SurFACTS in Biomaterials

Spring 2014
Volume 19, Issue 2

How New Biomaterials Will Enable Next-Generation Structures

By Josh Simon, Ph.D., business development manager, Secant Medical, Inc. (Perkasie, PA)

Through the introduction of new materials, the latest generation of biomedical textile structures will take the leap from minimizing interference with the natural healing process to structures that actively participate in tissue regeneration. Most resorbable devices on the market are made from a combination of poly lactic acid (PLA), poly glycolic acid (PGA), poly caprolactone (PCL), or poly dioxanone (PDO). In general, many engineers gravitate toward materials that have a long and successful track record, because taking a new biomaterial to market is associated with high costs and high risk. More stringent FDA and EU regulations for today's new biomaterials can involve additional testing requirements to demonstrate safety and biocompatibility.

Overcoming the challenges associated with using new biomaterials is not impossible. First, it requires relinquishing the fear of failure. Second, it requires partnering with entities that can conduct the studies that provide safety and biocompatibility data. In this scenario, it is important to separate the device developer from the material developer, as this can spread out the cost and risk. In addition, if material development companies or laboratories invest in the early research necessary to satisfy regulatory requirements, corporate interests will be more confident in their use of the material.

Newer materials, such as poly(glycerol sebacate) (PGS), are in the early stages of commercialization. Early testing of PGS demonstrates that it is a suitable candidate for inclusion in the latest generation of medical technologies.1, 2 PGS originates from the laboratory of Dr. Robert Langer and his post-doctoral assistant at the time, Dr. Yadong Wang. A combination of two monomers (glycerol and sebacic acid), the bioresorbable polymer's degradation products have known compatibility with the Krebs Cycle of metabolism.3 In addition, the degradation products are less acidic than

How New Biomaterial Will Enable Next-Generation Structures continues on pg. 2

Inside This Issue

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

lactic and glycolic acid, and have been shown to produce less acute and chronic inflammation due to polymer breakdown.4

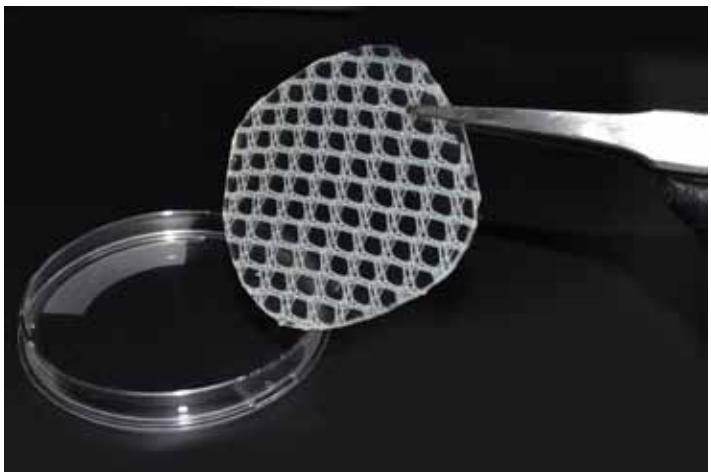
PGS can also have its own diverse formulations and act as a platform for regenerative healing. The reaction between glycerol and sebacic acid can occur over short periods of time (up to 48 hours) or longer periods (up to four days), all of which result in different degrees of polymerization. At low levels of polymerization, PGS becomes a hydrophilic gel; higher levels create a flexible bioelastomer. And as the reaction proceeds further, the bioelastomer becomes a thermoset with more hydrophobic character. At all points between these extremes, the polymer's acid number is specific, and this correlates to the number of free hydroxyl groups on the backbone. Free acid and hydroxyl groups act as attachment sites for other molecules, which can be useful for crosslinking the polymer or hooking up active agents to it.

The nearly limitless potential combinations, including changing the polymer's molar ratio and acid number, mean that PGS can be customized for next-generation medical applications. Textile coatings produced from these combinations are one way to add value to the medical devices they adorn; this value comes in the form of increased capabilities for new and established devices, and a more coherent method for addressing a specific injury or therapeutic application, such as an enhanced treatment that reduces the incidence of biomaterials-related complications and promotes tissue healing.

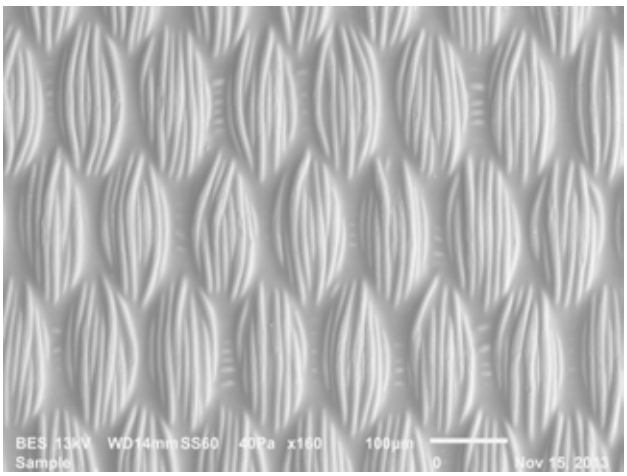
As a surface eroding material, the degradation profile of PGS can be controlled so the material does not experience a sudden breakdown. When working with bulk eroding materials such as PGA or PLA, loss of strength occurs as water molecules penetrate deeper into the structure to hydrolize its chemical bonds. This can lead to a drop in local pH, which can contribute to increased inflammation and catastrophic loss of mechanical strength. Surface degradation mechanisms like the one exhibited by PGS allow the cell load to be transferred in a manner that does not cause sudden failure, and there is a far less severe pH decrease, which helps preserve the tissue healing process. By controlling the exact ratio of the two monomers that make up the polymer, engineers can control the speed of this process.

PGS has considerable potential in a range of medical device applications, including surgical meshes, heart valves, tendon and ligament repair, and nerve regeneration. Fibers drawn from the material could have interesting properties as well. Depending on how many layers are built into the fiber, core-sheath techniques can be used to form fibers with dual, tri, or quad functionality. A multi-layer fiber can have a quickly degrading outer layer designed to address inflammation and an inner layer with a slower degradation profile that contains crucial agents for middle and later stages of healing. For bone tissue, this could be an outer layer with a polymer created from salicylic acid, set above an inner layer that contains osteocalcin or another growth factor involved in mid-to-late bone formation.

How New Biomaterial Will Enable Next-Generation Structures continues on pg. 3



A PGS barrier membrane reinforced with a knitted mesh.



This SEM image shows low-profile PET coated with PGS.

How New Biomaterial Will Enable Next-Generation Structures continued from pg. 2

An SEM image of a PGS-coated PET knitted mesh.

By creating structures that improve the long-term chronic response via reducing inflammation and enabling the body to regenerate on its own, a new generation of biomaterials will present a value proposition that cannot be ignored in the healthcare environment of today and the future.

References

1. Wang, Y., Ameer, G.A., Sheppard, B.J., & Langer, R. (2002). A tough biodegradable elastomer, Nature Biotechnology, 20(6), 602-606.
2. Rai, R., Tallawi, M., Grigore, A., & Boccaccini, A. (2012). Synthesis, properties and biomedical applications of poly(glycerol sebacate) (PGS): A review, Progress in Polymer Science, 37(8), 1051-1078.
3. Pomerantseva, I., et al. (2009). Degradation behavior of poly(glycerol sebacate), Journal of Biomedical Materials Research Part A, 1038-1047.
4. Sundback, C.A. (2005). Biocompatibility analysis of poly(glycerol sebacate) as a nerve guide material, Biomaterials, 26(27), 5454-5464.

Josh Simon, PhD, is business development manager at Secant Medical, Inc. (Perkasie, PA).

Regenerez™

Regenerez™, a bioresorbable elastomer from Secant Medical, is made from poly(glycerol sebacate). It is synthesized via a two-step polycondensation reaction between glycerol and sebacic acid. Its flexibility and inherent elastomeric properties make it an ideal biomaterial for tissue engineering in a variety of regenerative applications.

Features and Benefits

- Bioresorbable
- Simulates modulus of human tissue
- Tunable mechanical properties
- No harmful immune response
- Versatile platform for further modifications
- Surface eroding

secantmedical®

www.secantmedical.com

Member News

Medtronic released unfavorable results of the SYMPLICITY HTN-3 trial of renal denervation for hypertension treatment. The therapy was safe but did not show efficacy in reducing hypertension as compared to the control arm. The company remains committed to further clinical investigation of the technology. Medtronic also released results from the IN.PACT SFA Trial using drug coated balloons to treat arterial disease in the upper leg. Results showed reduced revascularization rates and better patency at 12 months for the drug coated balloon as compared to standard balloon angioplasty.

Saint Jude Medical received FDA approval for the Allure Quadra™ CRT, Assurity™, and Endurity™ pacemakers. The company also performed the first US implant of the Nanostim™ leadless pacemaker. This innovative device is implanted directly in the heart through the femoral vein and is expected to reduce pocket infection and lead failure.

Corline Systems was accepted to be part of a consortium led by the Bio-X grant vehicle of Uppsala University to develop its heparin coating technology for kidney transplantation. The project will develop pre-clinical data using Corline's CHC™ technology to prevent ischemia/reperfusion injury following kidney transplantation.

Boston Scientific received CE Mark approval for the REBEL™ platinum chromium coronary stent system in March. This stent is identical to the Promos PREMIER™ drug eluting stent but does not contain the Everolimus drug and is for use in patients not suitable for treatment with DES. Boston also launched the OffRoad™ Re-Entry catheter system to treat arterial blockages in the legs. The catheter is designed to navigate around the blockage in the subintimal space and then re-enter the vessel past the occlusion so that a guidewire can be delivered.

DSM Biomedical announced a partnership with Sayan Orthopaedics to use the Dyneema Purity® fiber to replace stainless steel in devices for trauma treatment. The braided fiber is expected to provide better patient comfort by promoting better integration with bone.

Carmeda announced the publication of a new study comparing hemocompatibility and antithrombin uptake on various heparin surfaces. In this study end-point attached heparin showed better thromboresistance and reduction of platelet attachment and activation as compared to other heparin surfaces.

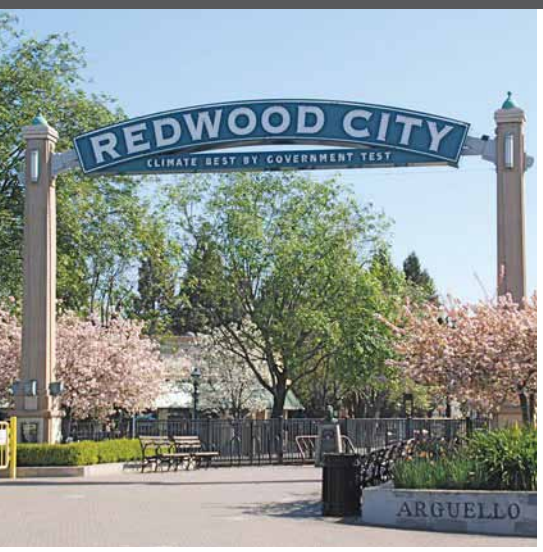
W.L Gore announced results of the REVISE clinical study on the use of stent-grafts to prevent stenosis and thrombosis in arteriovenous access patients. The study compared the GORE® VIABAHN® endoprosthesis to angioplasty in target lesions and showed superior patency at 24 months. There was no increase in adverse events and reduced repeated interventions. Gore also enrolled the first patient in a study using the TAG® Thoracic Branch Endoprosthesis. This device provides an endovascular option to treat thoracic aortic aneurysms requiring coverage of the left subclavian artery.

Bausch & Lomb launched PeroxiClear™ a new peroxide-based lens care solution. The new cleaning solution provides extended moisture and is neutralized in 4 hours rather than 6 as for most other peroxide-

Member News continues on pg. 5

SurFACTS in Biomaterials is the official publication of the foundation and is dedicated to serving industrial engineers, research scientists, and academicians working in the field of biomaterials, biomedical devices, or diagnostic research.

Save the **Date!**



Surfaces in *Biomaterials* Foundation

BioInterface 2014

October 6-8, 2014

Redwood City, California

Member News continued from pg. 5

based systems. The company also began to roll out its new ULTRA™ contact lenses with MoistureSeal™ technology. These lenses combine a new material and manufacturing process for improved lens performance.

Covidien issued a voluntary recall of its Pipeline™ Embolization Device and Alligator™ Retrieval Device due to issues with delamination of the PTFE coating from delivery wires. No reports of patient injuries have been received. In March, the company launched the Symbotex™ composite mesh for hernia repair. The mesh combines a porous hydrophilic textile for strength and memory shape with a bioabsorbable collagen film to minimize adhesions. Covidien will also discontinue the OneShot™ Renal Denervation program due to slow development of the renal denervation market.

CooperVision announced the start ofe Eye Care Prime Premier in the US. This service provided digital marketing, consulting and execution services to eye care practices.

Patent Valuations, Unlocking the Value in your Patent Portfolio

By Colin Fairman

While I have previously discussed various issues in patent prosecution and after-issue exams, in this issue I want to discuss the actual value that may accrue to a patent and how that value can actually be determined. While inventors always have subjective opinion of how much their inventions are worth, obviously, that value must have an objective basis. Any objective value of a patent must be based on how much particular aspects of a patent can be licensed for or how much the patent can be sold – in toto – to a third party. Such objective valuations have several methods of determination.

Generally, it is recognized that there are four approaches to patent valuations .

1) *Cost Approach*

This approach states that a patent's value is the replacement cost - the amount that would be necessary to replace the protection right on the invention. Essentially, this method simply identifies the costs incurred in acquiring the patent and seeks reimbursement.

2) *Income Approach*

This method looks to future cash flows in determining valuation. It states that a patent's value is the present value of the incremental cash flows or cost savings it will help provide.

3) *Market Approach*

This methodology involves determining what a willing buyer would pay for similar property. In other words, the patent's value is the value of similar patents or patented products that have been sold and purchased before. While this method factors in the cost of obtaining the patent, the market approach also requires that two things must be in place for this approach to be used for patent valuation:

- Existence of an active market for the patent, or a similar one; and
- Past transactions of comparable property.

Additionally, similar values for:
- Industry characteristics;
- Market share or market share potential; and
- Growth prospects;

will be identified for comparable patents.

4) *DCF based methods - Accounting for Time & Uncertainty*

Discounted Cashflow (DCF) methods of valuation are now used for all manner of applications. The two key factors they account for are the time value of money and to some extent the riskiness of the fore-

Patent Valuations, Unlocking the Value in your Patent Portfolio continues on pg. 8

Patent Valuations, Unlocking the Value in your Patent Portfolio continued from pg. 7

cast cashflows. These two problems can be solved in two ways. Either by using a risk adjusted discount rate to discount the forecast cashflows, thus accounting for both factors at once.

While the DCF approach may provide a more comprehensive valuation of a patent, it also requires more complex computer modeling of the economic environment, including the risk associated with estimating the variables for any of the analyses.

While the approaches to valuations listed above, provide a basis for valuing patents, a more preliminary step also includes a due-diligence review of the prosecution history of each patent with an eye to identifying any deficiencies in the prosecution of those patents. This due diligence must include both a legal diligence and financial diligence.

Legal diligence will support management decision-making for this transaction and will include:

- identifying all relevant IP, including
- aa obvious intangibles, such as patents, trademarks/trade dress, trade secrets and copyrights;
- aa less obvious intangibles, such as slogans, characters, and package designs;
- aaobscure intangibles, such as proprietary sales methods, and engineering designs and drawings;
- assessing and verifying patent ownership;
- assessing scope of IP protection and strength/extent of its protection of the company assets;
- assessing risks of any current or potential litigations;
- conducting a liens diligence (if necessary); and
- drafting, structuring and finalizing the appropriate agreement.

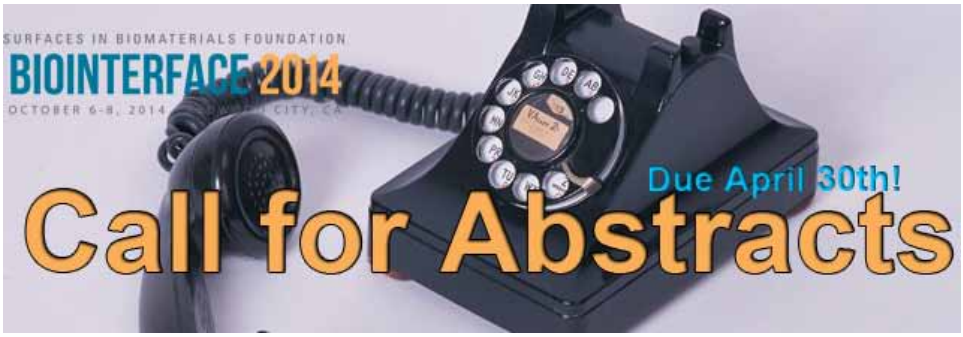
Financial diligence includes a valuation of the intellectual property assets and transfer pricing analysis. If desired, the financial diligence can also include analysis and recommendations on whether the asset transfer is best structured via license or acquisition, as well as identifying any relevant strategies that will provide optimal financial/tax outcomes. Preparing financial diligence requires identification of experts in the valuation of intangible assets, specifically accountants who specialize in the particular field of art encompassed by the patent.

Working closely with the financial diligence partner, your IP attorney can conduct a more comprehensive legal diligence by identifying those key patents that cover important commercial embodiments and a deeper diligence review on those patents. This can include a more in-depth analysis of patent validity & strength, assessment of the likelihood of grant and strength of coverage of pending patents, and a competitive landscape/freedom-to-operate assessment.

Finally, the patent owner needs to be aware that any of the time needed to accomplish any of the bulleted points listed above can vary enormously in scope depending on the needs/desires of the client. Each point can be the subject of a very cursory review or a very in-depth review, the cost of which will be reflected in the depth and time of that analysis.

---

[1]THE VALUATION OF PATENTS :
A review of patent valuation methods with consideration of option based methods and the potential for further research. Robert Pitkethly. The Said Business School University of Oxford Park End Street, Oxford, OX1 1HP. 1997.



Options for FDA Clarification of Device Premarket Submission Requirements: Part 2

By Phil Triolo PhD, RAC

Manufacturers (including specification developers) have several viable options for obtaining Agency feedback on the categorization of their product and, if it is a medical device, its classification (Class I, II, II) and premarket application requirements. Part 1 of this 2-part series (See Winter 2014 issue of SurFACTS) addressed Requests for Designations (RFDs). This part addresses 513(g) Requests for Information (513(g)s) and Pre-Submission Meetings (Pre-Subs or Q-Subs). To recap:

513(g) Requests for Information (513(g)s) are used to classify a device, to determine if a 510k can be submitted, and if so, the suitability of a proposed predicate device. The 513(g) can also be used to help determine the type of information (clinical, non-clinical) that will be required in a premarket submission, and standards and guidance documents that apply.
Pre-Submission Meetings and Materials (Pre-Subs) are used to ask specific questions and obtain FDA feedback on premarket submissions, including IDE's, clinical trial details including Significant Risk (SR) studies, premarket verification and validation test plans, and other issues.

513(g) and Pre-Sub meetings, materials, and processes are discussed in detail, below.

513(g) Request for Information

If you don't know whether or not your product is a medical device; or, are relatively certain that your product is regulated as a device, but are not sure what regulatory pathway: (510(k), PMA, De Novo petition, Letter to File) needs to be followed in order to market the device: Submit a 513(g).

Relevant Guidance

FDA provides a PowerPoint presentation on 513(g) requests at http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/ucm127147.htm as well as a guidance document that includes details on 513(g) preparation at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm

Contents of a 513(g)

- Cover Letter
- Complete Device Description
- Concise Indication(s) for Use Statement
- Either proposed labeling or labeling of a marketed similar product/device

513(g) Decisions

"Within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device."
In a somewhat dated document, the FDA indicated that the most frequent reasons 513(g) requests were sent to the Agency were to determine:

- Whether a product is subject to FDA regulations;
- Whether a device is exempt from the 510(k) requirements of the Act;
- Whether a 510(k) is needed for a modification to a legally marketed device; and
- The least burdensome regulatory pathway for a device which introduces a new technology or a new intended use.

Note that: "A 513(g) response does not constitute final Agency action, but provides responsive information based on the information provided by the requestor." The Agency can change its mind, especially if you change the device or its labeling.

Pre-Submission (Pre-Sub) Meetings

After the publication of Part 1 of this article, the FDA published, on Feb. 18, 2014, its final guidance on device pre-submissions, Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff. This guidance document serves as the

Options for FDA Clarification of Device Premarket Submission Requirements: Part 2 continues on pg. 10

Options for FDA Clarification of Device Premarket Submission Requirements: Part 2 continued from pg. 9

Agency's "current thinking" on the topic.

A Pre-Submission is defined by the FDA as a "formal written request from an applicant/sponsor for feedback from FDA to be provided in the form of a formal written response or, if the manufacturer chooses, a meeting or teleconference in which the feedback is documented in meeting minutes."

If you are sure that your product is classified as a Class II (or III) device, but you are not sure what pre-clinical and/ or clinical studies or data are required to establish substantial equivalence and / or a reasonable assurance of safety and efficacy: Submit Pre-Submission (Pre-Sub) Materials and request a Pre-Sub Meeting.

Relevant Guidance

The relevant FDA Guidance Document can be found at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf. Note that all Pre-Sub meetings had been previously categorized as "Pre-IDE (Investigational Device Exemption) Meetings," even though they didn't necessarily address IDE issues.

Informational Meeting requests will now be collectively referred to as "Q-Submissions" or "Q-Subs." The FDA will assign a unique identifier to each request, starting with "Q," followed by two digits representing the year, and four digits representing the order in which the request was received during that calendar year. Supplement submitted for this request will be identified as "Q140001/S001," "…./S002," etc. Contents will be kept confidential. Q-Subs will include Early Collaboration Meetings, PMA Day 100 Meetings, and Study Risk (Significant or Non-Significant Risk) Determinations, as well as Pre-Subs. FDA guidance documents for Formal Early Collaboration and PMA Day 100 Meetings already exist, and are only referenced in the new guidance.

Contents of a Pre-Sub Package

Pre-Sub materials should include specific questions regarding review issues relevant to planned IDEs or marketing applications (e.g., questions regarding pre-clinical and clinical testing protocols or data requirements), as FDA's advice will be guided by the manufacturer's questions and may not identify all submission requirements. So, provide the most detail on device characteristics or proposed test plans for which you are requesting FDA's feedback, and enough detail in other areas to allow the FDA to understand your technology and its proposed intended and indicated uses.
The new guidance document provides a detailed list of the information to include in Pre-Sub packages for different purposes. The general sections of the Pre-Sub should include the following information:

- Cover Letter
- Table of Contents
- Device Description
- Proposed Intended Use/ Indications for Use
- Previous Discussions or Submissions
- Overview of Product Development
- Specific Questions
- Method for Feedback
- Other Logistical Information

The appendices of the guidance document provide recommendations for the information to include in the packages of information for specific types of Pre-Subs. I have inserted this information in the Pre-Sub package just before the "Specific Questions" section, but other locations may be more appropriate, depending on the specific issues you'd like addressed. Following are the appendices:

A. Pre-Sub for an IDE Application
B. Pre-Sub for a NSR (Non-significant Risk), Exempt, or OUS (Outside of US) Study
C. Pre-Sub for a 510(k)
D. Pre-Sub for a PMA
E. Pre-Sub for an HDE
F. Pre-Sub for an IVD

Appendix 2 includes a checklist which identifies the information that must be present in order for the Agency to accept the Q-Sub for review.
This may be included with the cover letter. An eCopy of the Q-Sub must be provided, in addition to the hard-copy version.

Even when device classifications and regulatory pathways are relatively certain, Pre-Sub meetings are highly recommended, as they focus development activities and force the early creation of drafts of regulatory documents that will be used, in their final forms, in regulatory submissions. Further, they usually elicit one or more Agency concerns which can be addressed in

Options for FDA Clarification of Device Premarket Submission Requirements: Part 2 continues on pg. 11

your testing program and submission, instead of in a response to a deficiency letter. Overall, it has been my experience that the date the premarket submission is sent to the Agency is delayed when a Pre-Sub meeting is requested, but the overall time to obtain FDA approval or clearance is, on average, lessened.

FDA Response to Pre-Sub Requests

FDA feedback to Pre-Sub requests can be provided in multiple ways, including through an in-person meeting, a teleconference, fax or by email. If FDA feedback will be through a meeting or teleconference, at least 3 business days prior to the meeting, FDA will provide initial feedback to the applicant by email, which should include: written responses to the applicant's questions; FDA's suggestions for additional topics for the meeting or teleconference, if applicable; or, a combination of both. **Ask for both, so you can discuss the written responses and establish a relationship with the FDA's review team.**

The written responses may include a complete response to the applicant's questions, or may consist of some initial feedback and note the need for further discussion in the meeting or teleconference. If all of the applicant's questions are addressed through the written responses to the applicant's satisfaction, FDA and the applicant can agree that a meeting or teleconference is no longer necessary and the written responses provided by email will be considered the final written feedback to the Pre-Sub. FDA will aim to provide feedback to a Pre-Sub within approximately 90 days of receipt of a complete Pre-Sub package.

Note that a Pre-Sub and the FDA's response are considered "previous submissions" for 510k notification purposes. The preliminary assessment of a 510k includes an evaluation to determine if the issues raised by the Agency in the Pre-Sub process have been addressed in the 510(k). That is, the FDA's Pre-Sub response is considered more than guidance; its contents are considered de facto requirements and the preliminary RFA (Refuse to Accept) review (See Guidance for Industry and Food and Drug Administration Staff - Refuse to Accept Policy for 510(k)s) will evaluate whether or not the issues raised in FDA's Pre-Sub response have been addressed.

Summary

Although it is often difficult to convince management or other members of your product development team to pursue one of the options for obtaining FDA feedback before completing premarket submissions, the pursuit does payoff, typically, in a reduced time to market. So, start writing!

Please Welcome Dehua Yang as a New SurFacts Editor

Dr. Dehua Yang is the Founder and President of Ebatco, a Minnesota corporation specializing in providing high quality testing instruments and equipment, technical consulting and contract lab services. His expertise and experience spans from nanoscience and nanotechnology to product failure analysis. Prior to founding Ebatco, Dr. Yang was the Vice President, Commercialization of Hysitron Inc., a world leading manufacturer of nanomechanical testing instruments.

Dr. Yang, holds a Ph.D. in Physical Chemistry and a M.S. and B.S., in Solid State Physics and Metal Physics, respectively. He is a recipient of the Chinese Academy of Science top-ranked presidential award and natural science research award. The products he designed and managed at Hysitron, namely, nanoTensile 5000, and 3D OmniProbe, won the 2007 Micro/Nano 25 Award, and the 2005 Nano 50 Award respectively. In 2009 his company, Ebatco, has been selected to receive the Best of Business in Commercial Physical Research by SBCA. In addition, he has authored/coauthored more than 50 peer-reviewed publications on nanoscience and nanotechnology, tribology and surface science and engineering related topics. He is an inventor/co-inventor of 6 issued US utility patents. He is the 2010-2011 Vice Chair and 2011-2012 Chair of Minnesota Chapter of ASM International. He has served many times as a US National Science Foundation grant review panelist, journal referee, and international conference organizer and session chair.

More information about Dr. Yang can be viewed at www.ebatco.com.

Surface Science Calendar of Events

2014 IPrime Annual Meeting

May 27-29, 2014
University of Minnesota
Minneapolis East Bank Campus
Minneapolis, MN

Gordon Research Conference – Biointerface Science

June 15-20, 2014
Renaissance Tuscany II Ciocco Resort, Lucca, Italy
http://www.grc.org/programs.aspx?year=2014&program=biointerf

Gordon Research Conference – Bioinspired Materials

June 22-27, 2014
Sunday River Resort, Newry, ME
http://www.grc.org/programs.aspx?year=2014&program=bioinsp

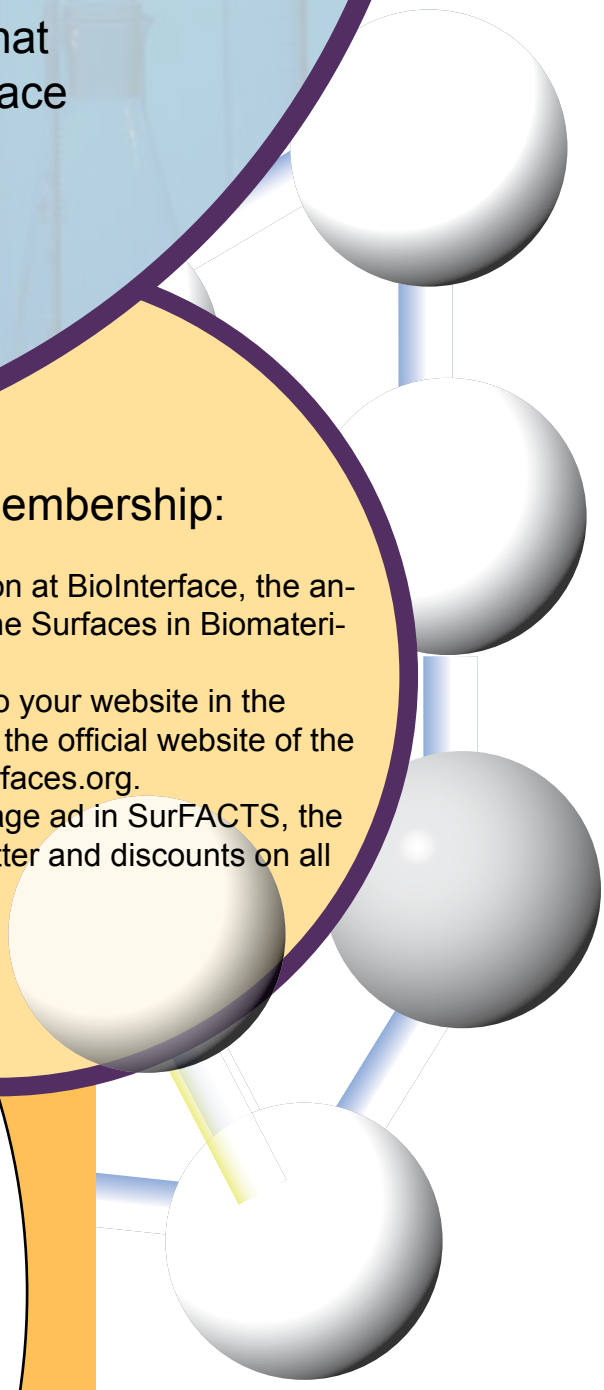
Wanted: Members

To be leaders in the surface science community

- Join a forum that fosters discussion and sharing of surface and interfacial information
- Have your voice heard and your interests represented within the surface science and biomedical community
- Help shape workshops and symposia that further the world-wide education of surface science
- Promote understanding of interfacial issues common to researchers, bio-medical engineers and material scientists.

Benefits of Membership:

- Discounted registration at BioInterface, the annual symposium of the Surfaces in Biomaterials Foundation.
- Your logo and a link to your website in the member directory on the official website of the Foundation, www.surfaces.org.
- Complimentary full page ad in SurFACTS, the Foundation's newsletter and discounts on all advertising.



Join the Foundation that connects the academic, industrial, and regulatory committees within the surface science/biomedical communities!

Visit the Foundation at www.surfaces.org for a membership application or call 651-290-6267.

Surfaces in **Biomaterials** Foundation

Coatings 2Go™

+1 978.369.7411

www.Coatings2Go.com

ORDER NOW!

Coatings2go, LLC provides **hydrophilic** and other coatings that are quickly delivered to you hassle-free, and in a cost-effective manner. Our coatings are perfect for on-site manufacturing, eco-friendly, and can be controlled by your employees, in your own facility, and are FDA Master Filed. They are easy to customize and offer you performance and versatility, with no license fees or royalty costs. You can purchase domestically or internationally through our quick and secure online ordering.

*Please visit **www.Coating2Go.com** to view a full selection of coatings.*

Surface Solutions Laboratories, Inc. was started in 1995. Our experienced staff holds nine U.S. patents—and brings a breadth of medical device industry expertise, with 35-plus years of design and formulation of coatings and adhesives across many market platforms. SURFACE SOLUTIONS LABORATORIES® coatings are based upon the proprietary technology of Surface Solutions Laboratories, Inc. Coatings2Go, LLC is a licensee of Surface Solutions Laboratories, Inc. technology.

Thank You to Our Members!