

**DEPARTMENT OF MICROBIOLOGY**  
**VALUE ADDED COURSE**  
**FOOD PROCESSING AND QUALITY ASSURANCE**

**Hours: 30**

**Course Outcomes:**

On successful completion of this course students are able to:

CO 1. Acquire knowledge on scope, sectors and classification of food.

CO 2. Identify the types of food processing and food packaging

CO 3. Investigate the food sampling for microbiological analysis.

CO 4. Analyze the responsibility and organization of the quality assurance department.

CO 5. Create entrepreneurial spirit among students for International organization of Standardization.

**UNIT I**

**6 hrs**

Scope and importance of food processing - Future prospects, sectors of food processing industry, Classification of food – perishable and semi perishable food.

**UNIT II**

**6 hrs**

Principles of Food Processing- Primary processing - Cleaning, Sorting, Grading, Cutting, Seeding, Bleaching, Chilling and freezing. Secondary processing – Slicing, Pulping, Paste, Frying, Chilling and Freezing, Milling. Food packaging- Requirements and types.

**UNIT III**

**6 hrs**

Principal aspects of sampling of food- Importance of sample collection, sampling tools and containers, sample collection techniques, sampling for microbiological analysis of food, routine versus investigational sampling, packaging and sealing of sample.

**UNIT IV**

**6 hrs**

General principles of Quality Assurance- Responsibility and organization of the quality assurance department- Quality management system- color, rheology- viscosity and consistency, size and shape, texture, flavor and sensory evaluation.

**UNIT V**

**6 hrs**

International Organization of Standardization (ISO): Overview, structure, interpretation and case studies of food safety and Quality management including ISO-22000, ISO-9001:2000, ISO22000:2005, ISO 17025/CODES/GLP.

**Text Books:**

**T.B-1** Rajat K.Baisya, Changing Face of Processed Food Industry in India, First edition Ane Books India, 2008.

**T.B-2** William C.Frazier and Dennis C.Westhoff. Food Microbiology, Fourth edition, Tata McGraw-Hill Publishing Company Limited New Delhi, 2006

# VALUE ADDED COURSE

## CLINICAL RESEARCH

**Hours: 30**

### **Course Outcomes:**

On successful completion of this course students are able to:

CO1. Acquiring knowledge on the Institutional Ethics Committee.

CO2. Describe the New drug discovery process.

CO3. Determine the toxicity test in animals.

CO4. Categorize the various regulatory requirements in clinical trials.

CO5. Formulate the Import and Export of Drugs in India.

### **UNIT I**

**6 hrs**

Basic terminologies used in clinical research, Types of clinical trials and their examples. Ethics committee and its members, Institution Ethics Committee. Basic conceptual knowledge about receptors, drugs and ADME.

### **UNIT II**

**6 hrs**

New drug discovery process- Phase-I, II, III, IV trials. Pre-clinical toxicology: General principles, Systemic toxicology, Carcinogenicity, Mutagenicity, Teratogenicity, Reproductive toxicity, Local toxicity, Genotoxicity and animal toxicity requirements.

### **UNIT III**

**6 hrs**

Biological standardization, general principles, Scope and limitation of bio-assays and bioassay of some official drugs. Preclinical drug evaluation of its biological activity. Toxicity test in animals, ED50 and LD50 determination. Various guidelines for toxicity studies.

### **UNIT IV**

**6 hrs**

Various regulatory requirements in clinical trials, Schedule Y, ICMR guidelines. Documents in clinical study Investigator Brochure (IB), Protocol & Amendment in Protocol, Case Report Form (CRF), Informed Consent Form (ICF). Essential Documents in Clinical Trial Good Clinical Practice guidelines.

### **UNIT V**

**6 hrs**

Study of various clinical trials (completed or ongoing) Clinical Trial Application in India. Import & Export of Drugs in India, Investigational New Drug application (IND), Abbreviated New Drug Application (ANDA). New Drug Application (NDA).

### **Text Books:**

**T.B-1** S.P.Maity, R.N.Chatterjee and A.K.Das, Pharmacology, Seventh edition, Books and Allied (P)Ltd, Kolkata 2017.

**T.B-2** J.G.Colleee, A.G.Fraser, B.P.Marmion and A.Simmons, Mackie & McCartney Practical medical Microbiology 14<sup>th</sup> Edition Longman Singapore publishers (pte) Ltd, 1996.