



**CUMMING SCHOOL OF MEDICINE  
GRADUATE COURSE OUTLINE**

<b>COURSE TITLE: MDGE 605 Regulatory Affairs</b>			
<b>Course</b>	<b>MDGE 605 Regulatory Affairs</b>		
<b>Pre/Co-Requisites</b>	<ul style="list-style-type: none"> <li>• Admission to the Master of Biomedical Technology program, OR,</li> <li>• If not in the program, as a graduate student of the University of Calgary with permission from the following:               <ul style="list-style-type: none"> <li>○ Instructor of the course</li> <li>○ Supervisor of the graduate student</li> <li>○ Director of the Master of Biomedical Technology Program</li> </ul> </li> </ul>		
<b>Faculty</b>	Cumming School of Medicine, Graduate Science Education		
<b>Instructor Name(s)</b>	Dr. Alexander (Sandy) Dubyk, BSC(Pharm), ACPR, PharmD, MBA, CHE	<b>Email</b>	<a href="mailto:amdubyk@ucalgary.ca">amdubyk@ucalgary.ca</a>
<b>Office Location</b>	Offsite	<b>Office Hours</b>	By Appointment
<b>Telephone No.</b>	403-831-8885		
<b>Class Term, Days</b>	See Course Timetable		
<b>Class Times</b>	See Course Timetable		
<b>Class Location</b>	G801E		

<b>COURSE INFORMATION/DESCRIPTION OF THE COURSE</b>
<p>This is both a didactic and experience-based course examining the regulatory requirements of the leading regulatory bodies globally. The emphasis will be on regulations applied by Health Canada (Canada), the Food and Drug Administration (United States) and the European Medicines Agency (European Union). Through readings, discussions, workshops, case studies, and quizzes, students will gain an understanding of the regulatory requirements necessary for health product and device development.</p>
<b>LEARNING RESOURCES/REQUIRED READING</b>
<p>Students will use the resources available as users of the University of Calgary library system and the grey literature. Additional reference material may be assigned through the course.</p>

<b>COURSE OBJECTIVES/LEARNING OUTCOMES</b>

- To provide a general understanding of the key regulations necessary for biopharmaceutical and medical device manufacturing
- To provide the tools and references necessary to guide the students for an application to the regulatory agencies
- To engage the students through experiential learning and situational knowledge of non-compliance in regulatory affairs

#### CUT POINTS FOR GRADES

This course adheres to the grading system outlined in the University of Calgary, Faculty of Graduate Studies Calendar. Grades of A+ and A are not distinguished in the calculation of GPAs. Percentage/letter grade conversion used for this course is as follows

Grade	Grade Point Value	Percentage Conversion	Graduate Description
A+	4.00	95-100	Outstanding
A	4.00	90-94	Excellent – superior performance showing comprehensive understanding of the subject matter
A-	3.70	85-89	Very Good Performance
B+	3.30	77-84	Good Performance
B	3.00	72-76	Satisfactory Performance
B-	2.70	68-71	Minimum Pass for Students in the Faculty of Graduate Studies
C+	2.30	63-67	All grades below ‘B-’ are indicative of failure at the graduate level and cannot be counted toward Faculty of Graduate Studies course requirements

**Assessment Components:** The University policy on grading related matters is outlined in the [2019-2020 Calendar](#).

Assessment Methods	Description	Weight %	Due Date and Time
Quizzes	Individual - Open Book. Administered at the beginning of each lecture addressing key points of knowledge from the assigned readings. They will be approximately 5 minutes in length. The instructor may, on occasion, substitute a group	20	TBD

	activity in lieu of a quiz and will notify the class accordingly.		
Case study	Team - Groups of 3-4 individuals will be evaluated on a case or issue in regulatory requirements. Topics will be chosen by the students, reviewed with the instructor, and presented. A rubric will be used to evaluate the presentations.	25	November 18 or 25, 2019, 14h00
Regulatory submission	Team/Individual assignment - Teams will choose a 'product-in-development' and navigate its regulatory path to approval; Individual assignment would be an opinion paper on a current regulatory issue	40	December 6, 2019, 14h00
Field trip Consult	Class visit to be discussed in class	15	December 9, 2019, 12h00

#### ASSESSMENT AND EVALUATION INFORMATION

**ATTENDANCE AND PARTICIPATION EXPECTATIONS:** Students are expected to act professionally

**GUIDELINES FOR SUBMITTING ASSIGNMENTS:** Due at the start of the class, submitted electronically to [amdubyk@ucalgary.ca](mailto:amdubyk@ucalgary.ca)

**FINAL EXAMINATIONS:** None

**EXPECTATIONS FOR WRITING:** Students are expected to follow University rules and write in an academic or business manner

**LATE AND/OR MISSING ASSIGNMENTS:** 10% penalty with additional 10% per 24 hours unless discussed in advance with the Instructor

Is a passing grade on a particular component essential to pass the course as a whole? No

COURSE TIMETABLE			
Course Schedule Date	Topic & Reading	Instructor	Assignments/Due Dates & Times
Friday October 25, 2019, 9h00 – 11h00	Introduction & Regulatory Affairs; ISO	A Dubyk	<i>Readings, Quiz</i>



Monday, October 28, 2019, 12h30 – 14h30	cGLP, LIMS, cGMP	A Dubyk	<i>Readings, Quiz, Case topic, Team topic</i>
Monday, November 4, 2019 12h30 – 14h30	Medical Device Filing, Drug Submission	A Dubyk	<i>Team outline</i>
Monday, November 18, 2019 12h30 – 14h30	SOPs, Advertising Requirements	A Dubyk	<i>Quiz, Case 1, 2, 3</i>
Monday, November 25, 2019, 12h30 – 14h30	Global Regulatory Affairs and cGMP	TBD	<i>Case 4, 5, 6</i>
Friday, December 6, 2019, 14h00 – 16h00	Field Trip Consult	A Dubyk	<i>Team Assignment due Dec 6, 2019 @ 14h 00 Field Trip Consult due Dec 9, 2019 @ 12h00</i>

#### INTERNET AND ELECTRONIC COMMUNICATION DEVICE INFORMATION

Cell phones must be turned off in class unless otherwise arranged with the instructor.

The use of laptop and mobile devices is acceptable when used in a manner appropriate to the course and classroom activities. Students are to refrain from accessing websites that may be distracting for fellow learners (e.g. personal emails, Facebook, YouTube). Students are responsible for being aware of the University's Internet and email use policy, which can be found at <https://www.ucalgary.ca/policies/files/policies/electronic-communicationspolicy.pdf>.

#### MEDIA AND RECORDING IN LEARNING ENVIRONMENTS

##### **Media recording for lesson capture**

The instructor may use media recordings to capture the delivery of a lecture. These recordings are intended to be used for lecture capture only and will not be used for any other purpose. Although the recording device will be fixed on the Instructor, in the event that incidental student participation is recorded, the instructor will ensure that any identifiable content (video or audio) is masked, or will seek consent to include the identifiable student content to making the content available on University approved platforms.

##### **Media recording for assessment of student learning**



The instructor may use media recordings as part of the assessment of students. This may include but is not limited to classroom discussions, presentations, clinical practice, or skills testing that occur during the course. These recordings will be used for student assessment purposes only and will not be shared or used for any other purpose.

#### **Media recording for self-assessment of teaching practices**

The instructor may use media recordings as a tool for self-assessment of their teaching practices. Although the recording device will be fixed on the instructor, it is possible that student participation in the course may be inadvertently captured. These recordings will be used for instructor self-assessment only and will not be used for any other purpose.

#### **Student Recording of Lectures**

Audio or video recording of lectures is prohibited except where explicit permission has been received from the instructor.

### **UNIVERSITY OF CALGARY POLICIES AND SUPPORTS**

#### **ACADEMIC ACCOMMODATIONS**

Students seeking an accommodation based on disability or medical concerns should contact Student Accessibility Services; SAS will process the request and issue letters of accommodation to instructors. For additional information on support services and accommodations for students with disabilities, visit [www.ucalgary.ca/access/](http://www.ucalgary.ca/access/). Students who require an accommodation in relation to their coursework based on a protected ground other than disability should communicate this need in writing to their Instructor. The full policy on Student Accommodations is available at <http://www.ucalgary.ca/policies/files/policies/student-accommodation-policy.pdf>

#### **IMPORTANT INFORMATION**

Any research in which students are invited to participate will be explained in class and approved by the appropriate University Research Ethics Board

#### **COPYRIGHT**

It is the responsibility of students and professors to ensure that materials they post or distribute to others comply with the Copyright Act and the University's Fair Dealing Guidance for Students ([library.ucalgary.ca/files/library/guidance\\_for\\_students.pdf](http://library.ucalgary.ca/files/library/guidance_for_students.pdf)). Further information for students is available on the Copyright Office web page (<https://library.ucalgary.ca/copyright>)

#### **A NOTE REGARDING INSTRUCTOR INTELLECTUAL PROPERTY**

Generally speaking, course materials created by professor(s) (including course outlines, presentations and posted notes, labs, case studies, assignments and exams) remain the intellectual property of the professor (s). These materials may NOT be reproduced, redistributed or copied without the explicit consent of the professor. The posting of course materials to third party websites such as note-sharing sites without permission is prohibited. Sharing of extracts of these course materials with other students enrolled in the course *at the same time* may be allowed under fair dealing



### **ACADEMIC INTEGRITY**

The Cumming School of Medicine expects intellectual honesty from its students. Course participants should be aware of University policies relating to Principles of Conduct, Plagiarism and Academic Integrity. These are found in the printed Faculty of Graduate Studies Calendar, or online under Academic Regulations in the Faculty of Graduate Studies Calendar, available at [Faculty of Graduate Studies Academic Regulations](#)

### **ACADEMIC MISCONDUCT**

For information on academic misconduct and its consequences, please see the University of Calgary Calendar at <http://www.ucalgary.ca/pubs/calendar/current/k.html>

### **EMERGENCY EVACUATION AND ASSEMBLY POINTS**

Assembly points for emergencies have been identified across campus. The primary assembly points for South Campus (Health Science Centre (HSC); Health & Research Innovation Centre (HRIC); Heritage Medical Research Building (HMRB) and Teaching, Research and Wellness (TRW)) are:

- HSC and HMRB: HRIC Atrium (alternate assembly point is Parking Lot 6)
- HRIC: HMRB Atrium (alternate assembly point is Parking Lot 6)
- TRW: McCaig Tower (alternate assembly point is HMRB – Atrium)

### **APPEALS**

If there is a concern with the course, academic matter or a grade, first communicate with the instructor. If these concerns cannot be resolved, students can proceed with an academic appeal, as per Section N of the Faculty of Graduate Studies Calendar. Students must follow the official process and should contact the Student Ombuds Office (<http://www.ucalgary.ca/provost/students/ombuds>) for assistance with this and with any other academic concerns, including academic and non-academic misconduct

### **THE FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY (FOIP) ACT**

This course is conducted in accordance with the Freedom of Information and Protection of Privacy Act (FOIP) and students should identify themselves on written assignments (exams and term work.) by their name and ID number on the front page and ID on each subsequent page. Assignments given by you to your course instructor will remain confidential unless otherwise stated before submission. The assignment cannot be returned to anyone else without your expressed permission to the instructor. Grades will be made available on an individual basis and students will not have access to other students' grades without expressed consent. Similarly, any information about yourself that you share with your course instructor will not be given to anyone else without your permission

### **WELLNESS AND MENTAL HEALTH RESOURCES**

The University of Calgary recognizes the pivotal role that student mental health plays in physical health, social connectedness and academic success, and aspires to create a caring and supportive campus community where individuals can freely talk about mental health and receive supports when needed. We encourage you to explore the excellent mental health resources available throughout the university community, such as counselling, self-help resources, peer support or skills-building available through the SU Wellness Centre (Room 370, MacEwan Student Centre), <https://www.ucalgary.ca/wellnesscentre/services/mental-health-services> and the Campus Mental Health Strategy website <https://www.ucalgary.ca/mentalhealth/>



### **SUPPORTS FOR STUDENT LEARNING, SUCCESS, AND SAFETY**

**Student Ombudsman:** The Student Ombuds' Office supports and provides a safe, neutral space for students. For more information, please visit [www.ucalgary.ca/ombuds/](http://www.ucalgary.ca/ombuds/) or email [ombuds@ucalgary.ca](mailto:ombuds@ucalgary.ca)

**Student Union:** The SU Vice-President Academic can be reached at (403) 220-3911 or [suvpaca@ucalgary.ca](mailto:suvpaca@ucalgary.ca); Information about the SU, including elected Faculty Representatives can be found here: <https://www.su.ucalgary.ca>

**Graduate Student's Association:** The GSA Vice-President Academic can be reached at (403) 220- 5997 or [gsa.vpa@ucalgary.ca](mailto:gsa.vpa@ucalgary.ca); Information about the GSA can be found here: <https://gsa.ucalgary.ca>

### **SAFEWALK**

Campus security will escort individuals, day or night, anywhere on campus (including McMahon Stadium, Health Sciences Centre, Student Family Housing, the Alberta Children's Hospital and the University LRT station). Call 403-220-5333 or visit <http://www.ucalgary.ca/security/safewalk>. Use any campus phone, emergency phone or the yellow phone located at most parking lot pay booths. Please ensure your personal safety by taking advantage of this service.