

# PHARMACIST

## EVALUATING EXAMINATION

### SYLLABUS

The Pharmacy Examining Board of Canada



**2010**

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# EVALUATING EXAMINATION SYLLABUS

## INTRODUCTION

The PEBC Pharmacist Evaluating Examination syllabus is available on our web site ([www.pebc.ca](http://www.pebc.ca)), effective March, 2010. If you would like a printed copy of this syllabus, please send your request along with the fee of \$35 (cheque, money order or international bank draft in Canadian funds only; cash is not accepted), to the PEBC office at 717 Church Street, Toronto, Ontario M4W 2M4.

This syllabus has been compiled to guide candidates who are preparing to write the PEBC Pharmacist Evaluating Examination. It contains sample outlines of Canadian university level pharmacy course outline material, in subject areas that are considered important to the background knowledge base in the pharmaceutical sciences and for preparation for the practice of pharmacy. It is emphasized that the material found within this syllabus gives selected sampling from a variety of sources, and its purpose is to serve as a guide to the curriculum content of current pharmaceutical education in Canada. This information may be helpful in your preparation to write the Pharmacist Evaluating Examination. However, this syllabus should **not** be interpreted to be the blueprint for the construction of any questions for the Pharmacist Evaluating Examination. PEBC examination questions are developed independently of this syllabus.

The syllabus is organized into four sections that correspond to the four major subject areas represented on the Pharmacist Evaluating Examination. These include:

- Biomedical Sciences
- Pharmaceutical Sciences
- Pharmacy Practice
- Behavioural, Social and Administrative Pharmacy Sciences

Both formal education and practice experience prepare you for the Pharmacist Evaluating Examination, Pharmacist Qualifying Examination and licensure as a pharmacist. In order to determine what additional learning needs you have, prior to taking the examination, you should assess the knowledge and skills that you have already acquired, in comparison with the subject areas outlined in the Pharmacist Evaluating Examination Information Booklet (available from the web site: [www.pebc.ca](http://www.pebc.ca)).

Remember that language proficiency will also affect your performance. Written and verbal language proficiency and communication skills, at a level satisfactory for a health professional, are essential for your preparedness for taking the PEBC examinations.

Once you have identified your learning needs, it is your responsibility to find suitable reference sources, materials and/or additional experience to prepare for the Pharmacist Evaluating Examination. A partial list of references and learning resources (review guides, textbooks, federal legislation and internet resources) is printed in the Pharmacist Evaluating Examination Information Booklet (available from the web site: [www.pebc.ca](http://www.pebc.ca)).

## BIOMEDICAL SCIENCES

Biochemistry/Genomics and Molecular Biology/Nutrition/Clinical Biochemistry

Physiology/Functional Anatomy and Immunology

Pathophysiology and Pathology

Medical Microbiology

BIOCHEMISTRY/ GENOMICS AND MOLECULAR BIOLOGY/  
NUTRITION/ CLINICAL BIOCHEMISTRY

**GENERAL DESCRIPTION: BIOCHEMISTRY AND NUTRITION**

The following topics should provide a fundamental understanding of biochemistry covering the topics of: intermediary metabolism of carbohydrates, lipids, proteins, nucleic acids and porphyrins; photosynthesis; the biochemical significance of hormones; and the molecular basis of information transfer for cell integrity and well being.

**TOPICS OF STUDY: BIOCHEMISTRY AND NUTRITION**

**Intermediary Metabolism**

Enzymes reaction rates and kinetics, the influence of xenobiotics, vitamins and trace elements

Carbohydrates, structure and function, synthesis/degradation

Glycolysis

Citric acid cycle, glyoxylate cycle and pentose phosphate cycle

Biosynthesis of lipids, regulation by insulin and glucagon, steroid hormones and atherosclerosis

Oxidative degradation of amino acids

Fatty acid oxidation, formation of ketone bodies

ATP and bioenergetics including oxidative phosphorylation, electron transport and the effects of xenobiotics

**Macromolecules**

Nucleic acids

Protein synthesis, effects of puromycin, tetracycline, chloramphenicol, streptomycin, tunicamycin and diphtheria toxin

Chromosome structure, DNA replication and transcription, effects of antibiotics, cancer-causing viruses

Lipids and membranes

## **TOPICS OF STUDY: BIOCHEMISTRY AND NUTRITION contd.**

### **Nutrition**

Human biochemistry

Digestion

Function of nutrients in the body

Dietary requirements and Canada Food Guidelines

Assessment of nutritional status

Malnutrition and effects on health

Metabolism and transport of nutrients

Regulation of blood glucose

Weight management and eating disorders

Nutrigenomics

Genetic make-up and diet influences on health

Nutritional Control of Chronic Disease Risk

Obesity as a risk factor

## **GENERAL DESCRIPTION: GENOMICS AND MOLECULAR BIOLOGY**

Molecular biology is an area of study that concerns the molecular basis of cell regulation, control of biochemical functions such as metabolism, secretion, gene expression, response mechanisms and other activities to preserve cell integrity and life.

Genomics encompasses recent advances in the field of molecular biology and the rapidly developing understanding of genetic information in life forms. Study of genomics aims to understand the structure and functions of the human genome and focuses on identifying the mapping of genes and DNA sequences, and the molecular interplay of genes and their role in biochemical processes and disease.

## **TOPICS OF STUDY: GENOMICS AND MOLECULAR BIOLOGY**

### **Molecular Biology: Basis of Information Transfer for Cell Integrity and Well-being**

Structure and functions of proteins and lipids

Biochemistry and cellular organization

Essential amino acids, degradation of purines and uric acid production

Cell signalling (neurotransmitters, hormones)

Cellular growth (the cell cycle)

### **Genomics**

Organization of the human genome  
Gene expression and regulation

DNA structure and function  
Instability of the human genome:  
Replication, Mutation and DNA repair  
Recombination and Developmental genetics

Relationship between genes and proteins  
Structure and function of proteins  
Protein folding and conformation  
Transcription into RNA  
mRNA translation into proteins

Genetic engineering and cloning of genes  
Cell-based DNA cloning  
Cloning vectors

Molecular pathology - Identifying human disease genes

Applications: Gene therapy and other molecular genetic-based therapeutic approaches

## **GENERAL DESCRIPTION: CLINICAL BIOCHEMISTRY**

This course studies the important elements of clinical biochemistry and relevant diagnostic tests and laboratory investigations associated with organ systems and diseases.

## **TOPICS OF STUDY: CLINICAL BIOCHEMISTRY**

### **Routine Hematology**

Hematocrit and hemoglobin

Red blood cell count

Red cell indices (MCV, MCH, MCHC)

Complete Blood Count (CBC)

WBC differential (components)

Platelets

### **Hematologic Diagnostic Tests**

Anemias (Iron, Ferritin, TIBC)

Coagulation tests (INR, aPTT, PT and other factors)

Coomb's test

### **Electrolytes and Blood Chemistry**

Sodium

Potassium

Chloride

Glucose (random or FBG)

BUN

Creatinine

Uric Acid

Cholesterol

Total serum protein

Arterial Blood Gases (PaO<sub>2</sub>, PaCO<sub>2</sub>)

## **TOPICS OF STUDY: CLINICAL BIOCHEMISTRY contd.**

pH

Anion gap

Bicarbonate

### **Liver Biochemistry**

Bilirubin

Alkaline phosphatase (ALP)

Transaminases (AST, ALT)

Albumin

Prothrombin and INR

$\alpha$ -Fetoprotein

### **Bone Metabolism**

Bone mineral density

Minerals (calcium, phosphates)

Magnesium

Vitamin D

### **Renal Function and Disorders**

Urinalysis

Urine electrolytes

Blood urea nitrogen (BUN)

Serum creatinine

### **Estimation of Glomerular Filtration Rate (GFR) and Renal Blood Flow**

Methods of calculation and use of nomograms

Creatinine clearance

Inulin clearance

Para-amino hippuric acid (PAH) clearance

## **TOPICS OF STUDY: CLINICAL BIOCHEMISTRY contd.**

### **Gastrointestinal Tract**

Fecal fat

Schilling's test

Occult blood

Endoscopy

Barium enema, CT scan

### **Pulmonary Function Tests**

Pulmonary function testing (FEV<sub>1</sub>)

Histamine, methacholine challenge test

### **Neurology**

Electroencephalogram (EEG)

Cerebral spinal fluid (CSF)

### **Cardiovascular Diagnostic Tests**

Cardiac Isoenzymes (including Creatine kinase)

Troponin

Lipoprotein profile (LDL, HDL, Triglycerides, Cholesterol)

### **Neoplasm Screening**

Prostate-specific antigen (PSA)

Breast self-examination

Mammogram

Pap smear

Biopsy

## **TOPICS OF STUDY: CLINICAL BIOCHEMISTRY contd.**

### **Endocrinology**

#### Hypothalamus-Pituitary axis

- Prolactin
- Growth hormone (GH)
- Gonadotropins (LH and FSH)
- Thyrotropin (TSH)
- Adrenocorticotropin (ACTH)

#### Adrenal disorders

- Plasma cortisol
- Urine and serum osmolality

#### Thyroid Function

- TSH
- T<sub>3</sub> suppression test
- T<sub>4</sub> (Thyroxine - direct and indirect)
- Thyroid iodine uptake

#### Sex Hormones

- Androgens
- Estrogens
- Progestins
- Pregnancy testing

#### Diabetes and Glucometry

- Glucose tolerance Test
- Fasting blood glucose
- Serum and urine glucose
- Urine ketones
- Glycosylated hemoglobin (A1C)

### **Infectious disease / Immunologic / Rheumatologic /Other Tests**

HIV tests

Western blot

CD4+ T-cell counts

Erythrocyte sedimentation rate

### **Laboratory Aspects of Antimicrobial Agents**

Culture and Sensitivity Assay

## PHYSIOLOGY/ FUNCTIONAL ANATOMY AND IMMUNOLOGY

### **GENERAL DESCRIPTION: HUMAN PHYSIOLOGY/FUNCTIONAL ANATOMY**

This course explains normal physiology of the human body (with emphasis on cellular mechanisms), and gives a general review of systemic human anatomy (with clinical applications). The goal of this course is to provide a basic understanding of how the human body is structured, in order to understand its function or dysfunction in the presence of disease.

### **TOPICS OF STUDY: HUMAN PHYSIOLOGY**

#### **Respiration**

How the body obtains oxygen and eliminates carbon dioxide

The balance of respiration and of the pH level in body fluid

Changes during exercise and various disease states

#### **Kidneys**

How kidneys regulate the volume and composition of the body fluids

How kidneys function during malnutrition and various diseases

Hormonal regulation

#### **Blood and the Immune System**

Cellular and molecular components of the blood and their roles in oxygen transport, clotting mechanisms and body's defence mechanisms

Immunology dealing with normal immune reactions

Causes of AIDS

Problems with tissue transplants

#### **Cardiovascular System**

The structure and contractile properties of the heart

Mechanical forces regulating blood pressure

Hormonal and neural regulating mechanisms

Interactions of commonly used drugs with the cardiovascular system

## **TOPICS OF STUDY: HUMAN PHYSIOLOGY contd.**

### **Gastrointestinal System**

Gastric acid secretion

How the body obtains nutrients, water, and electrolytes

Transfer into plasma and various tissues

Hormonal and neural regulatory factors in normal and diseased states

Elimination of undigested food

### **Neurophysiology**

Description of biological membranes and ionic channels

The basis of bioelectricity

Detailed explanation of synaptic transmission

The synapse as a primary subject of action of various drugs which act upon the nervous system

Major sensory systems such as the somatosensory, visual and auditory systems

The pain perception

Neural control of skeletal musculature

Basal ganglia disorders such as Parkinson's and Huntington's Chorea

Mental illnesses

### **Temperature Regulation**

The homeostatic mechanisms regulating body temperature

In normal condition

During disease

During exercise

### **Endocrinology & Reproduction**

The hypothalamic system controlling hormonal release

The pituitary gland; the thyroid gland; the adrenal gland

The reproductive cycle and its hormonal controls

## **TOPICS OF STUDY: FUNCTIONAL ANATOMY**

### **Introduction to Anatomy**

The anatomical position; movement

Ultrastructure of the cell

Examination of basic tissue types of the body, and their function

### **The Integument**

Histology of skin

### **The Musculoskeletal System**

Types of muscle; histology of muscle

How movement occurs

Regional study - role of calcium in skeletal contraction

Diaphragm; upper limb; lower limb; clinical aspects

### **The Cardiovascular System**

Mediastinum

Arteries versus veins - histological approach

Blood as a tissue

Heart - adult versus fetal structure and flow of blood

Coronary circulation; conducting system; clinical aspects

Regional supply

### **The Respiratory System**

Histological survey

Pleura and pleural cavity; breathing movement

Clinical aspects, development of respiratory system

## **TOPICS OF STUDY: FUNCTIONAL ANATOMY contd.**

### **The Digestive System**

Anterior abdominal wall

Palate and oral cavity; salivary glands

Esophagus

Peritoneal cavity

Abdominal viscera

Histological aspects and function

Clinical anatomy: Small intestine, large intestine, liver, pancreas

Blood supply including portal venous system and the "first-pass effect"

### **The Nervous System**

Introduction to terminology

Synaptic morphology; neurotransmission

Organization of the nervous system

#### Central Nervous System

Spinal Cord: anatomy; meninges; major ascending and descending tracts

Brain: gross anatomical features, location and function meninges

Cerebral Hemispheres - sulci, gyri, major sensory and motor regions

Brain Stem; Cerebellum; Ventricles

CSF: flow, composition, function; blood supply- clinical anatomy

#### Peripheral Nervous System

Cranial nerves; spinal nerves; dermatomes; brachial plexus;

lumbosacral plexus - pudendal and sciatic nerves- clinical anatomy

#### Autonomic Nervous System

Centres of control; sympathetic and parasympathetic systems;  
neurotransmitters

### **Organs of Special Sense**

Eye, Ear, Olfaction, Taste

## **TOPICS OF STUDY: FUNCTIONAL ANATOMY contd.**

### **The Urinary System**

Function; components and relations

Kidneys - location, gross anatomy; histology; flow of urine; ureter, bladder, male and female urethra; pelvic diaphragm

### **The Reproductive System**

Bony pelvis and perineal region; urogenital triangle; anal triangle; male external genitalia; the breast; the placenta; early embryology; susceptibility of the fetus to critical periods of development

### **The Endocrine System**

Pituitary gland

Thyroid gland

Pancreas

Parathyroid glands and adrenal glands

Gross anatomy; functional significance; clinical aspects

### **The Lymphatic System**

Significance

Gross anatomy and histology of lymphatic tissue

Lymphatic vessels; lymph node

Spleen, thymus, appendix

## IMMUNOLOGY

### **GENERAL DESCRIPTION: IMMUNOLOGY**

In this course, an overview is presented of the immune system, immune responses, defence mechanisms against infectious disease and treatment applications. The study of vaccines and vaccine-preventable diseases is included.

### **TOPICS OF STUDY: IMMUNOLOGY**

#### **Overview of the Immune System**

Specificity and memory

Cells and organs of the immune system

Clonal selection theory

#### **Humoral Immune Responses**

Antibodies: structure, classes, and function

#### **Cell Mediated Immune Responses**

T cell subsets and functions

T cell receptor

MHC (Major Histocompatibility Complex) molecules

Antigen processing and MHC-restricted presentation

T cell recognition of antigens

#### **Implications to Vaccine Design**

Conventional and modern vaccines

#### **Hybridoma Technology and Monoclonal Antibodies**

Clinical applications: as research tools and as diagnostic and therapeutic agents (eg: OKT3 and HA-1A)

See also: Section under **Biotechnology and Pharmacogenetics**

## PATHOPHYSIOLOGY AND PATHOLOGY

### **GENERAL DESCRIPTION: PATHOPHYSIOLOGY AND PATHOLOGY**

This course is designed to cover the basic mechanisms of pathophysiology, laboratory investigation and follow-up associated with diseases.

### **TOPICS OF STUDY: PATHOPHYSIOLOGY AND PATHOLOGY**

#### **Cell Injury and Death**

Mechanisms of Cell Injury  
    Ischemia/Hypoxia  
    Free Radicals  
    Chemical Injury

Laboratory Investigation  
    Morphology - Reversible Injury, Necrosis, Apoptosis  
    Biochemical changes

#### **Genetics**

Common Chromosomal Syndromes

Pharmacogenetics

#### **Fluid and Electrolyte Disorders**

Metabolic Acid-Base disorders

Disorders of Oxygenation

#### **Inflammation**

Acute Inflammation

Chronic Inflammation  
    Inflammatory events and mediators

Edema

#### **Immunopathology**

Hypersensitivity reactions  
    Four major types: anaphylactic, cytotoxic, immune complex, delayed

Autoimmune diseases

**TOPICS OF STUDY: PATHOPHYSIOLOGY AND PATHOLOGY contd.**

**FOR THE FOLLOWING DISEASES, PLEASE REVIEW THE: ETIOLOGY, PATHOGENESIS, CLINICAL PRESENTATION AND LAB INVESTIGATION**

**Obstructive Lung Disease**

Asthma

Chronic Obstructive Pulmonary Diseases (COPD)

Chronic bronchitis

Emphysema

**Gastrointestinal Diseases (Non- Neoplastic)**

Reflux esophagitis (GERD)

Peptic ulcer disease / Dyspepsia

Gastritis

Acute haemorrhagic/erosive gastritis

Chronic non-erosive gastritis

Infectious gastritis (i.e. *Helicobacter pylori*)

Inflammatory Bowel Disease

Crohn's disease

Ulcerative colitis

Zollinger-Ellison syndrome

**Liver Disease**

Cholestasis

Hepatitis (A, B, C)

Cirrhosis

Drug-induced hepatotoxicity

Tumours

Liver biochemistry (see Clinical Biochemistry section)

**Renal Disease**

Acute renal insufficiency

Chronic renal insufficiency

Lab investigation (see Clinical Biochemistry section)

## **TOPICS OF STUDY: PATHOPHYSIOLOGY AND PATHOLOGY contd.**

### **Endocrinology**

#### Thyroid Disorders

Hyperthyroidism

Hypothyroidism

#### Adrenal Disorders

Cushing's Syndrome

Addison's Disease

Pheochromocytoma

#### Metabolic bone disorders

Osteoporosis

Osteomalacia

Paget's Disease

#### Glucose Metabolism and Disorders

Diabetes mellitus (type 1 and type 2)

### **Cardiovascular**

Dyslipidemia

Ischemic Heart Disease

Myocardial Infarction

Hypertension

Congestive Heart Failure

Dysrhythmias

Coagulation and thrombotic disorders

### **Haematology**

#### Anemias

Normocytic (i.e. thalassemias, sickle cell anemia)

Microcytic (i.e. iron deficiency anemia)

Macrocytic (i.e. vit B<sub>12</sub> deficiency and folic acid deficiency)

Haemostatic disorders

## **TOPICS OF STUDY: PATHOPHYSIOLOGY AND PATHOLOGY contd.**

### **Neurology**

Neurodegenerative diseases

Alzheimer's Disease and dementias Parkinson's Disease

Pain and headache

Acute or chronic

Migraine

Nociceptive or neuropathic

Seizure disorders

Stroke

### **Psychiatry**

Anorexia, bulimia and eating disorders

Anxiety and agitation disorders

Attention Deficit Hyperactivity Disorder (ADHD)

Bipolar disorder

Depression (major depression)

Insomnia

Schizophrenia

### **Carcinogenesis and Neoplasia**

Genetic basis of carcinoma

Sites

Lung and gastrointestinal neoplasms

Gynecologic neoplasms

Urinary tract neoplasms

Hematology (i.e. leukemia and lymphoma)

Skin Neoplasms Malignant melanoma and others

Cancer of the bone, brain, breast, prostate

## MEDICAL MICROBIOLOGY

### **COURSE DESCRIPTION: MEDICAL MICROBIOLOGY**

This course of study includes the general biology of micro organisms and an overview of the host response to infection. Focus is on the main categories of human infections, their epidemiology, prevention and antimicrobial treatment. Topics also included are sterility and disinfection.

### **TOPICS OF STUDY: MEDICAL MICROBIOLOGY**

#### **Introduction to Microbiology**

Bacterial structure, replication and classification

Bacterial pathogenesis and virulence factors

Normal microbial flora / Host response to infection

Principles of diagnostic microbiology

#### **Bacterial Infections**

Infections of the circulatory system  
Endocarditis

Infections of bones and joints  
Osteomyelitis, arthritis, prostheses

Skin and Wound infections  
Cellulitis, Impetigo, wounds

Infections of the gastrointestinal tract  
Food poisoning, gastroenteritis, antibiotic-associated colitis

Infections of the eye  
Conjunctivitis

Infections of the Urogenital Tract  
Urinary tract infections  
Sexually transmitted infections

Infections of the CNS  
Meningitis  
Abscesses

## **TOPICS OF STUDY: MEDICAL MICROBIOLOGY contd.**

Infections of the respiratory tract

Otitis, pharyngitis, sinusitis

Tuberculosis

Pneumonia, bronchitis, pleurisy, croup

Mycoplasma, Legionella, Chlamydia

### **Antimicrobial Agents**

β-Lactams, Cephalosporins

Quinolones

Macrolides, Ketolides, Clindamycin, Tetracyclines

Aminoglycosides, Vancomycin

Sulfonamides and Trimethoprim

Metronidazole, Chloramphenicol

### **Viral Infections**

Properties, structure, replication, and transmission

Viral pathogenesis, host response and principles of diagnostic virology

Sites of viral infections

Respiratory tract

CNS

Prion diseases

Gastrointestinal tract

HIV and AIDS

Herpes viruses

Viral hepatitis

Measles, mumps, rubella

Chickenpox and shingles

Infections in the fetus and newborn

Skin, mucous membranes

Childhood Fevers

Antiviral Agents

## **TOPICS OF STUDY: MEDICAL MICROBIOLOGY contd.**

### **Parasitology**

Protazoal Diseases  
Protazoas and Helminths

Malaria

Ectoparasites  
Lice, Scabies, Ticks

### **Mycology**

Properties, structure, replication, and transmission

Systemic Mycoses  
Candida  
Aspergillus  
Histoplasmosis  
Blastomycosis  
Coccidioidomycosis  
Cryptococcosis

Superficial Mycoses  
Dermatophytes

Antifungal Agents

### **Sterilization and Disinfection**

Hospital epidemiology

Infection control methods (Clean room, Laminar Flow Hood)

### **Immunoprophylaxis and Vaccines**

## PHARMACEUTICAL SCIENCES

Pharmaceutics and Drug Delivery Systems

Pharmacokinetics and Biopharmaceutics

Medicinal Chemistry

Pharmacology

Toxicology and Clinical Toxicology

Pharmaceutical Analysis

Biotechnology and Pharmacogenetics

## PHARMACEUTICS AND DRUG DELIVERY SYSTEMS

### **GENERAL DESCRIPTION: PHARMACEUTICS AND DRUG DELIVERY SYSTEMS**

In this course of study, the emphasis is on physico-chemical properties related to the design and formulation of dosage forms and optimal delivery of drugs to a site of action for therapeutic usefulness. This study includes the role of biopharmaceutics, preformulation principles, drug stability and physical pharmacy in the development of safe and effective dosage forms. Bioequivalence, routes of administration and new design innovations are included.

### **TOPICS OF STUDY: PHARMACEUTICS & DRUG DELIVERY SYSTEMS**

#### **Solids and Solid Dosage Forms**

##### The solid state

Bonding - Van der Waal's, H bonding, covalent, electrostatic, metallic  
crystal systems and habits

Crystallization - saturated and supersaturated solutions, crystal growth

Crystallinity - amorphous solids, degree of crystallinity, crystal defects

Polymorphism - effects on formulation, bioavailability

Hydrates and solvates - hygroscopicity, deliquescence, phase diagrams, effects  
on formulation, bioavailability, lyophilization

Eutectic mixtures, solid solutions, clathrates and inclusion compounds

##### Solid dosage forms

Properties of powders, handling of powders, drying, mixing and milling

Particle size analysis - definitions, methods

Tableting - excipients and formulation, methods of granulation, tablet  
compression

Tablet coating - methods and types of coating

Capsules - hard gelatin, soft gelatin, non-gelatin based capsules, formulation

Evaluation tests - uniformity of weight, content, dissolution, disintegration,  
hardness, friability

Sustained/controlled release - formulation, effect on bioavailability

Effervescent powders and tablets - formulation, storage

## TOPICS OF STUDY: PHARMACEUTICS & DRUG DELIVERY SYSTEMS contd.

### Solutions and Solubility

#### Thermodynamics of Pharmaceutical Solutions

- 1st law, enthalpy, work
- 2nd law, entropy
- Gibbs free energy and chemical potential
- Phase equilibria

#### Pharmaceutical Solvents

- Waters, alcohols, hydroalcohols, cosolvents

#### Aqueous and non-aqueous solutions

- Syrups, elixirs, tinctures, collodions, spirits, liniments

#### Solvent/Solute Interaction

- Intermolecular bonding, functional groups, prediction of drug solubility in water

#### Liquid-Liquid solution

- Ideal and non-ideal solutions, Raoult's law, partial miscibility

#### Solid-Liquid solutions

- Colligative properties, solutions of electrolytes and non-electrolytes, ionic equilibria, buffers, isotonicity

#### Gas-Liquid Solutions

- Solubility of gases, Henry's law.

#### Factors affecting solubility

- pH, pKa, salts, temperature, esterification, complexation, solubilization, particle size, cosolvency, polarity, solubility parameters

#### Dissolution

- Theory, methods of measuring dissolution rate, factors affecting dissolution rate
- Hixson-Crowell Cube-Root Relation, Noyes-Whitney equation
- Types of dissolution apparatuses
- USP Dissolution monographs and acceptance criteria
- In vitro-in vivo* correlation

#### Partition

- Fick's first and second laws, Nernst distribution law, pH-partition theory, steady state and non-steady state diffusion

## **TOPICS OF STUDY: PHARMACEUTICS & DRUG DELIVERY SYSTEMS Contd.**

### **Surface Chemistry and Dispersed Dosage Forms**

#### Surface Chemistry

Interfacial tension, spreading, contact angle, tendency of wetting  
Nature & properties of surfaces, interfaces-absorption at liquid & solid interfaces  
Surfactants - classification, properties, pharmaceutical applications (HLB, wetting, solubilization, detergency)

#### Emulsions

Emulsion types, applications, emulsifying agents  
Physical stability - creaming, coalescence, cracking, inversion  
Formulation, preservation  
Microemulsions - formulation, physicochemical properties, applications

#### Suspensions

Desired characteristics, applications  
Electrical properties, Zeta potential, Nernst potential  
Physical stability - flocculation, deflocculation, sedimentation  
Formulation  
Rheological properties of vehicles including hydrocolloids, thixotropy, rheopexy, structured vehicles

### **Drug Stability**

#### Drug stability

Physical, chemical, microbiological stability - definitions, causes of instability

#### Chemical stability

Mechanisms of degradation - hydrolysis, oxidation, photolysis  
Zero and first order degradation - rate equations, half-life, shelf-life  
Effect of temperature, ionic strength, solvents and pH on reaction kinetics  
Factors affecting rates of hydrolysis and oxidation, stability programs, stability testing, accelerated stability studies  
Stabilization of drugs against hydrolysis, oxidation and photolysis

### **Intrapulmonary Drug Delivery**

Components of aerosols - propellants, valves, containers

Formulation of aerosols - solutions, suspensions, emulsions

Design of aerosols - metered dose inhalers, dry powder inhalers, nebulizers, spacer devices

Inhalation therapy - deposition of particles in the lungs, metered dose inhalers, powder inhalers, nebulizers

## **TOPICS OF STUDY: PHARMACEUTICS & DRUG DELIVERY SYSTEMS Contd.**

### **Dermal Drug Delivery**

Skin structure - nature of barrier to percutaneous absorption

Percutaneous absorption - diffusion, partitioning, flux

Factors affecting percutaneous absorption - skin intactness, age, site, hydration, partition coefficient, solubility, penetration enhancers and formulation

Types of dermatological vehicles - ointments, creams, gels, liquids, pastes, selection of appropriate vehicle in topical drug therapy

### **Parenteral Drug Delivery**

Methods of sterilization, sterility testing, pyrogen testing, tests for particulate matter

Routes of administration - advantages, disadvantages

Formulation - vehicles, additives, osmolarity, osmolality, particle size

Principles of aseptic technique, reconstitution, intravenous admixtures and causes of incompatibilities

Total parenteral nutrition - design of solution, preparation, administration, complications

### **Ophthalmic, Otic, Nasal Drug Delivery**

#### **Ophthalmic Drug Delivery**

Cornea as a barrier to drug absorption

Formulation - tonicity, sterility, pH additives

#### **Otic Drug Delivery**

Site of drug administration

Formulation

#### **Nasal Drug Delivery**

Formulation – pH, additives



### **Rectal and Vaginal Drug Delivery**

Physiology, local and systemic effects

#### **Rectal and vaginal suppositories**

Definition and uses

Preparation, excipients, density displacement factors

Stability

Vaginal tablets, ointments, creams, gels and aerosol foams

## **TOPICS OF STUDY: PHARMACEUTICS & DRUG DELIVERY SYSTEMS Contd.**

### **New Drug Delivery Systems**

#### Controlled/targeted delivery

Controlled drug release, targeted drug delivery - definitions, rationale, comparison to conventional delivery systems

Parenteral polymeric delivery systems - biodegradable, non-degradable polymers, reservoirs, matrices, mechanisms of drug release, formulation of implants, microspheres, nanospheres

Liposomes - formulation, interaction with cells, applications, targeting

Transdermal drug delivery - applications, mechanisms of controlled release formulations

Immunoconjugates and new innovations

#### Protein drug delivery

Protein drug delivery - formulation strategies to stabilize proteins, formulation of protein/peptide drugs using conventional injections, formulation of polymer implants or microspheres

Nasal and pulmonary delivery - physiology, use of penetration enhancers

Buccal delivery and other potential delivery systems

### **Good Manufacturing Practices (GMP)**

Batch Record

International Organization for Standardization (ISO)

Lot number

### **Product Quality Control and Risk Management**

Places

Premises and equipment

People

Personnel and quality assurance

Processes

Sanitation program and operations

Products

Specifications, stability, samples, batch records, recall reporting, sterile products

## PHARMACOKINETICS & BIOPHARMACEUTICS

### **COURSE DESCRIPTION: PHARMACOKINETICS & BIOPHARMACEUTICS**

This course is designed to cover biopharmaceutics and pharmacokinetics concepts. Biopharmaceutics considers the interrelationship of the physicochemical properties of the drug, the dosage form in which the drug is given, and the route of administration on the rate and extent of systemic drug absorption. Pharmacokinetics involves the time course of drug disposition in the body: the kinetics of drug absorption, distribution and elimination (excretion and metabolism). This includes the effect of pathophysiological changes on the pharmacokinetics of drugs and applications in pharmacotherapy. A selected group of drugs is discussed in the context of therapeutic drug monitoring.

### **TOPICS OF STUDY: PHARMACOKINETICS & BIOPHARMACEUTICS**

#### **Compartment Concepts**

One compartment open model

Multicompartmental models

Model-independent pharmacokinetics

#### **Absorption**

Kinetics of oral drugs (absorption and elimination)

Kinetics after one dose

Kinetics after multiple doses

Zero-order absorption model

First-order absorption model

Significance of absorption rate constant

Physiologic factors related to oral absorption

Modified release of drug products

#### **Distribution and Protein Binding**

Physiologic factors

Volume of distribution

Kinetics of protein binding

## **TOPICS OF STUDY: PHARMACOKINETICS & BIOPHARMACEUTICS contd.**

### **Elimination and Clearance Concepts**

Drug clearance

Renal clearance

Hepatic clearance

Biotransformation

### **Kinetics of Intravenous (IV) Drugs**

IV Bolus

IV infusion

IV intermittent infusion

Multiple daily dosage regimens

### **Kinetics of Doses**

After constant input

After 1st order input

### **Model-Independent Pharmacokinetics**

Nonlinear pharmacokinetics

### **Bioavailability and Bioequivalence Issues**

### **Clinical application of pharmacokinetics**

Dosage regimens

Effects of pathophysiologic changes: monitoring and adjustment of doses in renal and hepatic dysfunction

Kinetics of drug interactions

Special populations

    Pediatric patients

    Pregnant and lactating women

    Geriatric patients

## **TOPICS OF STUDY: PHARMACOKINETICS & BIOPHARMACEUTICS contd.**

### Therapeutic Drug Monitoring

Drugs in renal failure: Aminoglycosides; Cyclosporine A

Drugs with saturable kinetics: Phenytoin; Salicylates

Drugs with linear kinetics: Theophylline; Digoxin; Procainamide

### **Examples of Pharmacokinetics Calculations**

#### Pharmacokinetic rate constants

Apparent volume of distribution, elimination rate constant, half-life, clearance

#### Blood drug concentration following IV bolus dose administration

One compartment model

Two compartment model

From urinary excretion data for one compartment open model

#### Looking at drug concentration vs. time curves

Determining what model the drug follows

#### Clearance rates

#### Loading doses and time to reach steady state

## MEDICINAL CHEMISTRY

### **GENERAL DESCRIPTION: MEDICINAL CHEMISTRY**

The following list of topics indicates the breadth of material presented in Medicinal Chemistry courses. Some topics are closely integrated with other courses, and therefore it is difficult to define the precise depth of knowledge that is required in all sections.

### **TOPICS OF STUDY: MEDICINAL CHEMISTRY**

#### **Fundamental Aspects of Organic Chemistry**

Chemical bonding: introductory aspects, such as atomic orbitals, molecular orbitals, localized versus delocalized chemical bonding, specific bond types (e.g., covalent and ionic), aromaticity and tautomerism.

Nomenclature of organic chemistry

Stereochemistry

Solubility

Acidity and basicity

Functional groups

- Aliphatic and aromatic hydrocarbons
- Alcohols and phenols
- Ethers
- Aldehydes and ketones
- Amines
- Carboxylic acids
- Functional derivatives of carboxylic acids
- Sulfonic acids and sulfonamides
- Heterocycles
- Alkyl halides: halothane, isoflurane, etc.
- Nitrates, nitrites, and nitroglycerin
- Antioxidants in pharmaceutical preparations

#### **Fundamental Concepts of Medicinal Chemistry:**

Structure-activity relationships

Ionization and  $pK_a$  values: electronic effects in medicinal compounds

Metabolism: routes of metabolism, specific isozymes, induction and inhibition of enzymes giving rise to specific drug interactions, and genetic polymorphism of clinical relevance.

Transporters

Chemical and physical properties of related medicinal compounds

## **TOPICS OF STUDY: MEDICINAL CHEMISTRY contd.**

Biological properties: absorption, distribution, metabolism, excretion, pharmacological activity

Nomenclature that is specific to medicinal chemistry

### **Drug/Receptor Interactions: Theory and Practice**

Drug-receptor binding: importance of the equilibrium dissociation constant

Fraction of bound receptors and the analogous enzyme-substrate relationships

Importance of hydrophilic and hydrophobic interactions

### **History of Selected Anti-infective Agents**

Dihydropteroate synthetase inhibitors and bacteriostatic agents

Sulfanilamides and sulfones compared with p-aminobenzoic acid

Avoiding crystalluria through ionization

Dihydrofolate reductase inhibitors and related biochemical pathways

### **Review of Ion Channels (Sodium, Potassium And Calcium)**

State dependent interactions of voltage-gated ion channels

Resting state and use-dependent blocking

Local anaesthetics and anti-arrhythmic agents

Ion channel-related adverse effects of drugs

### **Therapeutic Applications of Steroids**

Cholesterol regulation and atherosclerosis: e.g., HMG-CoA reductase inhibitors

Steroid and thyroid hormone receptors

Steroids and gonadotropins.

Estrogens and progestin, including selective estrogen receptor modulators

Corticosteroids

### **Carbonic Anhydrase and Angiotensin Converting Enzyme**

Carbonic anhydrase inhibitors: therapeutic applications

ACE inhibitors and angiotensin II receptor antagonists

## **TOPICS OF STUDY: MEDICINAL CHEMISTRY contd.**

Comparison with diuretics in antihypertensive applications

### **Nicotinic Receptors**

Applications in the peripheral and central nervous systems

### **Muscarinic Receptors**

Importance in the heart and smooth muscles

General importance in the autonomic nervous system

Atropine: discussion of structures of anticholinergics

Acetylcholinesterase inhibitors: indirect-acting cholinergic agonists

### **Adrenergic Receptors**

General importance of the adrenergic or sympathetic nervous system

Agonists as vasoconstrictors, presynaptic  $\alpha_2$  receptors

Beta-blockers and treatment of hypertension

Treatment of asthma and  $\beta_2$ -selective agonists

### **Amphetamines and MAO Inhibitors**

Review of the structure of the blood-brain barrier

Discussion of amphetamines: CNS stimulants and anorectic agents

Selected MAO-A and MAO-B inhibitor structural classes

### **Dopamine Receptors**

L-dopa therapy in the treatment of Parkinsonism: decarboxylase inhibitors

Antipsychotic therapy by neuroleptic agents: important structural classes

### **Serotonin Receptors**

General importance in the central nervous system

Reuptake inhibitors and antidepressants

Some antiemetic and migraine therapeutic agents

## **TOPICS OF STUDY: MEDICINAL CHEMISTRY contd.**

### **Histamine Receptors**

Histamine and its role as a local hormone

Antihistamines (H<sub>1</sub> antagonists) and treatment of allergies

H<sub>2</sub> antagonists: development of these agents

Acid suppression by other mechanisms: proton pump inhibitors

### **GABA Receptors**

General importance in the central nervous system

Review of barbiturates and benzodiazepines

GABA deficiencies and certain diseases of the central nervous system

### **DNA Intercalating Agents** (anticancer and antibacterial applications)

Review of the DNA structure

Essential molecular characteristics of intercalating agents

Review of important antitumour antibiotics as well as antibacterial agents

### **Opioid Analgesics**

Morphine: structural link with the enkephalins

Enkephalins and endorphins

Codeine, heroin and meperidine and others related to morphine

### **Eicosanoids**

Endogenous compounds: prostanoids and leukotrienes

COX-1 and COX-2 inhibition (NSAIDs)

Leukotriene receptor antagonists and eicosanoid enzyme inhibitors.

Platelet activating factor, membrane lipids, and antiplatelet agents

### **Antibiotics**

Agents acting as protein synthesis inhibitors in bacteria

Agents acting on cell membranes, including antibacterial and antifungal applications

## **TOPICS OF STUDY: MEDICINAL CHEMISTRY contd.**

Mechanisms and structures of agents with narrow and broad spectrum profiles

**Microtubules** (anticancer, antifungal, antibacterial applications)

Paclitaxel, docetaxel, and vinca alkaloids as antitumor agents

Griseofulvin: antifungal therapies

Colchicine in gout and selected anthelmintic agents

### **Diabetes Mellitus**

Insulin and glucagon

Hypoglycemic agents

Selected agents for treating insulin resistance

### **Amino Acids, Proteins, Enzymes & Peptide Hormones**

Important hormones such as thyroid hormones

Peptidomimetics and peptide synthesis: e.g., hormones of hypothalamic origin such as gonadotropin-releasing hormone (superagonists)

## PHARMACOLOGY

### **GENERAL DESCRIPTION: PHARMACOLOGY**

The study of basic pharmacological principles is applied to representative clinically important drugs having their primary actions on various organ systems of the body. The course includes a study of chemotherapeutic agents used in the treatment of infectious and neoplastic diseases.

### **TOPICS OF STUDY: PHARMACOLOGY**

#### **General Principles of Pharmacology**

Drug absorption, disposition, biotransformation, elimination

#### **Receptors**

Receptor theory, macromolecular structure of receptors, signal transduction mechanisms, molecular pharmacology

Drug/Receptor interactions

Evidence of specific receptor-mediated processes

Agonists/antagonists

Dose-response curves

Desensitization and supersensitivity

#### **Autonomic Pharmacology (Autonomic Nervous System)**

Drugs and catecholamine metabolism

Sympathomimetics

Adrenoceptor blockade

Cholinomimetics

Anticholinesterases

Muscarinic blockade

Ganglionic blockade

Neuromuscular blockade

#### **Anaesthetics**

Local anaesthetics

General anaesthetics

## **TOPICS OF STUDY: PHARMACOLOGY contd.**

### **Pharmacology of Inflammation**

Chemical mediators of inflammation

Histamine, prostaglandins, leukotrienes, bradykinin, platelet activating factor, cytokines

Anti-inflammatory drugs

ASA, NSAIDs, COX-2 inhibitors  
5-ASA

Immunosuppressants

Drugs used in the treatment of inflammatory diseases

Asthma  
Rheumatoid arthritis  
Gout

### **Central Nervous System Pharmacology**

Pain and opioid analgesics

Anxiolytic drugs

Hypnotic drugs

Neuroleptic drugs

Antidepressants

Psychostimulants

Anti-Parkinson drugs

Antiseizure drugs

Anti-Alzheimer's drugs

### **Drugs Affecting the Haematopoietic System**

Iron, folic acid, vitamin B12, erythropoietin

Immunosuppressants used for heart transplantation

## **TOPICS OF STUDY: PHARMACOLOGY contd.**

### **Cardiovascular Pharmacology**

Antiarrhythmic drugs

Cardiac glycosides and inotropic drugs

Vasodilators

Calcium channel blockers

Beta-blockers

ACE inhibitors

Angiotensin receptor antagonists

Nitrates

Antihypertensive agents

### **Hemostasis and Thrombosis**

Vitamin K

Oral anticoagulants

Heparins (including low molecular weight heparins)

Anti-Xa inhibitors

Anti-platelet drugs

Fibrinolytics and anti-fibrinolytic drugs

### **Antihyperlipidemic Drugs**

### **Diuretics**

### **Cancer Chemotherapy**

Alkylating agents, antimetabolites, cytotoxic antibiotics, plant alkaloids, hormones,

Adjunctive agents including antiemetics

## **TOPICS OF STUDY: PHARMACOLOGY contd.**

### **Gastro-Intestinal Pharmacology**

Drugs affecting GI motility

Drugs affecting gastric secretion

Drugs for eating disorders

Anti-obesity drugs

### **Endocrine Pharmacology**

Insulin and oral hypoglycemics

Corticosteroids

Thyroid and anti-thyroid drugs

Androgens and anabolic steroids

Estrogens and anti-estrogens, progestins, hormonal contraception (oral and other routes)

Vasopressin

Oxytocin

Bone mineral homeostasis

### **Anti-Microbial Agents**

Antibacterial drugs

Beta-lactam antibiotics, cephalosporins, sulphonamides, trimethoprim, tetracyclines, chloramphenicol, aminoglycosides, erythromycin, macrolides, ketolides, lincosamides, fluoroquinolones, vancomycin, polymyxin, bacitracin, metronidazole, nitrofurantoin, antimycobacterial agents

Antiviral drugs

Antifungal drugs

Antiprotozoal drugs

Anthelmintic drugs

## **TOPICS OF STUDY: PHARMACOLOGY contd.**

### **Drugs of Abuse**

Ethanol, amphetamines, barbiturates, benzodiazepines (including flunitrazepam), nicotine, cannabis, GHB, cocaine/crack, heroin, ketamine, methadone, nitrites, solvents, hallucinogens: ecstasy, PCP, LSD, mescaline

## TOXICOLOGY AND CLINICAL TOXICOLOGY

### **GENERAL DESCRIPTION: TOXICOLOGY & CLINICAL TOXICOLOGY**

Concerned primarily with drug-induced diseases, this course provides a framework for understanding the broad spectrum of toxicological problems encountered in pharmacy practice, in drug development and regulation, and in medical research. Central biochemical mechanisms and the relevance of factors influencing toxicological expression will be included.

### **TOPICS OF STUDY: TOXICOLOGY & CLINICAL TOXICOLOGY**

#### **Introduction to Toxicology**

Perspective: subdisciplines, magnitude, monitoring, resources

Pharmacological principles: relation of toxic response to frequency, dose and tissue concentration

Discrimination among toxins

#### **Mechanisms**

Receptor-mediated vs. reactive intermediate-mediated toxicity

Covalent binding, oxidative stress

Elimination, bioactivation, detoxification, cytoprotection and macromolecular repair

#### **Modulators of Chemical Toxicity**

Pharmacological factors

Disposition, biotransformation, renal elimination

Physiological factors

Species, strain, age, sex, genetics, diet, pregnancy, functional reserve capacity, tolerance

Pathophysiological factors

Diseases of hepatic, renal cardiovascular, pulmonary, gastrointestinal and biochemical systems

#### **Neurodegenerative Disease**

#### **Hepatic Toxicology**

Mechanisms and clinical consequences

## **TOPICS OF STUDY: TOXICOLOGY & CLINICAL TOXICOLOGY contd.**

### **Toxicological Evaluation**

Chemical measurements

Biological relevance of measuring active and inactive parent chemical and metabolites, stereoisomers and reactive intermediary metabolites

Biochemical measurements of cellular response

Histological and functional measurements, animal models, in vivo and in vitro studies, ex vivo human assessment

### **Chemical Teratogenesis**

### **Carcinogenesis/Mutagenesis**

### **Immunological Toxicology**

### **Chemicals and Environmental Toxins**

Alcohols, glycols, aldehydes, nitrates and nitrites, sulfide, hydrocarbons

Carbon monoxide, cyanide

Pesticides

Metals

Corrosives

Plants

Warfare chemical weapons

### **Drug Toxicity**

Analgesics and Anti-inflammatory drugs

Opioids

CNS stimulants and depressants, antidepressants, hallucinogens

Anticholinergics

Cardiovascular drugs

Vitamins

### **Venoms**

## PHARMACEUTICAL ANALYSIS

### **GENERAL DESCRIPTION: PHARMACEUTICAL ANALYSIS**

The following study material should provide a thorough understanding of all those analytical processes involved in the qualitative and quantitative measurement of drugs and their metabolites. This would include specific analytical procedures and instrumentation, as well as the fundamental basis on which these procedures are based. Students should also be able to evaluate data obtained by these methods in terms of reliability and significance.

### **TOPICS OF STUDY: PHARMACEUTICAL ANALYSIS**

#### **Fundamental Basis for Sample Preparation and the Analysis of Drugs and/or Drug Metabolites**

Recognition of the origins of acidity and basicity of drug molecules

Prediction of pKa by inspection of molecular structure

Prediction of pH of an aqueous solution of drug and estimation of % charged or uncharged at any given pH

Impact of plasma proteins in drug analysis

Internal versus external standards

Choice of internal standard

Extraction methods, liquid/liquid and solid phase extraction

Partition coefficients and choice of extraction solvents

Standard curves and their use

Pharmacopoeia and in-house standards

Analytical validation and good laboratory practice

## **TOPICS OF STUDY: PHARMACEUTICAL ANALYSIS contd.**

### **Methods in Drug Analysis**

#### Chromatographic Separation Methods

Thin Layer and Paper Chromatography

High Pressure Liquid Chromatography (**HPLC has a major emphasis**)

Gas Liquid Chromatography (GLC)

For each:

Principles of the technique

Limitations, qualitative versus quantitative

Choice of stationary and mobile phases

Specialized reagents (spray reagents, derivatization reagents and chiral analyses) and detection systems

#### Other chromatographic detectors

Fluorescence

Radiometric assays (gamma and beta counting)

#### Spectrophotometry and other analytical methods

Ultraviolet-visible

Infrared and Nuclear Magnetic Resonance (NMR) spectrometry

Atomic absorption

Mass spectrometry

Gel electrophoresis and Western blot

### **Biological Extraction and immunoassay methods**

Immobilized enzymes and cells

Immunoassays, radioimmunoassay and EIA

Radioreceptor assays

Microbial assays

### **Statistical methods in analysis of data**

Regression

Correlation

Confidence intervals

### **Pharmaceutical Applications**

Standards for new drugs

Quality control of drug products

Stability testing (expiry, storage)

Assays for therapeutic drug monitoring

Assays for drug abuse or overdose

Innovations in biotechnology assays

## BIOTECHNOLOGY AND PHARMACOGENETICS

### **GENERAL DESCRIPTION: BIOTECHNOLOGY AND PHARMACOGENETICS**

In this course, the basic science and the pharmacotherapeutic implications of biotechnology-derived drugs are dealt with in some depth. The emphasis is on recent developments in the area and on the probable direction that future research in that field will take. An overview of the immune system, immune responses and treatment applications is also presented.

### **TOPICS OF STUDY: BIOTECHNOLOGY AND PHARMACOGENETICS**

#### **Introduction to Biotechnology**

Modern biotechnology and its impact on development of drugs and pharmacy practice

Pharmacoeconomics of biotechnology drugs

#### **Recombinant DNA Technology and Production of Protein Drugs**

Review of protein biosynthesis in prokaryotic and eukaryotic cells

Regulation of gene expression

Methods of creating recombinant DNA

Isolation of cloned genes

cDNA cloning, genomic DNA cloning

Expression of Recombinant Proteins

Host cells, expression vectors

Strategies in design of recombinant plasmids for pharmaceuticals (e.g. human growth hormone)

#### **Industrial Production of Protein Drugs**

Modern fermentation technology

Requirements for bacterial, yeast and mammalian cell culture

Overview of fermenter design and fermentation processes

Large-scale production of protein pharmaceuticals with examples

Production of Biotechnology drugs

Cultivation and downstream processing

Issues to consider in production and purification of proteins

## **TOPICS OF STUDY: BIOTECHNOLOGY AND PHARMACOGENETICS contd.**

### Formulation of biotechnology drugs

- Sterility, pyrogen removal

- Excipients used in biotechnology drugs (parenteral formulations)

- Shelf-life of biotechnology drugs

- Delivery of biotechnology drugs: route of administration and absorption enhancement; rate-controlled delivery; site-specific delivery

### Pharmacist's role with biotechnology products

- Dispensing biotechnology drugs: handling and special considerations; storage; preparation; administration; patient assessment and monitoring; outpatient/home care issues

### Pharmacotherapeutics of approved biotechnology products (clinical and regulatory aspects)

- Hematopoietic growth factors

- Interleukins and interferons

- Insulin

- Growth hormones

- Recombinant tissue-type plasminogen activator and factor VIII

- Follicle stimulating hormone

- Monoclonal antibody-based pharmaceuticals

## **Biotechnology-related Techniques**

Polymerase chain reaction

DNA sequencing

DNA hybridization

Protein engineering

- Site-directed mutagenesis

- Antibody engineering

Peptide chemistry/medicinal chemistry

- Peptidomimetic drugs

- Rational design of peptide drugs

Nucleic acid technologies

- Antisense oligonucleotides

- DNA triplex technology

- Ribozymes

Catalytic antibodies (abzymes)

*In vitro* screening and combinatorial chemistry

## **TOPICS OF STUDY: BIOTECHNOLOGY AND PHARMACOGENETICS contd.**

### **Transgenic (TG) Animals**

Production of TG animals by DNA injection (gain-of-function)

Production of TG animals by homologous recombination (loss-of-function)

Protein production in TG animals

TG animal models of disease and application in drug discovery and development

TG animal patents

### **Gene Therapy**

Approaches and targeted diseases

Methods for *ex vivo* and *in vivo* delivery of genes to somatic cells

Applications to diseases

ADA deficiency, cystic fibrosis, and cancer

Case studies of current clinical trials

ADA in immunodeficiency and IL-2 in cancer

Future prospects

Potential diseases where gene therapy could be applied to or is currently used for treatment

Gene transfer methods

Viral vectors (retrovirus vectors, adenovirus vectors, etc.)

### **Pharmacogenomics and genotyped prescribing (future role for pharmacists)**

#### **Antisense Oligonucleotide Therapy**

Inhibition of gene expression by oligonucleotides

Design of oligonucleotides and approaches to delivery

#### **Small interfering RNA (siRNA)**

Mechanism, potential applications

## **TOPICS OF STUDY: BIOTECHNOLOGY AND PHARMACOGENETICS contd.**

### **Immunology: Overview of the Immune System**

Specificity and memory

Cells and organs of the immune system

Clonal selection theory

Humoral immune responses

Antibodies: structure, classes, and function

Cell mediated immune responses

T cell subsets and functions

T cell receptor

MHC molecules

Antigen processing and MHC-restricted presentation

T cell recognition of antigens

Implications to vaccine design

### **Monoclonal Antibodies**

Hybridoma technology

Applications: as research tools, and as diagnostic and therapeutic agents  
(e.g.: OKT3 and HA-1A)

### **Vaccines: Biotechnology Approaches**

Cloned proteins: Hepatitis B

Synthetic peptides: AIDS

Synthetic carbohydrates: Cancer

Attenuated organism with site-specific mutation: Cholera

Vaccine delivery systems

Live vectors

Pharmaceutical formulations

### **Cytokines**

General characteristics, classification

Origin, molecular characteristics and physiological function of each cytokine

Therapeutic cytokines

Interferons, Interleukins and colony stimulating factors

**TOPICS OF STUDY: BIOTECHNOLOGY AND PHARMACOGENETICS contd.**

**Erythropoietin**

**Thrombolytic Agents**

Comparison of t-PA, streptokinase, and urokinase

**Formulation of Protein and Peptide Drugs**

Problems: stability, bioavailability and routes of administration

Recent approaches in protein and peptide drug delivery

## PHARMACY PRACTICE

Therapeutics (including Non-Prescription Medication)

Professional Practice Skills

## THERAPEUTICS (INCLUDING NONPRESCRIPTION MEDICATIONS)

### **GENERAL DESCRIPTION: THERAPEUTICS**

This course reviews the therapeutic approaches to the most frequently encountered diseases and critical issues relevant to pharmacy practice, using a problem-solving approach. Prescription medication, self-care (over-the-counter) medications, non-pharmaceutical (e.g. lifestyle) approaches as well as alternative therapies are included. Patient-specific factors, goals of treatment, desired patient-specific outcomes, care plan (options and management), patient education, monitoring parameters (including laboratory investigations) and evaluation of efficacy and adverse effects of therapy must be considered, in order to optimize patient care.

### **BASIC PRINCIPLES**

Using a patient-centred pharmaceutical care approach, a drug therapy problem is prevented or resolved using a process which involves the following steps:

1. Identifying pertinent patient information and assessing its relevance
2. Establishing desired clinical and therapeutic outcomes
3. Determining and assessing possible pharmaceutical and non-pharmaceutical treatment options
4. Selecting the most suitable option for the patient
5. Justifying the proposed therapy (explaining the rationale)
6. Developing and implementing the pharmaceutical care plan (including education and monitoring)
7. Following up on the interventions (assessing efficacy and adverse effects)
8. Documenting findings related to the patient's care

### **TOPICS OF STUDY: THERAPEUTICS**

**FOR THE FOLLOWING DISEASES, THERAPEUTICS CONSIDERATIONS SHOULD INCLUDE PRESCRIPTION MEDICATION, SELF-CARE (OVER-THE-COUNTER) TREATMENTS, NON-PHARMACEUTICAL APPROACHES AS WELL AS ALTERNATIVE (COMPLEMENTARY) TREATMENTS.**

#### **Respiratory Diseases**

Asthma  
Chronic obstructive pulmonary diseases (COPD)  
Croup  
Smoking cessation

## **TOPICS OF STUDY: THERAPEUTICS contd.**

### **Dermatology**

Acne  
Acne Rosacea  
Allergic dermatitis  
Burns  
Cellulitis  
Dermatomycosis  
Diaper rash  
Dry skin  
Impetigo  
Pediculosis and scabies  
Onychomycosis  
Sunburn and photosensitivity reactions  
Viral infections (including chicken pox, herpes and shingles)

### **Eye, Ear, Nose and Throat**

Acute Otitis media  
Allergic rhinitis  
Bacterial conjunctivitis  
Bacterial sinusitis  
Glaucoma  
Mucositis  
Pharyngitis  
Teething  
Viral upper respiratory tract infections

### **Gastroenterology**

Cirrhosis  
Constipation  
Crohn's disease  
Diarrhea  
Dyspepsia and Peptic ulcer disease  
Esophagitis  
Gastroesophageal Reflux Disease (GERD)  
Gastrointestinal bleeding  
Hepatotoxicity and liver dysfunction  
Infant feeding problems including colic  
Inflammatory Bowel Disease: including Crohn's disease and Ulcerative colitis  
Irritable Bowel Syndrome  
Nausea and vomiting  
Pseudomembranous colitis

## **TOPICS OF STUDY: THERAPEUTICS contd.**

### **Cardiovascular diseases**

Angina  
Cardiac insufficiency (including congestive heart failure)  
Cerebrovascular accident (including ischemic stroke)  
Venous thromboembolism (DVT and PE)  
Dyslipidemia and hypercholesterolemia  
Endocarditis prophylaxis  
Hypertension  
Myocardial infarction  
Rhythm disorders

### **Urology**

Benign prostate hypertrophy  
Prostate cancer  
Sexually Transmitted Infections  
Urinary incontinence  
Urinary tract infections (cystitis, pyelonephritis and prostatitis)

### **Musculo-skeletal diseases**

Chronic pain  
Multiple sclerosis (MS)  
Osteoarthritis  
Osteoporosis  
Rheumatoid arthritis  
Skeletal pain  
Post-operative pain  
Tendonitis and sport injuries

### **Gynecology**

Bacterial vaginitis  
Contraception (including emergency contraception)  
Endometriosis  
Erectile dysfunction  
Fertility  
Menopause  
Pregnancy  
Premenstrual syndrome (PMS)  
Sexually transmitted infections  
Vaginal candidiasis

## **TOPICS OF STUDY: THERAPEUTICS contd.**

### **Infectious Diseases**

Bone and joint infection (osteomyelitis)  
Central nervous system infection  
Infections of the traveller  
Endocarditis  
Fungal infections  
Gastrointestinal infections  
HIV and AIDS (including opportunistic infections)  
Intra-abdominal infections  
Malaria prevention  
Meningitis  
Pneumonia (community acquired pneumonia and nosocomial)  
Respiratory tract infections (lower and upper)  
Sepsis and septic shock  
Skin and soft tissue infections  
Surgical prophylaxis  
Tuberculosis  
Urinary tract infections (UTIs)

### **Neurology**

Alzheimer's disease and other dementias  
Headaches (migraine, tension headache, rebound headache)  
Neuropathic pain  
Parkinson's disease  
Seizure disorders (including partial, generalized, status epilepticus and others)

### **Endocrinology**

Breast cancer  
Diabetes mellitus (types 1 and 2)  
Hypothyroidism  
Hyperthyroidism

### **Psychiatry**

Aggressive behaviour  
Anxiety disorders  
Bipolar disorder (manic-depressive psychosis)  
Depression  
Drug withdrawal syndromes  
Insomnia and sleep disorders  
Panic disorder  
Personality disorders  
Schizophrenia

## **TOPICS OF STUDY: THERAPEUTICS contd.**

### **Nephrology**

Chronic renal dysfunction  
Nephrotoxicity  
Renal transplantation

### **Other**

Anemias  
Chemotherapy and related toxicities  
Dehydration  
Fluid and electrolyte disorders  
Obesity

## PROFESSIONAL PRACTICE SKILLS

### **GENERAL DESCRIPTION: PROFESSIONAL PRACTICE SKILLS**

Courses covering the broad subject area of Pharmacy professional practice skills encompass the study of:

- pharmaceutical care
- client records
- prescription processing and dispensing
- communications, patient counselling and education
- safety issues and incident prevention
- drug information and evidence-based decision-making
- jurisprudence: federal law, prescriptive authority and regulatory issues
- health promotion, disease prevention and social issues

### **TOPICS OF STUDY: PROFESSIONAL PRACTICE SKILLS**

#### **Patient Care Process**

##### Assessment

Meet the patient and establish the therapeutic relationship

Elicit relevant information from the patient

Determine whether the patient's drug-related needs are being met and identify drug therapy problems:

- The patient requires drug therapy but is not receiving it,
- The patient is taking or receiving the wrong drug,
- The patient is taking or receiving too little of the right drug,
- The patient is taking or receiving too much of the right drug,
- The patient is not taking or receiving the drug or is taking or receiving the drug inappropriately,
- The patient is experiencing an adverse reaction to the drug,
- The patient is experiencing a drug interaction (including drug-drug, drug-food, drug-laboratory test, drug-disease, or drug-blood product),
- The patient is taking or receiving a drug for no medically valid indication or substance abuse.

##### Care Plan

Establish goals of therapy

Select appropriate interventions for:

- Resolution of drug therapy problems
- Achievement of goals of therapy
- Prevention of drug therapy problems

Schedule a follow-up evaluation

### Follow-up Evaluation

Elicit clinical and/or lab evidence of actual patient outcomes and compare them to the goals of therapy to determine the effectiveness of drug therapy

Elicit clinical and/or lab evidence of adverse effects to determine the safety of therapy

Document clinical status and any changes in pharmacotherapy that are required

Assess patient for any new drug therapy problems

Schedule the next follow-up evaluation

### **Client Records**

Application of privacy legislation and ethical considerations

Preparation and maintenance of patient records (includes profiles, charts, etc)

## **TOPICS OF STUDY: PROFESSIONAL PRACTICE SKILLS contd.**

### **Prescription Processing and Dispensing**

Accurate interpretation of prescription orders

Accurate calculations

Application of legislative requirements (federal legislation) see Jurisprudence section also

Extemporaneous compounding

Sterile preparations and pharmaceutical biohazards

Safe storage, handling and disposal of Drugs  
Cold chain management

Checking processes for dispensing prescriptions, including:

- Appropriateness of medication choice

- Therapeutic duplication

- Correct dosage, route, dosage form, regimen and duration of therapy

- Allergies and contraindications

- Drug interactions

- Compliance issues (adherence)

- Financial considerations (pricing, third party billing, quantity restrictions, etc)

### **Communications, Patient Counselling and Education**

Pharmacist Interactions in the workplace

- Effective dialogue with clients, caregivers and other health providers

- Individual consultations

- Presentations to a group

- Staff relations

Development of effective communication skills

- Dialogue and interviewing techniques/process

- Verbal and nonverbal listening

- Probing and gathering information

- Empathy, assertive skills

- Cultural diversity and other patient variables

Patient counselling and education on prescription medications, including:

- Confirmation of identity of the client

- Indication for use of the medication

- Directions for proper use

- Duration of therapy and onset of action

- Management of common adverse effects, interactions and therapeutic concerns

- Storage and handling requirements

- Compliance issues (adherence) and missed doses

- When to seek medical attention and follow-up

- Non-pharmacological and lifestyle measures

## **TOPICS OF STUDY: PROFESSIONAL PRACTICE SKILLS contd.**

### **Communications, Patient Counselling and Education contd.**

Patient counselling and education for administration of various dosage forms, including:

- Pulmonary delivery
- Ophthalmic, otic and nasal delivery
- Topical products
- Vaginal and rectal delivery
- Transdermal delivery
- Oral, sublingual and buccal dosage forms
- Parenteral products
- Other

Patient counselling and education to promote adherence to regimens and therapy

- Strategies to optimize adherence
- Identification of under-utilization of medication
- Identification of over-utilization of medication

Patient counselling and education on diagnostic/monitoring tools, including:

- Home blood glucose monitoring
- Blood pressure monitors
- Home pregnancy/ovulation test kits
- Thermometers
- Peak Flow meters

Patient counselling and education on non-prescription medications

- Self-care topics and issues

Patient counselling and education on “no public access” medications

Patient counselling and education on herbal and complementary therapies

Patient counselling and education on home health care, including:

- Medical supplies
- Aids for daily living
- Foot care
- Wound care
- Other

Professional collaboration and teamwork

- Work collaboratively with other health care professionals to optimize patient outcomes
- Refer to other health care providers when required
- Promote health and wellness in the community

## **TOPICS OF STUDY: PROFESSIONAL PRACTICE SKILLS contd.**

### **Safety Issues and Incident Prevention**

Policies and procedures to ensure safety and effectiveness of persons, medical products and pharmaceutical services

Canada Vigilance Program - adverse drug reaction monitoring  
Development of actions and strategies and actions to prevent incidents  
Error-prone abbreviations and dosage designations  
Look-alike and sound-alike drug names

Identification, management, and documentation of medication incidents (errors) – National System for Incident Reporting (NSIR)

Institute for Safe Medication Practices (ISMP)

Health Canada MedEffect: advisories, warnings and recalls

Medication reconciliation

Canadian Patient Safety Institute (CPSI) – Safer Healthcare Now!

### **Drug Information and Evidence-Based Decision-Making**

Selection of Suitable References and Information Databases  
Cochrane Collaborative Library  
Medline  
Primary, secondary, tertiary references

Evaluation of Drug Literature and Scientific Information  
Clinical Trials  
Evidence-based medicine  
Clinical Practice guidelines

Response to Drug Information Requests

## **TOPICS OF STUDY: PROFESSIONAL PRACTICE SKILLS contd.**

### **Jurisprudence**

Provincial Regulatory Authorities (PRAs)

NAPRA

Federal law, prescriptive authority and regulatory issues

Food and Drugs Act and Regulations

Controlled Drugs and Substances Act

    Precursor Control Regulations

    Benzodiazepines and other Targeted Substances Regulations

Narcotic Control Regulations

Marijuana medical access

Methadone

    Maintenance treatment

    For pain management

Privacy legislation

### **Health promotion, disease prevention and social issues**

Development of Health Promotion Strategies

    Health and wellness of individuals and groups

    Collaboration with other health care providers

Public Health Agency of Canada

    Travel health

    Vaccines and immunizations

    Disease prevention

BEHAVIOURAL, SOCIAL AND ADMINISTRATIVE PHARMACY  
SCIENCES

Pharmacy Administration: Management / Health Care Systems  
Pharmacoeconomics

Biostatistics/Pharmacoepidemiology

Bioethics

## PHARMACY ADMINISTRATION

### **GENERAL DESCRIPTION: PHARMACY ADMINISTRATION**

The course of study of the social, behavioural and administrative pharmacy sciences encompasses a number of broad areas including:

- Canadian health care systems (including society and the profession of pharmacy)
- Pharmacy management
- Pharmacoeconomics

### **TOPICS OF STUDY: CANADIAN HEALTH CARE SYSTEMS**

#### **Governance and Standards**

About Health Canada (see Health Canada website also)

Branches and Agencies

Canada's Health Care System (Medicare)

Responsibilities of federal government in regulating health care services, new drug approval and manufacturing (Health Canada) and the Canada Health Act

Health Canada: Delivery of Drugs and Health Products

New Drug Development and Approval

Drug Product Database

Special Access (to drugs) Program

MedEffect: Advisories, warnings and recalls

Canada Vigilance Program - adverse drug reaction monitoring

Natural Health Products

Responsibilities of provincial governments in regulating health care services, professions and drug distribution

Function of provincial regulatory authorities in the establishment of standards for pharmacy practice and registration of pharmacists

National Association of Pharmacy Regulatory Authorities (NAPRA)

National drug scheduling (schedule I, schedule II, schedule II, and unscheduled status)

Model Standards of Practice

PIPEDA- Personal Information Protection and Electronic Documents Act

[www.privcom.gc.ca](http://www.privcom.gc.ca) – look for print version link

## **The Pharmaceutical Industry and related agencies**

### Pharmaceutical Industry

- New Drug Development and Approval by Health Canada

- Pharmaceutical marketing and advertising

  - Regulation of Advertising

- Canada's Research-Based Pharmaceutical Companies (Rx & D)

- Canadian Generic Pharmaceutical Association (CGPA)

- Non-prescription Drug Manufacturers Association of Canada (NDMAC)

### Canadian Agency for Drugs and Technologies in Health (CADTH)

- Healthcare technology assessment

- Common Drug Review directorate

### Patented Medicines Prices Review Board (PMPRB)

### Institute for Safe Medication Practices

[www.ismp.org](http://www.ismp.org) click on "Medication Safety Tools and Resources" section

## **Contemporary Issues in the Structure and Functioning of the Canadian Health Care System**

- Financing and the cost of health care services

- Health expenditures and trends

- Delivery of health care (primary, secondary)

- Care and changing models of primary care

- Access to privately funded (market driven) health care providers and facilities

- Telehealth resource services

- Human resources (shortages of health care personnel and changing scopes of practice)

## **TOPICS OF STUDY: CANADIAN HEALTH CARE SYSTEMS contd.**

### **Contemporary Issues in the Structure and Functioning of the Canadian Health Care System**

- Financing and the cost of health care services
- Access to Privately funded (market driven) health care providers and facilities
- Telehealth services
- Human resources (shortages of health care personnel and scopes of practice)

## **TOPICS OF STUDY: SOCIETY AND THE PROFESSION OF PHARMACY**

### **History of Pharmacy as a Profession**

- Evolution of pharmacy as a distinct profession
- Historical transition from a primary interest of pharmacy with the preparation of dosage forms, to the distribution of drug products, and now to the safe and effective use of drugs in patient care
- Voluntary pharmacy organizations, advocacy groups and political action by pharmacists

### **Pharmacy Law and Regulation of the Profession**

- Provincial regulation of pharmacy practice and the operation of pharmacies
- Potential liability of pharmacists under federal and provincial statutes
- Potential liability of pharmacists in civil disputes
- Application of business law to the operation of pharmacies

### **Scientific and Humanistic Approaches to Modern (“Western”) Medicine and Pharmacotherapy**

- Evidence-based practice
- Complementary and alternative therapies
- Pharmacist’s role in preventing medical error and drug-related misadventure
- Medication adherence and promotion of healthy lifestyles and wellness
- Health literacy
- Cultural competency and diversity
- Health care of “at risk” populations (e.g. mental illnesses, First Nations, seniors, drug dependencies)

### **Hospital Pharmacy Practice Developments**

- Medication reconciliation
- Regional management of institutional health system pharmacies
- Recruitment and retention of pharmacy personnel
- Medication use safety systems
- Promoting seamless care

## **Community Pharmacy Practice Developments**

- Reimbursement for clinical pharmacy services
- Influence of 3<sup>rd</sup> party drug insurance plans on pharmacy practice
- Rural and remote pharmacy practice
- Prescriptive authority for pharmacists
- Collaborative medication management with physicians and other providers

## **TOPICS OF STUDY: PHARMACY MANAGEMENT**

### **Basic Responsibilities of Management**

The classical functions of management

- Planning, organizing, staffing, directing, coordinating, controlling, reviewing, leading, budgeting

Entrepreneurship

- Risk and innovation

Components of the business plan

- Market analysis
- Business structure and corporate governance
- Product or service offering
- Competitive strategy
- Positioning
- Financing
- Human and physical resources, operations and monitoring of performance

### **Marketing Management in Pharmacy**

General principles of marketing

- "4 P's" of marketing management
- Merchandising

### **Human Resource Management in Pharmacy**

Theories of management and organizational behaviour

- Job descriptions, delegation, leadership and styles of management
- Trade unions, contracts and collective bargaining
- Employee motivation, performance appraisal, discipline
- Recruitment and retention of staff
- Increasing role of pharmacy technicians

### **Financial Management in Pharmacy**

Financial statements

- Basic accounting procedures
- Interpretation of Balance sheet, Income Statement information

Measures (ratios) of financial performance of a business

- Profitability, Solvency, Liquidity, Inventory control

## **TOPICS OF STUDY: PHARMACY MANAGEMENT contd.**

### **Community Pharmacy Management**

#### Forms of Legal Ownership

Sole proprietorship, partnership, corporation, cooperative

#### Pharmacy Ownership Structures

Independents, chain, franchise, food store, mass merchandise, specialty, mail order, banner groups, central fill facilities

### **Hospital Pharmacy Management**

#### Drug Distribution Control Systems

Unit dose, automated dispensing devices, IV additive services, computer-based order entry, controlled drug handling, drug disposal procedures, drug identification and labelling, investigational drugs, automated medication records, electronic health records

#### Medication Use Management Procedures

Clinical pharmacy activities, formulary systems, Pharmacy and Therapeutics committees, medication reconciliation, medication safety procedures, medical errors, documentation by pharmacists in the health record, medication counselling, drug use review, continuous quality improvement

## **TOPICS OF STUDY: PHARMACOECONOMICS**

### **Health Care Economics**

#### Supply and Demand Factors

Hospitals and health care facilities capacity  
Physician services  
Population demographics and incidence of disease  
Chronic disease management

#### Pricing and Demand for Pharmaceuticals and Pharmacy Services in Canada

Influence of pharmaceutical industry marketing and advertising  
Patented Medicines Prices Review Board (PMPRB)  
Pharmacist professional fees  
Markups, rebates and discounts  
Cognitive fees

#### Third Party Prescription Insurance Plans and Payment Policies

Role of private payers and provincial drug plans  
Formulary restrictions (generic substitution, therapeutic interchange and non-formulary drugs)  
Role of copayments and deductible limits  
Prescription quantity limitations  
Prior (special) authorization policies  
Reference-based drug policies

## **TOPICS OF STUDY: PHARMACOECONOMICS contd.**

### Drug Use Management Strategies

- Drug Use Review agencies
- Academic detailing
- Educational support to prescribers and pharmacists
- Clinical practice guidelines and protocols

## **Pharmacoeconomics**

### Types of pharmacoeconomic analyses

- Cost-effectiveness
- Cost-benefit
- Cost-minimization
- Cost utility

### Related pharmacoeconomic concepts

- Health utilities
- Quality of life tools
- Willingness to pay
- Time trade-off analyses
- Discounting
- Preferences
- Societal costs and benefits vs. individual costs and benefits
- Sensitivity analyses

## PHARMACOEPIDEMOLOGY AND BIOSTATISTICS

### **GENERAL DESCRIPTION: PHARMACOEPIDEMOLOGY AND BIOSTATISTICS**

In these courses of study, knowledge of biostatistics theory and the methods used in epidemiological research are necessary to critically evaluate the scientific literature and make evidence-based decisions in the practice of pharmacy.

### **BASIC PRINCIPLES: PHARMACOEPIDEMOLOGY AND BIOSTATISTICS**

- I Use of acquired knowledge in epidemiology and biostatistics to solve problems related to individual or collective health problems.
- II Use of acquired knowledge in epidemiology and biostatistics to evaluate drug utilization trends or draw conclusions about drug efficacy or effectiveness.
- III Use of acquired knowledge in epidemiology and biostatistics to critically evaluate scientific literature.

### **TOPICS OF STUDY: PHARMACOEPIDEMOLOGY AND BIOSTATISTICS**

#### **Pharmacoepidemiology**

Measures of frequency, prevalence, incidence, cumulative incidence

Population types, life expectancy, risk

Research Methods:

Experimental, causal-comparative, correlational, descriptive, historical

Randomized, case control, cohort, case reports, anecdotal, population studies

Study designs: placebo controlled, cross-over, washout, factorial, N of 1, parallel

Critical Appraisal of Research:

Relative risk reduction or benefit, absolute risk reduction or benefit, odds ratio, number needed to treat

Conflict of interest, publication bias, research funding source, research ethics, institutional review boards (IRB), Cochrane Collaboration and similar agencies

## **TOPICS OF STUDY: PHARMACOEPIDEMOLOGY AND BIOSTATISTICS contd.**

### **Biostatistics**

#### The Definition of Population

Sample, sampling, sample size, clusters, stratified

Sample error, sampling bias, representativeness

Inclusion criteria, exclusion criteria

#### The Characteristics of Data:

Types of data: continuous, interval, ordinal, nominal, ratio, qualitative, surveys

Distribution of data: normal, non-normal, skewed

Precision, validity, reliability, accuracy

Variables: dependent, independent, confounding

Outcomes and endpoints: primary, secondary, clinical, laboratory, quality of life, economic

#### Data Analysis

Descriptive analysis: mean, median, mode, relative position, variability, relationships

Inferential: hypothesis testing, significance, variance, confidence interval, power, error, probability, frequency, prediction, causality, correlation

Statistical Tests: parametric, nonparametric, meta-analysis

Significance: clinical, statistical, limitations, assumptions

## BIOETHICS

### **GENERAL DESCRIPTION: BIOETHICS**

The study of bioethics encompasses consideration of basic ethical principles and values that form the ethical foundations for the provision of care by the health professions including Pharmacy practice.

### **TOPICS OF STUDY: BIOETHICS**

#### **Dominant (normative) moral views in health care ethics**

Utilitarianism/consequentialism

Deontology



#### **Bioethical principles**

Beneficence, Nonmaleficence, Autonomy, Justice, Veracity, Fidelity

### **TOPICS OF STUDY: PHARMACY ETHICS**

Patient Consent and Decision-making

Capacity, encumbrances, competency

Patient surrogates: substituted judgement, best interest judgment, advance directives, living wills, children and minors, the place of the family

Confidentiality and privacy

Advocacy for the Patient

Conflict between the pharmacist and other health care providers about patient care

Respect for Life and the Autonomy of Patients

Contraception, emergency contraception, abortion

Euthanasia, assisted suicide

Palliative care, pain management, and end-of-life care

Pharmacist conscience clause

Other Issues in Pharmacy and Health Care Ethics

Clinical drug trials research and the place of pharmaceuticals in advancing health

Health reform and allocation of limited resources

Interdisciplinary decision-making

Ethics committees

Conflict of interest (gifts from patients and the pharmaceutical industry)

Access to health care and pharmaceuticals in underdeveloped countries

Professionalism

Trust, integrity, competence, respect, virtues, compassion, collegiality