

“The Challenge of Translation: From Bench to Bedside”

Scott P. Bruder, MD, PhD

Worldwide Vice President, Johnson & Johnson Regenerative Therapeutics

A symbiotic relationship between academic and industrial investigators is essential for the development of new therapies to treat various tissue injuries and disease. The purpose of this workshop is to provide practical information and insights regarding the pathways and processes required to bring inventions, particularly in the field of regenerative medicine, to the commercial market. The presentation will provide an overview of the product development process required of medical device and pharmaceutical companies. Discussion of intellectual property, including the creation and value of patents, will follow. Since marketing approval of products is regulated by government agencies (e.g. FDA), an exposition of the various pathways for approval will also be provided. Lastly, the presentation will describe the important scientific discipline required to translate lab scale implant formulation into reproducible and robust product manufacturing processes and controls. At the close of the session, attendees will have a greater understanding of the multi-year, multi-step process required to commercialize new products, including the major costs, hurdles and timelines. Examples of several products currently under review, or approved by the FDA, will be presented. This improved understanding has the potential to help the regenerative medicine research community function even more effectively.