



Entrepreneurship MiniSymposium: How to start a start-up

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Abstract—

Several important issues need consideration when launching a biomedical start-up. This Entrepreneurship Minisymposium will cover several crucial topics, including:

- Medical device new product development
- Technology and product idea generation process
- Venture capital (VC) funding, process and sources
- SBIR funding, process and successful grant writing tips
- Intellectual property (IP) roadmap for start-ups, how to optimally protect ideas, discussion of new changes in patent law
- Technology licensing and transfer process
- FDA approval of new devices
- How can Industry and Academia partner more closely together

Presentations:

1. Translating Ideas into Therapies

Presenter: Dr. Howard Levin

Dr. Levin, M.D. will share from his vast experience as founder of multiple companies and as an academic cardiologist and researcher. His talk will focus on translating medical device ideas into successful and novel therapies that benefit patients, but also provide a return to founding engineers and investors. Dr. Levin will share practical examples from his experience with founding Coridea, an idea generator that translates ideas into novel therapeutic solutions for clinical practice.

2. The secret to successful SBIR funding

Presenter: Dr. Dieter Haemmerich

Given limited funding, SBIR grants have become extremely competitive. Dr. Haemmerich has a wealth of experience with successful SBIR proposals. He is also a reviewer of SBIR grant proposals. Dr. Haemmerich's presentation will cover most important aspects of how to write a successful SBIR grant proposal and what to expect during the review process. Dr. Haemmerich will share some specific examples from his experience with co-founding Medical Engineering Innovations Inc., which commercializes surgical devices for cancer treatment. His company was successfully started and funded based on several NIH SBIR grants.

3. Start-Up lessons learned

Presenter: Dr. Richard Schmidt



Dr. Schmidt is a technical and business leader with extensive experience in engineering and commercializing complex medical devices focused on delivering cancer treatment. His talk will share specific lessons-learned examples about overcoming funding, development and regulatory hurdles.

4. Start-Up IP roadmaps: how to avoid common mistakes

Presenter: Theodore Papagiannis, J.D.

Dr. Papagiannis, J.D., has over ten years of experience in guiding start-up companies, particularly those in the medical device arena, to build and strengthen their intellectual property (IP) portfolios. His talk will address topics related to how patent due diligence activities are conducted and will focus on what venture capital firms, as well as other investors and strategic partners, expect to see in a start-up's patent portfolio and IP roadmap. Dr. Papagiannis will share practical examples about infringement analysis, IP risk evaluation, strategic IP positioning (both offensive and defensive) and a wide range of other IP matters.

5. How to start your own start-up

Presenter: Reese Terry, M.S.

Mr. Terry had the vision to help patients suffering of epilepsy and chronic depression, both being serious illnesses that affect the family and personal relationships, work or school life, sleeping and eating habits, and general health of hundreds of thousands of Americans. His vision materialized in the successful founding of Cyberonics, Inc. in 1987. Cyberonics, Inc. has been one of the most successful start-up stories in the medical device industry and it has recently merged with the Sorin Medical Group. His talk will cover the dos and don'ts of starting up your own company. Mr. Terry will take the audience through the early steps of finding seed funding for developing proof-of-concept prototypes; the importance of building a strong engineering team; getting additional funding or taking the company IPO; and through interacting with regulatory agencies on controversial matters.

6. Technology Transfer

Presenter: Dr. Nitish Thakor

Dr. Thakor has pioneered many technologies from brain monitoring to prosthetic arms and neuroprosthesis. He is an author of more than 290 refereed journal papers, more than a dozen patents, and co-founder of 3 companies. Dealing with Tech Transfer Offices is a process that requires focused energy, while successful outcomes may take longer than initially expected. Dr. Thakor's talk will present on the importance of the Tech Transfer process, on how to efficiently navigate this process and how to deal with the potential gap between investors' and founders' expectations and the realities of the Tech Transfer timing.

7. US and International Patent Law and Intellectual Property Updates. Role of US vs. PCT patent application filings.

Presenter: Michael R. Christensen, J.D.

Dr. Christensen, J.D., has a wealth of experience with helping clients build and protect patent portfolios for medical device start-ups. His talk will focus on developing strategies for expediting patent prosecution both in the United States and internationally. Dr. Christensen will also cover topics related to the use of provisional patent applications, to the recent 'Fast Track' process implemented by the US PTO and to details of the PCT patent application process.

8. How to establish an academia-industry partnership

Presenter: Mark Gelfand, M.S.

Mr. Gelfand has more than 25 years of experience developing medical devices in academic, startup and corporate environments. His expertise is in integrative physiology, systems engineering and intellectual property. Recognizing the role of Academia in medical-device idea generation, Mr. Gelfand's talk will cover the steps required by a successful academia-



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industry partnership. Drawing on his widely successful entrepreneurship experience at companies such as Axon Therapies, Soffio Medical, Cibiem, CHF Solutions, Ardian and Respicardia and on his academic research experience from The Johns Hopkins School of Medicine, he will also present on how academicians can develop their ideas into successful medical products.