# Entrepreneurship in the Biomedical Space Certificate Syllabus

**DISCOVERIES POWERING INNOVATION**

## I. Meeting and Contact Information:

| | | |
|---|---|---|
| Class Meets | See course schedule | |
| Virtual Office Hours | Wednesdays, 9am-10am | zoom |
| Contact | James Bezjian | jbezjian@gmail.com<br>714-642-3824 |

## II. Course Overview:

At the beginning of the program you will either (1) Come up with a novel technology that you wish to use as the foundation for your virtual company or (2) work with the MUSC Foundation for Research Development to assess an existing technology from MUSC. As you progress through the course content, you will complete exercises based on the content to assess the translational potential of your technology.

The program will close with learning economic practicality, how to pitch your idea, and how and where you can raise money. Resources you can use to help you move forward with a forming and developing a company will be provided during the course. This course will be layered in such a way that a business canvas and pitch deck is formed. At the end of the course, you will pitch your idea to a panel of judges in a pitch competition.

The course will be structured into six main modules – four of which will require full completion, and two of which will require completion for a minimum number of topics depending on which track you choose. The track should be chosen based on the technology you are working on in this course. Below you will find an overview of each of the modules and a description of the online lessons within each module.

## III. Evaluation Criteria

| Evaluation | Percent |
|---|---|
| Online Quizzes | 10% |
| Getting Started Project | 5% |
| IP Project | 10% |
| Business Canvas | 30% |
| Pitch Deck and Pitch | 25% |
| Participation/Attendance | 10% |
| Feedback | 10% |

The course will be evaluated according the table on the left. As this is a certificate course, you will not be receiving a letter grade. However, you must obtain an 80% in order to receive a certificate for the course. Provided you actively participate, complete the assignments and refine assignments based on feedback provided, all attendees should obtain at least an 80%.

**IV.    Course Policies**

GROUP WORK: We aim to have two-three people per project in this course. This is to reduce the workload and provide the opportunity for discussions around a project. It is up to you how you divide up responsibilities and how often you interact.

PARTICIPATION: The class will be online. Several videoconferences are scheduled for Thursday morning. Please be sure you are current on the course material, prepared to provide updates on your project and actively participate. At least 1 person from each group to participate (preferably the entire team) in the videoconference updates.

GRADING: Most of the projects here are meant to be discussed and refined (sometimes multiple times). You will have a chance to take feedback and update your project assignments for a change in grade.

FEEDBACK: This course is meant to help promote entrepreneurship training throughout the MUSC enterprise (and long term beyond), and therefore your feedback is critical. Feedback on what worked, and what did not, will be helpful for continued development of the course

**V.    Identifying a Technology:**

The technology you identify can be one you are currently researching or an idea you have that you think has potential. If you need help coming up with a project, message the course administrator who can help provide ideas or brainstorm with you to identify a project that fits well with the course. Further, the technology must be approved by the end of the Getting Started Section to make sure it is a good fit for the course.

> **Examples of projects:**
> 1. A novel biologic that possesses anti-inflammatory qualities
> 2. A known small molecule that failed for efficacy in fibrosis, but could be repurposed as an anti-cancer agent
> 3. An imaging diagnostic for early detection of Alzheimer's Disease
> 4. A medical device knee implant that retains mechanical stability over time compared to current devices
> 5. A new antimicrobial material that has uses in implantable medical devices
> 6. A software that can help a provider diagnose and treat injuries remotely

Properties of Technologies that would be the best fit:

You do not need to have a complete product profile for the technology in terms of what it would look like on the market. However, you should have an idea that is formed enough to perform a prior art search and/or assessment of the technology compared to competitors. In the case of therapeutics, that would mean knowing the sequence, formula or use of known compound. For a diagnostic, that would mean knowing the target or

method needed to diagnose a disease. For a medical device, it would be at minimum a drawing (preferably a CAD drawing) or prototype of the device. For a software, it would be having either a workable product or design features that can be implemented that will distinguish the technology from other technologies. If you have questions, the course administrator will work with you on determining if the technology is a fit.

*You should be in contact with your Technology Transfer Office (At MUSC [frd@musc.edu](mailto:frd@musc.edu)) if the technology you are working on is associated with your University.*

## VI.    Course Schedule:

| Welcome and Getting Started | *Required.* | Weeks 1-2 May 17th-28th |
|---|---|---|
| *Virtual Class Introductions* | *10-11am, Introductions and course overview and purpose* | May 19th |
| Lessons: | 1. Science vs Invention vs Business - Understanding Key Issues in Innovation and New Product/Service Development. <br> 2. Business Opportunity - Defining and evaluating opportunity <br> 3. Entrepreneurial Overview - How to determine if starting a company is the right move for you. <br> 4. Understanding Intellectual Property - Review of the types of IP and protections afforded by each. | 3.5 hrs. Due May 23th |
| *Pick technology* | Work with course administrators to identify and pick a technology for the course | May 17th – 28th |
| *Virtual Class Update* | *10-11am, provide class update on technology and team* | May 26th |
| *Class Project* | *Write out a preliminary target product profile on your technology* | Due: May 28th |
| *Intellectual Property* | *Copyright or Patent Track required* | Weeks 3-4 May 31 – June 11th |
| Lessons: | 1. US Patents Deep Dive  - Process, requirements, timeline and associated costs. *(Patent Track)* <br> 2. Case Laws that have Changed the Face of Patents - Myriad, Prometheus & Alice. *(Patent Track)* <br> 3. Foreign Patenting Strategies - How to determine in what countries to file patent applications. *(Patent Track)* <br> **4.** Freedom to Operate - Differences between being patentable and not infringing. **(All Tracks)** <br> 5. Copyright Deep Dive - What is protectable, how to secure, and advantages provided  *(Copyright Track)* <br> 6. Open Innovation - open source software licenses (BSD, etc). *(Copyright Track)* <br> **7.** Trademarks & Service Marks Deep Dive - What is protectable, how to secure, and advantages provided. **(All Tracks)** | 4-5 hr. Due June 7th |

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| | 8. Balancing Act of Innovating in Academia - Balancing publications, presentations, and grants, while protecting IP. Strategies and trade-offs. *(All Tracks)* | |
| *Virtual Class Update* | *10-11am: Discuss IP questions, concerns and draft of assignment* | June 9th |
| *Class Project* | *Perform a prior art search and preliminary assessment on your technology.* ==*(Patent Track).*== <br><br> *Identify similar products either in the market or being developed that could compete with your idea* *(Copyright Track)* | Due: June 11th |
| **Building Your Company** | *Required* | Weeks 5-7 <br> June 14th – July 2nd |
| Lessons: | 1. Developing a Business  - Overview of Developing a Successful Business <br> 2. Economics of a Start-Up - Expectations about size, growth, returns, and risk. <br> 3. Fundamentals of Startup Law - Company Creation, Structure and mistakes to avoid <br> 4. Building a Team - Identify your company's management team. | 6 hrs. <br> Due June 22nd |
| *Virtual Class Update* | *10-11am:Discuss model canvas draft, questions, concerns etc.* | June 23rd |
| *Class Project* | *Use the handout to build or refine your Business Model Canvas. Identify 15 people that you can target for a discussion to help further refine your canvas throughout the course.* | Due July 2nd |
| *Tangent: Regulatory and Reimbursement* | *Device, Diagnostic or Therapeutic Track* | Weeks 8-9 <br> July 5th – 17th |
| Lessons | *1.* Lessons Regulatory Overview - History and role of FDA in regulatory oversight *(All Tracks)* <br> *2.* FDA Medical Devices Regulation Deep Dive - Deep dive into device paths and review processes. *(Device Track)* <br> *3.* FDA Regulation of Therapeutics Deep Dive - Deep dive into FDA review and clinical trials. *(Therapeutic Track)* <br> *4.* FDA Regulation of Diagnostics Deep Dive - Deep dive into diagnostic development and review processes. *(Diagnostic Track)* <br> *5.* FDA regulation of Software - Deep dive into FDA regulation of digital health innovation development and review process. *(Device* and *Diagnostic Tracks)* <br> *6.* Developing Products for Rare Diseases and Special Conditions - Orphan Diseases; Humanitarian Use Exemption (HUD). *(Therapeutic Track)* <br> *7.* Waxman-Hatch Provisions - Effects on drug approval, changes in formulations & dosing. *(Therapeutic Track)* <br> *8.* Reimbursement - Commercial challenges, obtainment of a reimbursement code. *(Device* and *Diagnostic Tracks)* | 3-3.5 hrs. <br> Due July 9th |
| *Virtual Class Update* | *10-11am: Discuss regulatory strategy, question, concerns etc.* | July 14th |
| *Class Project* | *Determine how your technology will be regulated, and what studies will need to be done on the preclinical and clinical side, as well as a timeline of how long it will take for you to get to market.* | Due July 14th |

| *Tangent: Agreements* | *Required* | Week 11 July 19th – 23rd |
|---|---|---|
| | 1. Material Transfer and Confidentiality Agreements Terms - implications of Confidentially Agreement, Material Transfer Agreement purpose when sending and receiving materials.<br>2. Options and Licenses - Differences, structure, terms, definitions and purpose<br>3. Consulting Agreements - Management and provisions to watch for | 2 hrs. Due July 21st |
| *Virtual Class Update* | *10-11am: Project update, Discuss questions regarding agreements, business model canvas or otherwise* | July 21st |
| *Class Project* | *Interview at least 5 people you identified in the "Building your Company" section to further refine your canvas.* | Due by July 23rd |
| **Financing** | *Required* | Weeks 12-15 July 26th – Aug 15th |
| Lessons | 1. Primer on Finance - Sources of funding; how and when to go for which source.<br>2. SBIR/STTR Funding - Purpose, rule, requirements, agencies, etc.<br>3. Art of the Pitch - Attracting investors.<br>4. Dilutive Funding - Sources and implications.<br>5. Valuation and Deal Structure - How much is the product or company worth. Maximizing returns.<br>6. Constructing a Business Plan - Product to Business Concept to Business Model to Business Plan. | 7 hrs. Due July 30th |
| *Virtual Class Update* | *10-11am: Project update, feedback for pitch deck or elevator pitch* | July 28th |
| *Class Project* | *Draft of a pitch deck* | Aug 5th |
| *Final Class Project* | *Refine your target product profile and business model canvas with what you learned from this course, interviews and the regulatory assignment* | Due Aug 10th |
| Final Pitch | *Pitch your project to judges. Hand in final pitch deck* | Pitch Innovation Aug 13th |
| **Policies and Resources** | *Optional* | OPTIONAL |
| IP Policy & Disclosures | Overview of IP policy, record of inventions, etc. | 0.25 hrs. |
| Startup Policy | Overview of the MUSC startup Policy | 0.5 hrs |
| Local Resources | Regional services, facilities and companies geared towards fostering innovation. | 0.5 hrs. |