TRANSITIONING FROM ACADEMIC TO INDUSTRIAL SCIENCE: A CHRONOLOGICAL LESSONS LEARNED

R. E. Phillips, Ph.D.
Vice President, Technology
BioStable Science & Engineering
Austin, Texas

The speaker will provide insight into his experiences regarding the transition from academic science to industrial science, emphasizing key learning take-aways which has helped in his growth as an industrial scientist. He will provide information in a chronological fashion, which track his learning experiences and his mistakes as he learned what role an industrial scientist can and should play in industry, be it a large corporation or an entrepreneurial start-up.

Keys to this experience which will be discussed include:

(1) how to accept and thrive in the scientist's role in a for profit entity,
(2) the importance of and how to manage intellectual property,
(3) how to manage projects,
(4) the importance of project management as a disclipline
(5) the importance of product development processes which will facilitate reproducibility in new product development,
(6) the importance of "technical PR" in promoting not just the science of a technology but the product which was based on the science,
(7) how science should be customer oriented
(8) the value of a good scientific presentation/publication
(9) the importance of marketing and sales in a science based business

CALCIFICATION/DEGRADATION OF IMPLANTABLE BIOMATERIALS-MECHANISMS AND SOLUTIONS: AN INDUSTRIAL RESEARCHER'S PERSPECTIVE

R. E. Phillips, Ph.D.
Vice President, Technology
BioStable Science & Engineering
Austin, Texas

Blood/material interaction research continues to be of great interest not only to academic researchers, but industrial researchers as well as the search for better performing and more physiologically responding biomaterials continues. Uncovering and understanding the mechanisms by which biomaterials degrade, calcify, create thrombotic responses, etc. when in contact with body fluids, tissue and/or blood are the first steps that can lead to solutions to the failure modes of specific biomaterials.

This presentation will provide an overview of a twenty-year experience in blood/ material research activities from an industrial research perspective which has lead to a better understanding of *in vivo* polyurethane degradation and calcification, as well as calcification of glutaraldehyde fixed collagenous materials. Better materials and better material choices are being developed based on this research.

We have developed a hypothesis for one potential mechanism for the calcification of many biomaterials. Our hypothesis states that there is the potential for calcium ion binding in an interaction between blood and the biomaterial that is similar for both polyether urethane polymers and glutaraldehyde fixed collagenous-based biomaterials. Both types of biomaterials contain long chain, oxygen containing polymers which we hypothesize can complex calcium ions as the initial step in a biochemical process leading to the formation of mixed calcium phosphate mineral in and on the biomaterial. If this mechanism has credence, it should be possible to chemically engineer around this interaction for polyurethanes and glutaraldehyde fixed tissues. This presentation will present solutions to this interaction for both types of biomaterials and research supporting successful resolution to the calcification failure mechanism.

Curriculum Vitae

Richard E. (Rusty) Phillips, Ph.D.

R.E. (Rusty) Phillips currently is a Founding Member and Vice President Technology for BioStable Science & Engineering, Inc. a cardiovascular implantable device development start-up company based in Austin, Texas. His current responsibilities include managing the technology and intellectual property portfolio for BioStable and serving as its technical gatekeeper, finding and facilitating the evaluation of new technology opportunities for BioStable. He is also responsible for all clinical research activities and marketing for the company. BioStable Science & Engineering is currently developing an implantable surgical aortic valve repair device for patients with aortic insufficiency and has begun development of a percutaneous mitral repair implantable device system for patients with functional mitral regurgitation.

Prior to BioStable he served as Vice President, Research and Clinical Alliances for The Sorin Group and Vice President of R&D for CarboMedics, Inc, in Austin, Texas. The Sorin Group is a diverse, global medical products company with corporate offices in Milan, Italy. CarboMedics, a Sorin Group Company, was a manufacturer and distributor of implantable medical products to include mechanical heart valves, tissue valves, valve conduits, valve repair products and valve components. Dr. Phillips' responsibilities included implementing and managing research and clinical alliances globally for The Sorin Group.

Dr. Phillips has over forty years industrial experience in polymer research and development, marketing technical support, and quality assurance of commodity and engineering thermoplastics, and most recently, biomaterials and implantable devices. He has fifteen patents and numerous publications and presentations in polymer, tissue and implant product technology. His research interests have involved work to further identify chemical interactions between synthetic implantable materials and body chemistry, and how these interactions might impact *in vivo* device performance. This research has led to the identification of a mechanism which may help explain how certain implantable biomaterials calcify during the implant experience and the subsequent development of tissue and polymer chemistries with much improved implant performance.

His responsibilities for The Sorin Group included management of all R&D activities for CarboMedics, including biomaterials research and product development projects involving polymer and tissue based materials. His prior responsibilities at Intermedics Pacemaker Co. included designing and developing new pacemaker lead products, and providing technical support to the manufacturing departments of both leads and pacemakers. He served as a teaching participant in both the CarboMedics and Intermedics accredited Physicians Education Programs.

His implant device product development interests included methods to improve the pacemaker lead electrical performance by improving the electrode stimulating efficiency at the electrode-tissue interface, improving the pacing lead endocardial fixation, and the development of leads for use with rate responsive, temperature sensing pacemakers and efficient leads for use with implantable defibrillators. His biomaterials calcification

research has been applied to the development of calcification resistant polymer and tissue materials for implantable heart valves, vascular grafts, cardiovascular patches, blood pumps, and other implant applications. His team developed anti-bacterial technology suitable for use with cardiovascular implantable devices.

Dr. Phillips received his BS in Chemistry from Southwest Texas State University and his MS and Ph.D. degrees in Chemistry from the University of New Mexico where his fields of interest were Organic Chemistry and Biochemistry. His memberships have included the American Chemical Society, the Society of Plastics Engineers, the American Society for Artificial Organs, the American Association for Medical Instrumentation, the Society for Biomaterials, the Surfaces in Biomaterials Foundation, and The Society for Heart Valve Disease.

He was a member of the Editorial Advisory Board for the Journal of Biomaterials Applications and is past president of the Surfaces in Biomaterials Foundation. He is a Trustee for Southwest Research Institute, San Antonio, Texas, and was named Distinguished Alumnus of Southwest Texas State University in 1996. In early 2007 he was inducted as a Fellow in the American Institute for Medical and Biological Engineering. He has participated in many international technical and medical conferences where he has presented his work on biomaterials technology and implant device developments. He continues to be involved with his alma mater, Texas State University, and has served as a Board Member and Treasurer of the Texas State Development Foundation, a Member of the Advisory Board for the College of Science and Engineering, and Co-chair for the Athletic Pillar for the Pride in Action capital campaign.