New Course Outline

- The PharmD Approval Process for New Course Outlines document provides more information on next steps and approval timelines.
- The Course Outline Submission Overview document provides more detailed guidelines on course learning objectives, topic outlines/scheduling requirements, and assessment methods.
- The AFPC Educational Outcomes for Professional Programs document provides complete information on roles and key competencies for Pharmacy Degree Programs.

Course Number: PHM340 & PCL362

Course Title: Introductory Toxicology

Outline Version Code:

Course Description:
Concerned primarily with drug-induced diseases, this lecture course provides students with a conceptual framework for understanding the broad spectrum of toxicological problems encountered in clinical practice, in drug development and regulation, and in medical research. Central biochemical mechanisms and the relevance of clinical factors to toxicological expression will be integrated and applied to illustrative models of drug-related diseases in humans.

Semester: ☒ Fall ☐ Winter ☐ Summer

Course Type: ☐ Elective ☐ Selective ☒ Mandatory

1. Course Learning Objectives:
Upon completion of this course, students will have achieved the following level of learning objectives:
Introductory = knowledge and comprehension of concepts, definitions
Intermediate = application of concepts to simple situations
Advanced = application of concepts to more complex situations with ability to synthesize and evaluate

Knowledge
Introductory Level:

Intermediate Level:
In the first half of the course, the student will acquire a basic knowledge of the nature and magnitude of drug toxicity, diagnostic complications, mechanisms of drug toxicity, how individual risk is modulated by pharmacological, physiological and pathophysiological factors, and basic approaches for the evaluation of drug toxicities. Emphasis is placed upon toxicities due to electrophilic and free radical reactive intermediates and oxidative stress, while overlap with receptor-mediated mechanisms covered in courses in pharmacology and therapeutics is minimal. In the second half of the course, principles learned in the first half are applied in detail to a limited number of clinically
relevant examples of serious drug toxicities, including liver and kidney damage, neurodegeneration, teratogenesis, carcinogenesis and immune-mediated hypersensitivity reactions.

**Advanced Level:**

*Skills*
Introductory Level:

Intermediate Level:
To facilitate the development of an advanced level of learning, essay format examinations are employed for two midterm examinations and a final examination. Exam essay questions require students to use a detailed knowledge of concepts and underlying mechanisms to provide comprehensive answers to complex toxicological questions similar to those encountered in clinical practice and careers in government, the pharmaceutical industry and academia. To develop the student's ability to employ information from multiple sources in synthesizing comprehensive answers, tutorials are provided before and after each midterm examination showing the breadth and depth of approach required.

**Advanced Level:**

*Attitudes/Values:*
Introductory Level:
Students are acquainted with the relevance of toxicological expertise in health care and society, along with issues of professional responsibility and associated ethical issues, by the regular presentation of current news reports from the print and television media at the beginning of lectures, and several movies covering major issues in drug toxicity.

Intermediate Level:

Advanced Level:
2. Rationale for Inclusion in the Curriculum:
Adverse effects are a potential complication all drug therapy, including the use of non-prescription products. An informed knowledge of toxicological mechanisms, the determinants of individual risk, and the application of this knowledge to clinical problems, drug product development, the regulatory process and improved drug safety are essential for Pharmacists in clinical practice and in careers in the pharmaceutical industry, government and academia. Pharmacists also constitute the public's first line of evidence-based information on related aspects of chemical safety relevant to environmental exposures.

3. Pre-requisites:
PHM140, PHM142, PHM143, PHM144, PHM145; PSL205H1

4. Co-requisites:

5. Course Contact Hours and Teaching Methodologies:

<table>
<thead>
<tr>
<th>Didactic (lecture)</th>
<th>Hours: 26</th>
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<tbody>
<tr>
<td>Large group problem-based/ case-based learning (group size: 240)</td>
<td>Hours:</td>
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<tr>
<td>Laboratory or Simulation</td>
<td>Hours:</td>
</tr>
<tr>
<td>Tutorial/Seminar/Workshop/Small Group (group size: 240)</td>
<td>Hours: 4 (optional)</td>
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<tr>
<td>Experiential</td>
<td>Hours:</td>
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<tr>
<td>On-line</td>
<td>Hours:</td>
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<tr>
<td>Other (please specify):</td>
<td>Hours:</td>
</tr>
<tr>
<td><strong>Total Course Contact Hours</strong></td>
<td><strong>Hours: 26 + 4 optional</strong></td>
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6. Estimate and description of student's weekly out-of-class preparation time excluding exam preparation:
Students are expected to review the handouts prior to class, and may read supplementary papers posted on Blackboard or recommended textbooks for clarification of principles or application.

7. Topics Covered and Lecture Specific Learning Objectives

**Week 1**

**Lecture Topic:** Course introduction and general principles, adverse drug reactions; Pharmacological principles: relation of toxic response to frequency, dose and tissue concentration, discrimination among putative causes of disease (2 hr). (Dr. Peter Wells)

**Lecture Learning Objectives:**
- Understanding of the listed topic principles.
Week 2
Lecture Topic: Mechanisms: receptor-mediated vs. reactive intermediate-mediated toxicity, covalent binding, reactive oxygen species (ROS), oxidative macromolecular damage & signaling; Mechanisms: elimination, bioactivation, detoxification, cytoprotection and macromolecular repair (2 hr). (Dr. Wells)

Lecture Learning Objectives:
- Understanding of the listed topic principles.

Week 3
Lecture Topic: Mechanisms: oxidative DNA damage & repair (Dr. Rebecca Laposa); Mechanisms: ROS signal transduction, nuclear & mitochondrial processes (Dr. Laposa); Modulators of toxicity: Pharmacological factors: disposition, biotransformation, renal elimination (2 hr). Optional tutorial #1: Approach for answering essay format exams (1 hr).

Lecture Learning Objectives:
- Understanding of the listed topic principles.
- Tutorial: provide students with examples based on the previous year's 1st midterm exam that will assist them in understanding examination questions and writing appropriately comprehensive and focused essay answers.

Week 4
Lecture Topic: Modulators of toxicity. Pharmacological factors: species, strain, age, sex, genetics, diet, pregnancy. Physiological factors: species, strain, age, sex, genetics, diet, pregnancy. Pathophysiological factors: diseases of hepatic, renal, cardiovascular, pulmonary, gastrointestinal and biochemical systems. (3 hr) (Dr. Wells)

Lecture Learning Objectives:
- Understanding of the listed topic principles.

Week 5
Lecture Topic: Toxicological evaluation. Chemical measurements. Biological relevance of measuring active and inactive parent chemical and metabolites, stereoisomers and reactive intermediates; Toxicological evaluation. Biochemical measurements of cellular response. Histological and functional measurements, animal models, in vivo and in vitro studies (2 hr). (Dr. Wells)

Lecture Learning Objectives:
- Understanding of the listed topic principles.
Week 6
Lecture Topic: Hepatic toxicology: mechanisms and clinical consequences (2 hr). (Dr. Wells) Optional tutorial #2: exam question review (1 hr).

Lecture Learning Objectives:
- Understanding of principles and application to clinical and scientific problems.
- Tutorial: review of 1st midterm exam to provide students with a detailed understanding of the marking scheme for their information and to allow them to improve their ability to perform in subsequent essay examinations (1 hr).

Week 7
Lecture Topic: 1. Hepatic toxicology continued (1 hr). (Dr. Wells)
2. Chemical teratogenesis: mechanisms and clinical consequences (2 hr).

Lecture Learning Objectives:
- Understanding of principles and application to clinical and scientific problems.

Week 8
Lecture Topic: Chemical teratogenesis continued (2 hr). (Dr. Wells) Optional tutorial #3: approach for answering essay exams (1 hr)

Lecture Learning Objectives:
- Understanding of principles and application to clinical and scientific problems.
- Tutorial: provide students with examples based on the previous year’s 2nd midterm exam that will assist them in understanding examination questions and writing appropriately comprehensive and focused essay answers.

Week 9
Lecture Topic: No Class – Reading Week

Lecture Learning Objectives:

Week 10
Lecture Topic: Neurodegenerative disease (3 hr). (Dr. Wells)

Lecture Learning Objectives:
- Understanding of principles and application to clinical and scientific problems.
Week 11
Lecture Topic: Chemical carcinogenesis (Dr. Laposa) (2 hr). Optional tutorial #4: exam question review (1 hr).

Lecture Learning Objectives:
− Understanding of principles and application to clinical and scientific problems.
− Tutorial: exam question review (optional)

Week 12
Lecture Topic: Renal toxicology (Dr. Grazyna Kalabis)

Lecture Learning Objectives:
− Understanding of principles and application to clinical and scientific problems.

Week 13
Lecture Topic: Immunological toxicology (Dr. Jack Uetrecht) (2 hr).

Lecture Learning Objectives:
− Understanding of principles and application to clinical and scientific problems.

8. Assessment Methodologies Used:

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Course Learning Objectives Addressed</th>
<th>Assessment Method Used</th>
<th>Percent of Course Grade</th>
<th>For Group Work: Individualized or same mark for all group members</th>
</tr>
</thead>
<tbody>
<tr>
<td>☑ Assignment</td>
<td>☑ Mid-term</td>
<td>Essay Format</td>
<td>25%</td>
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<td>☑ Presentation</td>
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<td>☑ Participation</td>
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<td>☑ Final Exam</td>
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<td>Essay Format</td>
<td>25%</td>
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<tr>
<td>☑ Assignment</td>
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<td>Essay Format</td>
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<td>☑ Presentation</td>
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</table>
Expectation for pass grades for all Pharmacy courses is 60%

9. Policy and procedure regarding late assignments/examinations/laboratories:
No assignments or laboratories. The Faculty policy for missed examinations is provided in the print and online versions of the Faculty calendar.

10. Policy and procedure regarding missed assignments/examinations/laboratories:
No assignments or laboratories. The Faculty policy for missed examinations is provided in the print and online versions of the Faculty calendar.

11. AFPC Education Outcomes addressed (check all those that apply):
- Refer to AFPC Educational Outcomes for Professional Programs for further information about the role and key competencies.

As Care Providers, pharmacy graduates:

**CP1 – Practice within the pharmacist scope of practice and expertise**

☑ CP1.1 Apply knowledge from the foundational sciences to make decisions relevant to the contemporary and evolving scope of pharmacist practice;

☑ CP1.2 Integrate AFPC Communicator, Collaborator, Leader-Manager, Health Advocate, Scholar, and Professional roles in their practice of pharmacy;

☑ CP1.3 Recognize and respond to the complexity, uncertainty and ambiguity inherent in pharmacy practice;

☑ CP1.4 Explain the benefits, risks and rationale associated with pharmacist-provided care as an important step in obtaining and documenting consent to pharmacist care;

☑ CP1.5 Recognize and take appropriate action when signs, symptoms and risk factors that relate to medical or health problems that fall into the scope of practice of other health professionals are encountered.

**CP2 – Provide patient-centred care**

☑ CP2.1 Collect, interpret, and assess relevant, necessary information about a patient’s health-related care needs;
☐ CP2.2 Formulate assessments of actual and potential issues and in collaboration with the patient and other health team members as appropriate, prioritize issues to be addressed in a given patient encounter;

☐ CP2.3 Create and document plans in collaboration with the patient and other health team members as appropriate, and make recommendations to prevent, improve or resolve issues;

☐ CP2.4 Implement plans in collaboration with the patient and other health team members as appropriate, including:

  - CP2.4.1 obtaining consent
  - CP2.4.2 making a referral or consulting others
  - CP2.4.3 adapting, initiating, renewing/continuing, discontinuing or administering medication as authorized
  - CP2.4.4a dispensing and/or
  - CP2.4.4b compounding and/or
  - CP2.4.4c delegating/authorizing such tasks to others appropriately
  - CP2.4.5 engaging the patient or care-giver through education, empowerment and self-management, and
  - CP2.4.6 negotiating the role of pharmacy and non-pharmacy team members in continuity and transitions of care.

☐ CP2.5 Follow-up by monitoring, evaluating progress toward achievement of the patient’s goals of therapy, adjusting plans in collaboration with the patient and health team members across the care continuum.

CP3 – Actively contribute, as an individual and as a member of a team providing care, to the continuous improvement of health care quality and patient safety

☐ CP3.1 Recognize and respond to harm and potential harm from health care delivery, including patient safety incidents;

☐ CP3.2 Adopt strategies that promote patient safety and address human and system factors;

As Communicators, pharmacy graduates:

CM1 – Communicate in a responsible and responsive manner that encourages trust and confidence

☐ CM1.1 Select and use oral, non-verbal and written communication strategies (tools, techniques, technologies, etc.) effectively so that the patient’s best interests are foremost;

☐ CM1.2 Provide timely, clear responses that are tailored to the context and audience;

☐ CM1.3 Express facts, evidence, opinions and positions accurately and effectively, with clarity and confidence;

☐ CM1.4 Listen, actively solicit and respond appropriately to ideas, opinions and feedback from others;
CM1.5 Use language, pace, tone, and non-verbal communication that is suitable for:
   a) the intended outcomes of the communication, and
   b) the complexity, ambiguity, urgency and/or difficulty of a situation, conversation or conflict

CM1.6 Seek and synthesize relevant information from others in a manner that ensures common understanding and where applicable, clarifies and secures agreement and/or consent;

CM1.7 Compose and share oral, written, and electronic information in a manner that optimizes patient safety, dignity, confidentiality, and privacy.

CM2 – Communicate in a manner that supports a team approach to health promotion and health care

CM2.1 Engage in respectful, empathetic, compassionate, non-judgmental, culturally safe, tactful conversations with patients, communities, populations, and health team members;

CM2.2 Demonstrate awareness of the impact of one’s own experience level, professional culture, biases and power and hierarchy within the health team on effective working relationships, communication and conflict resolution with health team members and adapt the approach to the situation appropriately;

CM2.3 Demonstrate accuracy and appropriateness of communication as well as respect for the role of other health team members when disclosing information about harmful or potentially harmful situations;

CM2.4 In word and in action, convey the importance of teamwork in patient-centred care, patient safety, health care quality improvement and health program delivery.

As Collaborators, pharmacy graduates:

CL1 – Work effectively with members of the health team including patients, pharmacy colleagues and individuals from other professions

CL1.1 Establish and maintain positive relationships;

CL1.2 Recognize, respect and negotiate the roles and shared/overlapping responsibilities of team members;

CL1.3 Join with others in respectful, effective shared decision-making.

CL2 – Hand over the care of the patient to other pharmacy team members and non-pharmacy team members to facilitate continuity of safe patient care

CL2.1 Determine when and how care should be handed over to another team member;

CL2.2 Recognize, respect and honour the negotiate shared and overlapping responsibilities of patients, pharmacy team members and other health members when handovers occur;
CL2.3 Demonstrate safe handover of care, using oral, written, and electronic communication, during a patient transition to a different care provider or setting.

As Leader-Managers, pharmacy graduates:

LM1 – Contribute to optimizing health care delivery and pharmacy services

☒ LM1.1 Work with others to apply quality improvement strategies and techniques to optimize pharmacy care;
☒ LM1.2 Contribute to a culture of patient safety;
☒ LM1.3 Confirm the quality, safety, and integrity of products;
☐ LM1.4 Use health informatics to improve the quality of care, manage resources and optimize patient safety.

LM2 – Contribute to the stewardship of resources in health care systems

☐ LM2.1 Apply evidence and management processes to achieve cost appropriate care;
☐ LM2.2 Allocate health care resources for optimal patient care;
☐ LM2.3 Contribute to the management of finances and health human resources in pharmacy practice settings;

LM3 – Demonstrate leadership skills

☐ LM3.1 Demonstrate leadership skills to enhance pharmacy practice and health care.

LM4 – Demonstrate management skills

☒ LM4.1 Work with others to apply the principles of effective management and supervision of health human resources and medication use systems;
☒ LM4.2 Use effective strategies to manage and improve their own practice of pharmacy.

As Health Advocates, pharmacy graduates:

HA1 – Respond to an individual patient's health needs by advocating with the patient within and beyond the patient care environment

☒ HA1.1 Work with patients to address determinants of health that affect them and their access to needed health services or resources;
☒ HA1.2 Work with patients to increase opportunities to adopt healthy behaviours;
HA1.3 Incorporate disease prevention, health promotion and health surveillance into interactions with individual patients.

HA2 – Respond to needs of communities or populations they serve by advocating with them for system-level change in a socially accountable manner

HA2.1 Work with community or population to identify the determinants of health that affect them;

HA2.2 Participate in health promotion and disease prevention programs.

As Scholars, pharmacy graduates:

SC1 – Apply medication therapy expertise to optimize pharmacy care, pharmacy services and health care delivery

SC1.1 Use knowledge and problem-solving to arrive at recommendations and decisions that are appropriate, accurate, and practical;

SC1.2 Use professional experience to solve routine, previously encountered problems;

SC1.3 Use established decision-making frameworks and apply learning required to manage new situations and problems.

SC2 – Integrate best available evidence into pharmacy practice

SC2.1 Generate focused questions related to needs for information, recommendations and decisions in practice;

SC2.2 Use systematic approaches in the search for best available evidence;

SC2.3 Critically appraise health-related research and literature;

SC2.4 Incorporate best available evidence in the decision-making process.

SC3 – Contribute to the creation of knowledge or practices in the field of pharmacy

SC3.1 Apply scientific principles of research and scholarly inquiry;

SC3.2 Apply ethical principles that underlie research and scholarly inquiry.

SC4 – Teach other pharmacy team members, the public and other health care professionals including students

SC4.1 Provide effective education to others;

SC4.2 Employ appropriate teaching roles when teaching others;
SC4.3 Deliver effective feedback in teaching and learning situations;

SC4.4 Use appropriate learning assessment and evaluation strategies when working with patients, team members, students and teachers.

As Professionals, pharmacy graduates:

PR1 – Committed to apply best practices and adhere to high ethical standards in the delivery of pharmacy care

PR1.1 Exhibit professional behaviour whether face-to-face, in writing, or via technology-enabled communication. Professional; behaviour includes, but is not limited to:

a) demonstrating honesty, integrity, humility, commitment, altruism, compassion, respect for diversity and patient autonomy;

b) being accessible, diligent, timely and reliable in service to others;

c) abiding by the principle of non-abandonment;

d) maintaining appropriate interpersonal boundaries;

e) maintaining professional composure, demeanor, and language even in difficult situations, and;

f) maintaining privacy and confidentiality;

PR1.2 Use ethical frameworks as one component of professional judgment;

PR1.3 Recognize and respond to situations presenting ethical dilemmas, including conflicts of interest;

PR1.4 Engage in activities that:

a) protect the public, and;

b) advance the practice of pharmacy.

PR2 – Able to recognize and respond to societal expectations of regulated health care professionals

PR2.1 Take responsibility and accountability for actions and inactions;

PR2.2 Demonstrate a commitment to patient safety and quality improvement;

PR2.3 Honour the laws, ethical codes, and regulatory requirements (by-laws, standards, policies) that govern the self-regulated profession of pharmacy;

PR2.4 Demonstrate an understanding of federal, provincial/territorial, and municipal laws, policies and standards that apply to pharmacy workplaces;

PR2.5 Demonstrate an ability to maintain competence to practice through evaluating areas for improvement and planning, undertaking learning activities to address limitations in competence and/or performance and incorporating learning into practice;
PR2.6 Identify and respond to unprofessional, unethical, and illegal behaviours in pharmacists, other pharmacy team members, and other health professionals.

PR3 – Committed to self-awareness in the management of personal and professional well being

PR3.1 Set professional and personal goals, priorities, and manage their time to balance patient care, workflow, and practice requirements;

PR3.2 Examine, reflect upon, and manage personal attributes (knowledge, skills, beliefs, biases, motivations, emotions, etc.) that could influence self-development and professional performance;

PR3.3 Adapt their practice of pharmacy to fulfill evolving professional roles;

PR3.4 Recognize and respond to self and colleagues in need.