COURSE COLOUR CODE: MAROON

MASTER OF BIOTECHNOLOGY PROGRAM

Compulsory Course Component

BTC 1899H

DIGITAL HEALTH TECHNOLOGY

Jayson Parker

Fall Term, 2021
&
Winter/Spring Term, 2022

MASTER OF BIOTECHNOLOGY

UNIVERSITY OF TORONTO MISSISSAUGA

BTC 1899H – Digital Health

Course Outline (Fall 2021/ Winter 2022)

Class Location: Zoom links:

Join Zoom Meeting
https://utoronto.zoom.us/j/86064261662

Meeting ID: 860 6426 1662
Passcode: COVID&

Class Times: See iCal; Every other Wed 6-9 PM (unless otherwise listed).

Instructor: **Dr. Jayson Parker, *M.B.A., M.Sc., Ph.D.***

Office Hours: By appointment.

Contact E-Mail: jayson.parker@utoronto.ca

Twitter: @Jayson_Parker

Dr. Jayson L. Parker

Associate Professor (teaching stream)
Dept. of Biology
MBiotech Program (Digital Health)
University of Toronto Mississauga

Institute of Biomedical Engineering
(IBME; cross appointment)
University of Toronto

Email: jayson.parker@utoronto.ca
Twitter: @Jayson_Parker
Cell: 647-929-5315

PhD (University of Toronto)
MSc (University of Toronto)
MBA (Wilfrid Laurier University)

Professional Interests

Digital health technology, medical device regulation, clinical trial design, biomarkers, health and wellness.

My publications: https://www.researchgate.net/profile/Jayson_Parker/

Impact

My interests stem from my time conducting research in medical imaging, brain trauma and drug addiction. My commercial experience in investment banking and the pharmaceutical industry also animate my research goals.

Research on clinical trial failure rates in the context of new medicines and biomarkers is one of my main areas. Recently, we have started to combine this with advanced tools in machine learning.

The “Dark Data” project is my main activity in the context of digital health. We are looking at lifestyle choices can predict improved health and wellness outcomes within 24 hours. This project makes extensive use of wearable technology.

Digital health and more broadly medical device regulation, are active areas of research.

Miscellaneous

Hobbies include: Dungeons and Dragons, 3D-printing, digital modelling, tabletop wargaming (Warhammer 40k), computer games (MMOs, Fallout) and miniature painting.

Course Description

The course has looks at digital health technology (DHT). The emphasis is on different perspectives of looking at technology. Through their respective projects, students will seed class discussion through their view of prevailing and emerging trends in DHT.

The first half of the course has focused assignments to give students a chance to revisit challenges from the first year, and to do so in more detail. The second half of the course is forward looking and will be set on product proposal (start-up) ideas student teams will develop in a digital health context.

The course will involve significant contributions from students in the Digital Health Technology stream who are now in their advanced year of study.

Course Objectives

We want to tour the landscape of Digital Health Technology. We will do this by taking few technologies and examining them in detail.

The course will integrate prior concepts to apply them to the assignments in this course such as medical device regulation, healthcare industry practices and medical device reimbursement. New content will expose students to new areas such as human factor engineering and psychology applied to digital health technology.

The course will also focus on developing an understanding of minimum viable products to seed new product proposals.

Session	Date	Topic
I	**Sep 8**	Psychology Primer for Digital Health Technology & Human Factor Engineering Guidance
II	**Sep 22**	Digital Health Regulation-Guidance documents & Reverse Engineering
III	**Oct 13**	Critical Evaluation of Forecasting of Digital Health Technology; Device regulation discussion
IV	**Oct 27**	Forecasting Health Technology- Student Presentations (individual) Part I
V	**Nov 3**	Forecasting Health Technology- Student Presentations (individual) Part II
VI	**Nov 10**	Forecasting Health Technology- Student Presentations (individual) Part III
VII	**Nov 17**	Forecasting Health Technology- Student Presentations (individual) Part IV.
VIII	**Dec 8**	Project Formation & Selection
IX	**Jan 17**	Customer Need & Opportunity in your healthcare space
X	**Jan 31**	Product concept / Design/ Minimal viable product
XI	**Feb 28th**	Advisor Visit (need milestone, students need to use phones)
XII	**Mar 14**	Dry Run talks
XIII	**Mar 28th**	Final Project Presentations **(all DHT - send invites)**
	Apr 4th	Exam

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Grade Weighting

1. Mentor activity (solo)……..…….……5%
2. Medical device regulation (team)……..…10%
3. Technology forecasts (solo)…….……25%
4. Class participation (solo)..……..…….…..5%
5. Product / start-up idea (team)….……..….30%
    a. Report & Presentation…….…25%
    b. User / Potential customer interviews……..5%
6. Final exam (solo)…….….25%

TOTAL .....……..100

Assignment	Due Date	Mode of Submission
Medical Device Regulation	Oct 13th before lecture	email to instructor; Team name & CC team members
Technology Forecast	Reports due by 6 PM EST 2 days before your talk.	email to instructor
User interviews/ analysis	Feb 16th by 6 PM EST.	email to instructor
Product Proposal	March 25th before 6 PM EST; slide deck due to instructor the day of your presentation March 28th	email to instructor; Team name & CC team members
Final Exam	See syllabus	TBA

Course Assignments

Late assignments will be penalized 10% off the final grade of the report—and a further 10% if handed in the following day (thereafter, the grade is zero).

Medical Device Regulation Reverse Engineering Assignment

Each team will work with the same base case. Each team will be assigned a different regulatory path at the US FDA. Teams will then propose modest changes to their product that in theory look like it would create a better product, but also conform to the regulatory pathway assigned.

The focus of the grade will be on your regulatory argument (80%) and the balance of the grade on your alteration of the product (20%) that looks like an improvement to the base product that is technically feasible.

Context: you are to assume you are actually meeting with the FDA. That means that ALL relevant data, quotes, guidance documents must be included in this document (for guidance documents - screen shot the relevant portion you need for your argument).

Format: An example of this will be posted on Quercus. It's not a perfect example, so be prepared to go beyond the example provided. You are not expected to be engineers.

Regulatory Guide For your Submission:

1. Risk class argument. Don't assume that the instructors know the risk class – explicitly state your risk class in the document, telling us what it is - and on what basis you are arguing it belongs to that risk class.

2. Reference to FDA decision history of related or identical products. This is part of your supporting arguments and key to talking to the FDA.

3. *Side by side tabular comparisons of features for predicate identification vs. the new device.* This is a must and you will be docked marks for not presenting detailed comparisons. Where are they same and where are they different? Where differences exist, interpret the meaning of those differences with respect to safety or efficacy that can invalidate a substantial equivalence argument or demand a higher risk class. Just don't give us a technical summary - tell us what differences are important and why.

4. Safety is a concern even if it looks like an IMPROVEMENT, which demands some form of testing and discussion to address this point. Provide relevant Standards in the appendix, related to the testing. The bigger the safety *change*, the more likely the risk will increase. Provide justification for your risk level.

5. Hazard analysis is required. This is used to help defend your risk class argument, in addition to supporting other arguments, such as intended use changes. An example is in the book chapter for this course (by the instuctor/ editor Tong) and may also be found in the examples for this project on Quercus.

6. Some form of failure mode analysis should support your argument regarding the safety / risk of your change.

7. What are all the relevant guidance documents supporting your regulatory argument?

8. What kind of evidence is needed to explore any safety or efficacy issues? (animal, cell culture, written description or clinical study). Why? If you are saying such work is important, then does this underscore a safety uncertainty that would make your product look like a class III?

9. Screenshots of FDA device website - just don't give me references - show me the actual screens / quotes / tables you are referring to in your appendix from the sources you cite. *Your document should be able to act as a reference sheet to help you on a phone call to the FDA with all the information you need readily available.* Simply giving a reference does not do this - show us the actual information you plan to use.

Health Technology Portfolio - Forecasting Challenge

You can forecast one of two ways in this assignment: pick a trend you think will dominate OR pick a trend that interests you and forecast its future.

A Google doc has been sent to the class where you can rank order your 3 choices. We want to avoid overlap between students. The instructor will post some suggestions for the class to consider. This will make sense when we cover the **"hand in glove"** theme for this year's product ideas.

You will need to critically evaluate your product to set the stage for your forecast. As appropriate for your product, make sure the following areas are covered:

1. Regulatory path. What kind of evidence is required? What does the hazard analysis look like?
2. Reimbursement. Who will pay, choose, approve and use this technology? Are they the same people? What evidence is there that payment is likely to occur?
3. Customer need. What examples on the market lead you to believe there is untapped need here? Are there related products pertaining to the need that have been successful?
4. Psychology & human factors. How does the product look from a usability standpoint,

applying principles from psychology and human factors?

5. Scientific evidence. What is the evidence that the product, based on current science, should work? This will overlap to some extent with above areas.

Your project should show consider competitor analysis, industry forecast (vs. historical trends to date), start-up activity in this area, blue chip company activity in this area, barriers to adoption, surveys you have conducted to illustrate adoption receptivity, expert commentary on your trend (interview experts on your topic). You do not need to literally present on all of these facets (you won't have time), but they must be in your report as appropriate for your topic.

Focus your presentation to the key elements necessary to understand your technology trend and its plausibility.

Your forecast for your technology should look out 5 years (beyond 5 years is not realistic).

Social media: If you post your essay and figures on Medium for public viewing the instructor will Tweet and share on my own LinkedIn your work. You must identify yourself as the author.

Submission Format for the Essay

The introduction and discussion of your forecast and portfolio cannot exceed 3000 words. You will be limited to 10 figures or tables. *This work must be copyright compliant for commercial use.* You can fully type set / page layout your work, so that all figures can be embedded in your text (just as in a magazine our journal article).

Presentation Format

Your talk will be 20 minutes in duration followed by a question/discussion period of about 20-30 minutes. Be prepared to lead discussion and review in detail material you have presented to the class. *Have extra slides prepared for the question period you will not have time for in your presentation.*

Major Project: New Product Proposal

In this project in the winter term your team will work on the basics for proposing a new product. This is not a business plan, but will contain many of its elements as it intersects with this course.

Customer feedback and need identification. We want to you to conduct research on actual users of this technology – this is not about speaking to experts. Interviews, surveys and Internet forums are all potential sources – see instructors for details. Conclude your survey of feedback with clear needs you think needs to be addressed in your design.

Be prepared to "hack responses". Rather than ask someone how often they exercise, you might infer this from fitbit/ wearable scores. More indirectly, if you want to get a sense of whether someone will use a device, ask about other accessories they already use.

Your project will have the following elements, and more as you see fit: minimum viable product description and justification, regulatory path, reimbursement, adopter analysis, customer data, price point, SWOT, PEST, Porter 5 forces model, market size, competitor analysis, patent landscape/prior art review, patent eligibility, advertising claims/ indications and expert feedback on your idea.

Format: The report is to be 10 pages 1.5 line spacing. No embedded figures. Executive summary, index, title page, references and an appendix (for interviews, data, graphs, calculations, models, figures etc). There is no limit on the length of your appendix.

Presentation: 10 minute talks, 10 slides. Have slides ready for the question period. One figure per slide. Everyone must present.

Attendance

Attendance is mandatory. More than 2 absences without a doctor's note and you receive zero for participation. Your camera must be enabled - otherwise this will impact participation. If you have camera problems, please notify the instructor.

Readings for Sessions

No.	Topic	Readings / Viewing
I	Psychology primer for Digital Health Technology; human factors guidance documents	- Cognitive Map or Medium Materiality? Reading on Paper and Screen. J. Hou, Rashid, J. And K. M. Lee. Computers in Human Behaviour 67 (2017): 84-89. - FDA. Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff.
II	Medical Device Regulation-Guidance documents & Reverse engineering	- FDA. General Wellness: Policy for Low Risk Devices. Guidance for Industry and Food and Drug Administration Staff. - FDA. Proposed Regulatory Framework for Modifications to Artificial Intelligence/ Machine Learning. (AI/ML) - Based on Software as a Medical Device. If the Year / date is different than above that's fine - it means the guidance has been updated.

No.	Topic	Readings / Viewing
III	Identifying Hype in Health Technology	- Patents & Gorillas (Parker, unpublished book chapter) in Quercus - Buy side, Dark Side (Parker, unpublished book chapter) in Quercus
IV	Forecasting Health Technology- Student Presentations (individual) Part I	- What is a key finding and a key concern from each presentation?
V	Forecasting Health Technology- Student Presentations (individual) Part II	- What is a key finding and a key concern from each presentation?
VI	Forecasting Health Technology- Student Presentations (individual) Part III	- What is a key finding and a key concern from each presentation?
VII	Forecasting Health Technology- Student Presentations (individual) Part IV	- Review the Recording of the Digital Health Post COVID Digital Communication working Group (occurred Nov 23rd). **Link TBA**.
VIII	Project Formation & Selection: “hand in glove”	- Fulmer R, Joerin A, Gentile B, Lakerink L, Rauws M Using Psychological Artificial Intelligence (Tess) to Relieve Symptoms of Depression and Anxiety: Randomized Controlled Trial JMIR Ment Health 2018;5(4):e64
IX	Customer Need & Opportunity in your healthcare space	- Toth L, Hoffmann I, Gosztolya G, et al. A Speech Recognition-based Solution for the Automatic Detection of Mild Cognitive Impairment from Spontaneous Speech. *Curr Alzheimer Res*. 2018;15(2):130-138. doi:10.2174/1567205014666171121114930
X	Product concept / Design	- Gresham, G., Hendifar, A.E., Spiegel, B. *et al.* Wearable activity monitors to assess performance status and predict clinical outcomes in advanced cancer patients. *npj Digital Med* **1,** 27 (2018). https://doi.org/10.1038/s41746-018-0032-6
XI	Major Project Advisors Visit	- Be sure to log on early to Zoom. It’s good etiquette for external stakeholders in our digital world.
XII	Dry Run Talks	
XIII	Final Project Presentations	

No.	Topic	Readings / Viewing
	Exam	

Final Exam

Format will be announced. It will emphasize critical thinking pursuant to concepts reviewed in the course. Course readings may also appear on the exam.