New Course Outline

- The PharmD Approval Process for New Course Outlines document provides for 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: PHM382H1/PHC432H1

Course Title: Nanomedicines in Oncology

Outline Version Code:

Course Description:

This course covers a range of topics that pertain to the development and application of nanomedicines in oncology. Students will gain an understanding of the biological barriers to drug delivery in oncology as well as the tremendous heterogeneity in cancer and the challenge this presents for treatment. The concepts of passive and active targeting of nanomedicines will be covered with critical assessment of the enhanced permeability and retention effect. A detailed overview of the most advanced nanotechnology-platforms for drug delivery (i.e. liposomes, block copolymer micelles and polymer-drug conjugates) will be provided with additional discussion of new emerging platforms. The integration of imaging in drug development and development of theranostics and therapeutic-diagnostic pairs will also be discussed. Special emphasis on critical evaluation of scientific literature and pre-clinical/clinical studies will be made throughout the course.

Semester: ☒ Winter

Course Type: ☒ Elective

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:**

Knowledge of the various imaging modalities and their unique strengths and weaknesses. Knowledge of rationale for integration of imaging in drug development.

**Intermediate Level:**

Knowledge of the rationale for and history of advanced drug delivery for applications in oncology. Knowledge of the various nanotechnology platforms used most commonly for advanced drug delivery. Knowledge of the biological barriers to drug delivery in oncology including an appreciation of the heterogeneity in cancer, tumor microenvironment and their impact on drug delivery and efficacy.

**Advanced Level:**

**Skills**

**Introductory Level:**

**Intermediate Level:**

Ability to conduct a search of scientific literature in the area of nanomedicines in oncology. Critical assessment of pre-clinical studies and critical appraisal of scientific literature in this specific area of research. Oral communication and presentation skills will be developed with opportunity for peer-to-peer feedback.

**Advanced Level:**
2. Rationale for Inclusion in the Curriculum:

To educate students on the development of nanomedicines for applications in oncology. There are several drugs relying on formulation in nanotechnologies that have been approved for cancer treatment with many others in clinical and pre-clinical development. For this reason, this topic is of relevance to students in the PharmD program. This course will be included as a course offering within the Centre for Pharmaceutical Oncology with the intention of educating students on this aspect of pharmaceutical oncology and promoting research activity and interest in this important area.

3. Pre-requisites:

Not applicable – this course is not a co-requisite for other courses in our curriculum

4. Co-requisites:

5. Course Contact Hours and Teaching Methodologies:

<table>
<thead>
<tr>
<th>Didactic (lecture)</th>
<th>Hours: 20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large group problem-based/ case-based learning (group size: 320-340)</td>
<td>Hours:</td>
</tr>
<tr>
<td>Laboratory or Simulation</td>
<td>Hours:</td>
</tr>
<tr>
<td>Tutorial/Seminar/Workshop/Small Group (group size: 5-25)</td>
<td>Hours:</td>
</tr>
<tr>
<td>Experiential</td>
<td>Hours:</td>
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<tr>
<td>-----------------------------</td>
<td>--------</td>
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<tr>
<td>On-line</td>
<td>Hours:</td>
</tr>
<tr>
<td>Other (please specify): In class oral presentations by small groups and discussion with the full class</td>
<td>Hours: 6</td>
</tr>
<tr>
<td><strong>Total Course Contact Hours</strong></td>
<td>Hours: 26 +2hr optional tutorial</td>
</tr>
</tbody>
</table>

6. Estimate and description of student’s weekly out-of-class preparation time excluding exam preparation:

Students will be expected to spend one hour per week reviewing materials provided prior to each lecture

7. Topics Covered and Lecture Specific Learning Objectives

**Week 1**
**Lecture Topic:** Introduction to Nanomedicines in Oncology

**Lecture Learning Objectives:**
To learn the history of and rationale for development of nanomedicines for applications in oncology. To review the most advanced nano-delivery platforms including nanomedicines that have been approved for clinical use. To review the pre-clinical and clinical studies that are commonly involved and/or required for development and clinical approval of nanomedicines.

**Week 2**
**Lecture Topic:** Biological Barriers to Drug Delivery in Oncology

**Lecture Learning Objectives:**
To review common chemotherapeutics, their mechanism(s) and site(s) of action. To learn the barriers to drug delivery in oncology at the whole body, tumour and cellular levels. To review examples of biodistribution of small molecules administered in conventional formulations and various nano-delivery platforms. To gain an understanding of passive and active targeting strategies explored to enhance the therapeutic effect of nanomedicines.

**Week 3**
**Lecture Topic:** Targeting Solid Tumors: The EPR Effect De-constructed

**Lecture Learning Objectives:**
To gain an understanding of the enhanced permeability and retention (EPR) effect. To discuss the opposing opinions on EPR and to critically review the scientific evidence in this area.
Week 4
Lecture Topic: Heterogeneity in Cancer: Impact on Design and Effectiveness of Nanomedicines

Lecture Learning Objectives:
To gain an appreciation of the tremendous heterogeneity in cancer and the challenge this presents for treatment. To gain an understanding of the various tumour microenvironment parameters and their impact on drug delivery and efficacy.

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Week 5
Lecture Topic: Nanotechnology Platforms – Polymeric Conjugates, Micelles and Nanoparticles

Lecture Learning Objectives:
To review in detail the most advanced nanotechnology platforms used for drug delivery in oncology (i.e. liposomes (week 5), polymer–drug conjugates (week 6) and block copolymer micelles (week 7)) including method(s) of preparation, physicochemical properties, typical pharmacokinetics and biodistribution profiles for drugs administered in these platforms as well as strengths and weaknesses of each platform. To learn about new nanotechnology– based approaches (week 8) that been developed more recently (i.e. albumin–based, gold nanoparticles etc.)

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Week 6
Lecture Topic: Nanotechnology Platforms – Liposomes

Lecture Learning Objectives:
To review in detail, the most advanced nanotechnology platforms used for drug delivery in oncology (i.e. liposomes (week 5), polymer–drug conjugates (week 6) and block copolymer micelles (week 7)) including method(s) of preparation, physicochemical properties, typical pharmacokinetics and biodistribution profiles for drugs administered in these platforms as well as strengths and weaknesses of each platform. To learn about new nanotechnology– based approaches (week 8) that been developed more recently (i.e. albumin–based, gold nanoparticles etc.)

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Week 7
Lecture Topic: Nanotechnology Platforms – Thermosensitive Liposomes

Lecture Learning Objectives:
To review in detail the most advanced nanotechnology platforms used for drug delivery in oncology (i.e. liposomes (week 5), polymer–drug conjugates (week 6) and block copolymer micelles (week 7)) including method(s) of preparation, physicochemical properties, typical pharmacokinetics and biodistribution profiles for drugs administered in these platforms as well as strengths and weaknesses of each platform. To learn about new nanotechnology– based approaches (week 8) that been developed more recently (i.e. albumin–based, gold nanoparticles etc.)
Week 8
Lecture Topic: Nanotechnology Platforms – Other

Lecture Learning Objectives:

To review in detail the most advanced nanotechnology platforms used for drug delivery in oncology (i.e. liposomes (week 5), polymer–drug conjugates (week 6) and block copolymer micelles (week 7)) including method(s) of preparation, physico-chemical properties, typical pharmacokinetics and biodistribution profiles for drugs administered in these platforms as well as strengths and weaknesses of each platform. To learn about new nanotechnology–based approaches (week 8) that been developed more recently (i.e. albumin–based, gold nanoparticles etc.)

Week 9
Lecture Topic: Nanotechnology for Delivery of siRNA

Lecture Learning Objectives:

To review the various imaging modalities and the unique strengths and weaknesses of each modality. To gain an understanding of the rationale for integration of imaging in pre-clinical and/or clinical drug development. To review and discuss clinical trials that are evaluating image–based approaches to guide patient stratification and/or predict treatment outcomes. To discuss the rationale for the development of theranostics as well as therapeutic and image–based diagnostic pairs. To review examples of these approaches from the literature and current clinical trials (if any).

Week 10
Lecture Topic: Drug Combinations and Nanotechnology for their Delivery

Lecture Learning Objectives:

To review the various imaging modalities and the unique strengths and weaknesses of each modality. To gain an understanding of the rationale for integration of imaging in pre-clinical and/or clinical drug development. To review and discuss clinical trials that are evaluating image–based approaches to guide patient stratification and/or predict treatment outcomes. To discuss the rationale for the development of theranostics as well as therapeutic and image–based diagnostic pairs. To review examples of these approaches from the literature and current clinical trials (if any).

Week 11
Lecture Topic: In Class Presentations and Discussion

Lecture Learning Objectives:

To select and review a drug relying on formulation in an advanced delivery technology that has reached clinical evaluation. To critically assess the pre-clinical and clinical studies that have been performed on this formulation. To improve oral presentation skills and to gain experience in critical evaluation of scientific studies/literature.
**Week 12**
**Lecture Topic:** In Class Presentations and Discussion

**Lecture Learning Objectives:**
To select and review a drug relying on formulation in an advanced delivery technology that has reached clinical evaluation. To critically assess the pre---clinical and clinical studies that have been performed on this formulation. To improve oral presentation skills and to gain experience in critical evaluation of scientific studies/literature.

**Week 13**
**Lecture Topic:** In Class Presentations and Discussion

**Lecture Learning Objectives:**
To select and review a drug relying on formulation in an advanced delivery technology that has reached clinical evaluation. To critically assess the pre---clinical and clinical studies that have been performed on this formulation. To improve oral presentation skills and to gain experience in critical evaluation of scientific studies/literature.

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>Covers material from lectures 1-5 inclusive. Knowledge of the rationale for and history of advanced drug delivery systems for applications in oncology. Knowledge of the biological barriers to drug delivery in oncology including an appreciation of the heterogeneity in cancer, tumour microenvironment and their impact on drug delivery and efficacy. Knowledge of the EPR effect. Knowledge of liposomes as a nanotechnology platform used commonly for advanced drug delivery.</td>
<td>Oral Presentation - students will be asked to prepare a 15 min presentation (+ 5 mins for questions) on a drug relying on formulation in an advanced delivery technology that has reached clinical evaluation. In the presentation the</td>
<td>45%</td>
<td>Individualized or same mark for all group members</td>
</tr>
<tr>
<td>☐ Assignment</td>
<td>In depth knowledge of a drug relying on formulation in a nanotechnology platform that has now reached clinical development.</td>
<td>☑</td>
<td>10%</td>
<td></td>
</tr>
<tr>
<td>Assignment</td>
<td>Presentation</td>
<td>Participation</td>
<td>Mid-term</td>
<td>Final Exam</td>
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</tbody>
</table>

- **Knowledge of block copolymer micelles and polymer-drug conjugates as nanotechnology platforms used commonly for advanced drug delivery.**
- **Knowledge of new and emerging technologies being explored for drug delivery in oncology.**
- **Knowledge of the various imaging modalities and their unique strengths and weaknesses.**
- **Knowledge of rationale for integration of imaging in drug development.**

<table>
<thead>
<tr>
<th>Assignment</th>
<th>Presentation</th>
<th>Participation</th>
<th>Mid-term</th>
<th>Final Exam</th>
</tr>
</thead>
</table>

- **Expectation for pass grades for all Pharmacy courses is 60%**

9. **Policy and procedure regarding late assignments/examinations/laboratories:**

**Missed Midterm or Final Exam Policy:**

Students who miss an examination and who have a valid petition, approved by the Registrar, will be eligible to write a make-up exam. The format of this examination or test will be at the discretion of the course coordinator, and may include, for example, an oral examination.

10. **Policy and procedure regarding missed assignments/examinations/laboratories:**

**Missed Oral Presentation**

Students who miss their oral presentation and who have a valid petition, approved by the Registrar, will be given an opportunity to present to the Course Coordinator (and possibly class) at a different time.
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.