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Merging Medical Devices and Pharma

Dr. Ron Mojarrad, PhD (Senior Consultant Engineer and Research Advisor - Devices Advanced Development Delivery Device R&D at Eli Lilly) on the role of merging pharmaceuticals and devices to treat CNS conditions and neurodegenerative diseases - how pharmaceutical companies can work with medical device companies to develop more effective solutions.

There are many challenges in modern medicine, especially in the treatment of CNS conditions and neurodegenerative diseases, that limit the effectiveness of traditional modes of drug delivery and therapy. Challenges like the need to deliver drugs through the blood brain barrier (BBB), and the need to focus therapy to specific cell populations create the demand for new approaches to disease intervention.

Furthermore, the new devices must be designed with the patient in mind, requiring minimally invasive procedures to implement in order to increase the patient's acceptance and compliance. This is further complicated by the fact that most neural prosthetic devices require implantation for the drug to reach the targeted site while reducing the systemic side effects and gaining optimal bioavailability. Naturally, more compact and autonomous devices with greater reliability and dosing accuracy will be more desirable to deliver potent compounds.

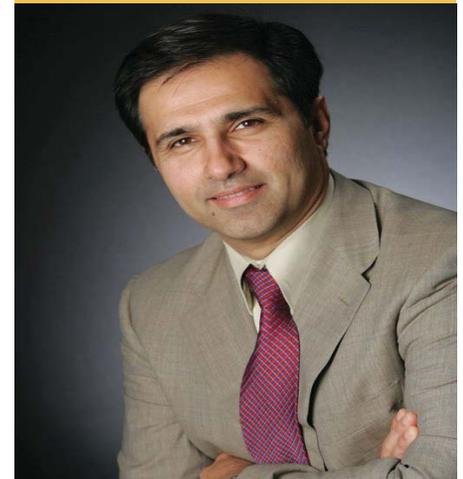
Intelligent drug delivery devices constitute an emerging field that addresses these concerns. Devices can deliver large or small molecules, including antibodies, neurotransmitters, hormones, or pharmaceuticals, across the BBB to specific sites within the brain. Without the use of such

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DIRECTOR'S MESSAGE

Mark S. Humayun, MD, PhD



Thank you to everyone who participated in our annual National Science Foundation (NSF) site visit and Industrial Advisory Board meetings this past June in Los Angeles. We had an impressive turnout by BMES ERC Industry partners, faculty and students. Overall, the meetings went well and we are happy to announce that the Center will continue to be funded through Year 7.

I would like to touch on a couple of key points that were raised by the NSF site visit team. In light of Dr. Sean Caffey's departure, it was recommended that additional staff hired have experience and background in ERC research. The BMES responded by hiring Jack Whalen, PhD, who will be

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the new Industrial Liaison Officer (please refer to Dr. Whalen's article in this newsletter). One of his many focuses will be to continue to identify and recruit corporate partners that complement the technology and research of the Center. Please join me in welcoming Dr. Whalen to our team.

Another recommendation was to increase the number of student internships with Industry partners. The BMES responded by putting together a subcommittee comprised of Industry partners to advise on ways to increase interaction between students and Industry and to provide insight on shaping the program (please refer to the article in this newsletter). Our objective is to develop a program that matches students and Industry partners with projects which are mutually beneficial. This will also allow Industry personnel to become more involved in specific ERC research projects. The Center will benefit from the knowledge industry personnel will bring to our research projects and industry personnel will benefit from exposure to the latest technologies ahead of the curve.

We are grateful for the NSF funding and will continue to pursue our goal of becoming self-sufficient by the time the ERC reaches the end of its term in 2013. We recognize that establishing long-term relationships with Industry partners is key to the ERC's sustainability. With the addition of Dr. Whalen, we hope to continue to strengthen our current Industry partnerships as well as establish new relationships in order to ensure that our mission to create innovative solutions for unmet medical and biomedical needs is realized.

Greetings from the New Industrial Liaison Officer

By J. Jack Whalen, PhD



A few months ago, Dr. Humayun offered me the opportunity to rejoin the BMES team to head the Industry Partnership Group. My prior involvement had been as a PhD candidate and a post-doctoral researcher over 3 years ago. Since then the Center has come a long way in developing new technologies, and so it is with great joy that I join this group again.

It has been exciting reorienting myself with the BMES and its progress. I hope to share this excitement and energy with all of its participants in the near future. To help set the tone that we would like to adopt in the industry group, I'd like to take a quote from the Engineering Research Center Association that defines what an ERC is "supposed to be" – something that I believe is particularly important that we revisit given today's economic environment:

"Each ERC provides an environment in which academe and industry can collaborate in pursuing strategic advances in complex engineered systems and systems-level technologies that have the potential to spawn whole new industries or to radically transform the product lines, processing technologies, or service delivery methodologies of current industries."

In a time when our headlines are overwhelmed with concerns over the cost of healthcare and job losses, the BMES has the unique opportunity of playing a leading role by first creating and developing new - and potentially cost-effective - solutions to medical problems; and second, by potentially helping spawn new industries – which translates into more jobs for all. I think we're up for the challenge!

The BMES is entering its 7th year many of the early technologies created in our laboratories are beginning to mature into more developed concepts, embodi-

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Similar Skills Applied in Different Settings

By Brooke Basinger, PhD



There is a vast, insurmountable divide between Academia and Industry. At least, that's what some in Industry would have you believe. And it's true – if you opt to go into industry you might find yourself wearing suits to work instead of pajamas, planning your 401(k) investment strategy instead of planning your free pizza smuggling strategy, speaking in code words and company-speak instead of in three-letter building name and department acronyms, or painfully waking up

on the wrong side of 6 a.m. everyday. But whatever those on the Industry side might think, the technical skills that you've developed in Academia are the same ones that you'll need to survive in Industry.

I graduated from USC with a Ph.D. in Biomedical Engineering in May, 2009. After finishing my thesis work (Modeling Retinal Prosthesis Mechanics) under the guidance of Dr. Mark Humayun and Dr. Jim Weiland, I began hunting for a medical device design job in industry. I landed several interviews, but quickly discovered that interviewers (and hiring managers) weren't quite sure what to do with me or my background. I was too experienced for an entry level position, but they weren't convinced that my primarily academic background would be useful in industry.

But, in part through the ERC and though USC's MDDE degree, I had experience contributing to FDA applications, understanding clinical trials, establishing intellectual property, designing experiments, buying equipment, analyzing data, documenting results, working with cross-functional groups, and reviewing and presenting my work both internally and externally. That experience helped to shape my resume into something more appealing to potential employers ... a PhD can come out of the labs with some real-world experience!

Despite the recent economic decline, I was fortunate enough to receive a

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BMES Faculty Awards & Recognition

Mark Humayun, MD, PhD

Congratulations to Dr. Humayun for being a newly elected member of the Institute of Medicine (IOM). The IOM elects 65 new members and 5 foreign associates annually. Election to the IOM is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service.

Ellis Meng, PhD

Congratulations to Dr. Meng for receiving the prestigious TR35 – a recognition by *Technology Review*. The editors of *Technology Review* select young innovators whose inventions and research they find most exciting and are changing the world – a list of technologists and scientists, all under the age of 35.

Dr. Meng's work on micro-pumps delivering drugs that prevent blindness was recognized. Her implantable device for drug delivery to the eye consists of a chamber that stores the medication; a pump; and a tiny tube that enters the eye. Dr. Meng's pump is refillable unlike existing implants that must be replaced once they run out of the drug. Its design eliminates the need for repetitive injections or monthly surgeries, allowing the patient to make one visit to the operating room which dramatically reduces both pain and risk. The pump is still in being tested in animals with human testing being a possibility within 5 years.

The Engineering for Health Academy: A Specialized Secondary Program Preparing High School Students for a Career in the Biomedical Engineering Profession

By Joseph Cocozza, PhD

The BMES ERC is acutely aware of the critical need for a well trained and highly skilled workforce in biomedical engineering. In order for the United States to remain competitive in science and engineering the education of the next generation in Science, Technology, Engineering and Mathematics (STEM) fields is critical. Too few US high school students, however, are choosing engineering as a college major and many of those who are interested in engineering do not take the requisite courses in high school that will help them succeed in college. In an effort to increase awareness and support of science and engineering among pre-college students, BMES ERC Outreach, under my directorship, has partnered with Francisco Bravo Medical Magnet High School in Los Angeles to establish the Engineering for Health Academy (EHA). The EHA is modeled as a small learning community within the context of the larger comprehensive high school. The Academy offers students in grades 10 through 12 a new and innovative course of study comprised of 4 integrated classes focused on biomedical engineering.

The EHA has four major goals: 1) to introduce high school students to the relationship between engineering and the medical sciences; 2) to design and implement a series of integrated core courses that are experiential in nature, standards-aligned and directly relate content knowledge and skill mastery to student-centered engineering projects; 3) to place third year EHA students in USC biomedical engineering research laboratories and/or in industry summer internships as part of a capstone course; and 4) to prepare students to undertake and succeed in a rigorous postsecondary engineering education pathway.



An EHA student monitors his heart rate and blood pressure while performing an aerobic exercise using a Wii.

It is hoped that as a result of offering EHA students a rigorous but relevant academic curriculum; opportunities to translate STEM theory into practice; college and career counseling; and other support mechanisms early in their education, these bright students will pursue and excel in baccalaureate and graduate programs in biomedical engineering. A longitudinal study of EHA students as they progress through their education and career trajectories will inform the continued development of the EHA program as it strives to become a national educational model.

The EHA receives funding from the California Department of Education and the National Science Foundation.

Merging Medical Devices and Pharma

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delivery devices, many therapeutic compounds cannot penetrate the BBB, and therefore cannot exert their therapeutic benefit. Further, the targeted delivery of these devices can limit the exposure of the therapeutic molecule to only those areas where therapy is needed.

There is also ample data supporting the effective use of electrophysiological stimulation in the treatment of CNS conditions where specific cell populations are affected. Implantable devices are used in the treatment of Parkinson's disease, supplying low-level, sustained electrical pulses to the basal ganglia, eliminating disease-associated motor impairment. Devices in development for the treatment of epilepsy can detect abnormal neuronal firing patterns in the cortex, and respond with electrical pulses that control the excitatory circuits that underlie involuntary seizures. Controlling the over-excitation responsible for epileptic seizures is widely accepted as vital to the prevention of damage to the surrounding neurons. This "preventive medicine" could effectively reduce costs that arise from complications of epileptic seizures.

The examples above indicate that devices can bridge the divide between a drug with an effective *in vitro* mechanism-of-action and chemistry, and its clinical use, through targeted delivery and minimal systemic side-effects.

The pharmaceutical and medical device industries should devote greater resources to the development of intelligent delivery devices in the neurologic disease categories. A potential advance in the field could combine the strategies discussed above in one intelligent device. Such a device could monitor electrophysiological signals from the brain and other parts of the body for abnormal activity, and take subsequent action by not only delivering electrical stimuli, but also metering precise doses of the drug to the site in question.

These are exciting times in medicine and biomedical engineering. Improving efficacy through new technologies, advances in currently approved therapies, and merging these efforts where possible, can create new markets within the industry, and provide a large impact on the treatment of disease. As researchers and developers in the areas of medical devices and pharmaceuticals, our challenge is to seize this opportunity to further advance the frontiers of medicine.

Subcommittee for Student-Industry Relations

In response to the National Science Foundation's recommendations this past June at our annual site visit, we have put together a subcommittee comprised of Industry partners.

Our goal is to create an environment for students and industry that fosters dialogue and an exchange of ideas, focusing on student development and enriching the BMES experience for both parties. We hope to achieve this by establishing a program that consists of a mentorship and/or internship component.

The subcommittee is scheduled to meet this fall. We have received enthusiastic support from our industry partners, faculty and students. We look forward to working with our partners to help shape this program. We would like to extend our gratitude to our subcommittee members for investing their valuable time to this new endeavor.

Academic Institutions Executing the BMES ERC's Research and Technology Transfer Programs:

Lead Partner:

- University of Southern California
(Los Angeles, CA)

Core Partners:

- California Institute of Technology
(Pasadena, CA)
- University of California, Santa Cruz
(Santa Cruz, CA)

Collaborating Institutions:

- Alfred Mann Institute
(USC, Los Angeles, CA)
- California State University, Los Angeles
(Los Angeles, CA)
- Jet Propulsion Laboratory
(Pasadena, CA)
- Los Angeles Unified School District
(Los Angeles, CA)
- North Carolina State University, Raleigh
(Raleigh, NC)
- University of Kentucky, Lexington
(Lexington, KY)
- Wake Forest University
(Winston-Salem, NC)

Greetings from the New ILO

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ments and even prototypes. Our goal as this ERC's industry group is to focus attention on translating these technologies from research & development into commercialization.

We do this by providing key support to researchers forging new collaboration and by facilitating interaction between the two parties. After speaking with some of you - our industry partners - I've become aware that more dialogue needs to take place between the center and you. In these first few weeks, we have already started to take action by: preparing this Newsletter release, working to update our BMES webpage, assembling a subcommittee to organize a student-industry interaction program, and preparing a compendium of current research activities that includes potential applications for each project.

In the next several weeks and months you will be hearing more from the industry partnership group as we try to help bridge that gap between science & technology and industry & commercialization. We look forward to an exciting year ahead!

Upcoming Events

- **Industrial Advisory Board Meeting—March 19, 2010 (Santa Cruz, CA)**
Please SAVE-THE-DATE and mark your calendars.
- **Industrial Advisory Board Meeting—June 2, 2010 (Los Angeles, CA)**
Please SAVE-THE-DATE and mark your calendars.
- **NSF ERC Site Visit—June 3-4, 2010 (Los Angeles, CA)**
Please SAVE-THE-DATE and mark your calendars.
- **NIC 2010—June 21-23, 2010 (Long Beach, CA)**
Visit www.neuralinterfaces2010.com for more information on the 39th Neural Interfaces Conference or contact Dr. Jim Weiland at jweiland@usc.edu.

Similar Skills Applied in Different Settings

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handful of offers from medical devices companies. Did I convince them I understood schedules, budgets, and the need to produce a profitable product? I guess so!

I accepted a position as a Program Engineer on a Research & Development team developing intraocular lenses at Abbott Medical Optics. I spend my time creating and revising test methods, troubleshooting equipment, improving the manufacturing process, modeling the interaction of our device with surrounding tissues, analyzing data, writing lots and lots of documents, and navigating the corporate environment. The work has been challenging and I learn new things every day (particularly about manufacturing processes)

but the technical skills, scientific curiosity and rigorous thought process that I developed as a graduate student are the very things that I've needed to be good at my new job.

The ERC has helped me develop many of the skills I need and use every day in Industry. I know many of my classmates will finish with those same skill sets as well. While a recently minted PhD researcher may not seem like the ideal fit in your R&D group, maybe they could make that additional impact that your R&D group is currently missing!

BMES ERC Students in the News....

- Biomedical Engineering PhD Candidate Jae Kyoo Lee won the American Society for Nanomedicine's "Young Investigator Award" at its inaugural conference in Potomac, MD (October 22-25, 2009). Lee is a student in Dr. Anupam Mahukar's lab.
- Biomedical Engineering PhD Candidate Xiwu Cao won the Biomedical Engineering Society's "Graduate Research Award" at its conference in Pittsburgh, PA (October 7-9, 2009). Cao is a student in Dr. Norberto Grzywacz's lab.



BMES ERC Student Events:

The 14th Annual Fred S. Grodins Symposium for graduate student research from the USC Viterbi School of Engineering will be held on April 10, 2010 (8am—5pm) at the Los Angeles Convention Center. For information, please contact Navya Swetha Davuluri at navyaswetha@gmail.com.



BMES ERC Website:

Visit the BMES website at <http://bmes-erc.usc.edu/industry> for information on the Center and regular updates on events and meetings.

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Senior Partners:

Abbott Medical Optics



Technology Partners:



Harvest Precision Components

