**JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD**

**IV Year B.Tech. Biotech.-II Sem**

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## (A82329) BIOPROCESS OPTIMIZATION AND PLANT DESIGN

**Objectives:** This course aims to inculcate the knowledge of process economics and optimization using various statistical and non statistical approaches.



**Unit I:**

**Basic Concepts**

Overview of experimental design in biological process, understanding of variables in biological processes. Introduction to optimization of bioprocesses.

**Unit II:**

**Optimization Approaches**

Statistical and numerical optimization, fundamental theory. First order and second order designs, differences in approaches, general response surface analysis. Statistical experimental procedures for Placket – Burman designs; Method of Ridge analysis, Nelder – Mead simplex method; Optimization of multi – response biological systems. **Non statistical approach:** Self directing optimization, case-studies with simple response and multi-response analysis.

**Unit III:**

**General Design Consideration**

Technical feasibility survey, process development, principles of equipment design and specification. Project consideration: Marketability of product, availability of technology, raw materials, equipment, human resources, land and utilizations. Other consideration: Site characteristics, waste disposal, government regulation and other legal restriction, community factors and other factors affecting investment.

**Unit IV:**



**Design of Heat Exchangers**

Evaluation of heat load for any fermentation process, design of heat exchanger using energy balance equation. Application of optimization techniques in the design of a heat exchanger in terms of heat transfer area, temperature differences, cost and project economics.

**Unit V:**

**Design of Bioreactors**

Bioreactor: Application of mass and energy balances in the design, evaluation of size and related features of the fermenter. Application of optimization techniques in the design of fermenter in terms of size, cost and project

economics.

**TEXT BOOKS:**

1. B. Volesky and J. Votrubla. Modeling optimization of fermentation process. Elsevier, Amsterdam.
2. Peters and Timmerhaus. Plant design and economics and for chemical engineers. Mc Graw-Hill. 4th Edition.

**REFERENCES:**

1. Rudd and Watson. Strategy of process engineering. Wiley.
2. D.C. Montgomery. Design and Analysis of Experiments. 5th edition. Wiley India (P) Ltd., New Delhi.

**Outcomes:** The students will be able to design the experiments and optimize the processes, will be able to calculate the optimum conditions for best production. The students will know how the product cost can be minimized.

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### (A82331) FOOD BIOTECHNOLOGY

### (Elective-IV)

**Objectives:** This course structure is envisaged to impart thorough knowledge and understanding of food related technical knowhow and problem for processecing, preservation quality control and food borne disease etc.

**Unit I:**

**Introduction To Food Processing**



Biotechnology in relation to the food industry, nutritive value of food, and microorganisms associated with food, its sources and behavior in foods.

**Unit II:**

**Food Preservation**

Bioprocessing of meat, fisheries, vegetables, dairy products, enzymes and chemicals used in food processing, Biochemical engineering for flavor and food production, cryopreservation, irradiated foods.

**Unit III:**

**Fermented Food Products & Quality control**

Dairy products, non-beverage plant products, beverages and related products of baking.

Quality control, case studies on Biotechnology in the evolution of food quality.

**Unit IV:**

**Food Spoilage & Food Borne Diseases**

Food -borne infections & intoxications.

**Unit V:**

**Food Microbiology**

Utilization of microorganisms in food Industry, Single cell protein, Neutraceuticals etc., Natural and artificial sweeteners and their role in controlling diseases and deficiencies.

**TEXT BOOKS:**

1. Roger A., Gordan B., and John T., Food Biotechnology.
2. Essentials of Food process Engineering. Chandra Gopala Rao. BS Publications. (2006).



**REFERENCES:**

1. George J.B., Basic Food Microbiology, CBS Publishers Distributors.

2. James M .J. Modern Food Microbiology, CBS Publishers & Distributors.
3. Lindsay, Willis Biotechnology, Challenges for the flavor and food Industries, Elsevier Applied Science.
4. Fundamentals of Food Engineering. D.G Rao. Prentice-Hall of India 2010.

**Outcomes:** At the end of the study the students will be competent to differentiate between food biotechnology benefits and types of microorganisms associated with food processing, preservation strategies and quality control.

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### (A82333) NANO BIOTECHNOLOGY

### (Elective-IV)

**Objectives:** The objective of this course is to provide exposure to the students to biological nano structures with their characterization and applications in Drug delivery, diagnostics, Imaging and development of sensors.

**Unit I:**



**Introduction to Nanobiotechnology**

Nanobiotechnology versus bionanotechnology

Nanoscale effects in biosystems, scope and future prospects.

Nanostructures: core/shell nanoparticles – classification – organic/inorganic, polymeric

**Unit II:**

**Fabrication and Characterization of Nanostructures**

Fabrication methods: self assembly, lithography, e-beam lithography, sol-gel process.

Characterization tools: AFM, STM, SEM, TEM, electron microscopy

**Unit III:**

**Drug delivery and Biomedical engineering**

Targeting cancer cells using PLGA nanoparticles, nanoengineered capsules for sustained drug delivery.

Core/shell nanoparticles in tissue engineering (organic, inorganic, polymeric)

**Unit IV:**



**Nanobiocompunds**

DNA polynode, RNA topoisomerase, biopolymers, procollagen, protein-magnetic materials.

Smart materials: Nanoscale biostructures, heterogenous nanostructures.

**Unit V:**

**Applications of nanobiotechnology**

Bioimaging, cell labeling, drugs-photodynamic therapy, molecular motors.

**TEXT BOOKS:**

1. Ratner and Ratner, Nanotechnology- a gentle introduction to the next big idea, Pearson education, 2007.

2. T. Pradeep, NANO: The Essentials, understanding Nanoscience & Nanotechnology, Mc Graw – Hill Education. (2010).

**REFERENCES:**

1. Harising nalwa, encyclopedia of Nanoscience and technology , scientic America
2. L.E.Foster, nanotechnology-science, innovation and opportunity, pearson education inc, 2007

**Outcomes:** After completion students will gain competence to distinguish between different types of nanostructures in biology. They gain awareness about changes in properties at nano level along with its applications.

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## (A82330) CLINICAL TRIALS AND REGULATORY AFFAIRS

**(Elective-V)**

**Objectives:** This course is designed with an aim to impart understanding of the best practices adopted for clinical trials. They get acquainted to the regulatory bodies with in India and at the global level.

**UNIT-I:**



**INTRODUCTION**

Licensing authorities-roles and responsibilities,ICH GCP,FDA, EU Clinical Trial; Directive, Data Protection Act & Regulations relating to electronic; signatures,Declaration of Helsinki 2000 amendment and financial disclosure; Regulation of drug preparation and Law, guidelines and codes of practice.

packaging,EMEA,European directives and MRECs,Ethics committees – history; structure regulation impact of ICH GCP recent development with regard to INDIA; / USA / EU Clinical Trial directive

**UNIT II:**

**ETHICAL ISSUES**

Ethics in all aspects of health care; Historical cases; Negligence , informed consent, mental competence; Up – to – date cases: cloning, human embryos and IVF; Shared responsibilities for decisions and understanding of risk.

**UNIT III:**

**REGULATORY REQUIREMENTS**

Definitions of GCP, auditing , monitoring and inspection; GCP auditing requirements from a regulatory perspective; GCP compliance and audit certificates; GCP auditor training; GCP audit team structure and SOPs; GCP audit planning; GCP audit conduct; Reporting GCP audit findings; Follow – up to GCP audit reports.

Roles and responsibilities in clinical research according to ICH GCP; Sponsor; Monitor; Investigator; IRB / IEC; Essential documentation. The INDIAN / USA / EU Directives on GCP in Clinical Trials: Purpose: How will the introduction affect clinical research; Extracts from the guidance documents. Possible sanctions for non- compliance (a) Legal and regulatory (b) Commercial and (c) Professional.

Regulations in clinical research; The purpose of audits; Types of audits; Preparing for audits; In company

On site; The audit process; Typical audit finding; What are they; Resolution;

How can they be avoided.

**UNIT IV:**

**REGULATORY AFFAIRS**



History of regulatory affairs; Main concepts QSE; Sources of information; Regulatory affairs for studies in human subjects;;What data is needed; Current and future European requirements and procedures; US perspective; Recognizing why clinical research has to meet the needs of regulatory Affairs.

Regulatory submissions for new products; What data is needed?; Requirements for gaining approval; US perspective; Regulatiion and control of marketing and sales of medical products; Regulations Codes of practice; Promotional materials.

**UNIT V:**

**RECENT DEVELOPMENTS**

Latest developments in ICH; Purpose; Implications; Guidance notes; Inspections. INDIAN / USA / EU Ethics approval system: Overview; Recent developments. Current issues in Clinical research: Confidentiality issues; Medicines for human use ( clinical trials ) regulations 2003. Other relevant issues

**TEXT BOOKS:**

1. Good Clinical Practices ,Central Drugs Standard Control Organisation, Govt. of India
2. Fundamentals of clinical trials. Third Edition. Lawrence M. Friendman, Curt D. Furberg, David L. DeMets. Springer International Edition. (2009).



**REFERENCES:**

1. International Clinical Trial, Volume 1 &2 Dominique P.Brunier and Gerhardt Nahler, Interpharm Press, Denver, Colorado.
2. Code of Federal Regulation by USFDA – Download.
3. ICH-GCP Guidelines – Download.
4. Biosafety issues related to genetically modified organism , Biotech Consortium India Limited, New Delhi.

**Outcomes:** At the end students would get awareness about factors which are important in GCP. They will also get knowledge of the guidelines followed in India and at the International level for GCP.

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### (A82332) METABOLIC ENGINEERING

### (Elective-V)

**Objectives:** The aim of the course is to give students an exposure to cellular metabolism, its regulation, metabolic flux, metabolic pathway modeling and its applications.

**UNIT I :**

**INTRODUCTION**



An Introduction to Metabolic Engineering, Overview of cellular metabolism. Models for cellular reactions, induction – Jacob Monod model and its regulation, Differential regulation by isoenzymes, Feed back regulation.

**UNIT II :**

**BIOSYNTHESIS OF PRIMARY METABOLITES AND SECONDARY METABOLITES**

Amino acid synthesis pathways and its regulation at enzyme level and whole cell level, Alteration of feed back regulation, Limiting accumulation of endproducts.

Regulation of secondary metabolite pathways, precursor effects, prophase, idiophase relationship, Catabolite regulation by passing control of secondary metabolism, producers of secondary metabolites, applications of secondary metabolites.

**UNIT III :**

**REGULATION OF ENZYME PRODUCTION**

Strain selection, Genetic improvement of strains. Metabolic pathway, manipulations to improve fermentation, Feed back repression, Catabolite Repression, optimization and control of metabolic activities. The modification of existing - or the introduction of entirely new - metabolic pathways

**UNIT IV :**

**METABOLIC FLUX**



Integration of anabolism and catabolism, metabolic flux distribution analysis of bioprocess, material balance, kinetic types, equilibrium reaction. Experimental determination method of flux distribution, Metabolic flux analysis and its applications.

**UNIT V :**

**METABOLIC ENGINEERING WITH BIOINFORMATICS AND APPLICATIONS**

Metabolic pathway modeling, Analysis of metabolic control and the structure.metabolic networks, Metabolic pathway synthesis algorithms,

Application in pharmaceuticals, chemical bioprocess, food technology, agriculture, environmental bioremediation and biomass conversion.

**TEXT BOOKS:**

1. Wang.D.I.C Cooney C.L., Demain A.L., Dunnil.P. Humphrey A.E. Lilly M.D.,Fermentation and Enzyme Technology, John Wiley and sons.
2. Stanbury P.F., and Whitaker A., Principles of Fermentation Technology, Pergamon Press.

**REFERENCES :**



Zubay G., Biochemistry, Macmillan Publishers.

http://ocw.osaka-u.ac.jp/contents/19/ME040512.pdf For unit VI & VII

http://ocw.osaka-u.ac.jp/contents/19/ME040421.pdf For unit VI

http://ocw.osaka-u.ac.jp/contents/19/ME040526.pdf For unit VII

http://ocw.osaka-u.ac.jp/contents/19/ME040602.pdf For unit VI & VII

http://www.bioinfo.de/isb/gcb01/poster/hurlebaus.html

**Outcomes:** After completion of the course students will be able to understand and differentiate between various metabolic routes and their regulation. Students will be able to apply their knowledge for it's practical applications in different areas.

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**(A80087) INDUSTRY ORIENTED MINI PROJECT**



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**(A80089) SEMINAR**



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**(A80088) PROJECT WORK**

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**(A80090) COMPREHENSIVE VIVA**