



MASTER OF BIOTECHNOLOGY PROGRAM

Compulsory Course Component

BTC 1842H

**MEDICAL DEVICE
REIMBURSEMENT**

Mark Smithyes

Summer Term, 2021

MASTER OF BIOTECHNOLOGY

UNIVERSITY OF TORONTO MISSISSAUGA

BTC 1842H – Medical Device Reimbursement

Course Outline (Summer 2021)

Class Location:	Online (Zoom)
Class Times:	See iCal; Tue, Wed, Thu 10:00AM-12:00PM (unless otherwise listed).
Instructor:	Mark Smithyes
Office Location:	Online
Office Hours:	TBA
Contact:	Cell: 416-277-4398 mark.smithyes@utoronto.ca

Course Description

Medical Device Reimbursement for medical devices is critical for successful product commercialization in Canada. Various aspects of the pathway to reimbursement will be presented and discussed including regulatory, health economics, stakeholder mapping and management, and the reimbursement landscape in Canada. A medical device reimbursement framework that can be applied when seeking medical device reimbursement will be utilized to build a reimbursement plan. The course involves lectures, cases and reimbursement challenges. In a team environment, students will conduct reimbursement assessments and develop and present reimbursement plans for real-world medical device reimbursement. At the conclusion of the course, students will have the knowledge and tools to build a medical device reimbursement plan.

Course Objectives

- 1) Attain basic understanding of the medical device reimbursement process and environment in Canada
- 2) Build a reimbursement plan for a medical device using the reimbursement framework and stakeholder mapping tool
- 3) Further students' understanding of turning data into insights, problem solving and working in an undefined environment

About the Instructor

Mark Smithyes is a transformational leader with over 25 years' experience in the Pharmaceutical and Medical Device industries. His extensive career includes numerous senior leadership positions in multinationals like Novartis and Alcon as well as founding, running, and exiting a successful life sciences start-up venture.



Currently, Mark is President of Life Sciences Consulting where he takes a hands-on

approach with life science start-ups building their internal competencies in the areas of strategy, financial forecasts, commercialization, building teams and culture, communications, and early-stage fundraising.

Mark is a regular contributor and speaker at industry conferences and has extensive corporate and non-profit governance experience. He is currently a Seasonal Lecturer at the University of Toronto Mississauga and serves as Board Director at Endeavour Consulting and as Board Chair of Nurosene Health and Life Sciences Ontario. Mark holds a BA from Western University and an MBA from the Kellogg School of Management and the Schulich School of Business.

Marking Scheme

The breakdown of the grade for the course will be as follows:

Class participation	10%
Quizzes	10%
In-class team challenges	15%
Reimbursement plan, written	15%
Reimbursement plan, presentation	15%
Final exam	35%
TOTAL	100%

SCHEDULE OF ACTIVITIES

Unit	Date	Pre-reads	Topics
1	3-Jun 9:00AM-12:00PM	Medical Device and Diagnostic Pricing and Reimbursement in Canada, Institute of Health Economics, 2015 – Section 1	<ul style="list-style-type: none"> ○ Course introduction ○ Discussion on the Reimbursement framework and final assignment introduction ○ Industry landscape overview ○ Written assignment
2	8-Jun 9:00AM-12:00PM	<ol style="list-style-type: none"> 1. https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-canada/ 2. Health Canada Fact sheet, 2007 3. Medical Device and Diagnostic Pricing and Reimbursement in Canada, Institute of Health Economics, 2015 – Section 2 <p><i>Optional</i></p> <ol style="list-style-type: none"> 4. Medical Devices Action Plan, Health Canada, 2018 5. Guidance Document Software as a Medical Device, Health Canada, 2019 	<ul style="list-style-type: none"> ○ Discussion of written assignment ○ Regulatory pathway for medical devices ○ Health Canada Software Medical Device Guidance Document ○ Team Challenge
3	10-Jun 10:00AM-12:00PM	None	<ul style="list-style-type: none"> ○ Government overview and its role in medical devices ○ Team Challenge
4	19-Jun 10:00AM-12:00PM	<ol style="list-style-type: none"> 1. Health Technology Assessment of Medical Devices: The Canadian Experience, Polisen, 2018 2. Value Based Healthcare, MEDEC, 2017 	<ul style="list-style-type: none"> ○ Health Economics & Health Technology Assessment ○ Team Challenge
5	21-Jun 10:00AM-12:00PM	<ol style="list-style-type: none"> 1. https://www.eseibusinessschool.com/the-8-keys-to-a-successful-business-presentation/ 2. https://www.salesforce.com/ca/blog/2015/06/10-communication-skills-for-business-success.html 	<ul style="list-style-type: none"> ○ Quiz #1 ○ Effective communications with internal and external stakeholders ○ Team Challenge

Unit	Date	Pre-reads	Topics
6	29-Jun 10:00AM- 12:00PM	<ol style="list-style-type: none"> 1. The Current Canadian Vaccine Environment, BIOTECanada, 2010 2. Pathway to Access: Evaluation and Recommendation, BIOTECanada, 2010 3. https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2017/10/canada-reimbursement-profile 4. https://www.innomar-strategies.com/insights/drug-reimbursement-in-canada <p><i>Optional</i></p> <ol style="list-style-type: none"> 1. Introduction to Vaccines, BIOTECanada, 2010 	<ul style="list-style-type: none"> ○ Drug & vaccine reimbursement ○ Team Challenge
7	6-Jul 11:00AM- 1:00PM	Medical Device and Diagnostic Pricing and Reimbursement in Canada, Institute of Health Economics, 2015 – Section 3 & 4	<ul style="list-style-type: none"> ○ Medical Device reimbursement process – Part I ○ Team Challenge
8	8-Jul 10:00AM- 12:00PM	Enabling health technology innovation in Canada, MacNeil, 2018	<ul style="list-style-type: none"> ○ Medical Device reimbursement process – Part II ○ Team Challenge
9	13-Jul 10:00AM- 12:00PM & 1:00- 3:00PM	None	<ul style="list-style-type: none"> ○ Case analysis presentations
10	15-Jul 10:00AM- 12:00PM	TBD	<ul style="list-style-type: none"> ○ Quiz #2 ○ Stakeholder mapping ○ Framework; Putting it all together – a review of each component and how they interact ○ Team Challenge
11	20-Jul 10:00AM- 12:00PM	None	<ul style="list-style-type: none"> ○ Policy & Government Relations ○ Team Challenge
12	22-Jul 10:00AM- 12:00PM & 1:00- 3:00PM	None	<ul style="list-style-type: none"> ○ Reimbursement plan presentations
13	27-Jul 10:00AM- 1:00PM	None	<ul style="list-style-type: none"> ○ Final Exam

Conduct of Classes

Full attendance, preparation and participation are required for all in-class sessions and group work. We recognize that there may be valid reasons of illness and other major circumstances which prevent full attendance. Due to the condensed nature of the course material any absence could seriously impact on your ability to satisfy the program requirements. We ask that you phone or email the instructor in advance and upon your return, provide the instructor with written documentation supporting the reason for your absence.

Expectation for Online Courses

Students are expected to display tolerance and respect in all communication. Communicate with others the same way you would in a traditional classroom. Comments and language should be respectful and appropriate for a university community. All comments should also follow acceptable grammar and spelling.

Students in an online course will login as requested by the instructor. Maintaining a professional appearance and attire throughout the duration of the online classes is required.

Online students must be self-starters and have the maturity and motivation to work independently. It is recommended to use time wisely, be organized, self-directed and be willing to use new modes of communication and learning. Students in online classes must follow the timetable of the class strictly. Although it is an online class, it is still a classroom session and punctuality is a must. It is important to put in the needed time for classes, read all the required course material carefully, and actively participate in online class activities.

Procedures & Rules

MISSED TEST(S)/FINAL EXAM: A student that misses a test due to illness must submit a completed University of Toronto Student Medical Certificate (available at: http://www.utm.utoronto.ca/registrar/sites/files/registrar/public/shared/pdfs/medcert_web.pdf) to the Instructor or Program Office (KN-209). Only the University of Toronto Student Medical Certificate will be accepted in support of petitions that cite illness as the reason for the request. Documentation concerning physician examinations must show that the physician was consulted on the day of the test date or immediately after, i.e. the next day. A statement from a physician that merely confirms a report of illness and/or disability made by the student is not acceptable. Documentation citing non-essential, preplanned medical procedures will not be acceptable. All documents must be originals and must be presented in person with a valid UofT student card within 72 hours of missing the test. Beyond 72 hours from the test date, further documentation of continued illness or disability will be required from a physician.

A student that misses a test due to domestic tragedy, at the discretion of the instructor, must provide acceptable documentation validating the explanation for absence. If a test is missed and the student does not provide acceptable documentation validating the explanation for absence, a grade of "0" may be assigned at the instructor's discretion.

If a test is missed and validating documentation is accepted the students are expected to write a make-up test. Students must contact the instructor immediately by phone or email to make arrangements.

LATE ASSIGNMENTS: Team assignments are due at the beginning of each class. **No assignments will be accepted late and a grade of ZERO will be given for that assignment.**

ACADEMIC MISCONDUCT: Students should note that copying, plagiarizing, or other forms of academic misconduct will not be tolerated. Any student caught engaging in such activities will be subject to academic discipline ranging from a mark of zero on the assignment, test or examination to dismissal from the university as outlined in the School of Graduate Studies academic handbook. Any student abetting or otherwise assisting in such misconduct will also be subject to academic penalties.

Students agree that by taking this course all required papers may be subject to submission for textual similarity review to Turnitin.com for the detection of plagiarism. All submitted papers will be included as source documents in the Turnitin.com reference database solely for the purpose of detecting plagiarism of such papers. The terms that apply to the University's use of the Turnitin.com service are described on the Turnitin.com web site.

Communication

LOGGING IN TO YOUR QUERCUS COURSE WEBSITE

Like many other courses, BTC 2030H uses Quercus for its course website. To access the BTC 2030H website, or any other Quercus-based course website, go to the UofT portal login page at: <https://q.utoronto.ca> and log in using your UTORid and password. Once you have logged in to the portal using your UTORid and password, look under the **Courses** menu item, where you'll find the link to the BTC 2030H course website along with the link to all your other Quercus-based courses.

E-MAIL COMMUNICATION WITH THE COURSE INSTRUCTOR

At times, the course instructor may decide to send out important course information by e-mail. To that end, all UofT students are required to have a valid UofT e-mail address. You are responsible for ensuring that your UofT e-mail address is set up AND properly entered in the ROSI system.

Forwarding your utoronto.ca e-mail to a Hotmail, Gmail, Yahoo or other type of e-mail account is not advisable. In some cases, messages from utoronto.ca addresses sent to Hotmail, Gmail or Yahoo accounts are filtered as junk mail, which means that e-mails from your course instructor may end up in your spam or junk mail folder.

You are responsible for:

1. Ensuring you have a valid UofT e-mail address, properly entered in the ROSI system
2. Checking your UofT e-mail account on a regular basis.

Standard of Conduct in this Course

Since this course is part of a program designed to give you a broad understanding of the world of business, we aim to run the course in a manner which is consistent with the world of business. We strive to provide accurate information, quality materials, and good service, consistent with our obligations to maintain the high academic standards of the Department of Management at the University of Toronto Mississauga.

In return, we expect that you will conduct yourself in a way that prepares you for the world of work.

1. We start on time, so please do not arrive late and disrupt others.
2. Leaving class early is also disruptive to your colleagues and will not be permitted unless you have made prior arrangements with the Instructor.

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3. Turn off all electronic devices (*e.g.*, cellular telephone, PDA, iPad, or similar devices, *etc.*) before entering class.
 4. Keep up to date. Make sure that you know the class schedule. Check on the course web page for updates and posted materials.
 5. During the class, respect the learning opportunities of others. Don't distract others by chatting with your neighbour. Our hope is that you will not only contribute to your own learning but also to that of others.