# PHARMACIST

# EVALUATING EXAMINATION

# SYLLABUS

## The Pharmacy Examining Board of Canada

# 2019

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# EVALUATING EXAMINATION SYLLABUS

# INTRODUCTION

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 foundational knowledge base 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 pharmacy 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
  - Clinical Sciences
  - Professional Practice Skills
- 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 evaluated in the Pharmacist Evaluating Examination.

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 available on the PEBC website.

## BIOMEDICAL SCIENCES

Biochemistry

Genomics and Molecular Biology

Physiology/Functional Anatomy

Immunology

Medical Microbiology

# BIOCHEMISTRY

## GENERAL DESCRIPTION

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

### 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

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

Lipids and membranes

# MOLECULAR BIOLOGY AND GENOMICS

## GENERAL DESCRIPTION

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: MOLECULAR BIOLOGY AND GENOMICS

### 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 approach

# PHYSIOLOGY/ FUNCTIONAL ANATOMY

## GENERAL DESCRIPTION

This course of study includes normal physiology of the human body (with emphasis on cellular mechanisms), and a general review of systemic human anatomy (with clinical applications). The goal 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

### Cardiovascular System

The structure and contractile properties of the heart

Mechanical forces regulating blood pressure

Hormonal and neural regulating mechanisms

**TOPICS OF STUDY: HUMAN PHYSIOLOGY cont'd.**

**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

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 cont'd.**

**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

Autonomic Nervous System
Centres of control; sympathetic and parasympathetic systems;
neurotransmitters

**Organs of Special Sense**

Eye, Ear, Olfaction, Taste

**TOPICS OF STUDY: FUNCTIONAL ANATOMY cont'd.**

**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

**The Lymphatic System**

Significance

Gross anatomy and histology of lymphatic tissue

Lymphatic vessels; lymph node

Spleen, thymus, appendix

# IMMUNOLOGY

## GENERAL DESCRIPTION

This course of study provides an overview of the immune system, immune responses, and defence mechanisms against infectious disease. 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 Histocompatability 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

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

# MEDICAL MICROBIOLOGY

## COURSE DESCRIPTION

This course of study includes the general biology of microorganisms 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, keratitis

Infections of the urogenital tract
- Urinary tract infections
- Sexually transmitted infections

Infections of the CNS
- Meningitis
- Abcesses

**TOPICS OF STUDY: MEDICAL MICROBIOLOGY cont'd.**

Infections of the respiratory tract
- Otitis, pharyngitis, sinusitis
- Pneumonia, bronchitis, croup
- Tuberculosis

**Antimicrobial Agents**

β-Lactams

Quinolones

Macrolides, clindamycin, tetracyclines

Aminoglycosides, vancomycin

Sulfonamides and trimethoprim

Metronidazole

**Viral Infections**

Properties, structure, replication, and transmission

Viral pathogenesis, host response, and principles of diagnostic virology

Sites/types of viral infections
- Respiratory tract
- CNS
- Gastrointestinal tract
- Genitourinary tract
- HIV and AIDS
- Hepatitis
- Measles, mumps, rubella
- Chickenpox and shingles
- Infections in the fetus and newborn

Antiviral agents

**TOPICS OF STUDY: MEDICAL MICROBIOLOGY cont'd.**

**Parasitology**

Protazoal diseases
- Protazoas and helminths

Malaria

Ectoparasites
- Lice, scabies, ticks

**Mycology**

Properties, structure, replication, and transmission

Systemic mycoses
- Candidiasis
- Aspergillosis
- Histoplasmosis
- Blastomycosis
- Coccidiodomycosis
- Cryptococcosis

Superficial mycoses
- Dermatophytes

Antifungal agents

**Sterilization and Disinfection**

Infection control methods

**Immunoprophylaxis and Vaccines**

# PHARMACEUTICAL SCIENCES

Pharmaceutics and Drug Delivery Systems

Phamacokinetics and Biopharmaceutics

Medicinal Chemistry

Pharmacology

Toxicology and Clinical Toxicology

Biotechnology and Pharmacogenetics

# PHARMACEUTICS AND DRUG DELIVERY SYSTEMS

## GENERAL DESCRIPTION

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 includes the role of biopharmaceutics, pre-formulation 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, hydrogen, 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 cont'd.**

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

Liquid-liquid solutions
- 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
- Hixon-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 cont'd.**

**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

**Pulmonary 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 cont'd.**

**Dermal and Transdermal 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 cont'd.**

**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

**TOPICS OF STUDY: PHARMACEUTICS & DRUG DELIVERY SYSTEMS cont'd.**

**Pharmaceutical Analysis**

Chromatographic separation methods
- High Pressure Liquid Chromatography (HPLC)
- Gas Liquid Chromatography (GLC)

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

# PHARMACOKINETICS & BIOPHARMACEUTICS

## COURSE DESCRIPTION

This course of study 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 cont'd.**

**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 cont'd.**

Therapeutic drug monitoring
- Drugs in renal failure: Aminoglycosides, cyclosporine
- Drugs with saturable kinetics: Phenytoin
- Drugs with linear kinetics: Digoxin

**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

Drug concentration vs. time curves
- Determining what model the drug follows

Clearance rates

Loading doses and time to reach steady state

Pharmacokinetic-pharmacodynamic modeling

# MEDICINAL CHEMISTRY

## GENERAL DESCRIPTION

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.

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
- Nitrates and nitrites

### 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 cont'd.**

**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

# PHARMACOLOGY

## GENERAL DESCRIPTION

The study of basic pharmacological principles is applied to representative clinically important drugs having their primary actions on various organ systems of the body. It includes the 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

Drugs and catecholamine metabolism

Sympathomimetics (adrenergic agents)

Sympatholytics (adrenergic blocking agents)

Cholinergic drugs

Anticholinesterases

Anticholinergics

Skeletal muscle relaxants

### Anaesthetics

Local anaesthetics

General anaesthetics

**TOPICS OF STUDY: PHARMACOLOGY cont'd.**

**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

Immunosuppressive drugs

Drugs used in the treatment of inflammatory diseases
- Asthma
- Rheumatoid arthritis
- Gout

Biologic response modifiers

**Central Nervous System Pharmacology**

Pain and opioid analgesics

Anxiolytic drugs

Sedative/hypnotic drugs

Antipsychotics

Antidepressants

Psychostimulants

Anti-Parkinson drugs

Antiseizure drugs

Drugs for Alzheimer's disease

Drugs for migraine

**Drugs Affecting the Haematopoietic System**

Iron, folic acid, vitamin $B_{12}$, erythropoietin, filgrastim

**TOPICS OF STUDY: PHARMACOLOGY cont'd.**

**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

Direct thrombin inhibitors

Anti-platelet drugs

Thrombolytics

**Drugs for Dyslipidemia**

**Diuretics**

**Cancer Chemotherapy**

Alkylating agents, antimetabolites, cytotoxic antibiotics, plant alkaloids, hormones, biologic response modifiers

Adjunctive agents including antiemetics

**TOPICS OF STUDY: PHARMACOLOGY cont'd.**

**Gastrointestinal Pharmacology**

Drugs affecting GI motility

Drugs affecting gastric secretion

Anti-obesity drugs

**Endocrine Pharmacology**

Insulin and oral antihyperglycemics

Corticosteroids

Thyroid and anti-thyroid drugs

Androgens and anabolic steroids

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

Gonadotropins

Vasopressin

Oxytocin

Bone mineral homeostasis

**Anti-Infective Agents**

Antibacterial drugs

Beta-lactam antibiotics, carbapenems, sulphonamides, trimethoprim, tetracyclines, aminoglycosides, macrolides, fluoroquinolones, vancomycin, metronidazole, nitrofurantoin

Antiviral drugs

Antifungal drugs

Antiprotozoal drugs

Anthelmintic drugs

**TOPICS OF STUDY: PHARMACOLOGY cont'd.**

**Respiratory Drugs**

Antihistamines

Antitussives

Anti-inflammatory agents

Bronchodilators

**Ophthalmic Drugs**

Antiglaucoma agents

Mydriatics

**Drugs of Abuse**

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

# TOXICOLOGY AND CLINICAL TOXICOLOGY

## GENERAL DESCRIPTION

Concerned primarily with drug-induced diseases, this course of study 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

**TOPICS OF STUDY: TOXICOLOGY & CLINICAL TOXICOLOGY cont'd.**

**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

# BIOTECHNOLOGY AND PHARMACOGENETICS

## GENERAL DESCRIPTION

In this course of study, 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 cont'd.**

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
- Gonadotropins
- 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 cont'd.**

**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

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 cont'd.**

**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

**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 cont'd.**

**Erythropoietin**

**Thrombolytic Agents**

**Formulation of Protein and Peptide Drugs**

Problems: stability, bioavailability and routes of administration

Recent approaches in protein and peptide drug delivery

## PHARMACY PRACTICE – Clinical Sciences

Pathophysiology

Clinical Biochemistry/ Laboratory and Diagnostic Testing

Pharmacotherapeutics (including Prescription, Non-prescription and Complementary Therapy)

Health Promotion and Disease Prevention

Patient Care Process (Assessment/ Intervention/ Monitoring/ Follow-up/ Documentation)

Special Populations (including Geriatrics, Pediatrics, Pregnancy and Lactation)

Nutrition

# PATHOPHYSIOLOGY

## GENERAL DESCRIPTION

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

## TOPICS OF STUDY: PATHOPHYSIOLOGY

### 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: immediate (anaphylactic), cytotoxic, immune complex, delayed

Autoimmune diseases

**TOPICS OF STUDY: PATHOPHYSIOLOGY cont'd.**

**Obstructive Lung Disease**

Asthma

Chronic obstructive pulmonary disease (COPD)

**Gastrointestinal Disease**

Gastroesophageal reflux disease (GERD)

Peptic ulcer disease

Inflammatory bowel disease
- Crohn disease
- Ulcerative colitis

Zollinger-Ellison syndrome

**Liver Disease**

Cholestasis

Hepatitis (A, B, C)

Cirrhosis

Drug-induced hepatotoxicity

**Renal Disease**

Acute renal insufficiency

Chronic renal insufficiency

**TOPICS OF STUDY: PATHOPHYSIOLOGY cont'd.**

**Endocrine Disorders**

Thyroid disorders
- Hyperthyroidism
- Hypothyroidism

Adrenal disorders
- Cushing's Syndrome
- Addison's Disease

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

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., vitamin $B_{12}$ deficiency and folic acid deficiency)

Haemostatic disorders

**TOPICS OF STUDY: PATHOPHYSIOLOGY cont'd.**

**Neurology**

Neurodegenerative diseases
- Alzheimer's disease and dementias
- Parkinson's Disease

Pain and headache
- Acute or chronic
- Migraine

Seizure disorders

Stroke

**Psychiatry**

Anorexia, bulimia, and eating disorders

Anxiety

Attention deficit hyperactivity disorder (ADHD)

Bipolar disorder

Depression

Insomnia

Schizophrenia

**Carcinogenesis and Neoplasia**

Sites
- Lung neoplasms
- Gastrointestinal neoplasms
- Gynecologic neoplasms
- Urinary tract neoplasms
- Hematology (e.g., leukemia and lymphoma)
- Skin neoplasms (e.g., malignant melanoma and others)
- Cancer of the bone, brain, breast, prostate

# CLINICAL BIOCHEMISTRY / LABORATORY AND DIAGNOSTIC TESTING

## GENERAL DESCRIPTION

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

## TOPICS OF STUDY: CLINICAL BIOCHEMISTRY / LABORATORY AND DIAGNOSTIC TESTING

### 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)

### Electrolytes and Blood Chemistry

Sodium

Potassium

Chloride

Glucose (random or FBG)

Uric Acid

**TOPICS OF STUDY: CLINICAL BIOCHEMISTRY / LABORATORY AND DIAGNOSTIC TESTING cont'd.**

Arterial blood gases ($PaO_2$, $PaCO_2$)

pH

Anion gap

Bicarbonate

**Liver Biochemistry**

Bilirubin

Alkaline phosphatase (ALP)

Transaminases (AST, ALT)

Albumin

$\alpha$-Fetoprotein

**Bone Metabolism**

Bone mineral density

Minerals (calcium, phosphate)

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

**TOPICS OF STUDY: CLINICAL BIOCHEMISTRY/LABORATORY AND DIAGNOSTIC TESTING cont'd.**

**Gastrointestinal Tract**

Schilling's test

Occult blood

Endoscopy

**Pulmonary Function Tests**

Pulmonary function testing

Histamine, methacholine challenge test

**Neurology**

Cerebral spinal fluid (CSF)

**Cardiovascular Diagnostic Tests**

Cardiac isoenzymes (including creatine kinase)

Troponin

Lipoprotein profile (LDL, HDL, triglycerides, total cholesterol)

**Neoplasm Screening**

Prostate-specific antigen (PSA)

Breast self-examination

Mammogram

Pap smear

**TOPICS OF STUDY: CLINICAL BIOCHEMISTRY/LABORATORY AND DIAGNOSTIC TESTING cont'd.**

**Endocrinology**

Hypothalamus-pituitary axis
- Prolactin
- Growth hormone (GH)
- Gonadotropins (LH and FSH)
- Adrenocorticotropin (ACTH)

Adrenal disorders
- Plasma cortisol
- Urine and serum osmolality

Thyroid function
- TSH
- Free $T_3$
- Free $T_4$

Sex hormones
- Pregnancy testing

Diabetes and glucose monitoring
- Glucose tolerance test
- Fasting blood 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 tests

# PHARMACOTHERAPEUTICS
## (INCLUDING PRESCRIPTION, NONPRESCRIPTION AND COMPLEMENTARY THERAPY)

**GENERAL DESCRIPTION**

This course of study 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 (nonprescription) 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 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 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: PHARMACOTHERAPEUTICS**

**For the following diseases, therapeutics considerations should include prescription medication, self-care (nonprescription) treatments, non-pharmaceutical approaches, as well as alternative (complementary) treatments.**

**Respiratory Diseases**

Asthma
Chronic obstructive pulmonary disease (COPD)
Croup
Smoking cessation

**TOPICS OF STUDY: PHARMACOTHERAPEUTICS cont'd.**

**Dermatology**

Acne
Acne rosacea
Allergic contact dermatitis
Atopic 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
Otitis externa
Pharyngitis
Teething
Viral upper respiratory tract infections

**Gastroenterology**

Cirrhosis
Constipation
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 disease and ulcerative colitis
Irritable bowel syndrome
Nausea and vomiting
Pseudomembranous colitis

**TOPICS OF STUDY: PHARMACOTHERAPEUTICS cont'd.**

**Cardiovascular diseases**

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

## Genitourinary diseases

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

**Musculoskeletal diseases**

Chronic pain
Multiple sclerosis
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)
Vaginal candidiasis

**TOPICS OF STUDY: PHARMACOTHERAPEUTICS cont'd.**

**Infectious Diseases**

Bone and joint infections (osteomyelitis)
Central nervous system infections (meningitis)
Infections related to travel
Endocarditis
Fungal infections
Gastrointestinal infections (including *C. difficile*-associated diarrhea
HIV and AIDS (including opportunistic infections)
Intra-abdominal infections
Malaria
Pneumonia (community acquired pneumonia and nosocomial)
Respiratory tract infections (lower and upper)
Sepsis and septic shock
Sexually transmitted infections
Skin and soft tissue infections
Surgical prophylaxis
Tuberculosis
Urinary tract infections (UTIs)

**Neurology**

Alzheimer's disease and other dementias
Headaches (migraine, tension-type, cluster, medication overuse)
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
Depression
Drug withdrawal syndromes
Insomnia and sleep disorders
Obsessive-compulsive disorder
Panic disorder
Personality disorders
Schizophrenia

**TOPICS OF STUDY: PHARMACOTHERAPEUTICS cont'd.**

**Nephrology**

Chronic renal dysfunction
Nephrotoxicity
Renal transplantation

**Other**

Anemias
Chemotherapy and related toxicities
Dehydration
Fluid and electrolyte disorders
Obesity

# HEALTH PROMOTION AND DISEASE PREVENTION

## GENERAL DESCRIPTION

This course of study reviews the principles of health and wellness in the provision of individual, as well as population-based health and wellness information.

## TOPICS OF STUDY: HEALTH PROMOTION AND DISEASE PREVENTION

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

Preventative health services (e.g., immunizations, tobacco cessation counselling)

# PATIENT CARE PROCESS

## TOPICS OF STUDY: 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
Assess patient for any new drug therapy problems
Schedule the next follow-up evaluation

### Documentation

Document clinical status and any changes in pharmacotherapy that are required
Application of privacy legislation and ethical considerations
Preparation and maintenance of patient records (includes profiles, charts, etc)

# SPECIAL POPULATIONS

**TOPICS OF STUDY: SPECIAL POPULATIONS**

Unique pharmacotherapeutic considerations for special populations including:

- Neonates
- Pediatrics
- Geriatrics
- Pregnant women
- Lactating women

# NUTRITION

**TOPICS OF STUDY: NUTRITION**

Digestion

Function of nutrients in the body

Dietary requirements and Canada's Food Guide

Assessment of nutritional status

Malnutrition and effects on health

Metabolism and transport of nutrients

Regulation of blood glucose

Weight management and eating disorders

## PHARMACY PRACTICE - Professional Practice Skills

Prescription Processing and Product Preparation (including Non-sterile and Sterile Compounding)

Prescription Calculations

Communication / Patient Counselling

Drug Information

Literature Evaluation / Research Methods / Evidence-Based Decision Making (including Pharmacoepidemiology)

Medication / Patient Safety Practices

Law / Jurisprudence

Professionalism / Ethics

Collaborative Patient Care

# PRESCRIPTION PROCESSING AND PRODUCT PREPARATION

**TOPICS OF STUDY: PRESCRIPTION PROCESSING AND PRODUCT PREPARATION**

Accurate interpretation of prescription orders

Application of legislative requirements (federal legislation only) - see Law/Jurisprudence section also

Non-sterile and sterile compounding

Handling of hazardous drugs

Cold chain management

Checking processes for dispensing prescriptions, including:

- Appropriateness of medication choice
- Therapeutic duplication
- Correct dosage, route, dosage form, frequency, and duration of therapy
- Allergies and contraindications
- Drug interactions
- Adherence issues
- Financial considerations (pricing, third party billing, quantity restrictions, etc)

# PRESCRIPTION CALCULATIONS

**TOPICS OF STUDY: PRESCRIPTION CALCULATIONS**

Systems and units of measure (including metric system, SI)
- Intersystem conversion

Dosage calculations
- Amount of drug
- Number of doses
- Dosing based on body weight, body surface area
- Dosing based on age or pharmacokinetic parameters

Compounding calculations (non-sterile and sterile)
- Ratio and proportion
- Percentage
- Dilution and concentration
- Stock solutions
- Alligation
- Electrolyte solutions (milliequivalents, millimoles, osmolarity)

Dosing calculations for parenteral medications
- Reconstitution
- Infusion flow rate
- Total parenteral nutrition (TPN)

Prescription processing calculations
- Dispensing fees
- Insurance co-payments

# COMMUNICATION / PATIENT COUNSELLING

**TOPICS OF STUDY: COMMUNICATION / PATIENT COUNSELLING**

Pharmacist interactions in the workplace
- Effective dialogue with patients, 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
- Adherence issues and missed doses
- When to seek medical attention and follow up
- Nonpharmacological and lifestyle measures

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

**TOPICS OF STUDY: COMMUNICATION / PATIENT COUNSELLING cont'd**

Patient counselling and education on nonprescription 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

# DRUG INFORMATION

**TOPICS OF STUDY: DRUG INFORMATION**

Selection of suitable references and information databases
- Cochrane Collaborative Library
- Medline
- Micromedex
- Lexicomp
- RxFiles
- RxTx
- Primary, secondary, tertiary references

Response to drug information requests

# LITERATURE EVALUATION / RESEARCH METHODS / EVIDENCE-BASED DECISION-MAKING
## (including PHARMACOEPIDEMIOLOGY)

**TOPICS OF STUDY: LITERATURE EVALUATION / RESEARCH METHODS / EVIDENCE-BASED DECISION-MAKING (including PHARMACOEPIDEMIOLOGY)**

Evaluation of drug literature and scientific information (critical appraisal)
- Clinical Trials
- Evidence-based medicine
- Clinical practice guidelines
- Systematic reviews and meta-analysis
- Observational studies
- Conflict of interest, publication bias, research funding source, research ethics, institutional review boards (IRB)
- Cochrane Collaboration and similar agencies

**Research Methods**

Design
- Placebo-controlled, cross-over, washout, factorial, N of 1, parallel
- Randomized, cohort, case-control, cross sectional, case reports, population studies
- Experimental, causal-comparative, correlational, descriptive, historical

Measures
- Frequency
  - Prevalence, incidence, cumulative incidence, risk
- Association
  - Relative risk reduction or benefit, absolute risk reduction or benefit, odds ratio, number-needed-to-treat, hazards ratio

Validity
- Internal
  - Bias and confounding
- External
  - Generalizability

Diagnostic testing
- Sensitivity, specificity, positive predictive value, negative predictive value, likelihood ratio

# MEDICATION / PATIENT SAFETY PRACTICES

**TOPICS OF STUDY: MEDICATION / PATIENT SAFETY PRACTICES**

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

Canada Vigilance Program - adverse drug reaction monitoring

Health Canada MedEffect: advisories, warnings and recalls

Development of strategies and actions to prevent medication incidents
- Error-prone abbreviations and dosage designations
- Look-alike and sound-alike drug names

Identification, management, and documentation of medication incidents – National System for Incident Reporting (NSIR) and Canadian Medication Incident Reports and Prevention System (CMIRPS)

Institute for Safe Medication Practices (ISMP)

Medication reconciliation

Canadian Patient Safety Institute (CPSI)

# LAW / JURISPRUDENCE

**TOPICS OF STUDY: LAW / JURISPRUDENCE**

Provincial Regulatory Authorities (PRAs)
- Mandate, Roles, Responsibilities

NAPRA
- Mandate, Roles, Responsibilities

Federal legislation

- Prescriptive authorities and regulatory issues pertaining to the profession of pharmacy

- Food and Drugs Act and Regulations

- Controlled Drugs and Substances Act
  - Precursor Control Regulations
  - Benzodiazepines and other Targeted Substances Regulations
  - Marihuana medical access

- Narcotic Control Regulations

- Privacy legislation
  - Personal Information Protection and Electronic Documents Act (PIPEDA)

- Hazardous Products Act
  - WHMIS

# PROFESSIONALISM/ ETHICS

## GENERAL DESCRIPTION

The study of professionalism and ethics encompasses consideration of basic principles and values that form the ethical foundations for the provision of care by health care professionals including pharmacists.

## TOPICS OF STUDY: PROFESSIONALISM / ETHICS

Ethical principles
- Beneficence, nonmaleficence, autonomy, justice, veracity, fidelity

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

Continuity of care

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, Medical Assistance in Dying (MaiD)
- Palliative care, pain management, and end-of-life care

Respecting professional boundaries

Pharmacist conscientious objection (right to refuse)

Other Issues in pharmacy and health care ethics
- Clinical drug trials research
- Health reform and allocation of limited resources
- Interdisciplinary decision-making
- Ethics committees
- Conflict of interest (gifts from patients and the pharmaceutical industry)

Professionalism
- Trust, integrity, competence, respect, altruism, compassion, collegiality

# COLLABORATIVE PATIENT CARE

**TOPICS OF STUDY: COLLABORATIVE PATIENT CARE**

Collaboration with other health care professionals to optimize patient outcomes

Referral to other health care providers for specific services
- Identifying need
- Most appropriate resource or health care professional

Effective working relationships
- Establishing rapport
- Decision-making strategies
- Accountability
- Conflict resolution
- Scopes of practice

Promotion of health and wellness in the community

# BEHAVIOURAL, SOCIAL AND ADMINISTRATIVE PHARMACY SCIENCES

Pharmacy Management (including Financial, Personnel, Marketing, Quality Improvement, Risk Management and Workplace Safety)

Canadian Health Care System

Pharmacoeconomics

Biostatistics

# PHARMACY MANAGEMENT

## TOPICS OF STUDY: PHARMACY MANAGEMENT

### Basic Responsibilities of Management

The classical functions of management
- Planning, organizing, staffing, directing, coordinating, controlling, reviewing, leading, managing conflict, budgeting, managing risk

Entrepreneurship
- Risk and innovation

Components of the business plan
- Market analysis (SWOT)
- Business structure and corporate governance
- Product or service offering
- Competitive strategy
- Positioning
- Financing
- Human and physical resources, operations and monitoring of performance
- Risk management

Workplace safety
- WHMIS (Workplace Hazardous Materials Information System)

### 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, styles of management
- Trade unions, contracts, collective bargaining
- Employee motivation, performance appraisal, discipline
- Recruitment and retention of staff
- Scope of practice for pharmacists, pharmacy technicians, non-regulated staff

## TOPICS OF STUDY: PHARMACY MANAGEMENT cont'd

### 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

### Community Pharmacy Management

Forms of legal ownership
- Sole proprietorship, partnership, corporation, cooperative

Pharmacy ownership structures
- Independents, chain, franchise, mass merchandise, specialty, mail order, banner groups, central fill facilities

Medication Use Management Procedures
- Cognitive pharmacy services, medication reconciliation, medication safety procedures, medication error reporting, continuous quality improvement

Risk Management

### Hospital Pharmacy Management

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

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, drug use review, continuous quality improvement

Risk management

# CANADIAN HEALTH CARE SYSTEM

**TOPICS OF STUDY: CANADIAN HEALTH CARE SYSTEM**

**Governance and Standards**

About Health Canada
- 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 Programme
- 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 and pharmacy technicians

National Association of Pharmacy Regulatory Authorities (NAPRA)
- National drug scheduling (schedule I, schedule II, schedule III, and unscheduled status)
- Model Standards of Practice

PIPEDA- Personal Information Protection and Electronic Documents Act

**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)
- Nonprescription Drug Manufacturers Association of Canada (NDMAC)

Canadian Agency for Drugs and Technologies in Health (CADTH)
- Healthcare technology assessment
- Common Drug Review directorate

## TOPICS OF STUDY: CANADIAN HEALTH CARE SYSTEM cont'd

Patented Medicines Prices Review Board (PMPRB)

Institute for Safe Medication Practices (ISMP) Canada

Canadian Institute for Health Information (CIHI)

Canadian Institutes for Health Research (CIHR)

Public Health Agency of Canada (PHAC**)**

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

Financing and the cost of health care services
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)

### 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

**TOPICS OF STUDY: CANADIAN HEALTH CARE SYSTEM cont'd**

**Community Pharmacy Practice Developments**

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

# PHARMACOECONOMICS

**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 and cognitive fees
- Markups, rebates and discounts

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

Drug use management strategies
- Drug use review agencies
- Academic detailing and 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
- Perspective

# BIOSTATISTICS

**TOPICS OF STUDY: BIOSTATISTICS**

Definition of population
- Sample, sampling, sample size, clusters, stratified
- Sample error, sampling bias, representativeness, generalizability
- Inclusion criteria, exclusion criteria

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, covariant
- 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