# Jaypee Institute of Information

# Technology M.Sc. Microbiology

## Semester III

# Course Descriptions

**Detailed Syllabus**

**Lecture-wise Breakup**

| | | | |
|---|---|---|---|
| **Course Code** | 19M21BT211 | **Semester :** ODD | **Semester: III**<br>**Session:** 2020 -2021<br>**Month from:** July to December |
| **Course Name** | Food and dairy Microbiology | | |
| **Credits** | **4** | **Contact Hours** | **3-1-0** |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | Dr. Smriti Gaur |
| | **Teacher(s) (Alphabetically)** | Dr.Smriti Gaur |

| **Sl. No.** | **DESCRIPTION** | **COGNITIVE LEVEL (BLOOM's TAXONOMY)** |
|---|---|---|
| **CO1** | Explain the interactions between microorganisms and food environment. | Understanding level (Level 2) |
| **CO2** | Illustrate the role of microorganisms in spoilage of food and dairy products with associated diseases. | Understanding level (Level 2) |
| **CO3** | Analyze the effects of fermentation on quality of the dairy and non-dairy products. | Analyzing level (Level 4) |
| **CO4** | Examine food preservation, safety and quality control. | Analyzing level(Level 4) |
| **CO5** | Identify applications of food and dairy Microbiology | Applying level (Level 3) |

| Module No. | Title of the Module | Topics in the Module | No. of Lectures for the module |
|---|---|---|---|
| 1. | **Food and microorganism** | Food as substrate for microorganism, Microorganisms important in food and dairy microbiology; Mold yeast and bacteria, Factors influencing microbial activity | 05 |
| 2. | **Food Spoilage and Food borne diseases** | Contamination of food, general principles underlying spoilage, Spoilage of various foods and food products; cereals and cereal products, bakery products, dairy products, meat poultry and sea foods, Eggs, vegetables and fruits, sugar and sugar products,<br><br>Microbiological examination of milk and milk products, source of their contamination and control,<br><br>Food borne diseases: Staphylococcal, *E.coli*, Salmonellosis, Shigellosis, Listerial infections, Mycotoxins. | 10 |
| 3. | **Food** | General principles of food preservation, pasteurization of milk, Preservation by use High Temperature,Low | 10 |
| | **Preservation & Principles** | temperature, drying, food additives, radiation, High Pressure Processing Pulsed Electric Fields, Aseptic Packaging , Manothermosonication, | |

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|---|---|---|---|
| **4.** | **Fermented food** | Microbiology of fermented food products, traditional fermented food items like beverages (cereal and fruit juice based), bakery, fermented Vegetables and dairy products (cheese, yoghurt, fermented milk, cultured buttermilk, Kefir) | 06 |
| **5.** | **Food safety and control** | Microbiological quality standards of food, FDA, HACCP, ISI. | 05 |
| **6.** | **Applications of Food Microbiology** | Functionl food, Intestinal Beneficial Bacteria-Concept of Prebiotics and Probiotics, Genetically modified foods, Biosensors in food, Milk as a source of bioactive peptides | 06 |

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|---|---|
| **Total number of Lectures** | 42 |

**Evaluation Criteria**

**Components Maximum Marks**

T1 20
T2 20
End Semester Examination 35
TA 25 (presentation and viva)
**Total 100**

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| **1.** | Food Science & Food Biotechnology, G.F.G Lopez and GVB Canovas CRC Press, Florida(2003) |
| **2.** | Bioprocess and Biotechnology for functional foods and Nutraceuticals, J.R Neeser , J.Bruce German Marcel and Dekker , New York (2004) |
| **3.** | Food Microbiology, Frazier W C, Westoff DC, Vanitha NM, Mc Graham Hill Education (2013) |

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|---|---|
| **4.** | Fundamental Food Microbiology, 3rd edition by B. Ray., CRC press, (2006). |
| **5.** | Food Microbiology by M.R. Adams, Royal Society of Chemistry, (2008). |

## Detailed Syllabus

**Lecture-wise Breakup**

| | | | |
|---|---|---|---|
| **Subject Code** | 19M21BT212 | **Semester:** Odd | **Semester:** III<br>**Session :** 2020 -2021<br>**Month from:** July to December |
| **Subject Name** | **Recombinant DNA Technology** | | |
| **Credits** | **4** | **Contact Hours** | **3** |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | 1. Dr. S Krishna Sundari |
| | **Teacher(s) (Alphabetically)** | 1. Dr. S Krishna Sundari |

| **COURSE OUTCOMES** | | **COGNITIVE LEVELS** |
|---|---|---|
| **CO1** | Summarize the fundamental concepts of RDT, cloning vectors, prokaryotic vs. eukaryotic hosts and expression systems | **Understanding Level (Level II) C2** |

| | | |
|---|---|---|
| **CO2** | Illustrate different methods of gene transfer, cloning, genomic libraries and molecular tools for microbes, plants and animals | **Applying level (Level III) C3** |
| **CO3** | Analyse RDT tools, techniques and its applications in environment, Medicine and agriculture | **Analysis level (Level IV) C4** |
| **CO4** | Identify importance as well as ethical and biosafety issues related to transgenics | **Understanding Level (Level II) C2** |

| **Faculty (Names)** | **Coordinator(s)** | Dr. Krishna Sundari | |
|---|---|---|---|
| | **Teacher(s) (Alphabetically)** | Dr. Krishna Sundari | |
| **Module No.** | **Subtitle of the Module** | **Topics in the module** | **No. of Lectures for the module** |
| **1.** | **Introduction** | Basic Concepts of Recombinant DNA technology, origin of RDT, pioneering discoveries and significance of tailoring microbes, model plants and animals in present context | 4 |
| **2.** | Enzymes, Vectors and Hosts for Cloning | Restriction enzymes and other DNA modifying enzymes; Cloning vectors, expression vectors, prokaryotic and eukaryotic expression systems, bacterial, fungal and plant hosts for cloning, methods of gene transfer | 6 |
| **3.** | **Recombinant DNA** | Basic techniques of gene manipulation, - Gel electrophoresis, DNA transformation techniques, Cloning | 6 |

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|---|---|---|---|
| | **Technology** | of PCR products, Construction of Genomic and cDNA libraries, Screening Libraries with Gene Probes, Screening Expression Libraries, Positional Gene Cloning, Subtractive cloning, Functional cloning | |
| **4.** | **Molecular tools supporting RDT** | PCR, RT-PCR, Blotting techniques, Sequencing methods, NGS, Gene editing, Mutagenesis, Gene expression techniques, Regulation of gene expression, microRNAs, Microarrays | 4 |
| **5.** | **Methods & Applications of Plant Genetic engineering** | Molecular Biology of DNA transfer in Plant through *Agrobacterium tumefaciens,* methods for artificial gene transfer, Applications in agriculture such as golden rice, BT Cotton, Nif and Nod gene clusters and Nitrogen fixing, etc. | 5 |

| | | | |
|---|---|---|---|
| **6.** | **RDT for Environmental Biotechnology** | Environmental Applications: biodegradation and bioremediation Energy based applications: Biogas, biodiesel and bioethanol production by microorganisms. Biotechnological applications. Biotechnological applications. | 5 |
| **7.** | **RDT in Medicine & Therapeutics** | Production of recombinant vaccines and antibiotics, phytopharming, microbes as cell factories for production of therapeutic molecules, insulin and other major discoveries, gene therapy | 6 |
| **8.** | **Animal cloning & Issues** | Transferring gene in animal oocytes, eggs embryos and specific animals tissues, Application of rDNA technology in animal cell lines, tailoring model animals, Controlling the expression of transgene in time and space, case studies exposing risks of animal cloning | 4 |
| **9.** | **Ethics & Biosafety in RDT** | Ethical issues, Biosafety guidelines and regulations | 2 |

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|---|---|
| **Total number of Lectures** | **42** |

**Evaluation Criteria**

**Components Maximum Marks**

T1 20
T2 20
End Semester Examination 35
TA 25
**Total 100**

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| **1.** | Genes XII: Benjamin Lewin, 2016 |
| **2.** | Molecular Biology of the Gene, Seventh Edition: James D. Watson, Tania A. Baker, Stephen P. Bell, Alexander Gann, Michael Levine, Richard Losick, 2004Microbial Biotechnology: Progress and Trends, FarshadDarvishiHarzevili, Hongzhang Chen, First edition CRC Press/Taylor & Francis Group, 2017 |
| **3** | Molecular biotechnology : principles and applications of recombinant DNA / Bernard R. Glick and Jack J. Pasternak, Cheryl L. Patten. ASM Press |
| **4.** | Gene Cloning and DNA Analysis: An Introduction, Seventh Edition-T. A. Brown, John Wiley & Sons Ltd. 2016 |
| **5.** | Microbial Biotechnology: Progress and Trends, FarshadDarvishiHarzevili, Hongzhang Chen, First edition CRC Press/Taylor & Francis Group, 2014 |


## Detailed Syllabus

**Lecture-wise Breakup**

| | | | |
|---|---|---|---|
| **Course Code** | 19M21BT213 | **Semester** Odd | **Semester: III**<br>**Session :** 2020-21<br>**Month from: July to December** |
| **Course Name** | Bioinformatics and Omics | | |
| **Credits** | 3 | **Contact Hours** | **3** |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | Dr Chakresh Kumar Jain |
| | **Teacher(s) (Alphabetically)** | Dr Chakresh Kumar Jain |

| **COURSE OUTCOMES:** Upon completion of the course, students will be able to | | **COGNITIVE LEVELS** |
|---|---|---|
| CO1 | Overview of the bioinformatics methdos and resources | Understanding Level Level C2 |
| CO2 | Explain about the Sequence analysis and highthotuput methodologies | Understanding Level Level C2 |
| CO3 | Apply Genome annotation and proteome analysis in solving biological problems. | Apply Level Level C3 |
| CO4 | Analyzing the use of Phylogenetic analysis in Microbial System annotation | Analyse Level Level C4 |

| Module No. | Title of the Module | Topics in the Module | No. of Lectures for the module |
|---|---|---|---|
| **1.** | Overview of bioinformatics and Microbial Informatics | Introduction to Bioinformatics, Information flow, Scope of Bioinformatics, computers and microbes, basics of internet, Network-based services (Cloud & Grid Computing), microbial informatics, environment and diversity | 5 |
| **2.** | Biological databases, microbial genomes Projects | Basics of Database designing and modeling, Designing policies, File formats (FASTA, PIR, Genbank), data storage, retrieval,*Microbial* Genomes, Genbank, Pfam, KEGG, Brenda, MBGD, *biodiversity databases* | 5 |
| **3.** | Sequence analysis (Sequence, retrieval, methods, substitution matrices, submission and analysis) | String comparison (substring, subsequence), Hamming and Levenshtein distance, Sequence alignment (pair wise, multiple) Dot plot method, Dynamic programming, *Needleman–Wunsch* and *Smith–Waterman* algorithm, BLAST algorithm ,FASTA algorithm comparison, PSI blast, gap penalty, e-value, statistical importance, PAM and BLOSUM matrices, log odd score, Sequence submission tools (Banklt, Sequin) | 8 |
| **4.** | High throughput data generation and analytics (NGS and Microarray) | Genome sequencing projects, NGS generation, Computational tool and pipelines, microarray technology, data analysis methods and tools | 5 |
| **5.** | Genome annotation procedures and analysis tools | Gene structure, Gene finding strategies Glimmer,Genscan, promoter region identification, promoter signals, genome annotation tools, Gene ontology, biological networks | 4 |

| | | | |
|---|---|---|---|
| **6.** | Protein Structure prediction and proteome analysis | Protein sequence and structures (primary, secondary and tertiary) and prediction, protparam, *Chou–Fasman*algorithm, GOR method, Concepts of structural modeling and tools (Comparative homology modeling, Threading), PHD, ANOLEA, Transmembrane protein prediction tools, Mass spectrometry data and analysis | 6 |
| **7.** | Phylogenetic analysis | Phylogeny, Phyloegenetic reconstruction distance matrix, types of trees, Rooted un-rooted, distance based methods (UPGMA, FM, NJ Methods), Character based methods (Parsimony method, Maximum likelihood method), tree evaluation, (bootstrapping, Jackknifing), functional inferences. Phylogenetic profiles. | 5 |
| **8.** | Microbial System biology, Environment, and | System biology, microbial diseases. Metagenomics, Environmental *Informatics and health* | 4 |
| | Metagenomics | | |
| | | **Total number of Lectures 4** | |

**Evaluation Criteria**

**Components Maximum Marks**
T1 20
T2 20
End Semester Examination 35
TA 25 (Assignment 1, MCQ, Presentations, Viva)
**Total 100**

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| **1.** | Attwood T.K. & Smith Parry., “Introduction to Bioinformatics”, Benjamin Cummings, 2001 |

| | |
|---|---|
| **2.** | BaxevanisA., D & Ouellette "Bioinformatics A practical guide to analysis of genes and protein", Wiley Interscience, 1998. |
| **3.** | David Mount "Bioinformatics: Sequence and Genome analysis", Cold Spring Harbor Laboratory Press, 2001. |

## Detailed Syllabus

**Lab-wise Breakup**

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|---|---|---|---|
| **Course Code** | 19M25BT211 | **Semester** Odd | **Semester** III |

| | | | |
|---|---|---|---|
| | | | **Session** 2020-21<br>**Month from** July to December |
| **Course Name** | Microbiology Lab-III | | |
| **Credits** | 4 | **Contact Hours** | 8 |

| **COURSE OUTCOMES** Students will be able to | | **COGNITIVE LEVELS** |
|---|---|---|
| **CO1** | Apply concepts of food microbiology | Level III (Apply) |
| **CO2** | Analyze bacterial transformation techniques | Level IV (Analyze) |
| **CO3** | Evaluate cloning techniques | Level V (Evaluate) |

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|---|---|---|
| **CO4** | Apply bioinformatics tools for microbial genome analysis | Level III (Apply) |

| **Module No.** | **Title of the Module** | **List of Experiments** |
|---|---|---|
| 1. | **Food microbiology** | Enumeration of yeasts and moulds in food; microscopic examination of moulds; microbial standards for different foods and drinking water; food adulteration: methods of detection of common adulterants in food, heat preservation of food; food fermentations |
| 2. | **Bacterial Transformation** | Competent cells preparation and transformation of plasmid DNA, calculation of transformation efficiency |
| 3. | **Cloning and screening of recombinants** | Restriction digestion of vector and insert; ligation of gene of interest in vectors; transformation; Screening of recombinants |
| 4. | **Bioinformatics** | Bioinformatics tools (BLAST, genome analysis & phylogenetic analyses tools) and resources (NCBI); proteome and transcriptome analyses; network studies |

**Lecture-wise Breakup**

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|---|---|---|---|
| **Course Code** | 17M12BT116 | **Semester** Odd | **Semester** X **Session** 2020-2021<br>**Month from** July-Dec 20 |

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|---|---|
| **Course Name** | Regulatory Affairs |

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|---|---|---|---|
| **Credits** | 3 | **Contact Hours** | 3 |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | Dr Shweta Dang |
| | **Teacher(s) (Alphabetically)** | Dr Shweta Dang |

| **COURSE OUTCOMES** | | **COGNITIVE LEVELS** |
|---|---|---|
| **C120.1** | Explain regulatory markets and agencies; preclinical and clinical trials | Understanding (Level 2) |
| **C120.2** | Analyze the guidelines for approvals of new drugs/biologics | Analyzing (Level 4) |
| **C120.3** | Compare innovator and generic pharmaceutical industry with Patent and Non patent exclusivity | Evaluating (Level 5) |
| **C120.4** | Interpret ICH guidelines applicable to drugs and biotechnology based therapeutic products. | Understanding (Level 2) |
| **C120.5** | Assess regulatory approvals via related case studies | Evaluating (Level 5) |

| **Module No.** | **Title of the Module** | **Topics in the Module** | **No. of Lectures for the module** |
|---|---|---|---|

| | | | |
|---|---|---|---|
| **1.** | **Introduction To Regulatory agencies** | CDSCO, India<br>USFDA, USA<br>EMEA, Europian Union<br>TGA, Australia | **2** |
| **2.** | **Introduction To Pharmacopoeias and Monographs** | Indian Pharmacopoeia (IP)<br>British Pharmacopoeia (BP)<br>United Sates Pharmacopoeia (USP)<br>International Pharmacopoeia (Int. Ph.)<br>European Pharmacopoeia (Eur. Ph.) | **2** |
| **3.** | **Safety and efficacy of drugs/biologics, preclinical studies, Clinical phases** | Case studies of safety issues in history, Preclinical requirements, acute and chronic toxicity, dose determination, NOAEL, phases of clinical trials (I,II III) | **4** |
| **4.** | **Approval pathways for Drugs/ biologic/ biopharmaceutic als in USFDA** | FDA,CDER, CBER, IND, NDA, BLA, recalls, Phase IV, filing procedures | **7** |
| **5.** | **Approval pathways** | EMEA, market authorization application. Centralized, | **4** |

| | | | |
|---|---|---|---|
| | **for Drugs/ biologic/ biopharmaceuticals in europe** | Decentralized, National, Mutual recognition procedure. CTD, eCTD, Nees Submissions, ICH M4 | |

| | | | |
|---|---|---|---|
| **6.** | **Approval pathways for Drugs/ biologic/ biopharmaceuti cal s in India and Japan** | Central Drug Standard Control Organization, INDIA, Pharmaceutical and Medical Devices Agency of Japan | **3** |
| **7.** | **Generics and Biosimilars** | Hatch Wax man Act (Para I,II,III and IV filings), BPCI act USA, CDSCO guildines, EMEA guidelines, Status of guidelines | **6** |

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|---|---|---|---|
| **8.** | **Non Patent Exclusivities** | Orphan Drug law, Market exclusivity, Pediatrics exclusivity, First to file exclusivity | **5** |
| **9.** | **ICH Guidelines for Biologics and Good Clinical Practices** | Overview of ICH guidelines, ICH QSEM, ICH Q5 ,Q6,. ICH E6, ICH Q8,9,10 | **5** |
| **11.** | **Case Studies** | Relevant Case studies | **4** |
| | | **Total number of Lectures** | **42** |

**Evaluation Criteria**

**Components Maximum Marks**
T1 20
T2 20
End Semester Examination 35
TA 25 (Class Test, Assignment I and II)
**Total 100**

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| **1.** | Sandy Weinberg, GUIDEBOOK FOR DRUG REGULATORY SUBMISSIONS, 2009 (first edition), John Wiley & Sons, Inc. |

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|---|---|
| **2.** | The Common Technical Document (CTD), Internet: http://www.ich.org/ |
| **3.** | Guideline for submitting supporting documentation in drug applications for the manufacture of drug substances, February 1987, Internet: http://www.fda.gov/cder/guidance/drugsub.pdf |
| **4.** | ICH Guideline: The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality - M4Q; Quality Overall Summary of Module 2, Module 3: Quality, Internet: http://www.ich.org/MediaServer.jser?@_ID=556&@_MODE=GLB |

## Detailed Syllabus

**Lecture-wise Breakup**

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|---|---|---|---|
| **Course Code** | 17M12BT111 | **Semester** Odd | **Semester** III<br>**Session** 2021-2022<br>**Month from:** July-December |

| | | | |
|---|---|---|---|
| **Course Name** | Biosensors | | |
| **Credits** | 3 | **Contact Hours** | 3 |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | Prof.Sudha Srivastava |
| | **Teacher(s) (Alphabetically)** | Prof.Sudha Srivastava |

| **COURSE OUTCOMES** | **COGNITIVE LEVELS** |
|---|---|

| | | |
|---|---|---|
| **CO1** | Explain principle and working of biosensors and characterization techniques | Understand Level(C2) |
| **CO2** | Evaluate different methods of immobilization and their effect on biosensor performance | Evaluate Level (C5) |
| **CO3** | Analyze performance of a biosensor for disease diagnosis, environmental pollution, pathogen quantification | Analyze Level (C4) |
| **CO4** | Design strategy for fabrication of a given biosensor with high sensitivity and wide detection range | Create Level (C6) |

| Module No. | Title of the Module | Topics in the Module | No. of Lectures for the module |
|---|---|---|---|
| **1.** | **Introduction:** | Sensors and biosensors, definitions, types of sensors, markets, target analytes, glucose and other medical sensors | 2 |
| **2.** | **Biosensor Advancements and nanotechnology** | First-, second-, third generation biosensors, Nanotechnology and present day biosensors | 3 |
| **3.** | **Basic Design Considerations** | Calibration, dynamic Range, signal to noise, sensitivity, selectivity, interference. | 3 |
| **4.** | **The biological component** | Whole cell sensors, enzymes – sensing substrates or inhibitors, antibodies (Mab, Fab). And other binding proteins, oligonucleotides and aptamers. | 3 |
| **5.** | **Types of biosensors** | Optical biosensors, Electrochemical biosensors, Piezoelectric biosensor, Calorimetric biosensors | 8 |

| | | | |
|---|---|---|---|
| **6.** | **Immobilization method** | Non-covalent immobilization - entrapment and multipoint electrostatic attachment. Covalent attachment via thiol, amino and hydroxyl groups. Affinity interactions - avidin/biotin, , complementary oligonucleotides. | 4 |
| **7.** | **Techniques for sensing : Physical and chemical** | Absorbance, fluorescence, chemi/bioluminescence and phosphorescence, Surface Plasmon Resonance (SPR), quartz crystal microbalance, cyclic voltammetry | 8 |
| **8.** | **Sensor stabilization** | Storage and operational stability. Polyols, polymers and low Mw compounds as stabilizing agents for drying and long term storage. Stabilization mechanisms. | 3 |
| **9.** | **Applications** | Pharmaceutical**,** agricultural, food safety, biomedical applications, food processing: state of the field, market potential, unique design criteria and needs, current sensors in use. | 8 |

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|---|---|
| **Total number of Lectures** | **42** |

**Evaluation Criteria**

**Components Maximum Marks**
**T1** 20
T2 20
End Semester Examination 35
TA 25 (Class Test, Presentation)
**Total 100**

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| **1.** | Ligler, F.S. and Rowe Taitt, C.A. 2002. Optical Biosensors: Present & Future. Elsevier, The Netherlands. ISBN: 0-444-50974-7. |

| | |
|---|---|
| **2.** | Yang, V.C. and T.T. Ngo. 2000. Biosensors and Their Applications. Kluwer Academic/Plenum Publishers, New York, NY. ISBN: 0-306-46087-4. |
| **3.** | Recent research articles |

## Detailed Syllabus

**Lecture-wise Breakup**

| | | | |
|---|---|---|---|
| **Course Code** | **17M12BT118** | **Semester** Odd | **Semester** III<br>**Session** 2021-2022<br>**Month from:** July-December |
| **Course Name** | **Product Development in Biotechnology** | | |

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|---|---|---|---|
| **Credits** | 3 | **Contact Hours** | 3 |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | Dr.NeerajWadhwa |
| | **Teacher(s) (Alphabetically)** | Dr.NeerajWadhwa |

| **COURSE OUTCOMES** | | **COGNITIVE LEVELS** |
|---|---|---|
| **CO1** | Outline various processes relevant for Biobusiness | **Understand Level (C2)** |
| **CO2** | Compare marketing techniques and related ethics | **Apply Level (C2)** |

| | | |
|---|---|---|
| **CO3** | Select appropriate technology for the production of Biological products | **Understand Level (C3)** |
| **CO4** | Explain financial, regulatory, health policy aspects for biobased industries | **Understand Level (C2)** |

| Module No. | Subtitle of the Module | Topics in the module | No. of Lectures for the module |
|---|---|---|---|
| **1.** | **Biotechnology Industries overview** | Biotech industries in India and abroad, Biotechnology as a function of science and business ,Company structures versus other non-biotech companies , Functional units<br>Company structure and functions<br>Emerging technology and technical convergences issues | **5** |
| **2.** | **Business in the context of biotechnology**<br>**Entrepreneurship** | Science/development, the idea and its development, Plant tissue culture lab-equipment- glassware chemical requirement- construction,techniquesin culturing and export abroad, Vermitechnology, Mushroom cultivation, single cell protein, Biofertilizer technology production, Textile processing, leather treatment, Detergent industry, bakery, diary Pharmaceutical drug development, Medical device product development ,Technology product development Other biotech product development, such as biofuels, bioengineered foods, etc.- commercialization of Bakery and dairy products | **10** |

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|---|---|---|---|
| **3.** | **Product develop me nt** | a. Production of commercially important primary metabolites like organic acids, amino acids and alcohol & Production processes for various classes of secondary metabolites: Antibiotics, Vitamins and Steroids.<br>b.Production of Industrial Enzymes, Biopesticides, Biofertilizers, Biopreservatives, Biopolymers Biodiesel. Cheese, Beer, SCP & Mushroom culture, Bioremediation.<br>c.Production of recombinant proteins having therapeutic and diagnostic applications, vaccines. | **12** |
| | | Bioprocess strategies in Plant Cell and Animal Cell culture.<br>d.Biotransformation applications of enzymes - Hydrolytic- Ester bond, Amide, Epoxides, Nitriles, Reduction reactions –aldehydes, Ketones, C=C, Oxidation reactions – Alkanes, Aromatic, Baeyer Villiger, Enzymes in organic synthesis– esters, amide, peptide , Modified and Artificial Enzymes , Catalytic antibodies | |
| **4.** | **Intellectu al property, Bioethics ,le gal issues** | Patents, Confidentiality , Licensing agreements Business Development/Licensing, Strategy Marketing and public perception in product development, genetically modified products and organism transgenic products licencing and branding concerns | **5** |
| **5.** | **Biobusi nes s plans** | Concerns and oppurtunities, Bank loan and finance strategy, Budget planning,Policy and regulatory concerns,Corporate partners marketing- Model project Case studies of different industries and strategic planning | **10** |

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|---|---|
| **Total number of Lectures** | **42** |
| **Evaluation Criteria**<br>**Components Maximum Marks**<br>**T1** 20<br>T2 20<br>End Semester Examination 35<br>TA 25 (Class Test, Presentation)<br>**Total 100** | |

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Papers, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| **1.** | Satyanarayana, U. "Biotechnology" Books & Allied (P) Ltd., 2005. |
| **2.** | Kumar, H.D. "A Textbook on Biotechnology" 2nd Edition. Affiliated East West Press Pvt. Ltd., 1998. |
| **3.** | Balasubramanian, D. etal., "Concepts in Biotechnology" Universities Press Pvt.Ltd., 2004. |
| **4.** | Ratledge, Colin and Bjorn Kristiansen "Basic Biotechnology" 2nd Edition Cambridge University Press, 2001 |
| **5.** | Faber K , Biotransformations in Organic Chemistry, IV edition , Springer |
| **6.** | Dubey, R.C. "A Textbook of Biotechnology" S.Chand& Co. Ltd., 2006. Trevor Palmer , Enzymes II edHorwood Publishing Ltd |
| **7.** | Cruger,Wulf and AnnelieseCrueger, "Biotechnology: A Textbook of Industrial Microbiology", 2nd Edition, Panima Publishing, 2000. |
| **8.** | Richard Oliver " The coming Biotech Age ; the business of Biomaterials" Mc Graw Hill Publication , New York USA2000 |

| | |
|---|---|
| **9.** | Karthikeyan,S and Arthur Ruf.” Biobusiness”MJP Publication Chennai India 2009 |
| **10.** | Cynthia Robins,” The business of Biotechnology”. UK Harper Collins 2001 |


## Detailed Syllabus

**Lecture-wise Breakup**

| | | | |
|---|---|---|---|
| **Subject Code** | **19M22BT211** | **Semester**<br>**Odd** | **Semester III Session 2020-21**<br>**Month from July to December** |
| **Subject Name** | Diagnostic Microbiology | | |
| **Credits** | **3** | **Contact Hours** | **3** |

| | | |
|---|---|---|
| **Faculty** | **Coordinator** | 2. Dr. Sonam Chawla |
| | **Teacher** | 2. Dr. Sonam Chawla |

| **COURSE OUTCOMES** | | **COGNITIVE LEVELS** |
|---|---|---|
| **CO1** | Interpret the fundamental concepts, tools and methods of microbial diagnostics in relation to various human diseases/disorders | **Applying level (Level III) C3** |
| **CO2** | Apply principles of Molecular diagnostics to genetic counselling, communicable, non-communicable and lifestyle diseases/disorders | **Applying level (Level III) C3** |

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| **CO3** | Correlate different advances in microbial diagnostics to human microbiome, their significance in disease management and therapy | **Analysis level (Level IV) C4** |
| **CO4** | Identify importance as well as ethical and biosafety issues related to the field of diagnostics | **Understanding Level (Level II) C2** |

| **Module No.** | **Subtitle of the Module** | **Topics in the module** | **No. of Lectures for the module** |
|---|---|---|---|
| 1. | Introduction | Fundamentals of Microbial diagnostics and its significance in post genomic era in health care industry | 03 |
| 2. | Microbiological diagnostic tools for bacterial pathogen detection | Microscopy and other culture based tests, Blood and other body fluids based biochemical methods for pathogen detection, strategies for antimicrobial sensitivity testing, Urea Breath Tests for *Helicobacter pylori* | 08 |
| 3. | *Advanced Techniques in Diagnostic Microbiology* | Principles and characteristics of techniques ranging from rapid antigen testing, to advanced antibody detection, *in vitro* nucleic acid amplification techniques, Gene and signal amplification techniques, non PCR mediated target amplification, RT-PCR and microarray based Identification, probe technologies, FISH, RFLP, RNA inhibition analysis, OLA, DNA finger printing | 10 |
| 4. | Diagnostics for assessing viral infections | Methods in basic virology, Human Immunodeficiency Virus (HIV), Hepatitis C, B & A Virus, Covid and emerging microorganism detection and genotyping | 04 |

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| 5. | Diagnostic tools for Genetic counseling and Cytogenetics | Genetic analysis for inherited disorders, mutation detection, detection of allelic diversity (SSCP/DGGE/ DHPLC, PTT tests), Heterozygote Testing,<br>Presymptomatic Testing, Prenatal Testing, and Newborn Screening | 05 |
| 6. | Lifestyle diseases/disorders, Human microbiome | Human microbiome and Cancer, sequence-based gut microbial identification and applications in disease management and therapy | 06 |
| 7. | Applications in Health care & Forensics | Diagnostic tools applicable in Hemoglobinopathies, Plasmapheresis, Blood Banking, blood and blood product screening forensics & Quarantine | 04 |
| 8. | Regulatory, Ethical and biosafety issues in diagnostics | Laboratory safety and specimen management, regulatory controls, case studies related to ethics in diagnostics | 02 |
| | | Total number of Lectures | 42 |

**Evaluation Criteria**

**Components Maximum Marks**
**T1** 20
T2 20
End Semester Examination 35
TA 25 (Class Test, Presentation)

**Total 100**

Recommended Reading material: Author(s), Title, Edition, Publisher, Year of Publication etc.
(Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)


| | |
|---|---|
| 1. | **Tang**, Yi-Wei, **Stratton**, Charles W. (Eds.), "Advanced techniques in Diagnostic microbiology", 2018, Springer publication |
| 2. | Bailey & Scott's Diagnostic Microbiology, 14th Edition, **by Patricia Tille, 2017, Elsevier Evolve** |
| 3. | Jean-Louis Serre, "Diagnostic techniques in Genetics", 2006, John Wiley& Sons publication |

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|---|---|
| 4. | Trent R J, “Molecular Medicine : An Introductory text”, Churchill Livingston publication |
| 5. | Refereed papers from scientific journals for case studies |

## Detailed Syllabus

**Lecture-wise Breakup**

| | | | |
|---|---|---|---|
| **Course Code** | **18M12BT116** | **Semester** Odd **(specify Odd/Even)** | **Semester** III **Session** 2020 - 2021 **Month from** July to December |
| **Course Name** | IPR in Biotechnology | | |
| **Credits** | 3 | **Contact Hours** | 3 |

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|---|---|---|
| **Faculty (Names)** | **Coordinator(s)** | Dr. Indira P. Sarethy |
| | **Teacher(s) (Alphabetically)** | Dr. Indira P. Sarethy, Dr. Shweta Dang |

| **COURSE OUTCOMES** | | **COGNITIVE LEVELS** |
|---|---|---|
| **CO1** | Explain and interpret the types of intellectual property rights, related laws and systems | **Understand (C2)** |
| **CO2** | Apply specific IPR issues pertaining to medical biotechnology | **Apply (C3)** |
| **CO3** | Evaluate plant and traditional knowledge protection | **Evaluate (C5)** |

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|---|---|---|
| **CO4** | Appraise commercialization of intellectual property, infringements and laws applicable | **Evaluate (C5)** |

| Module No. | Title of the Module | Topics in the Module | No. of Lectures for the module |
|---|---|---|---|
| **1.** | **Introduction** | Intellectual Property Rights - their Relevance, Importance and Business Interest to Industry, Academia, Protection of Intellectual Property, Relationship of IPRs with biotechnology | **2 [CO1]** |
| **2.** | **Types of Intellectual Property Rights** | Patents, Trademarks, Copyrights, Industrial Designs, Geographical Indications, Trade secrets, non disclosure agreements | **2 [CO1]** |
| **3.** | **Patents** | General Introduction to Patents, Patent Terminology, Patent Claims, Patent Life and Geographical Boundaries, Utilization of Intellectual Patents, Licensing of patents | **4 [CO1, CO2]** |
| **4.** | **Elements of patentability** | Invention/Discovery, What constitutes Patentable subject matter, the Utility, novelty and non-obviousness of an invention, Patentability in Biotechnological Inventions: Case studies | **2 [CO2, CO3]** |
| **5.** | **Preparation and Process for** | Procedural steps to grant of a patent, Process of filing patents in India, PCT application, protocols of application, pre-grant & | **3 [CO2, CO3]** |
| | **Patenting** | post-grant opposition | |
| **6.** | **Patent Search** | Invention in context of "prior art", Patent Search methods, Patent Databases & Libraries, online tools, Country-wise patent searches (USPTO, EPO, India etc.), patent mapping | **2 [CO2, CO3]** |

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| **7.** | **IPR laws** | Basic features of the Indian Patent Act, the Indian Copyright Act, and the Indian Plant Varieties Protection and Farmers' Rights Act, A brief overview of other Patent Acts & Latest Amendments of Indian, European & US patent systems | **2 [CO1, CO2, CO3]** |

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| **8.** | **Patent issues in Drugs and Pharmaceu ti cal s** | Generics, Compulsory Licensing, Exclusive Marketing Rights (EMR), Bolar provision, Bayh-Dole act, Second medical use | **2 [CO2, CO3]** |
| **9.** | **Worldwide Patent Protection, WTO & TRIPS Agreement** | Brief Background of different International conventions such as Paris convention, TRIPS, WTO, PCT and Patent Harmonisation including Sui-generis system, The relationship between IPRs and international trade, Overview of WTO & TRIPS Agreement, Enforcement and dispute settlement under the TRIPS Agreement, The implication of TRIPS for developing countries in the overall WTO system | **2 [CO1, CO2, CO3]** |
| **10.** | **Gene patents** | Introduction & overview, what constitutes gene patents, Bayh Dole Act, ESTs, Cohen-Boyer technology, PCR patents, EPO case, BRCA gene, Types of IPR involved, Genetic Use Restriction Technologies, Patenting of biologics, Hatch Waxman Act | **9 [CO3, CO4]** |
| **11.** | **Protection of Plant Varieties /Seeds** | The interface between technology and IPRs in the context of plants, Key features of UPOV 1978, UPOV 1991 and TRIPS with respect to IPRs on plants, Indian Law on Protection of Plant Varieties, DUS criteria, patenting of genetically modified plants, The significance of IPRs in agricultural biotechnology, Biodiversity, Conventions & Treaties, plant patents, Plant Varieties Protection Act, Plant Breeders' Rights, UPOV, benefit sharing, *sui generis* systems Case studies | **4 [CO3, CO4]** |
| **12.** | **Traditional Knowledge and Intellectual Property Rights** | The importance and relevance of Traditional Knowledge for developing nations, The various approaches to protecting TK, The local, national and global dimensions of the issues in TK and IPRs, Traditional Medicine & IP Protection, Folklore, Patenting of Health Foods: Case studies | **4 [CO3, CO4]** |

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|---|---|---|---|
| **13.** | **Patent Infringement and Commercializin g Intellectual Property Rights** | What all are considered as patent Infringement: Case studies, defenses to infringement including experimental use, patent misuse, legal considerations, Patent Valuations, Competition and Confidentiality issues, Assignment of Intellectual Property Rights, Technology Transfer Agreements | **4 [CO4]** |
| | | **Total number of Lectures** | **42** |

**Evaluation Criteria**

**Components Maximum Marks**

T1 20

T2 20

End Semester Examination 35

TA 25 (Assignments 1, 2. Presentation 1)

**Total 100**

**Recommended Reading material:** Author(s), Title, Edition, Publisher, Year of Publication etc. ( Text books, Reference Books, Journals, Reports, Websites etc. in the IEEE format)

| | |
|---|---|
| **1.** | USPTO Web Patent Databases at: www.uspto.gov/patft |
| **2.** | Government of India's Patents Website: patinfo.nic.in |
| **3.** | Intellectual property India: www.ipindia.nic.in |
| **4.** | “Indian Patent Law : Legal and Business Implications” by AjitParulekar, Sarita D'Souza Macmillan India publication, 2006 |
| **5.** | “Agriculture and Intellectual Property Rights”, edited by: Santaniello,V., Evenson, R.E., Zilberman, D. and Carlson, G.A. University Press publication, 2003 |

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| **6.** | Research papers and Reports provided from time to time |