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SurFACTS in BioMaterials

Fall 2015 Volume 20 - Issue 3

Note to Our Readers

This is the second edition of SurFacts transitioning from our traditional PDF to a web-based format. The reason for this change is to make reading and accessing the newsletter content faster and easier. We have included news and announcements in the body of the newsletter with links to individual PDF versions of the longer technical articles. We hope you like the change.

Feedback regarding this new format is encouraged and should be provided to the newsletter Executive Editor Joe McGonigle at jmcgonigle@surmodics.com.

25th Anniversary of BioInterface

Surfaces in Biomaterials Foundation History

By Larry Salvati, SIBF Founder and Past President

So you want to know the history of the Surfaces in Biomaterials Foundation. Well here goes.

It was February 1969, I was listening to a lecture on Boyle's Law in science class and it hit me. "Someday I am going to be a famous scientist, I am going to make a major medical breakthrough and I am going to found the Surfaces in Biomaterials Foundation. So here it is 40 years later, I am 1 for 3 and someday I may still make that breakthrough medical discovery and become a famous scientist. But for now, let's concentrate the one goal that I did manage to accomplish.
The Surfaces and Biomaterials Foundation was founded in October, 1991. It was founded during the "First Annual" Surfaces and Biomaterials Symposium, which later was renamed as BioInterface. By the way the first Surfaces in Biomaterials Symposium was not planned, sponsored or hosted by the Surfaces in Biomaterials Foundation. As a matter of fact, there was only one sponsor for the very first symposium and that sponsor was Perkin-Elmer, Physical Electronics.

Read More About Surfaces in Biomaterials Foundation History (PDF)

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Member News

BioInterface 2015 was held at the Fairmont Scottsdale Princess from September 21 -23. This 25th anniversary of the BioInterface was attended by over 130 people and featured a one day workshop on hemocompatibility and two days of the main conference program. The meeting was the 25th anniversary of BioInterface. For more on the history of the meeting please see the article by Larry Salvati in this issue. The SIBF would again like to thank all the sponsors, exhibitors and attendees for continuing to make this a successful and unique meeting. We look forward to seeing everyone next year in Minneapolis (Date TBD). If you have any feedback on the meeting or would like to be involved in future meeting planning please let us know.

SIBF is looking for volunteers to help with the membership and SurFacts newsletter committees. If you are interested in getting more involved with the group please contact someone from the SIBF board. Board members were elected at the most recent meeting.

SIBF 2016 Board of Directors

- President: Chander Chawla, DSM
- President Elect: Bill Theilacker, Medtronic
- Vice President/Workshop Chair: Joe McGonigle, Surmodics
- Past President: Aylvin Dias, DSM
- Treasurer: Rob Kellar, Development Engineering Sciences
- Secretary: Roy Biran, W.L. Gore & Associates
- Individual Representative: Joe Chinn, J Chinn LLC

- Academic Member Representative: Norman Munroe, Florida International University

Bausch & Lomb received FDA 510K clearance of a special lighting system for its Stellaris® PC Vision Enhancement System. This system is an adjustable chandelier fiber system to provide improved lighting for surgeons during vitroretinal procedures. Bausch & Lomb also announced FDA acceptance of an IND filing for a new glaucoma drug called VESNEO™. The drug is a nitric oxide donating prostaglandin receptor antagonist designed to lower intraocular pressure and functions though both signaling by latanoprost and nitric oxide.

SurModics received FDA IDE approval to conduct a first-in-human early feasibility study of its SurVeil™ drug coated balloon. The approval is a major step forward in the company's plan to become a whole-product solution provider to the medical device industry. The company expects to enroll its first patient in the second quarter of its 2016 fiscal year and has lined up three clinical sites in the U.S. The SurVeil drug coated balloon uses a proprietary drug-excipient formulation in combination with a new manufacturing process and the SurModics Serene™ low-friction, low-particulate coating.

DSM Biomedical announced through its parent company, Royal DSM, a collaboration between Somos®, a DSM additive manufacturing materials business, and EnvisionTEC, a supplier of professional grade 3D printing solutions. The collaboration is intended to take advantage of high performance materials to open the door to new applications in the 3D printing industry.

Medtronic made several acquisitions in the last few months including: Twelve, a developer of Transcatheter mitral valve replacement technology; Lazarus Effect, a device company developing products for removal of clots in ischemic stroke; and Medina Medical, a manufacturer of a novel intrasaccular mesh device for treatment of aneurysms. In the area of drug coated balloons, Medtronic released positive two year data from the IN.PACT SFA trial showing superiority to standard balloon angioplasty. It also released results showing cost effectiveness for drug coated balloons overall, and effectiveness for these devices in treating in stent restenosis. The company will be initiating a new study, called REALITY, to look at drug coated balloon treatment after directional atherectomy.

Medtronic also released new data on the use of its novel Drug-Filled Stent (DFS). Early results showed well controlled stent coverage which may be an advantage compared to bioabsorbable or polymer free technologies. The company also released data on its CoreValve® Evolut® R System showing exceptional results at one year. A study in Europe demonstrated a very low rate of mortality in extreme and high risk patients using the next-generation recapturable, self-expanding valve. Medtronic also launched the Arc™ support catheter for use with the Solitaire™ stent retriever. The device uses a novel progressive coil design for improved delivery of the stent retriever for the fastest route to restoring blood flow.

Brightlands opened a new biomedical laboratory as part of the Chemelot Institute for Science and Technology (InSciTe). The new facility provides a common space for scientists and entrepeneurs to work jointly on commercialization of new scientific concepts in a public-private partnership model. An early program is the fabrication of materials for engineering blood vessels. The lab features specialized facilities and equipment and is designed to accommodate multiple projects simultaneously.

Evans Analytical Group released a new white paper on Surface and Interface Characterization of Polymers. The paper can be downloaded on their website at: http://www.eag.com/08-20-15-surface-and-interface-characterization-of-polymers.html. On the lighter side, the company was excited to win 1st place in the category of Artistic Microscopy at the 2015 Microscopy and Microanalysis conference in Portland, Oregon. The winning entry was an image of metal shavings that came from sword during the forging process.

Cooper Vision opened a new 300 employee facility in the Rochester area. The building in Victor, New York will be home to employees in marketing, sales, finance, information technology, customer service, and supply chain management. Currently Cooper Vision has over 80 percent of its US operations and global manufacturing and logistics in the region.

W.L. Gore & Associates was very pleased at a recent announcement from CMS to reclassify endovascular aneurysm repair (EVAR) to a new category that will result in increased reimbursement for procedures. The decision came as a result of a data analysis by Gore to better align payment with cost with the ongoing shift from open surgery to minimally invasive surgery. Currently EVAR accounts for 80% of abdominal aortic aneurysm repair in the U.S. which is a major growth since its first use in 1992.

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Update on CDRH Research Priorities Relevant to Biomaterials and Surface Science

By Phil Triolo PhD, RAC

FDA's CDRH (Center for Devices and Radiologic Health) recently published its "Regulatory Science Priorities (2016)" after its RSS (Regulatory Science Subcommittee) assessed and prioritized the Center's regulatory science needs. Two of the ten identified priorities, all which can be found at http://www.fda.gov/MedicalDevices/ScienceandResearch/ucm467550.htm, are of particular interest to the surfaces community:

- Modernize biocompatibility / biological risk evaluation of device materials
- Advance methods to predict clinical performance of medical devices and their materials

The specific information provided by RSS on these priorities follows:

> **Modernize biocompatibility / biological risk evaluation of device materials:** The typical biological risk / biocompatibility assessment approach for devices would benefit from considering alternative approaches to the standard biocompatibility battery of tests. For example, the development of improved tools/methods to assess and predict biological risk factors of devices as well as the integration of chemical characterization, computational or *in silico* modeling could translate into lessening the dependence on animal testing.
>
> **Advance methods to predict clinical performance of medical devices and their materials:** There is a gap in the availability of tools and methodologies to assess the impact of various materials and material types on the quality, performance and safety of medical devices, particularly when trying to predict long-term clinical outcomes. There is a need to improve the nonclinical assessment of physicochemical and mechanical performance of devices. Methodologies and tools to more accurately predict the clinical impact of new materials and technologies such as surface coatings, materials corrosion and additive manufacturing, on device quality, performance and safety, could promote the development of alternative materials, enhance predictability of nonclinical performance to represent longer-term performance and increase safety in device design.

Both of these priorities emphasize the need for improved tools and methods to assess physicochemical and mechanical performance of materials and devices and to more accurately predict risk factors and clinical safety and performance. CDRH's priorities with regards to materials used in devices (including surface coatings!) are the same as those of the SIB and its members. There appears to be an opportunity for collaboration with CDRH to address its research priorities. According to the report, the priorities serve as a precept for making strategic intramural research funding decisions to ensure that intramural research funding and efforts are relevant to CDRH's regulatory science needs. The report further states, "We envision that our external stakeholders can use these priorities to better target their regulatory science resources as well complement these activities. In addition, we believe that collaboratively we can work to maximize the impact of regulatory science research investments."

RSS can be reached at CDRHRegScience@fda.hhs.gov **for details on its priorities and to discuss potential collaborations.**

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Zeta Potential Measurements for Particles and Solid Surfaces

By Dehua Yang, Ph. D.; *Ebatco*
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Part I: Zeta Potential of Silica Slurry as a Function of pH

In colloidal systems, Zeta potential is the electric potential at the slipping plane in the double layer surrounding a particle suspended in a fluid, in reference to a point in the bulk fluid far away from the particle. In other words, zeta potential is the potential difference between the dispersion medium and the stationary layer of fluid attached to the dispersed particle. The double layer is composed of the Stern layer attached to the particle and the diffuse layer. The Zeta potential, measured in mV at the slipping plane is widely used as a measure of the particle stability in colloids. The higher the Zeta potentials absolute values are the more stable the particles in the colloids.

Read More About Zeta Potential Measurements (PDF)

Discerning *in-vivo* Corrosion Mechanisms and Failure Modes of Explanted Prostheses – Part II

By Norman Munroe, Vishal Musaramthota, Christopher Emerson and Kinzy Jones

Because of their excellent mechanical, tribological, and electrochemical properties, cobalt chromium molybdenum alloys have been used in orthopedic implants and as the material for both the stem and head of modular hip implants. Corrosion is one mechanism by which metal debris from these implants is generated, which can lead to adverse events that require revision surgery. Manufacturing process of hip implants, such as wrought, as-cast, and powder metallurgy, and post processing treatments will determine the microstructure of each implant alloy.

Read More About Discerning *in-vivo* Corrosion (PDF)

Membership

The Foundation proudly spotlights your corporate/institutional expertise throughout the Foundation's print and online publications. As a Supporting Member, you are a leader with a voice in the future development of the surface biomedical community by participating in the governing committee. You will have the opportunity to participate in topic selections for the annual BioInterface Conference. Your company also has a voice in selecting the governing Board of Directors. Each supporting member has one vote. Other Benefits Include:

- Discounted member rates at BioInterface
- Name recognition in Foundation publications distributed to surface science professionals around the world
- One complimentary registration to the BioInterface symposium (does not include the Workshop)
- Complimentary exhibit booth at the BioInterface Exhibition

- 40% discount on all advertisements in SurFACTS newsletter and the Surfaces website

Join Surfaces Today!

Submit Content for Next Issue by January 8

"Surface Highlight"

The *Surface Highlight is a half-page article dedicated to one company in the surface science industry!**

Your article will be placed in SurFACTS in Biomaterials, the official newsletter of the Surfaces in Biomaterials Foundation! Reach the unique niche the Foundation has to offer with an entire article dedicated to your company, giving potential clients detailed information on your products and services.

For further exposure, place a half-page advertisement next to your *Surface Highlight* article for even more visibility!

For general information on advertising contact our Business Development Department at (651) 290-6267 for more information.

*The *Surface Highlight* article is limited to 1500 words and should be submitted to Executive Editor Joe McGonigle on or before the Submissions Deadline. Article submission does not guarantee publication.

Submission Deadlines

Winter (2016 edition) - January 8, 2016

This includes stories and advertisements. Most SurFACTS are published a few weeks after the Submission Deadline ends.

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Members are encouraged to submit articles for future editions of SurFACTS. Please email your report (with all appropriate figures and graphics) to Staff Editor Jazzy McCroskey at jasperm@surfaces.org for consideration in a future issue. Deadlines for upcoming issues are posted.

Surfaces in *Biomaterials* Foundation

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