

MS 1st Semester

Course Code	Course Title	Class Hours/Week	Credit
BGE 5101	Advanced Molecular Biology	3	3
BGE 5103	Genomics and Proteomics	3	3
BGE 5105	Advanced Immunology	3	3
BGE 5107	Advanced Bacterial Genetics	3	3
BGE 5109	Advanced Agricultural Biotechnology	3	3
		Total	15

BGE 5101 **Advanced Molecular Biology**

3 Credits

Course Objectives:

The main aim of this subject is to introduce and explain the advanced molecular biology techniques used to functionally characterize and validate the mechanisms of cellular and Molecular biology. This course will also discuss with the functional significance of the non-coding RNAs (RNAi pathway), protein-protein interaction studies and protein localization by using green fluorescent proteins and dyes.

1. **Gene regulation by RNAi:** Small RNAs and insights into a new level of gene regulation, postranscriptional RNA silencing (PTGS) – RNA interference (RNAi) gene silencing role of dsRNA in triggering PTGS/RNAi; formation of dsRNA; role of Dicer (Rnase III- type protein) and RISC (RNA Induced Silencing Complex) in RNAi gene silencing system RNA silencing as a tool for knocking down genes and to counter foreign sequences. RNAi application: diagnosis and treatment, RNAi against cancer.
2. **Real time PCR:** Procedure and application, different type of probe used in RT PCR and their mode of action, result interpretation.
3. **Array Techniques:** data processing: image analysis, normalization, design of microarray experiments and analysis of microarray data, applications of microarray in identification of complex genetic diseases: drug discovery, mutation and polymorphism detection (SNPs) and differing expression of genes over time, between tissues and disease states, protein array.
4. **Protein-protein interaction study:** Immuno pull down assay, bacterial and yeast two hybrid system, protein-protein interaction study by FRET.
5. Pulsed field gel electrophoresis, 2-D gel electrophoresis and their application.
6. **Functional characterization of proteins:** differential display, phage display, history of GFP, use of GFP to visualize proteins in live tissues, immuno localization.

Text Books:

1. Discovering Genomics, Proteomics, & Bioinformatics. Campbell & Heyer (2003) Pearson Education.

BGE 5103 **Genomics and Proteomics**

3 Credits

Course Objectives: The major objective of this course will be to introduce the cutting edge knowledge of genomics that attempt to determine complete DNA sequences and perform genetic mapping to help understand disease. Students will also be able to understand the application of recent proteomic and bioinformatics approaches for functional studies of proteins in living system.

1. **Genomics:** Definition, genetics to genomics, whole genomes sequencing, genome

sequence acquisition and analysis, evolution and genomes, biomedical genome research: genomic sequences to make new vaccines, new types of antibiotics, new types of medications.

2. **Genomic Variations:** Variation in the human genome, known examples of SNPs that cause diseases, pharmacogenomics, ethical consequences of genomic variations.
3. **Proteomics:** Introduction, protein 3D Structures, protein identifications (2-hybrid system, 2-D gel electrophoresis, mass spectrometry/MALDI-TOF, other arrays). statistical models and stochastic processes in proteomics, signal processing for proteomics, protein-DNA interactions, protein-protein interactions, large-scale databases of information for protein sequences, structures, functions and interactions; clinical proteomics, protein biomarker, applications to human disease studies.
4. **Networks in Bioinformatics/Proteomics:** Communication Networks, Biological networks (Protein Interaction Networks, Gene regulation networks, Metabolism, Biochemical reactions), Databases and search tools for biological network analysis. Genomic Circuits: in Single Genes, Complex integrated Genomic Circuits, Modeling Whole Genome Circuits: Genomics vs. Proteomics Case study Yeast Protein Interaction Network (random network, Scale free network, Hierarchical network).

Text Books:

1. Discovering Genomics, Proteomics, & Bioinformatics. Campbell & Heyer (2003) Pearson Education, ISBN: 0-8053-4722-4.
2. Veenstra, T., & Yates, J. (2006). Proteomics for Biological Discovery
3. Bioinformatics, Methods of Biochemical Analysis Series Vol. 43, Baxevanis & Ouellette (2001) John Wiley & Sons, ISBN 0-471-38391-0.
4. Computational Molecular Biology. Pevzner, P.A. (2000) MIT Press.

BGE 5105 Advanced Immunology

3 Credits

Course objectives

This course is intended for students who already have knowledge about basic immunology. This course is aimed to understand the advanced phenomenon of immunity and its clinical implications. This course will be effective for advance thinker who are interested in clinical, immunological as well as modern biological research and drug discovery.

1. **Regional Immunity:** General features of immunity at epithelial barriers, immunity in the gastrointestinal system, immunity in other mucosal tissues, The cutaneous immune system, immune privileged tissues.
2. **Immunological Tolerance and Autoimmunity:** General features of tolerance, B lymphocyte tolerance, T lymphocyte tolerance, tolerance induced by foreign protein antigens.
3. **Transplantation Immunology:** The Immunology of Allogeneic Transplantation, Effector Mechanisms of Allograft Rejection , Prevention and Treatment of Allograft Rejection, Xenogeneic Transplantation, Blood Transfusion, Bone Marrow Transplantation
4. **Immunity to Tumors:** General Features of Tumor Immunity , Immune Responses to Tumors, Evasion of Immune Responses by Tumors, Immunotherapy for Tumors.
5. **Hypersensitivity Disorders:** Causes of hypersensitivity disorders, mechanism and classifications of hypersensitivity disorders, diseases caused by antibody, diseases caused by T lymphocytes, Therapeutic approaches of immunologic diseases
6. **Immunodeficiency:** Primary immunodeficiencies; deficiencies of innate immunity; primary B cell deficiency; primary T cell efficiency, combine immunodeficiency; secondary immunodeficiency.
7. **Immunity to infection:** immunity to extracellular and intracellular bacteria; bacterial survival strategies; immunity to viral infection; innate and specific immune response to

viruses; strategies for evading immune defenses for viruses; immunity to parasitic infection.

Text Books:

1. Abul K. Abbas, Andrew H. Lichtman. Cellular and Molecular Immunology. Elsevier.
2. Roitt, Brostoff, Male. Immunology. 4th edition, Publisher: Dianne Zack: Mosby, (1996).
3. Roitt, I. Essential Immunology. 8th edition. Blackweell Scientific Publication, London, (1994).
4. Benjainini, E. Siney Leskowitz; Immunology- A Short Course. 2nd edition; (1992). Wiley-Liss, Jolm Wiley & Sons, Inc publications, New York, Singapore.

BGE 5107 Advanced Bacterial Genetics

3 Credits

Course Objectives

This course focuses on the advanced bacteriology and genetics. The objective of the course is to give the students latest state of the art knowledge like biofilm, CRISPR, extremophiles and several important bacterial genetics at their M.Sc. level.

1. **Introduction:** Major features of bacteria. Classification of bacteria. Subtyping of bacteria. Natural bacterial flora.
2. **Bacterial Biofilm:** Definitions. Steps of biofilm formation. Biofilm architecture. Conditionally Viable Environmental Cells (CVEC). Genetics of cells in biofilm. Single species biofilm and multi-species biofilm. Interactions among species in a mixed-species biofilm. Community level processes.
3. **Quorum Sensing Network:** Definitions. Quorum sensing pathway. Components of quorum sensing pathway. Different types of quorum sensing network. Quorum sensing inhibiting molecules.
4. **CRISPR:** Definitions. Basic architecture of CRISPR system. Functions of CRISPR system. Applications of CRISPR array. CRISPR system in different bacteria.
5. **Extremophiles:** Different types of extremophiles. Genetic features of some extremophile. Heat shock proteins. Cold shock proteins. Applications of extremophiles.
6. **Genetics of some common bacterium:**
Eschericia coli
Vibrio cholerae
Mycobacterium tuberculosis

Text Books:

1. Uldis N. Streips, Ronald E. Yasbin. Modern Microbial Genetics.
2. S.M. Faruque, G.B. Nair. *Vibrio cholera*: Genomics and Molecular Biology. Caister Academic Press.
3. J. Craig Venter et.al. Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome. Science. Vol.329. 2 July 2010. P.52.
4. P. Watnick and R. Kolter. Biofilm, City of Microbes. Journal of Bacteriology. May 2000. P. 2675.
5. M.E.Davey and G.A.O'toole. Microbial Biofilms: from Ecology to Molecular Genetics. Microbiology and Molecular Biology Reviews. Dec.2000. P. 847.
6. W.L.Ng and B.L.Bassler. Bacterial Quorum-Sensing Network Architecture. Annual Review of Genetics. 9 August, 2009. P.197.
7. R.Sorek, V.Kunin, P.Hugenholtz. CRISPR – a widespread system that provides acquired resistance against phages in bacteria and archaea. Nature Reviews – Microbiology. Vol.6. March 2008. P.181.
8. S.M.Faruque et.al. Epidemiology, Genetics and Ecology of Toxigenic *Vibrio cholera*. Microbiology and Molecular Biology Reviews. Dec. 1998. P.1301.

Course Objectives

The main aim of the course is to introduce the students about the modern technologies of biotechnology used in agriculture field.

1. **Introduction:** Concept; Objectives; Link of biotechnology to agriculture; Traditional, conventional and modern approach of biotechnology; Techniques; Application of biotechnology to agriculture; Biotechnology to healthcare, process industry, environment management, etc.; Importance.
2. **Plant/Germplasm Conservation:** Introduction, Scope and potential; Techniques: *in situ* and *ex situ* conservation; Importance; Philosophical and ethical concern; Evolution of *ex-situ* conservation; Conservation of threatened species; Conservation of world's largest mangrove forest and its restoration; Modern tools for conservation.
3. **Production of disease free plants:** Objectives; Techniques: meristematic tissue culture, shoot tip culture and shoot tip grafting; Virus elimination technique; Filter bridge and its utilization; source of meristematic tissue; advantages.
4. **Crop Improvement through Genetic Variability:** Concept; Somaclonal and gametoclonal variation; Kinds of variation; Mechanism of production of somaclonal/gametoclonal variants; Selection, Sources and causes of variation, Application in crop improvement; Advantage and limitations.
5. **Crop Improvement through Hybrid Seed Production:** Concept; History; Principles of hybrid seed production; Development of hybrid seed; Technique of hybrid variety development; Hybrid seed in China; Achievement of hybrid seed in Bangladesh; Advantages and disadvantages of hybrid seed; Impact on socio-economic conditions of Bangladesh.
6. **Crop Improvement through Conventional and Gene Transformation Techniques:** Introduction; History; Conventional and modern approach; Techniques of crop improvement; Placement of modern techniques over conventional; Achievement of conventional breeding in Bangladesh; GM crop in the globe; Bt brinjal and its recent achievement in Bangladesh; Advantage and limitations.
7. **Transformation of Cell and organelles:** Introduction; history; chloroplast and mitochondria as DNA containing organelles; Pt-DNA; characters, Mt-DNA; methods of transformation and success; novel gene; advantages.
8. **Plant as Biofactories:** Concept; Production of important components through biofactory e.g. chemicals, pigments, perfume, flavours, insecticides, anticancer agents and other important compounds; types and applications; production of novel components (enzymes, vaccines, fatty acid, isoflavone, biopolymers, antibodies, blood proteins, hormones, antimicrobial proteins, etc.) from genetically modified biofactory.
9. **Biofertilizer: Organisms and Production:** Microbes for biofertilizer (*Rhizobium*, *Azotobacter*, *Frankie* and *Micrrhizae*, Blue green algae, *Azolla*, Green manure); Free-living and symbiotic nitrogen-fixing micro-organisms; Isolation, identification and classification of microorganisms used as biofertilizer; Nodule formation in leguminous crops; Mechanism of nodulation; Importance.
10. **Biological control:** Basic concepts; Biological control vs. Chemical control; Classical biological control; Augmentation; Biological control with microorganisms; Application in controlling insects, pathogens, nematodes and weeds; environmental effect; Integrated pest management (IPM) and its history; Principles; Process.

Text Books:

1. Crispeels – ASPB, 2002 Plants, genes and crop improvement.
2. A. Altman. Agricultural Biotechnology.
3. S.S. Bhojwani, 1990. Plant Tissue Culture: Applications and Limitations. Elsevier, Amsterdam.
4. P.C. Debergh and R.H. Zimmerman, 1990. Micropropagation: Kluwer Academic Pub. Dordrecht.

5. Lindsey and Jones. Transgenic plants.

**BGE 5111 In Plant Training/Laboratory Training on Biotechnology
(Non-Thesis Group)**

3 Credits

- A. Biochemistry:
 - a. Estimation of Vitamin-C from Lemon/orange juice.
 - b. Estimation of Amylase from Saliva.
 - c. Estimation of Glucose.
 - d. Estimation of cholesterol from egg yolk.
- B. Microbiology:
 - a. Colony count
 - b. Gram Staining
 - c. Growth curve
 - d. Antibigram
- C. Molecular biology:
 - a. Polymerase Chain Reaction (PCR)
 - b. Random Amplification of Polymorphic DNA (RAPD)
 - c. Restriction Fragment Length Polymorphism (RFLP)
 - d. Isolation of DNA from Bacteria/Plant origin.
 - e. Gel Electrophoresis.
 - f. Preparation of competent cell.
 - g. Transformation of plasmid into Bacteria
- D. Plant Genetic Engineering:
 - a. Plant tissue culture of economical important crop eg. Rice.
 - b. Agrobacterium mediated gene transformation in rice.
 - c. Conformation of transgene in putative transgenic plants.

MS 2nd Semester

Course Code	Course Title	Class Hours/Week	Credit
BGE 5201	Systems Biology	3	3
BGE 5203	Neuroscience	3	3
BGE 5205	Developmental Biology	3	3
BGE 5207	Business Perspective of Biotechnology	2	2
BGE 5209	Pharmaceuticals Biotechnology	3	3
BGE 5211	Course Viva		1
		Total	15

BGE 5201 Systems Biology

3 Credits

Course Objectives:

Systems Biology a newly emergent field that combines experimental and theoretical approaches from engineering and other disciplines to solve both fundamental and applied problems in the life sciences and medicine. Systems Biology attempts to understand how biological processes, within cells, a group of cells, or an entire tissue work at the ‘network level’, and generally seeks to determine how biological components (e.g., genes, proteins and biochemical reactions) interact to produce defined physiological responses and behaviors. The ultimate goal of this course is to better understand the causes and progression of human diseases, as well as to discover new therapeutic strategies that can increasingly be personalized.

1. **Introduction:** A brief introduction with the concepts, history, and future aspirations of systems biology, besides understanding the nature of modern biological science in relation to the concepts, approaches, methods and tools of systems biology, finally, de novo designing of biological systems using the techniques of synthetic biology and computational simulation.
2. **Data Acquisition and Handling (DAH):** Components of biological data, their biochemical properties and function, the techniques used to acquire data in the various ‘omics’ approaches (transcriptomics, proteomics and metabolomics), as well as in high-throughput genetics, structured vocabularies and component ontologies, algorithms for comparative approaches in deciphering and mining component lists.
3. **Modelling and Analysis of networks (MAN):** The module will focus on mathematical and statistical methods used to evaluate and analyse large-scale data sets and use them for the reconstruction of biological networks (e.g., metabolic, gene-regulatory, and large-scale networks). the contents will cover bottom-up and top-down approaches, global topological properties and local structural characteristics, network motifs, network comparison and query, detection of functional modules and network motifs, function prediction from network analysis, inferring molecular networks from biological data as well as representative databases and software tools; besides, learning of network topology and dynamics, discrete and continuous approaches to network modelling, then hybrid model systems (FSLM), deterministic differential equations, stochastic simulations, control theory, biophysics and cell mechanics, as well as statistical approaches, such as bayesian inference.
4. **Synthetic and Executable Biology (SEB):** The design, simulation, and analysis of biological modules using some of the main computational techniques, kinetics of dimension-restricted conditions, mechanisms generating ultrasensitivity, bistability (λ -

phase toggle switch), and oscillations in signal transduction (Hopf bifurcation and *E.coli* K12 glycolytic oscillator), employing biological circuit to quantify receptor tyrosine kinase in time and space, dynamic instabilities within living cell; besides, topics range from biological building blocks and their characterization as, e.g. input/output relations, filters, amplifiers, robustness to environmental noise, as well as control theory, metabolic flux analysis, hysteresis and reverse genetic engineering.

5. **Software and Program Applications (SPA):** Systems Biology Workbench: Cytoscape, CellDesigner, and their extensions include COBRA Toolbox, CellNetAnalyzer, Metatool, PathwayAnalyser and SNA. Else, application of SBML models; Support Vector Machine (SVM) and BBRF-MEGN Method;

Text Books:

1. From molecular to modular cell biology, L H Hartwell, J J Hopfield, S Leibler & A W Murray, Nature 402, C47 – C52 (1999)
2. A New Approach to Decoding Life: Systems Biology Trey Ideker, Timothy Galitski, Leroy Hood Annual Review of Genomics and Human Genetics Sep 2001, Vol. 2: 343-372.
3. Discovering Genomics Proteomics and Bioinformatics. Campbell, 2nd edition.
4. Systems and synthetic biology. Vikram Singh, Springer.
5. Systems Biology: Simulation of dynamic network states. Bernhard Ø
6. Discovering functions and revealing mechanisms at molecular level from biological networks. S. Zhang, Proteomics 7, 2856–2869 (2007)
7. Current approaches to gene regulatory network modeling. T. Schlitt, BMC Bioinformatics 8, S9 (2007)
8. A first course in Systems Biology. Eberhard O. Voit. Garland Science.

BGE 5203 Neuroscience

3 credit

Course Objective:

The course gives idea about structural and functional organization of central nervous system and the basis of nerve impulse and synaptic conduction. The course also gives idea how neuron and endocrine gland inter-connected. The students will also get basic idea to generate animal model.

1. Structural and chemical specialities of the brain.
2. **Gross and fine structure of brain:** Different parts of brain, their functions and growth characteristics, cells of the brain, classification of neurons and glia, their structure, location and function. blood brain barrier
3. **Synapse:** Structure, their types.
4. **Electric signals of nerve cells, membrane permeability, channels and transporters:** Ionic basis of membrane potential and action potential, voltage clamp method, ion channels under action potential, patch clamp method, the diversity of ion channels.
5. **Synaptic Neurotransmission and Neurotransmitter:** Electrical and chemical synapse, properties of neurotransmitter, release of transmitters from synaptic vesicles, local recycling of synaptic vesicles, the role of calcium in transmitter secretion molecular mechanisms of transmitter secretion , neurotransmitter receptors, postsynaptic membrane permeability changes during synaptic transmission, excitatory and inhibitory postsynaptic potentials, summation of synaptic potentials, two families of postsynaptic receptors, different categories of neurotransmitters, mechanisms, their metabolism, storage and release.
6. **Neuroendocrinology:** HPA axis, neuroendocrine circuit of vasopressin, epinephrine, norepinephrine, serotonin, TRH, somatostatin, oxytocin.

7. **Animal model:** Knock-in and Knock out animal model, molecular tools and vectors to generate mouse model.
8. **Biochemistry of memory:** short term memory, long term memory.
9. Animal handling and behaviour

Text Books:

1. Neuroscience, Edited by Dale Purves, George J Augustine
2. Guide to Research techniques in Neuroscience, Matt carter, Jennifer sheieh
3. Neuroscience: Exploring the brain. Mark F Bear, Barry Connors. 4th edition.

BGE 5205 Developmental Biology

3 Credits

Course Objective: Developmental biology is the study of the process by which organisms grow and develop. After finishing the course, student will be able to understand the different developmental processes such as fertilization, axis patterning, organogenesis and limb development utilizing the model organisms *Drosophila*, Chick, Sea-urchin, mice and human. This course will also focus on special developmental events during metamorphosis and epigenetic events as well as discuss with regenerative perspective of development and their importance in therapeutic purpose.

1. **Fertilization and cleavage:** Structure of the gametes, recognition of egg and sperm, gamete fusion and the prevention of polyspermy, the activation of egg metabolism, fusion of the genetic material, rearrangement of the egg cytoplasm, cleavage: the onset of development.
2. **Axis Patterning and early development in *Drosophilla*:** Early drosophilla development, origins of anterior-posterior polarity, generation of dorsal-ventral polarity.
3. **Gastrulation and Neurulation:** Definition of the terms blastula, blastocoel, blastopore, archenteron, gastrula, epithelial and mesenchymal cells, gastrulation, comparison of the movements of gastrulation to the movements of neurulation.
4. **Organogenesis and Limb Development:** Development of different internal organs from ectoderm, endoderm and mesoderm, development of tetrapod limb, proximal-distal, anterior-posterior and dorsal-ventral axes of limb.
5. **Developmental Genetics:** Genetic core of development, differential gene expression, gradients, cascades and signalling pathways.
6. **Metamorphosis, regeneration and aging:** Metamorphosis: the hormonal reactivation of development, regeneration, aging: the biology of senescence.
7. **Epigenetics and Imprinting:** Examples of epigenetic inheritance, the process of imprinting, comparing it to other kinds of local or chromosomal inactivation Predict whether a gene is imprinted in the male or female germline dependent on the outcome of a cross, why imprinting may have been selected for in mammals. Imprinting in humans
8. **Stem cells and their applications:** Definition of a stem cell and its general properties, using blood stem cells as an example, the potential and the current limitations of human stem cell research, stem cells for tissue replacement therapy.

Text Books:

1. Developmental Biology, 7th ed., by Scott Gilbert.
2. Molecular Biology of the Cell, 4th edition, by B. Alberts et al.
3. Genes VIII. Benjamin Lewin.

Course Objectives

After successful completion of the course students will learn how the biotechnology products can be managed economically in the market with significant profit. They will also learn about the process to gain intellectual property of a new biotechnology product.

1. **Business Management:** The company, its environment, stakeholders, corporate strategies, some basic economic principles (e.g. profit maximisation, shareholder value), business planning and decision making processes, methods of business analysis, introduction into technology development, introduction into procurement, introduction into operations management, introduction into marketing/sales.
2. **Project Management:** Fundamentals of project management, the life cycle of a project: (project definition; project planning; project execution and -controlling; project close out), tools and methods of project management (e.g. planning methods; problem solving methods), social competence in project management (teamwork; communication).
3. **Cost accounting and Management:** Basics of cost accounting, structure of cost accounting, approaches of cost accounting.
4. **Price Estimation:** Cost estimates, process design, design exercise, marginal cost, marginal revenue, determining cost of capital.
5. **Practical Applications of business biotechnology:** Biotechnology used for, biotechnological companies-their care and nurturing, investment in biotechnology, management needs.
6. **The Biotechnology Industry:** Environmental release of genetically engineered organisms; product labelling, technology transfer; health insurance and reimbursement; entrepreneurship, venture capital, and the life cycle of a biotechnology company; public perceptions of biotech products; the global marketplace for biotechnology products and biotech forecast.
7. **Commercialization, Marketing and Management of Biotechnological Products:** Fundamentals of marketing, the marketing and selling of biotechnology, creating and marketing the image of the biotechnology company, power and importance of positioning of a company name and product, the art of negotiation, workable marketing and the strength of distribution, effective advertising and marketing, opportunities of international, marketing and lessons to be learnt, steps involved in commercialization of a biotechnological product.
8. **Intellectual Property Rights in Biotechnology:**
 - a. **Introduction:** General introduction, patent claims, the legal decision-making process, ownership of intellectual property.
 - b. **Basic Requirements of Patentability:** Patentable subject matter, novelty and the public domain.
 - c. **Special Issue in Biotechnology Patents:** Disclosure requirements, collaborative research, competitive research, foreign patents.
 - d. **Patent Litigation:** Substantive aspects of patent litigation, procedural aspects of patent litigation, and recent developments in patent system and patentability of biotechnological invention.

Text Books:

1. Harold Koontz and heint Weihrich, management, McGraw-Hill book Company, New York (USA).
2. P. Chanda, Project; Preparation, Appraisal, Budgeting and Implementatation, Tata-Mcgraw-Hil, Publishing company LTD, New Delhi India.
3. R. J. Ruffin and P.R. Gregory, Priciples of Microeconomics, Scott Foreguson and company, illinois.
4. Introduction to Biotechnology by William J. Thieman and Michael A. Palladino. 2004. Pearson Education/Benjamin Cummings, San Francisco CA. ISBN 0-8053-4825-5.
5. The ethical dimensions of the biological sciences. Edited by Ruth Ellen Bulger et al. NY: Cambridge University Press. 1993.
6. The coming biotech age: The business of biomaterials. Richard Oliver. NY: McGraw Hill.

BGE 5209 Pharmaceutical Biotechnology**3 Credits****Course objectives**

This course is focused on comprehensive knowledge about Pharmaceutical biotechnology. This covers all areas of biotechnology related to drug discovery, drug delivery, clinical and toxicity studies, role of regulatory authorities, product analysis as well as post market surveillance of biopharmaceuticals.

1. **Introduction to biopharmaceuticals:** Biotechnology versus pharmaceutical biotechnology, historical perspective of pharmaceutical biotechnology, traditional pharmaceuticals of biological origin: pharmaceuticals of animal, plant and microbial origin, pharmacokinetics.
2. **The drug development process:** Introduction: discovery of biopharmaceuticals, the impact of genomics and related technologies upon drug discovery, gene chips, proteomics, structural genomics pharmacogenetics, initial product characterization. **Patenting:** What is a patent and what is patentable? Patenting in biotechnology. **Delivery of biopharmaceuticals:** Oral delivery systems, pulmonary delivery, nasal, transmucosal and transdermal delivery systems. **Preclinical studies:** Pharmacokinetics and pharmacodynamics, protein pharmacokinetics, tailoring of pharmacokinetic profile, protein mode of action and pharmacodynamics. **Toxicity studies:** Reproductive toxicity and teratogenicity, Mutagenicity, carcinogenicity and other tests. **Clinical trials:** Clinical trial design, trial size design and study population. **The role and remit of regulatory authorities:** The food and drug administration, the investigational new drug application. the new drug application, European regulations, national regulatory authorities the European medicines agency and the new EU drug approval systems, the centralized procedure, mutual recognition, drug registration in japan, world harmonization of drug approvals.
3. **Product analysis:** Introduction, protein based contaminants, removal of altered form of protein, product potency, and determination of protein concentration, detection of protein based product impurities, immunological approach to detection of contaminants, endogenic and other pyrogenic contaminants.
4. **Therapeutics based on biotechnology:** Interferons, hormones, enzymes, antibiotics, antibodies, vaccines, adjuvant technology, blood products, nucleic acid therapies.
5. **Advanced drug delivery:** Basic principles; controlled and sustained release: polymer-based drug carriers, lipid-membrane-based drug carriers; permeation enhancement; molecular approaches of drug delivery.

Text Books:

1. Gary Walsh, Pharmaceutical Biotechnology; Concepts and Application. John Wiley and Sons Ltd.
2. O. Kayser, R.H Muller, Pharmaceuticals Biotechnology, Drug discovery and Clinical Applications.
3. Goodman and Gillman, The Pharmaceutical Basis of Therapeutics

BGE 5211 Course Viva**1 Credit****BGE 5213 Research Project/Survey Report (Non Thesis Group)****3 Credits**

The students (Non thesis group) will have to undertake a project involving literature survey including critical analysis of an experimental investigation or observation, and finally they will have to prepare their project/survey report on the selected topic.

BGE 5300 Thesis Work**6 Credits**