Industrial Innovations in Biomaterials

Panelists: Leonard Pinchuk, David L. Kaplan, Christine E. Schmidt, Robert S. Ward
Co-Organizers: Buddy Ratner, Ann Beal Salamone
Innovia LLC, Tufts University, University of Florida, ExThera Medical Corporation, University of Washington, Rochal Industries LLP

Statement of Purpose: This panel session is to highlight four examples of successful commercialization of biomaterials. Each speaker will discuss biomedical engineering factors as well as business factors that were encountered during commercialization.

Leonard Pinchuk, Innovia LLC, Miami, FL
Dr. Pinchuk patented Nylon 12 materials for use in angioplasty catheters in 1987 and sold them to Cordis Corporation. Cordis retained >95% of the world-wide angioplasty market for the 20 year duration of the patents. *These Nylon 12 materials did very well with hundreds of tons of material sold at a cost of $6/lb.* Dr. Pinchuk also patented polycarbonate urethanes (PCU) for implantable applications. PCUs were a potential alternative to the polyether urethanes (available commercially from industry ~ $5/lb.) which demonstrated slow biodegradation as a result of oxidation of the carbon groups next to the ether in the polyether urethane. PCU does not have ether groups and showed less degradation. However, the PCU costs were 20 times that of polyether urethanes as the quantities were sufficiently small which precluded ordering chemicals by the tank car. *Selling PCU to the medical device industry was not big business.* Dr. Pinchuk then patented SIBS (poly(styrene-block-isobutylene-block-styrene)) for implant applications. SIBS does not have any labile groups on the back-bone or side-groups of the polymer to degrade. These materials demonstrated excellent bio-stability and consequently lack of inflammation; however, the cost to produce them is in the order of $2,000 - $3,000 per pound. However, *SIBS is an enabling biomaterial that enabled the TAXUS drug eluting coronary stent sold by Boston Scientific Corporation (~$3 billion/year sales) as well as the InnFocus MicroShunt® used to treat glaucoma*, which is currently in world-wide clinical trials (InnFocus, Miami, FL). The message is that synthesizing and selling biomaterials for implant applications is not big business. Enabling a new medical device with a unique biomaterial is big business. Developing biomaterials for disposable applications for high volume products can also be a big business.

David L. Kaplan, Department of Biomedical Engineering, Tufts University, Medford, MA 02155
A range of novel biomaterial systems have been generated from silk proteins. These proteins, derived from silkworm and spider silks, provide useful features such as water-based processing, biocompatibility, tailorable mechanical properties and degradability and versatility in material format. We exploit control of structure, morphology and chemistry of these protein systems to optimize biomaterial features, cell interactions and tissue related outcomes. Fundamental insight into the rules that govern some of these protein assembly processes leading to predictable material features will be discussed. These insights lead to examples of how to utilize such systems in new biomedical devices and in a broad range of new advanced materials. *These insights and applications have led to a series of new start-up companies that exploit the novel properties of silk biomaterials*, from the mechanics to stabilization and sustained delivery features. Examples will be described along with future perspectives.

Christine Schmidt, J. Crayton Pruitt Department of Biomedical Engineering, University of Florida, Gainesville, FL
Over 200,000 people in the United States suffer with paralysis resulting from a spinal cord injury. Schmidt's research team developed processing techniques for intact natural neuronal tissues so they are more usable from a clinical standpoint by (1) removing from nerve tissue its antigenic cellular components, which are the predominant cause of transplant rejection, while (2) preserving the intricate basal laminae tubes and collagen architecture of the nerve. *AxoGen (Alachua, FL) licensed the decellularization technology, creating an allogenic transplant tissue called Avance®, which it provides to surgeons as a graft for injuries to peripheral nerves, such as those in the hands and face. Avance has now been used in more than 3,000 patients.* Dr. Schmidt is currently developing multi-component hydrogels composed of natural components as a promising option to direct neuronal progenitor cell differentiation after transplantation as high efficiency is achievable without the use of non-specific growth factors.

Robert S. Ward, ExThera Medical, Berkeley, CA
Bob Ward is President/CEO of ExThera Medical, and founder of The Polymer Technology Group (PTG), now DSM Biomedical. *Bob has 43 years of experience developing polymeric biomaterials and (Class III) medical devices.* He has a long list of patents, publications and awards, plus considerable practical experience in translation to quality-system manufacturing. He will compare two commercialization examples: a device and a biomaterial.

1.) ExThera's Seraph® Microbind® Affinity Blood Filter, A broad-spectrum whole-blood hemoperfusion *device to treat drug-resistant bloodstream infections caused by MRSA, CRE, ESBL, Ebola,* etc.
2.) Reactants, and technology supporting >$2BB in sales of silicone-hydrogel contact lenses. *PTG started as a contract R&D vendor and became the largest supplier of 'reactive monomer mixes',* e.g., for J&J Vistakon's Acuvue Advance®, Oasys®, and TruEye® lenses.