



43rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society

Starting your own company

Theme 09: Therapeutics Systems and Technologies

Keywords: Entrepreneurship, Start-Up, Intellectual Property, Venture Capital, SBIR

Abstract—

Part II of the Special Sessions is a continuation of Part I, with the same title. Whereas Part I goes into details of first seven topics, Part II expands on the last three items. These Special Sessions cover several important steps that need to be address when launching a biomedical engineering start-up, including:

- Medical device product development process
- Raising funds for early-stage proof-of-concept work
- SBIR funding, process and successful grant writing tips
- Technology transfer: how to use it and how to benefit from it
- Regulatory approval cycle (FDA, CE Mark, ISO 13485 certification) for new devices
- Clinical trials process, requirements and strategies
- Intellectual property (IP) roadmap for start-ups – proactive steps to help IP diligence go more smoothly during financing, acquisition or IPO diligence
- Overview of patent process and costs in key commercial markets
- Tips to improve patent application quality and to maximize value of IP portfolios in a cost-effective manner
- Venture capital (VC) funding, process and sources

PART I

1. How to start your own start-up

Presenter: Dr. Dorin Panescu

Dr. Panescu developed many early-stage medical technologies. He is an inventor on over 185 issued US patents and many more additional foreign patents. His talk will cover the dos and don'ts of starting up your own company. Dr. Panescu will cover important first steps in motivating entrepreneurs to pursue their ideas: identifying unmet clinical needs, performing early validation of potential solutions and obtaining actual customer feedback. He will then take the audience through how to fund development of proof-of-concept prototypes, how to build a strong engineering team, how to estimate the market potential of the entrepreneurs' idea and how to develop a regulatory strategy and to interact with respective regulatory agencies. The presentation will end with details about planning the early clinical validation of the first iteration of the product and with how to protect ideas by developing an intellectual-property (IP) roadmap.

2. SBIR grants as funding source for early-stage Start-Ups

Presenter: Dr. Dieter Haemmerich

Small business grants (SBIR and STTR) are attractive funding sources for start-ups, but have become increasingly competitive. Dr. Haemmerich has a wealth of experience with successful SBIR proposals and has also served as a reviewer of NIH SBIR grant proposals. Dr. Haemmerich's presentation will cover the 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 IP roadmaps: how to avoid common mistakes

Presenter: Theodore Papagiannis, J.D.

Mr. Papagiannis, J.D., has over 15 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. Mr. 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.

4. 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.

PART II

5. Overview of patent rights, the patent process, and typical patent costs in key commercial markets.

Presenter: Michael R. Christensen, J.D.

Mr. Christensen, J.D., has a wealth of experience with helping clients build and protect patent portfolios for medical device start-ups. His presentation will focus on providing an overview of the basic rights that patents provide, the patent process, and the typical costs of obtaining patents in key commercial biomedical markets. The presentation will also address different types of intellectual property protection and key differences in the process of obtaining patent protection in key countries/regions around the world.

6. Patent Application Basics and Tips for how to maximize value of IP portfolios in a cost-effective manner

Presenters: Theodore Papagiannis, J.D. and Michael R. Christensen, J.D.

This session will introduce various filing strategies and programs at the various patent offices around the world to maximize value of IP portfolios. For example, topics will include:

- Introduction to a patent application and general tips for patent drafting
- Strategies to reduce overall costs associated with the patent process in the US and around the world
- Opportunities to defer costs to provide more time to assess product viability and to obtain additional funding
- Strategies and tips for maximizing the value of each patent family included in a company's IP portfolio

7. Start-Up lessons learned

Presenter: Mr. Richard Schmidt, M.S.

Mr. Schmidt is a technical and business leader with extensive experience in engineering and commercializing complex medical devices focused on delivering cancer treatment. He is CSO of a medical-technology start-up company. His talk will share specific lessons-learned examples related to overcoming funding, development and regulatory hurdles. In addition, he will share helpful hints about what you need to know about your market, yourself, time management, and corporate operations. To make this all work you will need to raise money, and Mr. Schmidt will provide a guide for the various types of pitches needed and what type of information that investors are seeking.