St. Xavier's College – Autonomous, Mumbai

Syllabus

For Semester III Courses in M.Sc. in Biotechnology

(June 2019 onwards)

Contents

Syllabus for the following courses:

SUBJECT (THEORY): BIOTECHNOLOGY
CLASS: MSC- SEMESTER III COURSE CODE: SBTS0901
TITLE: BIOSTATISTICS AND BIOINFORMATICS
No of Hours: 60 (inclusive of self-study)
Credits: 4
Course Objectives:

The Biostatistics module will introduce students to the science of collecting and analysing numerical data for study designs and basic methods for testing the various hypothesis with emphasis on parametric and nonparametric tests. The Bioinformatics module is designed to provide theory and practical experience of the use of computational tools and databases to investigate molecular biology and evolution related concepts.

UNIT 1: INTRODUCTION TO BIOSTATISTICS 15 lectures

- Measure of central tendency (mean, median and mode)
- Measure of dispersion (Standard deviation, variance, and coefficient of variance)
- Z- test (one mean, two means and paired)
- t-Test (one mean, two mean, paired and Cochran's)
- χ^2test (test of homogeneity, Independence Goodness of fit)
- P- value for all tests (Reading tables)
- Regression
- ANOVA

UNIT 2: APPLIED BIO-STATISTICS 15 lectures

- Statistical Experimentation: Introduction, test, control
- Experimental design and terms
- Theory of probability, density function (Estimation etc.)
- The standard Normal distribution
- Hypothesis Testing: step, errors
- Non-parametric tests: Sign, Wilcoxon, and Mann- Whitney test
- Use of R programme

UNIT 3: DATABASES AND SEQUENCE ALIGNMENT 15 lectures

- Introduction to Programming Languages in Bioinformatics
- Biological databases:
  - Study of biological databases - Concept of databases, classification
  - Submission of sequences to the databases
  - Biological data retrieval and study of data formats
  - Pitfalls of biological databases and annotations of biological data File formats and
  - The biological database management system
- Sequence alignment:
  - Pairwise sequence alignment, Multiple sequence alignment, Phylogenetic analysis and importance

UNIT 4 PROTEIN SEQUENCE AND STRUCTURE ANALYSIS 15 lectures

- Protein secondary and tertiary structures
- Protein structure analysis
    - Protein structure databases, Structure descriptors, protein structures
    - Protein structure visualization, comparison and importance
- Protein functions
    - Analysing structure-function relationships, classification and assignment of protein function: The Enzyme Commission; The Gene Ontology Consortium protein function classification , Allergenic Protein Databases and Protein-Allergenicity Prediction , Prediction of Post-Translational Modification and Sorting

Reference Books:

- Wayne W Daniel (1999), Biostatistics: a foundation for analysis in health sciences, John Wiley and sons
- N Gurumani (2004), Introduction to Biostatistics, MJP Publishers.
- David Mount (2004) Bioinformatics: Sequence and Genome Analysis. 2nd edition, Cold Spring Harbor Laboratory Press, New York.
- Jonathan Pevsner (2009) Bioinformatics and Functional Genomics. 2nd edition, John Wiley and Sons, New Jersey.
- Teresa K. Attwood and D. J. Parry Smith (1999) Introduction to Bioinformatics. 1stedition, Pearson Education Limited, England
- Andreas D. Baxevanis and B. F. Francis Ouellette (2001) Bioinformatics A Practical Guide to the Analysis of Genes and Proteins. 2ndedition, A John Wiley & Sons, Inc., Publication
- Arthur M. Lesk (2005) Introduction to Bioinformatics, 2nd edition Oxford University Press
- Jian Xiong (2006), Essential Bioinformatics, 1st edition, Cambridge university press,

ASSESSMENT:
Continuous Internal assessment :40%

End Semester Assessment: 60%

SUBJECT (THEORY): BIOTECHNOLOGY
CLASS: MSC- SEMESTER III COURSE CODE: SBTS0902
TITLE: DRUG DEVELOPMENT

No of Hours: 60 (inclusive of self-study)
Credits: 4
Course Objectives:
The course will provide an insight into the research and development carried out in drug discovery. The core of this course will encompass the journey of a drug from bench to bedside.

UNIT 1: DRUG DEVELOPMENT 15 lectures

- Drug discovery
    - Steps involved in drug discovery, Production and characterization, Preclinical studies and Validation studies
- Computer-aided drug designing and docking
    - General Principles of CADD
    - Types of drug designing
    - Ligand-based molecular interactions
    - Structure-based Drug designing
    - Examples of Ligand and structure-based drug designing
- Applications and importance of CADD

UNIT 2: PRECLINICAL ASPECTS OF DRUG DEVELOPMENT 15 Lectures

- Principles of pharmacokinetics and pharmacodynamics
    - intestinal absorption, metabolic stability, drug-drug interactions, plasma protein binding assays, metabolite profile studies
- Principles of toxicology: Reproductive toxicity and teratogenicity, Mutagenicity, carcinogenicity and other tests
- Experimental design for preclinical and clinical PK/PD studies
    - *In vitro* preclinical tests
    - Selection of animal model
    - The scope of GLP, SOP for the conduct of clinical & non-clinical testing

UNIT 3: CONSIDERATIONS DURING BIOPHARMACEUTICALS MANUFACTURING 15 lectures

- Guides to good manufacturing practice
  The manufacturing facility, Clean rooms, Cleaning, decontamination and sanitation (CDS), Water for biopharmaceutical processing
- Microbiological considerations and Excipients
- Delivery systems
- Product analysis:
    - Protein-based contaminants

  - Removal of altered forms of the protein of interest from the product stream
  - Detection of protein-based product impurities
  - Immunological approaches to detection of contaminants
  - Endotoxin and other pyrogenic contaminants
  - Microbial and viral contaminants
  - Miscellaneous contaminants
  - Validation studies
- Labelling and Packaging

UNIT 4: CLINICAL RESEARCH AND REGULATORY AFFAIRS 15 lectures

- Introduction, Good clinical practice guidelines, Ethical aspects of clinical research
- Clinical research methodologies and data management, Regulatory requirements
- Pharmacovigilance: Adverse Events and Classifications, Pharmacovigilance methods Adverse drug reaction reporting
- Drug safety : the role of FDA and ICH, Investigational New Drug Applications

References:

- Ed. Hardman G Limbird LE (2001) "Goodman Gillman's The Pharmacological Basis of
- Therapeutics" McGraw Hill Press
- Daan J. A. Crommelin, Robert D. Sindelar. (2002) Pharmaceutical Biotechnology: An Introduction for Pharmacists and Pharmaceutical Scientists. Taylor & Francis.
- Gary Walsh. (2006) Biopharmaceuticals: Biochemistry and Biotechnology. John Wiley & Sons.
- Gary Walsh. (2007) Pharmaceutical Biotechnology Concepts and Applications John Wiley & Sons.
- Oliver Kayser, Rainer H. Müller. (2006) Pharmaceutical Biotechnology. John Wiley & Sons.
- Thomas M. Jacobsen, Albert I. Wertheimer. (2010) Modern Pharmaceutical Industry: Primer. Jones & Bartlett Publishers.
- Tommy Liljefors, Povl Krogsgaard-Larsen, Ulf Madsen. (2010) Textbook of Drug Design and Discovery. 4th Edition. CRC Press
- https://www.who.int/biologicals/good_manufacturing_practice

ASSESSMENT:
Continuous Internal assessment :40%

End Semester Assessment: 60%

SUBJECT (THEORY): BIOTECHNOLOGY
CLASS: MSC- SEMESTER III **COURSE CODE: SBTS0903**
TITLE: BIOPROCESS TECHNOLOGY

No of Hours: 60 (inclusive of self-study)
Credits: 4
Course Objectives:
The course aims at educating students about the strategies employed in process industries and its implementation into biological systems to produce valuable biotech-based metabolites. The engineering concepts including cell growth kinetics, process design, and transport operation will be covered during the course.

UNIT 1: PRINCIPLES OF BIOPROCESS TECHNOLOGY 15 lectures

- Industrial substrates and stoichiometry
- Kinetics of microbial growth, substrate utilization, and product formation: Batch, Fed-Batch and continuous processes
- Scale up concepts with respect to fermenter design and product formation
- Solid state fermentation
- Processes using recombinant organisms: hosts, vectors, genetic instability.

UNIT 2: PROCESS DYNAMICS AND OPERATIONS 15 lectures

- Gas exchange and mass transfer: O_2 transfer, critical oxygen concentration, determining the oxygen uptake rate, Heat transfer, Sterilization – processes, thermal death curve, *in situ* sterilization
- Enzyme Technology in Food manufacture and Processing: Mechanisms of enzymatic reactions and bioconversions (e.g. hydrolysed protein); associated downstream processing (e.g. de-oxygenation and de-sugaring); case studies (e.g. Cheese making)
- Microbial technology in food production process and operations: Role of microbial fermentation in food and beverages; food ingredients and additives prepared via microbial fermentation, bioconversion from food wastes to useful products; food preservation via microbes

UNIT 3: DOWNSTREAM PROCESSING 15 lectures

- Flocculation and floatation
- Filtration
- Centrifugation
- Cell disruption
- Liquid extraction
- Precipitation and Adsorption
- Dialysis and Reverse osmosis
- Chromatography
- Crystallization and drying

UNIT 4: INDUSTRIAL PRODUCTS 15 lectures

- Polysaccharides/ biopolymers/micro-polymers- Xanthan gum, Dextran
- Enzymes – proteases, amylases, pectinases, lipases
- Antibiotics
- Vitamin B_{12}
- Amino acids and alcohols
- *Invitro* systems and bioprocess technology for industrial production of secondary metabolites-

  Cell suspension cultures (Bioreactors), Immobilized cell systems, Hairy root cultures, enhancement of SM yield

References:

- Glazer A.N. & Nikaido H. (1995) Microbial Biotechnology: Fundamentals of Applied Microbiology. W.H. Freeman & Company, New York.
- Michael L. Shuler, Fikret Kargı (1992) Bioprocess Engineering: basic concepts. Prentice Hall Publishers. New York.
- Stanbury P.F., Whitaker A, Hall S.J. (1999) Principles of Fermentation Technology. 2nd edition, Butterworth-Heinemann
- Wulf Crueger and Anneliese Crueger (1990) Biotechnology: A Textbook of Industrial Microbiology. Panima Publishers. New Delhi
- Karl-Hermann Neumann, Ashwani Kumar, Jafargholi Imani, 2009, Plant Cell and Tissue Culture - A Tool in Biotechnology, Basics, and Application, Springer-Verlag Berlin Heidelberg
- Razdan, M.K.: Introduction to plant tissue culture. (2nd Ed.) New Delhi. Oxford & IBH Publishing Co. Pvt. Ltd., 2003. 81-204-1571-X--(581.0724RAZ)

ASSESSMENT:

- **Continuous Internal assessment :40%**
- **End Semester Assessment: 60%**

SUBJECT (THEORY): BIOTECHNOLOGY
CLASS: MSC- SEMESTER III COURSE CODE: SBTS0904
TITLE: ENVIRONMENTAL BIOTECHNOLOGY
No of Hours: 60 (inclusive of self-study)
Credits: 4
Course Objectives:

The course includes biotechnology-based solution aspects for environmental issues. An overview of quality, ethical and safety aspects of genetically modified products is also included in the coursework. The course aims for the student to understand concepts and strategies related to nutraceutical and functional foods production and applications.

UNIT 1: ENVIRONMENTAL POLLUTION AND BIOREMEDIATION 15 lectures

- Environmental pollution: urban aspects (biomedical waste, e waste, solid waste)
- Environmental Monitoring: concepts, strategies, and applications of nanotechnology
- Biofouling and biodeterioration: agents and protection methods
- Bioremediation: Biodegradation and bioconversion of natural and xenobiotic compounds
- Phytoremediation overview, microbially assisted phytoremediation, phytoremediation of saline soil, genetic strategies for advancing phytoremediation potential in plants.
- Heavy Metal Bioremediation- conventional and advanced methods
- Oil pollution remediation.

UNIT 2: ENVIRONMENTAL SUSTAINABILITY 15 lectures

- Concept of sustainability, carbon footprint and credits
- Biomass management
- Sustainability in agriculture: Bio-pesticides, Bio-fertilizers and Integrated Pest management
- Energy and Environment: Bioenergy
- Metagenomics: concept, strategies, and applications in environmental biotechnology

UNIT 3: GM CROPS AND NUTRACEUTICALS 15 lectures

- GM crops- national and global scenario (*Bt* based & others and fallacies associated)
- GM based phytonutrients
- Food security dilemma- GM food Vs Organic food
- Nutraceuticals and Functional Foods: Nutraceuticals and Functional Foods- Definition, characteristic features, and classification; Sources (with examples e.g. microbes, plants,

algae); Applications of nutraceuticals in human health and nutrition- health effects of commonly used nutraceuticals and functional foods (case studies), Safety and Regulatory guidelines

UNIT 4: SAFETY, ETHICS AND QA ASPECTS IN BIOTECHNOLOGY 15 lectures

- Biosafety- history, Need for containment and levels (microorganisms, plants and animals – both GMOs and LMOs), primary containment of biohazards, BSCs, Clean Room technology
- Regulatory guidelines: both national and International for food and food ingredients produced using GMOs, GM crops and livestock
    - Cartagena Protocol, Role of IBSC, RCGM, GEAC, and others
    - Safety and Environment Impact concerns with respect to GMOs, LMOs, GM foods, Crops and Livestock, Risk assessment, management and communication including GMP, GLP, and HACCP, Generally, Recognised as Safe (GRAS)
- Bioethical conflicts in Biotechnology: ELSI of HGP, Ethical concerns in GM utilized for consumption, agricultural benefits or human therapy.
- Quality assurance and validation: concept, documentation – SOPs
- ISO aspects

Reference Books:

- A.G. Murugesan and C. Rajakumari (2006) Environmental Science and Biotechnology Theory and techniques MJP Publishers, Chennai
- Alan H. Scragg (2006) Environmental Biotechnology, 1st edition, Oxford University Press
- Alexander N. Glazer and Hiroshi Nikaido (2010) Microbial Biotechnology, 2nd edition, Cambridge University Press.
- Bernard R. Glick, Jack J. Pasternak, Cheryl L. Patten. (2010) Molecular Biotechnology: Principles and Applications of Recombinant DNA. ASM Press.
- Rajul K Gupta (2017) Food Safety in the 21st Century: Public Health Perspective, Academic Press Elseivier.
- Biosafety in Microbiology and biomedical laboratories, 5th Ed. (2009): CDC, NIH publication. HHS publication (21-1112)
- Gareth M. Evans and Judith C. Furlong (2003) Environmental Biotechnology Theory and Application, John Wiley & Sons Inc.
- Gwendolyn Holmes Bruce *et al*, (2000), Handbook of Environmental management and technology, Wiley Interscience Publishers
- http://dbtbiosafety.nic.in

- Humberto Vega-Mercado, Michael Dekleva, Rizwan Sharnez, and Luis Baez, May 2003, HACCP: A Process Validation Tool for Ensuring Quality of Biotech and Pharmaceutical Products, *Bioprocess technology*
- Indu Shekhar Thakur (2006) Environmental Biotechnology: Basic Concepts and Applications, I. K. International Pvt Ltd, 2006
- N. Alexandrova, K. Georgieva & A. Atanassov (2005) Biosafety Regulations of GMOs: National and International Aspects and Regional Cooperation, Biotechnology & Biotechnological Equipment, 19:sup3, 153-172.
- S.K. Agarwal (2007) Environmental Biotechnology, APH Publishing Co-operation New Delhi
- Secretariat of the Convention on Biological Diversity (2000). Cartagena Protocol on Biosafety to the Convention on Biological Diversity: text and annexes. Montreal.
- Traavik. T and Lim Li Ching, (2007): Biosafety first. Tapir Academic Press
- Recent research articles.

ASSESSMENT:

Continuous Internal assessment (40M)
CIA I & CIA II: Field Study Report Presentation

End Semester Exam Pattern:60 Marks:		
No. of Units	No. of Questions	Marks per Question
4	4 (1 from each Unit)	15 marks per question.
100 Marks:		
No. of Units	No. of Questions	Marks per Question
4	5 – 1 from each Unit &1 based on all units	20 marks per question.

SUBJECT (PRACTICALS): BIOTECHNOLOGY
CLASS: MSC- SEMESTER III
COURSE CODE: SBTS09PR
Title: BIOINFORMATICS AND RESEARCH METHODOLOGY

Credits: 8

- **Course Objectives:**
  The course is designed to teach the basics of *in - silico* analysis of biological data and experimental design for *invitro* assays in a problem-oriented manner. The course will introduce the process of research designs from its inception to documentation.

Contents:

I. BIOINFORMATICS

- Study of databases – primary, secondary, specialised databases
- Sequence annotations -
- Sequence alignment and phylogenetic analysis
- Protein sequence and structure analysis

II. EXPLORING *IN VITRO* (CELL LINE BASED) ASSAYS

III. RESEARCH METHODOLOGY (Bioprocess and Environment Biotechnology aspects to be explored for projects)

References:

- C.R. Kothari, Research methodology: methods and techniques, 2nd edition, New Age International Publishers, 2004
- David Mount (2004) Bioinformatics: Sequence and Genome Analysis. 2nd edition, Cold Spring Harbor Laboratory Press, New York.
- Hansmauder Schmauder, Methods in Biotechnology (1997), Taylor and Francis Publications
- James Morris, A students guide to writing in the life sciences, The President and Fellows of Harvard University, 2007
- R Ian Freshney, Culture of Animal Cells, Wiley Publications, 5th / 6th Ed

ASSESSMENT:

CIA: 80M
End Semester Exam: 120M