Clinical Research Methods and Industrial Biochemistry

A Value-Added Course

Course Duration : 30 hours **Year: 2018-19**

Offering Department: PG Biochemistry

Course Outcome

Specify in detail the characteristics of clinical practice

Deliberate on the clinical research methods

Learn drug-discovery concepts

Contact: Head of the Department, Room No. 356. 3rd Floor, JSS College, Mysuru 570025

M.Sc. Degree Programme in Biochemistry		
VALUE ADDED COURSE - II		
Programme Code	**Title of the Course**	**Total Hours**
BIC	**CLINICAL RESEARCH METHODS AND INDUSTRIAL BIOCHEMISTRY**	**30**
Course Outcome(s): **CO1** Specify the classification and characteristics of clinical practice and clinical research **CO2** Learn in details with application, if applicable, clinical Research methods **CO3** Identify in depth fermentation technology and downstream Processing		**No. of Lectures**
Unit I:		
1.1	**Introduction to Clinical Research**	
1.1.1 1.1.2 1.1.3 1.1.4	Introduction to Clinical Research, Terminologies and definition in Clinical Research, Origin and History of Clinical Research Difference between Clinical Research and Clinical Practice, Types of Clinical Research, Phases of clinical research Clinical Trials in India–The National Perspective, Post marketing surveillance Pharmaceutical Industry–Global and Indian Perspective Clinical Trial market, Career in Clinical Research	**10**
Unit II:		
2.1	**Clinical Research Methods**	
2.1.1 2.1.2 2.1.3	Design of experiments, factorial experiments, randomization, interaction among factors. Types of studies: Cohort studies, double blind, placebo control, cross over and double dummy. Introduction to Good Clinical Practices, Clinical Trial Development: Protocol Design and Development, Case Report Form Design and Development, Principals of Data Management, Clinical Trial Management: Maintaining and Managing Essential Documents, Recording and Reporting Non–Serious and Serious Adverse Events.	**10**
Unit III:		
3.1	**Bioprocess Methods**	
31.1 3.1.2	Basics of chemical engineering, mass transfer, heat generation and removal, fluid dynamics: Bernoulli's principle, viscosity, hydraulic conductivity,	

3.1.3	capillary flow, control and applications of industrial processes, process evaluation and development, over production of metabolites and methods; Fermentation–Submerged and solid state fermentation Fermentor design, Industrial use of microbes. Strain improvement, Inocula preparation, Downstream processing–Recovery and purification of intracellular and extra cellular products. Methods to maximize the yield.	**10**

References

[1] Basic Test for Drugs, WHO-GENEVA 1998 edition
[2] Who Expert Committee on Specification for Pharmaceutical Preparation WHO-GENEVA, 2005 edition
[3] Who Expert Committee on Biological Standardization WHO-GENEVA 2003 edition
[4] Clinical Research Fundamental and Practice –Vishal Bansal Parar Medical Publisher, 2010 edition
[5] Introduction to Pharmacopoeia CBS Publishers and Distributors 1991 edition
[6] Essential of Clinical Research –Dr. Ravindra B. Ghooi and Sachin C. Itkar Nirali Prakashan 2010 edition
[7] Basic Principle of Clinical Research and Methodology, Jaypee Brothers Medical Publishers (P) Ltd. 2009 ed.
[8] A Comprehensive Clinical Research Manual-Samir Malhotra, Nusrat Shafiq, Promila Pandhi Jaypee Brothers Medical Publishers (P) Ltd, 2008 edition
[9] Industrial microbiology, A.H. Patel
[10] Principles of Fermentation technology, Stanburry. P. Whitaker and S.J. Hall,