol					
5	Preparation of proforma					
	Total score			<u> </u>		<u> </u>

**Resolution No. 4.4.1.3 of BOM-55/2018:** Resolved to approve the revised syllabus of 'Research Methodology and Biostatistics' subject for all the PG courses (including 3 years) and to shift it in 2nd semester with effective from the batch admitted in the Academic Year 2018-19 onwards under MGM School of Biomedical Sciences. **[Annexure-13]** 



Innexu

# To compulsorily include in the BOS agenda

1 message

10/4/2018

6 September 2018 at 14:17

Registrar <registrar@mgmuhs.com> To: drravindrai@gmail.com, inamdar123456@gmail.com, ipseetamohanty@yahoo.co.in, jaishreeghanekar@gmail.com, drspravin22@gmail.com, dr\_spravin@hotmail.com, sudhirkul1979@gmail.com, marsibiotech79@gmail.com, sbsnm@mgmuhs.com, rajani.kanade@gmail.com, mgmschoolofphyslotherapy@grrail.com, prabhadasila@gmail.com, mgmnewbombaycollegeofnursing@gmail.com, gashroff2006@gmail.com, rupalgshroff@yahoo.com, manjushreeb@yahoo.com, drshobhasalve@gmail.com, spdubhashi@gmail.com, javantkarbhase@gmail.com, veenashatolkar@gmail.com, sharathcrisp@gmail.com, mgmlpth@themgmgroup.com, anuradhamhaske@hotmail.com, principalconabad@gmail.com

Cc: registrarmgmihs@gmail.com, mgmihsaurangabad@gmail.com, dr.rajeshkadam@7@gmail.com, aradmin@mgmuhs.com

Dear Sir/Madam,

Please find attached herewith request from Dr. Rita Abbi, Professor, Biostatistics regarding Modification in the syllabus of 'Research Methodology and Biostatistics' subject and Proposal to make this subject compulsory in all the PG courses. You are requested go through this and include it in your agenda for forthcoming BOS in September, 2018.

Thanks and regards,

Dr. Rajesh B. Goel

Registrar

MGM Institute of Health Sciences, Navi Mumbai

(Deemed University u/s 3 of UGC act, 1956)

3rd Floor, MGM Educational Campus,

Plot No. 1 & 2, Sector -1, Kamothe,

Navi Mumbai - 410 209

Tel.: 022 - 27432471 / 27432994

Fax: 022 - 27431094

Email: registrar@mgmuhs.com

Website: www.mgmuhs.com

Modification in the syllabus of Research Methodology and Biosta.pdf 2261K

#### MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI

(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)

(Deemed University u/s 3 of UGC Act 1956)

Grade "A" Accredited by NAAC

Sector 1, Kamothe Navi Mumbai-410209, Tel.No.:022-27437631,27432890

Email. sbsnm@mgmuhs.com / Website : www.mgmsbsnm.edu.in

7-6-2018

The Director MGM School of Biomedical Sciences Kamothe, Navi Mumbai – 410 209

Subject: Modification in the syllabus of 'Research Methodology and Biostatistics' Subject and Proposal to make this subject compulsory in all the PG courses

#### Dea: Madam,

To.

Research Methodology and Biostatistics subject is a significant tool for academic research. It has been observed that majority of post graduate courses have this subject as a part of their course work. There is a need to modify the curriculum of 'Research Methodology and Biostatistics subject' due to the following reasons:

- While going through the Research Methodology and Biostatistics syllabus it was found that in some courses more weightage was given to computer hardware e.g. History and development of computers(old pattern) which may not be needed now as we have witnessed the revolution in Information Technology. Students should be taught latest technology and software.
- 2. Secondly, in most of the syllabi 'Vital Statistic' is missing which is an important topic for healthcare field. Some of the essential topics like 'Normal distribution' etc are missing.
- 3. By streamlining the syllabus it will save teacher's teaching time, paper setting time. Moreover, Exam section need not call multiple examiners for the same subject, this will be economical for exam section.

This subject is well recognized as an essential tool in medical research, clinical decision making, and health management. It is recommended to streamline the syllabus and make Research Methodology and Biostatistics' compulsory in all the post graduate courses of School Biomedical Sciences. The modified syllabus is enclosed. This is for your kind perusal and necessary action please.

With regards,

ù

Dr. Rita Abbi Professor, Biostatistics

Copy for information to Registrar MGMIHS Navi Mumbai; Hon'ble Vice Chancellor, MGMIHS Navi Mumbai Hon'ble Medical Director, MGM Medical College

Meddaning to speak

BOS -> Faculty > Academic Commed.

**MGM Institute Of Health Sciences** INWARD NO. 5720 DATE: 2576118

# MGM INSTITUTE OF HEALTH SCIENCES

### M. Sc. Students

# Syllabus for Research Methodology and Biostatistics

		No. of	f Hours
	I. Research Methodology:	Theory	Practical
	1 Scientific Methods of Research : Definition of Research, Assumptions, Operations and Aims of Scientific Research. Research Process, Significance and Criteria of Good Research, Research Methods versus Methodology, Different Steps in Writing Report, Technique of Interpretation, Precaution in interpretation, Significance of Report Writing, Layout of the Research Report	5	
	2 Research Designs: Observational Studies: Descriptive, explanatory, and exploratory, Experimental Studies: Pre-test design, post-test design, Follow-up or longitudinal design, Cohort Studies, Case Control Studies, Cross sectional studies, Intervention studies, Panel Studies.	5	
	3 Sampling Designs : Census and Sample Survey, Implications of a Sample Design, Steps in Sampling Design Criteria of Selecting a Sampling Procedure, Characteristics of a Good Sample Design, Different Types of Sample Designs (Probability sampling and non probability sampling), How to Select a Random Sample?, Systematic sampling, Stratified sampling, Cluster sampling, Area sampling, Multi-stage sampling, Sampling with probability proportional to size, Sequential sampling.		4
	4 Measurement in research: Measurement Scales, Sources of Error in Measurement, Tests of Sound Measurement, Technique of Developing Measurement Tools, Scaling Meaning of Scaling, Scale Classification Bases, Important Scaling Techniques, Scale Construction Techniques, Possible sources of error in measurement, Tests of sound measurement	5	5
[!	5 Methods of Data Collection: Types of data, Collection of Primary Data, Observation Method, Interview Method, Collection of Primary Data	5	3
	<b>6 Sampling Fundamentals :</b> Need and importance for Sampling, Central Limit Theorem, Sampling Theory, Concept of Standard Error, Estimation, Estimating the Population Mean Estimating Population Proportion, Sample Size and its Determination, Determination of Sample Size through the Approach Based on Precision Rate and Confidence Level.		3
	II. Biostatistics		
	<b>Data Presentation</b> : Types of numerical data: Nominal, Ordinal, Ranked, Discrete and continuous. Tables: Frequency distributions, Relative frequency, Graph: Bar charts, Histograms, Frequency polygons, one way scatter plots, Box plots, two way scatter plots, line graphs		4
	<ul> <li>Measures of Central Tendency and Dispersion : Mean, Median, Mode Range, Inter quartile range, variance and Standard Deviation, Coefficient of variation, grouped mean and grouped standard deviation (including merits and demerits).</li> </ul>	3	4

	Total hours	60	60
]       	variables, sorting & filtering, merging, appending data sets. Frequencies, descriptive statistics, cross tabulations. Diagrammatic presentation include histogram, bar chart, pie chart, scatter diagram, box plot, line chart. Parametric test of hypothesis-one sample, Independent and paired sample t test, one way ANOVA& post HOC test. Testing for normality, Chi-square test with measures of association. Pearson correlation. Non parametric test		
	Computer Application Use of Computer in data analysis and research, Use of Software and Statistical package. Importing data from excel, access, tab and comma separated files. Entering data, labeling a variable, coding and recoding a categorical and continuous variable. Converting data from string to numeric variables, sorting & filtering maning a variable and continuous variable.	3 ¢	(
	Vital Health Statistics: Measurement of Population: rate, crude rate, specific rate, Measurement of fertility: specific fertility rate, Total fertility rate, Reproduction rate, Gross Reproduction Rate, Net Reproduction Rate, Measures related to mortality: Crude Death Rate (CDR), Age-specific death Rate, Infant and child mortality rate, Measures related to morbidity.	4	
	Nonparametric or Distribution-free Tests: Important Nonparametric or Distribution-free Test Sign test, Wilcoxon signed-Rank Test, Wilcoxon Rank Sum Test: Mann-Whitney U test Kruskal Walli's test, Friedman's test, and Spearman Correlation test.	3	
	Analysis of Variance and Covariance: Analysis of Variance (ANOVA):Concept and technique of ANOVA, One-way ANOVA, Two-way ANOVA, ANOVA in Latin-Square Design Analysis of Co-variance (ANOCOVA), ANOCOVA Technique.		4
[	Analysis		2
4	<ul> <li>Populations.</li> <li>4 Chi-square Test: Chi-square as a Non-parametric Test, Conditions for the Application Chi-square test, Steps Involved in Applying Chi-square Test, Alternative Formula, Yates' Correction, and Coefficient by Contingency.</li> </ul>		2
	3 Testing of Hypotheses: Definition, Basic Concepts, Procedure for Hypothesis Testing Measuring the Power of a Hypothesis Test, Normal distribution, data transformationImportant Parametric Tests, Hypothesis Testing of Means, Hypothesis Testing for Differences between Means, Hypothesis Testing for Comparing Two Related Samples, Hypothesis Testing of Proportions, Hypothesis Testing for Difference between Proportions, Hypothesis Testing for Comparing a Variance to Some Hypothesized Population Variance, Testing the Equality of Variances of Two Normal Populations		6

Security .....

Ŋ

٠

6. j. s.

. . .

#### Resolution No. 4.13 of BOM-55/2018: Resolved as follows:-

- (i) Slow learners must be re-designated as potential learners.
- (ii) Students scoring less than 35% marks in a particular subjects/course in the 1<sup>st</sup> formative exam are to be listed as potential learners. These learners must be constantly encouraged to perform better with the help of various remedial measures.
- (iii) Students scoring more than 75% marks in a particular subjects/course in the 1<sup>st</sup> formative exam are to be listed as advanced learners. These learners must be constantly encouraged to participate in various scholarly activities.

#### Resolution No. 3.1.4.2 of BOM-57/2019:

- i. Resolved to include "Gender Sensitization" into UG (from new batch 2019-2020) and PG (from existing batches) curricula. [Annexure-21]
- **ii.** Resolved to align the module of "Gender Sensitization" with MCI CBME pattern for MBBS students.
- iii. Resolved that Dr. Swati Shiradkar, Prof., Dept. of OBGY., MGM Medical College, Aurangabad will coordinate this activity at both campuses.

# Annexure - 21

Gender sensitization for UG (2<sup>nd</sup>, 3<sup>rd</sup>, 8<sup>th</sup> semesters) and PG (3 hours)

### **INCLUSION OF "GENDER SENSATIZATION" IN CURRICULUM**

#### Introduction :

The health care provider should have a healthy gender attitude, so that discrimination, stigmatization, bias while providing health care will be avoided. The health care provider should also be aware of certain medico legal issues related with sex & gender.

Society particularly youth & adolescents need medically accurate, culturally & agewise appropriate knowledge about sex, gender & sexuality. So we can train the trainers for the same. It is need of the hour to prevent sexual harassment & abuse .

To fulfill these objectives, some suggestions are there for approval of BOS.

### <u>Outline</u>

1)For undergraduates :- Three sessions of two hours each, one in  $2^{nd}$  term, one in  $3^{rd}$  term & one in  $8^{th}$  term.

2)For Faculties and postgraduates :- One session of two hrs .

3)For those want to be trainers or interested for their ownself, value added course, which is optional about sex, gender, sexuality & related issues.

### **Responsibility**

ICC of MGM, MCHA , with necessary support from IQAC & respective departments.

#### **Details of undergraduate sessions**

#### 1)First session in 2<sup>nd</sup> term

Aim – To make Students aware about the concept of sexuality & gender.

To check accuracy of knowledge they have,

To make them comfortable with their own gender identify & related issues.

To make them aware about ICC & it is functioning.

**Mode** – Brain storming , Interactive power point presentation experience sharing.

**Duration** – Around two hours

**Evaluation** – Feedback from participants.

# 2)Second session in 3<sup>rd</sup> / 4<sup>th</sup> term

**Aim** – To ensure healthy gender attitude in these students as now they start interacting with patients.

To ensure that the maintain dignity privacy while interacting with patients and relatives, particularly gender related.

To make them aware about importance of confidentiality related with gender issues.

--2--

To encourage them to note gender related issues affecting health care & seek solutions.

Mode – focused group discussions on case studies, Role plays & discussion.

--3--

Duration – Around two hours.

Evaluation – Feedback from participants.

Third session in 8<sup>th</sup> term.

**Aim** – To understand effect of gender attitudes on health care in various subjects.

To develop healthy gender attitude while dealing with these issues.

**Mode** – Suggested PBL by departments individually. (In collaboration with ICC till faculty sensitization is complete)

**Evaluation** – Feedback

\*\*\*\*

--4--

### FOR POSTGRADUATES

Session of 2-3 hrs preferably in induction program.

- **Aim** To introduce medically accurate concept of gender, sex, gender role & sex role.
- To ensure healthy gender attitude at workplace.

To understand gender associated concepts on health related issues & avoid such bias wile providing health care.

To make them aware about ICC & it's functioning.

Mode – Interactive PPT

Role plays & discussion

Duration – 2 to 3 hrs

**Evaluation** – Feedback.

### --5--

### FOR FACULTIES

Session of 2 hours may be during combined activities.

**Aim** – To ensure clarity of concept abut gender & sex.

To discuss effect of these concept on health related issues.

To identify such gender & sex related issues in indivual subject specialties.

To discuss methodology like PBL for under graduate students when whey are in  $7^{\text{th}}-8^{\text{th}}$  semester.

Mode – Role play

Focused group discussion

**Case studies** 

**Evaluation** – Feed back.

\*\*\*\*\*

Sdp-Pimple/joshi-obgy