

**Audrey's Life Science Meeting Picks for March - May 2013**  
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**March 7, 2013**

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**BioCentury TV Today, See new program Webcast Starting Sunday, March 10, 2013**  
**www.biocenturytv.com, Available anytime starting at 9:00 a.m. EDT**

Date: Original broadcast Sunday, Starts March 10, 2013

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**Real Endpoints Symposium, Monday and Tuesday, March 11-12, 2013**

Topic: "Disruptors: Revolutionizing Drug/Dx Reimbursement"  
 Speakers: Lewis Sandy, MD, SVP, Clinical Advancement, UnitedHealth; Michael Sherman, MD, CMO, Harvard Pilgrim; Carolyn Clancy, MD, Director, AHRQ; Robert Galvin, MD, CEO, Equity Healthcare; Rob Epstein, MD, former CMO, Medco and president, Medco Research; Jeff Berkowitz, SVP, Pharmaceutical Development and Market Access, Walgreen Co.; William Shrank, MD; Director, Rapid Cycle Innovation, CMS; Ira Klein, MD; Chief of Staff to CMO, Aetna; Annalisa Jenkins, MD; EVP, Head of Global Development, Merck Serono; Jack Bailey, SVP, Policy, Payers & Vaccines, GlaxoSmithKline; Steve Wooding; VP, Head of Market Access, Janssen EMEA, J&J...And more!  
 Date and Time: Monday and Tuesday, March 11-12, 2013, (reception Monday night)  
 Location: Hyatt Regency, Penn's Landing, Philadelphia, PA  
 Registration Rates

Registration Type	by December 31	After December 31
<input type="checkbox"/> Standard	\$1,295	\$1,695
<input type="checkbox"/> Payer	\$750	\$850
<input type="checkbox"/> Health Systems/Medical Centers	\$750	\$850
<input type="checkbox"/> Academic	\$750	\$850
<input type="checkbox"/> Government	\$750	\$850

Register at <https://realendpoints.ontrackevents.com/register.cfm>

**Topic Description**

If you attend one conference to understand the **key challenges**, the innovative solutions, and the enormous opportunities, it should be the *Real Endpoints Symposium*. You'll meet the payers, policymakers and industry leaders at the forefront of the revolution, senior executives representing millions of patients and billions of dollars in drug and diagnostic spend. And the sessions are laser-focused on the seven fundamental issues that will set the reimbursement agenda for the next 24 months – and beyond.

You'll leave this meeting with the contacts and concepts that will allow payers to dramatically improve the returns from their drug and technology spend — and pharmas to prosper by identifying and satisfying the evolving requirements. Leverage your time. One meeting. Enormous personal and professional ROI.

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**French American Chamber of Commerce, Tuesday Evening, March 12, 2013**

Topic: "Universities, an engine for entrepreneurship"

Speakers:

- Marta Gaia Zanchi PhD, Chief Executive Officer at RenovoRx, Mentor at Stanford StartX Med, Co-Director at Stanford "Biodesign for Mobile Health"
- Alain Harrus PhD, Partner at Crosslink Capital
- Zineb Laraki, VP External Relations at Business Association of Stanford Entrepreneurial Students (BASES)
- Dr Burton Lee PhD MBA, Lecturer in "European Entrepreneurship and Innovation" at Stanford Engineering School, Managing Director at Innovarium Ventures

Date and Time: Tuesday, March 12<sup>th</sup>, 6:00 pm - 9:00 pm

Location: PRIME, 2325 Third Street (@20th) #231, 2nd floor, San Francisco, CA 94107

Price: Member: \$30, Non-member: \$45, At the door: \$50

Register at <http://www.faccsf.com/civicrm/event/register?id=399&reset=1>

Topic Description

Why American universities are one of entrepreneurship's major driving force in the US?

How can universities help students become entrepreneurs?

Can creativity and change be taught?

Join us for a conversation with our panel and an inspiring networking event.

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**Bio2Device Group, Tuesday Evening, March 12, 2013**

Topic: "Technology for Pharmacist-Patient Collaboration Improves Adherence & Hospitalization Risk"

Speaker: David Parpart, Founder, and Sunit Gala, Ph.D. Impact Meds

Date and Time: Tuesday, March 12, 2013, 6:00 – 9:00 pm

Location: Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto CA 94304

Cost:

\$6 - Students/In-transition - Members only

\$11 - Early-bird Registration - Members only

\$20 - Late Registration and Non-Members

\$25 - Walk-ins

Register at [www.Bio2DeviceGroup.org](http://www.Bio2DeviceGroup.org) a week prior to meeting

Topic Description

One of the most dangerous trends for pharmaceutical manufacturers, payers and patients is poor medication adherence. When people who need medications to control chronic illness stop taking them early, it causes manufacturers to lose \$188Bn in drug sales and 350 preventable deaths each day. Parpart and Gala are working in collaboration with leading healthcare and technology organization to deploy the World's largest medication adherence project.

Investment in Health Tech and mHealth is on the rise. The duo leads a group of more than 1,100 developers and entrepreneurs in the space and will discuss emerging trends. IMPACTMeds is a medication adherence platform that identifies patients at risk, and provides doctors, pharmacists and patients with simple tools to improve medication adherence. IMPACTMeds open platform enables rapid development of analytics driven applications leveraging healthcare data and mobile devices in the market and can be used in multiple verticals.

#### Speaker Bios

David Parpart, Founder of Health2.0 Silicon Valley, is a leading Health-Teach and M-Health visionary. With expertise in technology and services in medication adherence, David founded IMPACTMeds to solve the massive problem of medication adherence using technology.

Sunit Gala, Ph.D. is a leading expert in distributed database technologies and BI platforms. He holds a PhD in Electrical Engineering and formerly ran the Business Intelligence business unit at Oracle.

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### **Women in Bio, Tuesday Evening, March 12, 2013**

Topic: "Pathway to Success—Be Smart Out Loud—Everywhere"

Speaker: Fran Zone

Date: March 12, 2013, 6:00 p.m. – 8:30 p.m. PST

Location: Genentech Hall, Mission Bay Campus, UCSF, 600 16th St., San Francisco, CA 94158

Register: Register at

[https://netforum.avectra.com/eweb/DynamicPage.aspx?Site=WIB&WebCode=EventDetail&evt\\_key=7e0551ac-ceb5-416a-ab53-305a85f7c7c2&msm=8ca73637-2ac8-4929-b8a8-9c2e61e0f564&cst=266f0fc3-f6e8-4f9d-9be3-41080345b8fb&ent=91b58190-7406-434b-aafd-27255c8f233d](https://netforum.avectra.com/eweb/DynamicPage.aspx?Site=WIB&WebCode=EventDetail&evt_key=7e0551ac-ceb5-416a-ab53-305a85f7c7c2&msm=8ca73637-2ac8-4929-b8a8-9c2e61e0f564&cst=266f0fc3-f6e8-4f9d-9be3-41080345b8fb&ent=91b58190-7406-434b-aafd-27255c8f233d). Deadline to register by March 10, 2013

Are guests allowed? Yes

Cost: Members: \$30 - Non-Members: \$60

*Women in Life Sciences (WILS) at UCSF: Register with special code, please email either of the following WILS chairs to obtain registration code:*

Brittany Anderton - [Brittany.Anderton@ucsf.edu](mailto:Brittany.Anderton@ucsf.edu)

Nicole Giordani - [Nicole.Giordani@ucsf.edu](mailto:Nicole.Giordani@ucsf.edu)

(To be paid by UCSF WILS fund)

#### Topic Description

In a world of short attention spans and brief encounters, standing out from the pack requires the ability to be Smart Out Loud in real time. The Smart Out Loud do not necessarily know all the right answers; they know the right thing to say, when to say it, how to say it, and how to turn every interaction into an opportunity. The future belongs to them because they own the present. Award-winning executive coach and leadership expert, Fran Zone, will join us to share her proven tools for transforming 'showing up' into seizing the day.

#### Speaker Bio

Fran Zone is the creator of The Zone Method™, an award-winning program for maximizing personal leadership style, creating compelling presentations, and mastering the art of 'deliberate communication'. The Zoned™ include leaders at Johnson & Johnson, NBC

Olympics, Genentech, and the White House. Fran transforms lives via strategic communication workshops, executive coaching sessions, leadership seminars, and on-air appearances. Known for creating tools for 'in the now' compelling communication, Fran is the #1 rated keynote speaker at business conferences nationally. Her Monday missive, stellarStarters™, is read weekly by Fortune 500 leaders, best-selling authors, media editors, and individuals ready to be more rather than just 'do' more. Fran founded Zone Communication in 1991 and is based in San Francisco.

#### Contact Us

For membership information contact: [sanfrancisco@womeninbio.org](mailto:sanfrancisco@womeninbio.org)

For general information visit our website: [www.womeninbio.org/chapter-sanfrancisco.shtm](http://www.womeninbio.org/chapter-sanfrancisco.shtm)

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### **UCSC Extension and CACO, Clinical Trials Essentials: A One-Week Intensive Course, March 11-15, 2013**

Event: "Clinical Trials Essentials: A One-Week Intensive Course" 825. NATSC (3.5 CEU) 35.0 hours CA BRN/LVN Credit—Provider #CEP13114

Offered in Collaboration with University of California at Santa Cruz – Silicon valley Extension  
Location: Crowne Plaza Hotel, Foster City, CA.

Monday March 11, 2013 – 8:30 am—12:30 pm

Drug Development Process 4 hours – Edward Rozhon

- Overview of the drug discovery & development process
- Major players in drug development
- Assay development and discovery of new medical entities
- Non clinical and clinical development of new drugs
- History and regulatory oversight of FDA
- Structure of Phase I, II, & III clinical trials
- FDA review of New Drug Application.

Monday March 11, 2013 – 1:30 pm—5:30 pm

Science of Clinical Trials Design 4 hours – Mike Huston

- Phases of drug development
- Objectives of clinical studies
- Basic clinical trials designs
- Underlying science for clinical trials designs.

Tuesday March 12, 2013 – 8:30 am—12:30 pm

GCP & ICH Investigator & Clinical Research Site 4 hours – Jacquie Mardell

- Historical and legislative roads to good clinical practice
- Role and regulation of ethical review
- The research-care conflict and elements of informed consent
- Investigator and sponsor obligations.

Tuesday March 12, 2013 – 1:30 pm—2:30 pm

Global Clinical Trials Perspective 1 hour -- Jacquie Mardell

- What to watch for in global clinical trials.

Tuesday March 12, 2013 – 2:45—5:30 pm

Applied Statistics in Clinical Trials 3 hours – Pete Shabe

- The role statistics plays in clinical research

- Basic data summarization techniques
- Estimation and Hypothesis Testing Introduction
- Estimation and Confidence Intervals
- Statistical Hypothesis Testing.

Wednesday March 13, 2013 – 8:30 am—12:30 pm

Monitoring Clinical Trials 4 hours – TBA

- Review the basic regulatory requirements of monitoring a clinical research study
- Describe the tasks that should be performed before, during, and after a monitoring visit
- Learn how to track all key parameters involved in monitoring a site
- Know how to complete visit reports and follow-up on action items after each site visit.

Wednesday March 13, 2013 – 1:30 pm—3:30 pm

Business of Clinical Research 2 hours – Nanette Nanjo-Jones

- The Market Players – Pharma, Biotech, Contract Research Organizations (CROs)
- Cost of Doing Business – Cost of conducting clinical research
- Outsourcing and CROs – It costs money to make money
- Innovative Ways to Reduce Cost – Business Strategies and Process Innovations.

Wednesday March 13, 2013 – 3:45 pm—5:30 pm

Study Site Perspective 2 hours – Laila Craveiro

- Translational research in an academic center: fundamental strengths and weaknesses
- Research Process and Operations management as the success of a trial
- Essential conversations between academia, biomedical and pharmaceutical companies, venture capitalists and consultants
- Data Integrity and well-supported metrics (Case Studies).

Thursday March 14, 2013 – 8:30 am—12:30 pm

Clinical Data Management 4 hours – Susanne Prokscha

- Key data management activities for study startup, conduct, and closeout
- Regulations applicable to data management activities
- Clinical data management systems and electronic data capture (EDC)
- Working with contract research organizations (CROs) for data management.

Thursday March 14, 2013 – 1:30 pm—5:30 pm

Clinical QA/Compliance Audits and the FDA 4 hours – Frances Ann McKenney

- Qualifications needed for GXP auditors and FDA Inspectors
- Objectives of sponsor audits and regulatory inspections
- Similarities and differences between sponsor audits and regulatory inspections
- General approach to hosting an audit or inspection
- Types of findings that cause concern for auditors or inspectors.

Friday March 15, 2013 – 8:30 am—12:30 pm

Good Manufacturing Practices and the Transition to Full Scale Manufacturing 4 hours – Steven Kuwahara

- The transition from the GMP for Phase 1 products to full GMP requirements.
- GMP for drugs.
- GMP for biologics and related products, including Good Tissue Practices.
- Considerations for process validations.

Friday March 15, 2013 – 1:30 pm—5:30 pm

Medical Devices, An Overview 4 hours – Deborah Tolomeo

- Legislative and regulatory overview of clinical trials with medical devices
- FDA Investigational Device Exemptions, 510(k)s, PMAs, and HDEs
- Post-approval studies and Post-market requirements
- Globalization and the changing regulatory environment.

In order to make it easy for you to attend, we have arranged this 1-week course into 10 half-day modules. You can either sign up for the full week or pick/choose any of the 10 modules.

To register, visit [www.CACO-PBSS.org](http://www.CACO-PBSS.org).

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**sfAWIS, Wednesday Evening, March 13, 2013**

Topic: "Careers in Pharma Technical Development from a PhD perspective"

Speaker: Marge Winkler, PhD, VP, US Biologics Technical Development, Genentech, Inc.

Date and Time: Wednesday, March 13th, 2013

6:30-7:00 pm Dinner/Networking

7:00-8:00 pm Presentation by Dr. Winkler

8:00-8:30 pm Q&A and Networking

Location: Amgen, Building 2, 1120 Veterans Blvd., South San Francisco, CA 94080

Parking is available.

Cost: Online registration: \$5 AWIS members/students; \$10 non-members. Register via ACTEVA at <http://www.acteva.com//booking.cfm?bevaid=235292> by Monday March 11, 2013; Onsite registration available: \$8 AWIS members/students; \$15 non-members.

For additional information check <http://www.sfawis.com/>

Topic Discussion

Are you curious about drug development and process technology?

Want to know more about industry positions in this area?

How do you transition from research to drug development and process technology?

Come hear Marge Winkler describe her transition from a protein chemist in research to becoming Vice President of US Biologics Technical Development at Genentech. During her career, Dr. Winkler has worked in a wide range of departments from Protein Purification, to Analytical Chemistry, to Manufacturing Sciences and Technology. She has held numerous leadership positions including Project Team lead for Nutropin, Avastin, and Lenercept as well a CMC Team Leadership position. Following the Roche-Genentech integration, Dr. Winkler has directed global teams and is a member of the Roche Global Pharma Technical Development Organization.

This event is open to all scientists and non-scientists. You do not need to be an AWIS member to attend.

Light dinner provided.

< All professionals and students in the sciences are welcome.

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**CABS, Saturday Afternoon, March 16, 2013**

Topic: "Next Generation Sequencing Technologies"

Date: March 16, 2013; 1:00 pm to 5:00 pm

1:00 - 1:30 Registration and networking

1:30 - 2:15 Technologies for efficient and accurate personal genome sequencing. Brock A. Peters, Director of Research, Complete Genomics Inc.

2:15 - 3:00 Next generation sequencing and its application. Yongming Andrew Sun, Sr Staff Bioinformatics Scientist at Ion Torrent, part of Life Technologies

3:00 - 3:30 Break and networking

3:30 - 4:15 Actionable Network Biology Leveraged by Big Genomics Data. Dawei Lin, Associate Director for Bioinformatics and Senior Advisor to the Director of Division of Allergy, Immunology and Transplantation, NIAID, NIH

4:15 - 5:00 Networking

Location: Syracuse Room, Crowne Plaza Hotel, 1221 Chess Drive, Foster City, CA

Registration Requirement:

Online registration is strongly encouraged.

Online registration: Active members: \$5; Non-members: \$10

Onsite registration: Active members: \$10; Non-members: \$20

Registration

<http://www.cabsweb.org/CABSweb/feventslist.jsp?id=1034>

### **Speaker**

#### **Brock A. Peters, PhD**

Director of Research, Complete Genomics Inc.

Brief Bio: Brock A. Peters has served as Director of Research at Complete Genomics since 2012. In his current role he leads a team of scientist in the development of library methods for high throughput sequencing. Dr. Peters joined Complete Genomics in 2008 as a senior scientist, during this time he developed a method for sequencing and haplotyping genomic DNA called Long Fragment Read (LFR) technology. From 2005 to 2008 Dr. Peters was an Associate Scientist at Genentech, where he led the sequencing effort for Genentech's Cancer Genome Project. Prior to joining Genentech Dr. Peters held a postdoctoral fellowship at Johns Hopkins University School of Medicine. Dr. Peters received his Ph.D. in Pharmacology from Johns Hopkins University School of Medicine and his B.S. in Biochemistry from the University of Washington.

#### **Yongming Andrew Sun, Ph.D.**

Sr Staff Bioinformatics Scientist at Ion Torrent, part of Life Technologies

Brief Bio: Yongming Andrew Sun, Ph.D. is Sr Staff Bioinformatics Scientist at Ion Torrent, part of Life Technologies. Ion Torrent is a pioneer in using semiconductor technology in DNA sequencing. He is working in the development of sequencing applications, working with collaborators in applying Ion Torrent Semi-conductor sequencing technologies in research, diagnostics, and health care. Prior to Ion Torrent, he worked in Life Technologies for 6 years in the area of microarray and next-generation sequencing where he participated in international projects (such MAQC microarray, 1000 Genomes Project). Prior to Life Technologies, he led bioinformatics effort in biomarker identification at diaDexus, a joint venture between Glaxo-SmithKline and Incyte. He has Ph.D. in Medical and Molecular Genetics from Indiana University.

#### **Dawei Lin, Ph.D.**

Associate Director for Bioinformatics and Senior Advisor to the Director of Division of Allergy, Immunology and Transplantation, NIAID, NIH

Brief Bio: Dr. Dawei Lin received his PhD from Peking University, China in Computational

and Structural Biology. He started his career at the Protein Data Bank (PDB) at Brookhaven National Laboratory, a worldwide repository for macromolecular structures. For the last seven years, he had been the funding Bioinformatics Core Director at the UC Davis Genome Center and had collaborated with more than 100 research groups. He led his team to provide expertise and infrastructure to carry out acquisition curation, and distribution of complex data sets as well as to develop and perform computations, analyses and simulations addressing a wide variety of biological questions from genomics to network biology. Before he joined NIH recently, he served on the the Scientific Advisory Board of Tiatros, Inc. a HealthIT company selected as one of 2012 CNBC "The World's Most Promising New Companies". He is currently the Associate Director for Bioinformatics and Senior Advisor to the Director of Division of Allergy, Immunology and Transplantation, NIAID, NIH with responsibility for overseeing, directing, and leading all aspects of Bioinformatics activities within the Division.

#### Event Description

Over the last decade, the advent of next generation sequencing (NGS) technologies has brought revolutionary new ways to analyze DNA sequences with incredible high throughput and low cost. Currently, NGS technologies are being applied in a variety of applications, including de novo whole-genome sequencing, sequence variation identification, and mRNA and non-coding RNA profiling. At this workshop, industry leaders and experts will provide an overview of NGS technologies and elaborate their applications in genetic testing, personalized medicine, and clinical diagnostics.

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#### **Bio2Device Group, Tuesday Morning, March 19, 2013**

Speaker: John L. Bishop, Chairman and Chief Executive Officer

Topic: "Cepheid at the forefront of diagnostic development and what the future holds"

Date and Time: Tuesday, March 19, 2013, 8:30 – 10:30 am

Location: Sunnyvale City Council Chambers, 456 W. Olive, Sunnyvale

Cost: Free

No registration is required.

#### Topic Description

In the aftermath of the September 11<sup>th</sup> 2001 attacks, a second shockwave was sent around the world in the form of Anthrax-spore-laden letters carried by the US Postal Service to high profile domestic targets. Cepheid, together with Northrup Grumman, was asked to respond by developing a PCR-based mail surveillance system to bring the power of molecular diagnostics to a decentralized testing approach that can be implemented in a low skill environment on a 24/7 basis. At the time, this was viewed as an impossible task given the available molecular technologies, which needed to be run in batches from central labs using highly skilled personnel.

Eight years and nearly 11 million cartridges later (with no false positives to date), this program remains in effect as the most successful bioterror detection program in the world. More importantly, it proved that molecular diagnostic technologies were ready for implementation on a distributed basis...and no longer limited by skill sets or geography. The medical value of rapid, decentralized testing has been dramatically illustrated by the global impact of Cepheid technology for detection of tuberculosis, and is now a driver behind the mainstreaming of molecular testing in laboratories throughout the world.

#### Speaker Bio

Mr. Bishop joined Cepheid as Chief Executive Officer and as a director in April 2002. Mr. Bishop served as President and a director of Vysis, Inc., a genomic disease management company that was acquired by Abbott, from 1993 to 2002 and as Chief Executive Officer from 1996 to 2002. From 1991 until 1993, Mr. Bishop was Chairman and Chief Executive Officer of MicroProbe Corporation, a biotechnology company, and, from 1987 until 1991, of Source Scientific Systems, a biomedical instrument manufacturing company. From 1984 to 1986, Mr. Bishop was President and Chief Operating Officer of Gen-Probe, Inc. From 1968 to 1984, Mr. Bishop held various management positions with American Hospital Supply Company and its affiliates, including a three-year assignment in Japan as an Executive Vice President and Chief Executive Officer of International Reagents Corp., a joint venture between American Hospital Supply Company and Green Cross Corporation. Mr. Bishop currently serves as a director of Conceptus, Inc. In addition, he is a member of the Health Section Governing Board of the Biotechnology Industry Organization and a member of the AdvaMed Dx Board, a division of The Advanced Medical Technology Association.

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### **BioScience Forum, Wednesday Evening, March 20, 2013**

Topic: "The Next Generation of Cancer Research: Bringing Benefit and Discovery to Patient"

Speaker: Ira Mellman, Ph.D., Vice President of Research Oncology, Genentech

Professor of Biochemistry & Biophysics, UCSF

Date and Time: Wednesday, February 27th 2013, 6:00 pm

6 pm - 7 pm networking

7 pm - 8 pm dinner

8 pm - 9 pm presentation

Location: The Holiday Inn, 275 S. Airport Blvd., South San Francisco, CA 94080

#### **Event Registration (\$3 service fee will apply)**

General Pre-Registration	\$45.00
General On-Site Registration	\$55.00
Student Pre-Registration	\$35.00
Student On-Site Registration	\$45.00

Pre-Registration ends Monday, March 17, at 9 pm

Cash or check accepted on the day of the event

Register at <http://biosf.org/>

### Speaker Biography

Ira Mellman received his Ph.D. degree in genetics from Yale University School of Medicine. He was a postdoctoral fellow and later Assistant Professor at The Rockefeller University, working with the late Ralph M. Steinman, the 2011 Nobel Prize winner in Physiology or Medicine. Dr. Mellman joined the faculty of the Yale University School of Medicine in 1981 as an Assistant Professor in the Department of Cell Biology, later becoming Chair. The recipient of many honors including Yale's prestigious Sterling Professorship, Dr. Mellman is a member of the US National Academy of Sciences, a fellow of the American Academy of Arts & Sciences, and an elected foreign member of the European Molecular Biology Organization (EMBO). He also served as Editor-in-Chief of the Journal of Cell Biology and as a member of the editorial boards of Cell, The JCB, The Journal of Experimental Medicine, and EMBO Journal. Dr. Mellman is the founder of CGI Pharmaceuticals, Inc. (now owned by Gilead) and Athersys, Inc., and is an advisor to research institutes and foundations around the world.

Dr. Mellman's work has contributed numerous fundamental concepts to our understanding of cell biology and immunology, beginning with the discovery, definition, and naming of a "new" organelle, the endosome. His laboratory has also elucidated the mechanisms by which epithelial cells polarize to form tissues and initiate cancer, and revealed the mechanisms underlying how dendritic cells initiate immune responses.

Dr. Mellman began at Genentech in 2007 as Vice President of Research Oncology, and is responsible for leading all aspects of oncology research and advancing both antibody and small molecule drug candidates into the clinic. Dr. Mellman also serves as Professor of Biochemistry & Biophysics at the University of California, San Francisco.

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### **EMBS, Wednesday Evening, March 20, 2013**

Topic: Image Processing for Clinical OCT

Speakers: Jonathan Oakley and Daniel Russakoff, Co-founders, Voxeleron

Wednesday, March 20, 2013, 7:30 PM

Location: Room M-114, Stanford University Medical School

Optional dinner location: Stanford Hospital Cafeteria, 6:15 PM (no host, no reservations)

### Topic Description

Optical Coherence Tomography (OCT) is an imaging modality capable of generating in vivo, cross sectional images of tissue at sub-micron resolution. Its widespread adoption has been primarily driven by applications in ophthalmology, where structural measurements made on the data are used to support the clinical management and diagnosis of key ocular diseases such as macular degeneration and glaucoma. Such automated measurements are also used as end points in the clinical trials of pharmaceuticals that are being developed in an effort to cure these causes of blindness. The technologies underlying these measurements are image processing algorithms that analyze the volumetric data to extract quantitative metrics of the anatomical change indicative of pathology. This talk will focus on these algorithms, specifically what they are and how they work.

In addition to the core ophthalmic OCT applications, we will review new research in the wider field of neuro-ophthalmology. As an extension of the central nervous system, the

retina and its layers have correlates with measurements made using MRI of the brain. Here, new structural measurements being taken from retinal OCT images are starting to be used clinically in the management of multiple sclerosis. While this field is very much in its infancy, the implications are far reaching for other neurodegenerative diseases and the development of neuro-protective agents. We will give an overview of the current state of the art, summarize the significant interest seen in the neuro-ophthalmic space, and again discuss the supporting image processing technologies.

**Speaker Bio**

Jonathan Oakley has a B.Sc. in Computer Science from the University of York, England, a Masters from the department of Medical Physics at University College, London, and a Ph.D. in medical image processing from the Swiss Federal Institute of Technology. Since then, he has spent more than a decade working on image processing algorithm development for KLA-Tencor, Fujifilm and, more recently, Carl Zeiss Meditec Inc. While at Zeiss, he worked solely on the development of algorithms for OCT and collaborated widely with academia to generate a number of key OCT-related clinical publications. This is also his current focus at Voxeleron, the company he co-founded in 2010 with Daniel Russakoff.

Daniel Russakoff received an A.B. in Geophysics from Harvard University and his Ph.D. in Computer Science from Stanford. His research interests are in computer vision and pattern recognition in general, and biomedical image analysis in particular. He has authored numerous conference and journal papers and holds several patents on topics ranging from stereo vision to medical image registration. He has worked as a Computer Scientist at the National Institute of Standards and Technology and as Chief Scientist at Fujifilm's San Jose Research Lab. His more recent work has been using probabilistic shape analysis and machine learning for segmentation of deformable structures in 2D and 3D radiological images.

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**HBA, Wednesday Evening, March 20, 2013**

Topic: "My Mind and Me: An Exploration of Innovations in Mental Health"

Speakers: Naomi Lam, MD, psychiatrist; Tracey Dawson, PhD, Genentech; and Manuel Lopez-Figueroa, PhD, VP, Bay City Capital

Date and Time: Wednesday, March 20, 5:30-8:15pm

Location: University of California, San Francisco, Mission Bay Campus (600 16th St, SF, CA 94158)

Registration: Please visit [hbanet.org](http://hbanet.org) for additional information and to register for the event.

Fee: Member: \$40\*; Nonmember: \$50\*; Student: \$15\* (\*after March 1, fees increase \$5)

**Topic Description**

This thought-provoking and informative program will discuss innovations in mental health with a specific focus on issues relating to women's mental health. Our speakers include: Naomi Lam, MD, an adult psychiatrist who focuses on women's health, stress management, and holistic/alternative practices; Tracey Dawson, PhD, a director and commercial team leader at Genentech, overseeing the US launch of a new psychiatric drug; and Manuel Lopez-Figueroa, PhD, a vice president at Bay City Capital and the scientific liaison for the Pritzker Neuropsychiatric Disorders Research Consortium. This event is co-hosted by UCSF Women in Life Science (WILS).

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**BioSpace Career Fair, Thursday Afternoon, March 21, 2013**

Event: Biotech Bay Career Fair-- Biotech \* Pharmaceutical \* Medical Device & Diagnostics  
Date and Time: Thursday, March 21, 2013; 1pm to 6pm  
Location: San Francisco Airport Waterfront Marriott  
Cost: Free—see details at  
<http://www.biospace.com/jobs/careerfairdetails.aspx?CareerFairId=244>  
Register at <http://www.biospace.com/jobs/seekersignin.aspx>

Event Information

Attend the Biotech Bay Career Fair!  
Job seekers can spend a day with HR representatives and Hiring Managers from top biotech, pharma, medical device and diagnostics companies in the Bay area.  
Who should attend?  
Candidates with a 4-year degree in the life sciences and a minimum of 2-years of industry related experience are invited to attend. Just register by clicking the button below.  
*(Equivalent work experience may be considered in lieu of a four-year college degree. PhD and Postdoc candidates welcome.)*  
What companies will be there?

If you can't make it on event day, you can still pre-register online to allow exhibiting companies to view your resume and contact you outside of the career fair.

What types of positions are available?

Exhibiting companies are recruiting for positions in areas such as: QA/QC, clinical research, engineering, manufacturing, biostatistics, clinical data management, chemistry, regulatory affairs, and research. Exhibitors who have jobs posted on BioSpace.com have their company name linked to their job postings in the list below. We highly recommend researching open positions before you attend the event. It will help you determine which companies are a good match and make you look more prepared and knowledgeable when approaching recruiters.

To help research what exhibitors are recruiting for, see the list of general disciplines each company is interested in below. You may also click on the company name at the bottom of the page to view job postings.

<http://www.biospace.com/jobs/careerfairdetails.aspx?CareerFairId=244>

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**Bio2Device Group, Tuesday Morning, March 26, 2013**

Topic: Medical Reliability Testing  
Speaker: Mike Silverman, Founder, Ops A La Carte  
Date and Time: Tuesday morning, March 26, 2013, 8:30am  
Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA  
Cost: \$0  
No registration is required

Topic Description

Mike Silverman will explain the basic steps medical device companies must follow in developing a new medical product, as well as strategies for the efficient evaluation of risk-based testing for reliability, FDA and human safety. The presentation will include case histories and testing recommendations.

## Speaker Bio

Mike Silverman is founder and managing partner at Ops A La Carte, a Professional Consulting Company that has an intense focus on helping customers with end-to-end reliability. Mike has over 25 years of experience in reliability engineering, reliability management and reliability training. He is an experienced leader in reliability improvement through analysis and testing. Through Ops A La Carte, Mike has had extensive experience as a consultant to high-tech companies, and has consulted for over 500 companies in over 100 different industries in most of the United States and 15 countries around the world. About 30% of Ops' work is in the Medical Industry. Mike is an expert in accelerated reliability techniques and owns HALT and HASS Labs, one of the oldest and most experienced reliability labs in the world. Mike has recently completed his first book on reliability entitled "How Reliable Is Your Product: 50 Ways to Improve Product Reliability". The book was published December, 2010. Mike has authored and published 25 papers on reliability techniques and has presented these around the world including Canada, China, Germany, Japan, Korea, Singapore, Taiwan, and the USA. He has also developed and currently teaches over 30 courses on reliability techniques. Mike has a BS degree in Electrical and Computer Engineering from the University of Colorado at Boulder, and is a Certified Reliability Engineer (CRE) through American Society for Quality (ASQ). Mike is a member of ASQ, IEEE, Stanford PRN, PRG, SME, ASME, PATCA, and IEEE Consulting Society. Mike is currently the IEEE Reliability Society Santa Clara Valley Chapter Chair.

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## **Sharevault and Pullan Consulting, Tuesday Morning, March 26, 2013**

Topic: "Biotech and Pharma Licensing Negotiations"

Speaker: Linda Pullan, Pullan Consulting

Date and Time: Tuesday, March 26, 2013, 10:00 – 11:00 am PT

Cost: Complementary

Register on Sharevault website at <http://www.sharevault.com/resources/webinars>

### Webinar Description

Biotech companies seeking to partner their drug candidates should decide in advance what they want to achieve in deal negotiations. Getting the best outcome depends on non-financial, as well as financial terms. In this ShareVault webinar, Linda Pullan will discuss negotiation goals, BATNAs and power, the process to the deal, the basics of term sheets and common deal structures. She'll discuss frequent problem areas and some ideas on how to work through them, from the things in a university license that will trouble your future partner, to judging your development partner by the negotiation process. Join us on March 26th as we explore this business development look at licensing terms, negotiations and their variations and prepare your team for the big deal.

### Speaker Bio

Linda M. Pullan, Ph.D. offers biotech and pharmaceutical companies consulting in all aspects of partnering through Pullan Consulting ( [www.pullanconsulting.com](http://www.pullanconsulting.com)). Linda has a Ph.D. in Biochemistry and a B.S. in Chemistry. Linda has more than 20 years of drug industry experience, beginning in drug discovery at Monsanto/Searle/now Pfizer and ICI/Zeneca/now AstraZeneca. After doing licensing at what is now AstraZeneca, Dr. Pullan continued as head of oncology and hematology licensing for Amgen. She then joined Kosan Biosciences as VP of Business Development and experienced all the tasks of out-licensing and business development in a small company. For several years, she has been providing companies help in identification, valuation, negotiation and strategy for partnering in or out. She has an

extensive deal sheet ranging from company acquisitions to Phase III compounds and from preclinical candidates to technologies, with both in- and out-licensing. She writes a free monthly newsletter Pullan's Pieces, with tidbits of science and business for about 3,600 readers. Interested readers may sign up by sending an email [linda@pullanconsulting.com](mailto:linda@pullanconsulting.com) .

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**CIS-Partners & Advanced Orthopaedic Solutions, Wednesday Morning, March 26, 2013**

**FREE breakfast symposium for medical device companies**

Event: "Sunshine - How to Weather the Storm of Federal and State Regulations: What Every Medical Device Company Should Know"

Speakers: Paul Doner Vice President, Operations, Advanced Orthopaedic Solutions (AOS); Judy Fox, Director, Transparency Compliance, CIS; Peter Lee, Director of Commercial Compliance,

West Coast Operations, CIS; Adam Toronto, Associate Director, Commercial Compliance, CIS

Date and Time: March 26 at 8:30 - 10:30 a.m.

Location: Renaissance Long Beach Hotel, 111 East Ocean Boulevard, Long Beach, CA 90802

Cost: Complimentary, includes full set of program materials

RSVP by emailing Christine Pahl at [christinepahl@cis-partners.com](mailto:christinepahl@cis-partners.com)

Topic Description

Industry experts from Compliance Implementation Services (CIS) and Advanced Orthopaedic Solutions (AOS) will discuss the key Sunshine Act regulations and lead you through a practical application that aligns with Federal and State Compliance and Reporting requirements. By attending this breakfast, you will learn key insights and best practices from medical device companies who have successfully implemented the Federal and State compliance and reporting requirements.

Program Outline

- Federal and State Workshop - Key Sunshine Act elements and practical application
- Ensuring Compliance, Minimizing Impact - Aligning your compliance program to the reporting requirements and the impact of exposure on your program
- AOS's Journey to Compliance - A medical device company's perspective on compliance requirements including a timeline on when to engage experts and resources
- Panelist Roundtable - The medical device selling model and the challenges of meeting the regulations based on that model

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**BayBio Drug Development Series, Wednesday Morning, March 27, 2013**

Topic: "Optimizing Drug Development in a Resource Constrained Environment"

Speakers: Anne-Marie Duliege, M.D., M.S., Chief Medical Officer and Head of Research & Clinical Development, Affymax, Inc.; Lori Lehman, Ph.D., Vice President Project and Portfolio Management, Gilead Sciences, Inc. ; Barbara Klencke, M.D., Senior Vice President, Clinical Development, Onyx Pharmaceuticals, Inc.; Gisela Schwab, M.D., Executive Vice President and Chief Medical Officer, Exelixis, Inc.; Steven R. Deitcher, M.D., President & CEO, Talon Therapeutics; Lynn Seely, Chief Medical Officer, Medivation; Kitty Yale, Senior Director, Clinical Operations, Gilead Sciences, Inc.

Date and Time: March 27, 2013, 9:00AM – 1:30PM

Location: Gilead Sciences, Inc., 320 Lakeside Dr., Foster City, CA 94404-1147

This event is open to qualified life science companies only. FREE Members, \$50.00 Non-Members

Time	Topic	Presenter
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Topic Description

Life science companies are challenged by the need to streamline their research and development operations in a resource constrained environment. A well informed decision making process is critical to establishing an affordable and trustworthy infrastructure to enable your organization to efficiently nominate and move forward drug candidates. The BayBio Drug Development Series, a new half-day educational program, will feature case studies from Northern California life science companies, interactive panel discussions focused on best practices, and provide opportunities to network with industry peers.

Who should attend:

Executives focused on biopharmaceutical R&D,  
key scientific (i.e. biology, toxicology, pharmacology),  
medical and clinical operations staff.

A small, but focused, exhibit area will save you time and provide value by offering direct access to dozens of companies specialized in providing the external scientific resources critical to supporting virtual and semi-virtual companies from conception to commercialization.

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**CACO Workshop, Thursday Afternoon, March 28, 2013**

Topic: "In vitro ADME Assays & Techniques: Fundamentals, Advances, & Best Practices (jointly with BAADME)"

Speakers: T.Carlson (Amgen), M.Grillo (Amgen), B.Murray (Gilead), L.Salphati (Genentech), S.Wong (Amgen)

Date and Time: Thursday, March 28, 2013, 11:45 am -5:30 pm

Location: Crowne Plaza Hotel, Foster City, CA

12:45pm - 12:50pm	CACO-PBSS/ BAPKPD Welcome	Organizer
12:50pm - 2:00pm	1. Application of translational pharmacokinetics and pharmacodynamics in R&D: principles and biologics case examples	Lorin Roskos (MedImmune)
2:00pm - 2:10pm	Major Sponsor Presentation	Vendor name
2:10pm - 2:25pm	Break & Vendor Show	
2:25pm - 3:00pm	2. Translational PK/PD: Application to Therapeutic Proteins	John Gibbs (Amgen)
3:00pm - 3:35pm	3. Translational PKPD in Oncology: Special Considerations and Case Studies	Jin Yan Jin (Genentech)
3:35pm – 3:50 pm	Break	
3:50pm - 4:25pm	4. Translation of Preclinical to Clinical CNS Receptor and Transporter Occupancy: A PK/PD Approach	David Bourdet (Theravance)
4:25pm - 5:00pm	Panel Discussion	All speakers

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**Bio2Device Group, Tuesday Morning, April 2, 2013**

Topic: "Medical Device Excise Tax – Getting Ready for Your First Quarterly Excise Tax Return"

Speaker: Brian Jenkins, Manager, and Ashley Price, Senior Manager, National Federal Tax Services, Deloitte Tax LLP

Date and Time: Tuesday morning, April 2, 2013, 8:30am

Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA

Cost: \$0 No registration is required

**Topic Description**

Please join Ashley Price and Brian Jenkins from Deloitte’s Medical Device Excise Tax Services practice for a session on the Medical Device Excise Tax – Getting Ready for Your First Quarterly Excise Tax Return. Ashley and Brian have been involved with the MDET since inception and have devoted 100% of their time the past year to assist companies throughout the U.S. with the development of initial MDET readiness plans as well as MDET compliance implementation plans. More specifically the session will focus on the following: Guidance on the types of medical devices subject to the excise tax; Common issues arising as organizations prepare for the new tax, such as the taxable price and taxable uses of products, kits, and combination products; Potential compliance challenges and a practical approach to addressing them.

**Speaker Bios**

Brian Jenkins is a Manager in Deloitte Tax LLP's National Federal Tax Services practice with 7 years of public accounting experience. Brian specializes in the area of tax innovation by taking newly enacted areas of tax legislation and developing and implementing service offerings for Deloitte Tax on a national basis. Brian's most recent work with newly enacted tax legislation has involved the Medical Device Excise Tax (IRC 4191) and the Qualifying Therapeutic Discovery Project Credit (IRC § 48D).

Brian has extensive experience providing federal and state tax consultative services to companies in the areas of corporate restructuring and bankruptcy emergence, dividend or reorganization planning, and analysis of net operating losses, loss disallowance, and other complex issues within the consolidated Regulations.

Brian received his Bachelor of Science Degree of Accounting from Michigan State University and his Masters of Science Degree of Accounting specializing in taxation from the University of Illinois. Brian holds a CPA license in Illinois.

Ashley Price is a Senior Manager in Deloitte Tax LLP's National Federal Tax Services practice with more than 15 years of public accounting experience. Ashley specializes in the area of tax innovation by taking newly enacted areas of tax legislation and developing and implementing service offerings for Deloitte Tax on a national basis.

Ashley's most recent work with newly enacted tax legislation has involved the Medical Device Excise Tax (IRC § 4191), the Qualifying Therapeutic Discovery Project Credit (IRC § 48D), the Qualifying Advanced Energy Project Credit (IRC § 48C) and the ARRA Section 1603 Cash Grant.

Ashley is a frequent speaker at Deloitte internal education events as well as external industry events such as AdvaMed conferences. Ashley also has extensive experience with Federal tax accounting methods as well as extensive experience with mergers and acquisition tax issues such as tax due diligence and tax structuring for several private-equity clients, as well as advising both strategic and private equity buyers and sellers on alternative strategies for acquisitions, dispositions and restructuring of businesses. Ashley is also active representing clients before the IRS and the Department of Treasury.

He received his Bachelor of Science Degree of Accounting from the University of Akron. Ashley holds a CPA license in Ohio and has over 15 years of experience with the Big 4; including 5 years at Deloitte.

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### **Women in Bio-San Francisco Bay, Thursday Evening, April 4, 2013**

Event: Spring Connections Speed Networking Event in South San Francisco

Date and Time: April 4, 2013, 6:00 p.m. to 8:30 p.m. PST

6:00 p.m. – 6:30 p.m.: Registration and mingling, food and drink served

6:30 p.m. – 8:00 p.m.: Speed networking

8:00 p.m. – 8:30 p.m.: More mingling

Location: Onyx Pharmaceuticals, 249 East Grand Avenue, South San Francisco, California 94080

Register by date: April 4, 2013

Space is limited so please register early. Registered guests are welcome.

Cost: Members: \$20, Non-Members: \$35

#### **Event Description**

Wear spring colors and bring your enthusiastic networking skills for a memorable night guaranteed to leave a new spring in your step! Women In Bio's speed networking events have quickly become an anticipated repeat performance here around the Bay Area.

Members and nonmembers are equally welcome to join us for food, wine, and card swapping. This time we're upping the ante and will raffle prizes! Don't miss this fantastic event on April 4, 2013 from 6:00 p.m. to 8:30 p.m. PST!

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### **UC Berkeley Extension, Bioscience Essentials for Industry Professionals: An Intensive Seminar, April 8 – 12, 2013**

#### Dates and Times:

April 8: Mon., 1-5 pm; also

April 9: Tues., 8:30 am-5:30 pm

April 10: Wed., 8:30 am-5:30 pm

April 11: Thurs., 8:30 am-5:30 pm

April 12: Fri., 8:30 am-4:30 pm

Location: San Francisco: Room 806, UC Berkeley Extension Downtown Center, 425 Market St., 8th Floor (enter on Fremont St.)

Course fee: \$1,975 (EDP 406439)

Register at <http://extension.berkeley.edu/catalog/course389.html>

Get a focused introduction to the fundamental concepts and principles of biology in the context of their relevance and application to the bioscience industry. Develop the basic conceptual framework and vocabulary necessary to communicate effectively with technical specialists and comprehend the basic scientific concepts in proposals, prospectuses, and market and technical assessment reports. Explore current techniques and technologies while developing an appreciation of the process and the challenge of turning scientific discoveries into successful products. This course is for marketing, business development, legal and scientific professionals working in the bioscience arena. Entrepreneurs can also benefit from this interactive course.

Guest instructors are scientists and experienced teachers with the proven ability to make scientific concepts comprehensible and relevant.

Breakfast, lunch and course materials are included in the course fee.

#### Lead Instructor

Mary Alice Yund, Ph.D., Extension Honored Instructor, has more than 15 years of experience in developmental genetics research at the University of California, Berkeley. She also has 10 years of experience in technology assessment and market research, consulting for the biopharmaceutical industry. Yund has taught genetics at UC Berkeley; California State University, East Bay; and Mills College. She also has taught genetics, developmental biology, biochemistry, functional genomics and introductory biotechnology courses at UC Berkeley Extension.

#### Guest Speakers

Barbara H. Bowman, Ph.D., teaches molecular cell biology and general biology at Mills College, and has taught biochemistry and molecular biology at UC Berkeley Extension and UC Berkeley. Previously, she was a postdoctoral fellow and senior scientist at Roche Molecular Systems.

Jennifer Lange, B.S., M.S., teaches biology and anatomy at Chabot College. She has taught physiology, anatomy and cell biology at UCLA and UCLA Extension, and physiology and

anatomy for UC Berkeley Extension.

Monica Raney-Goldberg, Ph.D., currently teaches at UC Santa Cruz Extension. Since 1994, she has taught courses in immunology, microbial pathogenesis, cancer biology and introductory biology for UC Berkeley Extension.

John M. Young, Ph.D., is a former senior pharmaceutical executive and now consultant with more than 40 years of experience in all aspects of development. He now focuses on pharmacology, pharmacokinetics and toxicology in support of biotechnology development.

#### Schedule and Outline of Topics

Day 1: 12–5:30 pm

- Introduction to living systems, basic chemistry and biological molecules
- Hierarchical organization of living species
- Atoms, molecules, chemical bonds, water, noncovalent interactions and chemical reactions
- Biological molecules: lipids, carbohydrates, nucleic acids and proteins

Day 2: 8:30 am–5:30 pm

#### Cellular and Molecular Biology

- Proteins and cell organization and structure
- Cell division: mitosis and meiosis
- DNA and RNA and proteins

#### Molecular and Mendelian Genetics

- Expression of genetic material and gene regulation
- Inheritance and genetics and heredity

Day 3: 8:30 am–5:30 pm

#### Organisms and Development

- Organisms: cells, tissues, organs and physiology
- Development: a generative program
- Stem cells and aging

#### Genomics

- Techniques for working with nucleic acids and proteins (cloning, polymerase chain reaction [PCR], sequencing, 2-D gels)
- Genomics: genome structure and analysis from sequence
- Expression analysis and microarrays
- Proteomics and structural genomics
- Comparative genomics
- Metabolomics
- Functional analysis and RNAi

Day 4: 8:30 am–5:30 pm

#### Immunology and Infection

- Microorganism and pathogens
- Immune system and immune defenses
- Allergy, autoimmune disease, inflammatory disease and HIV and AIDS
- Cancer

#### Biomedical Applications and Technologies

- Single-nucleotide polymorphism (SNPs), genome-wide association (GWAs), and pharmacogenomics
- Human genetic variation and complex disease
- Evolution of personalized medicine

- Diagnostics and genetic testing
- Embryonic stem cells and regenerative medicine
- Transgenic mice and transgenic production of pharmaceutical proteins
- Gene therapy

Drug Discovery

- Disease genes and target identification
- High throughput screening and combinatorial chemistry
- Drug discovery process and input from pharmacogenomics and biomarkers

Day 5: 8:30 am–4:30 pm

Bioscience of Human Diseases and Therapeutic Strategies

- Physiology and hormones (diabetes)
- Nervous system (Alzheimer’s and neurodegenerative diseases)
- Cardiovascular system (atherosclerosis)

Drug Development

- The FDA and a regulated industry
- Preclinical studies (absorption, distribution, metabolism and excretion (ADME) and animal toxicology)
- Clinical trials
- Manufacturing biologics

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**BioDesign, Monday Evening, April 8, 2013**

Event: “From the Innovators Workbench”

Speakers: Howard Levin and Mark Gelfand, Co-Founders, Corldea

Date and Time: Monday, April 8, 2013, 5:30 -7:00 pm

Location: Li Ka Shing Berg Hall, Stanford University

Fee: Public \$45 advanced, \$60 at the door; Stanford Alumni \$35 adv, \$40 door; Biodesign Alumni Fellows \$25

Stanford students, faculty, staff Free but please register

Register at <http://biodesign.stanford.edu/bdn/networking/workbench.jsp>

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**Bio2Device Group, Tuesday Morning, April 9, 2013**

Topic: “The brave (and economical) new world of medtech innovation”

Speaker: Paul Yock, MD, Stanford University

Date and Time: Tuesday, April 9, 2013, 6:00 – 9:00 pm

Location: Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto CA 94304

Cost:

\$6 - Students/In-transition - Members only

\$11 - Early-bird Registration - Members only

\$20 - Late Registration and Non-Members

\$25 - Walk-ins

Register at [www.Bio2DeviceGroup.org](http://www.Bio2DeviceGroup.org) a week prior to event

Topic Description

We are in the early stages of an historic shift in medical technology innovation in which global developing economies will play a critical role. The markets for medical technologies are expanding much more rapidly in the BRIC countries than in the West, particularly China and India. The dynamics of these markets are spawning new technologies with a lower cost profile than in the U.S. or Europe. At the same time, in America we have entered a perfect storm for medical technology innovation as we have known it, with increased regulatory barriers, uncertain reimbursement reform and diminished venture funding. One positive outcome for America is the potential for a virtuous cycle of low-cost innovation, where more affordable technologies developed for markets abroad will enter the U.S. market—and, in turn, will help force a new emphasis on affordability for products developed here.

**Speaker Bio**

Paul Yock is the Martha Meier Weiland Professor of Medicine and Mechanical Engineering (by courtesy) and Founding Co-Chair of Stanford’s new Department of Bioengineering. He also holds a courtesy appointment on Operations, Information and Technology in the Stanford School of Business.

Dr. Yock is internationally known for his work in inventing, developing and testing new devices, including the Rapid Exchange™ balloon angioplasty system, which is now the primary system in use worldwide. He also invented a Doppler-guided access system known as the Smart Needle™ and PD-Access™. The main focus of Dr. Yock’s research program has been in the field of intravascular ultrasound. He authored the fundamental patents for mechanical intravascular ultrasound imaging and helped conduct the initial clinical trials. In 1986 he founded Cardiovascular Imaging Systems, which was acquired by Boston Scientific in 1994. Dr. Yock has cofounded several other medical technology companies.

In his academic career, Dr. Yock has authored over 300 peer-reviewed publications, chapters and editorials, a textbook and over 45 US patents. Recent awards include the Transcatheter Therapeutics (TCT) Career Achievement Award, the American College of Cardiology Distinguished Scientist Award and an honorary doctorate from Amherst College. Dr. Yock is a member of the National Academy of Engineering. Current research interests of Dr. Yock’s group at Stanford focus on development and testing of catheter-based delivery systems for cardiac cell transplantation and new catheter and molecular imaging techniques for cardiology. Dr. Yock also founded and directs the Program in Biodesign, a unit of Stanford’s Bio-X initiative that focuses on invention and technology transfer related to biomedical engineering.

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**RAPS San Francisco Chapter, Wednesday Evening, April 10, 2013**

Event: “Career Fair and Networking Event”

Date and Time: Wednesday, April 10, 2013, 5:00-8:30 pm

5:00–6:45 pm Networking, Career Fair and Refreshments

6:45–7:00 pm Break

7:00–8:30 pm Panel Discussion and Q/A Period

Location: **University of California Santa Cruz Extension–Silicon Valley**, 2505

Augustine Drive, Santa Clara, CA 95054

**List Price: \$20.00; Member Price \$20.00**

**Online Registration**

To register for this meeting, please provide your payment information below, or use the downloadable form (PDF) at

[http://www.raps.org/Portals/0/Documents/RegForm\\_SF\\_041013.pdf](http://www.raps.org/Portals/0/Documents/RegForm_SF_041013.pdf) for registration by mail/fax. If you require assistance, please call our Solutions Center at +1 301 770 2920, ext. 200

**Local Contact:** Kiran Gulati, RAPS San Francisco Chapter Chair, +1 510 541 7919

**Event Description**

The RAPS San Francisco Bay Area Chapter invites you to engage with your local regulatory colleagues and to interact with recruiters from local regulatory companies. In addition, a panel of mid- to senior-level regulatory and quality professionals will discuss their career paths and offer suggestions, observations and advice related to navigating the regulatory field.

This session, hosted by UC Santa Cruz Extension–Silicon Valley, is sponsored by the RAPS San Francisco Bay Area Chapter and is intended to facilitate networking among local regulatory professionals. Recruiters from local companies will be onsite to provide participants with a summary of local job opportunities and to collect resumes. Don't miss this unique opportunity to hear from seasoned regulatory professionals and to engage with recruiters from your region. The nominal registration fee allows us to provide light refreshments for all attendees.

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**UC Berkeley Extension Intensive Course, Thursday and Friday, April 11-12, 2013**

Topic: "Life Science Business and Marketing: Their Integral Role for Success"  
Instructor: Audrey S. Erbes, Ph.D.; Guest Speakers: Joyce Chiarenza, Stan Skrzypczak, M.S., M.B.A., Genomic Health, Linda L. Schock, CIS-Partners, Julie Tompkins, M.B.A.  
Date and Time: Thursday and Friday, April 11-12, 2013; 8:30 am – 5:00 pm  
Location: New Belmont Center, UC Berkeley Extension, Room 3B, 1301 Shoreway Road, Suite 400, Belmont, CA 94002  
Fee: \$795; (EDP 408302)  
Register at <http://extension.berkeley.edu/catalog/course190.html>

**Course Description**

The life science industry presents very different challenges found in other industries and requires specialized knowledge and skills to navigate the unique regulatory path requirements, lengthy development times, expensive clinical trial process, FDA control of advertising and labeling, and impact of managed care on reimbursement and pricing. This course conveys the foundational research and analysis skills needed on the job to make good marketing and business recommendations and decisions across company functions.

Course includes two days of intensive classroom work and mentoring by instructor available for balance of term while completing term project. Students will learn how to research and analyze markets and environments for making recommendations and decisions useful for all professional functions in bioscience companies. They will learn how to do typical business and marketing assignments common to the workplace and receive templates/outlines for documents. In the process students will develop a basic understanding of the role and benefits of various business and marketing functions involved in company's success, underscoring their roles across all stages of company and product lifecycle. Participants will learn what makes the industry "tick," identify challenges and opportunities critical to the success of a company and its products that might otherwise be overlooked until too late in the development process. Students will complete business investment analysis of a company and its technology/products of their choice for term project.

## **Deliverables**

Students receive an extensive student reader with lecture slides for note taking, lists of Internet-accessible information resources and gratis access to otherwise paid subscription databases to assist in researching their term project.

## **Who Will Benefit from This Course**

Experienced and newer business and marketing professionals--as well as scientific, clinical, regulatory, and legal professionals--can benefit from this introduction to the important business and marketing aspects of the life science industry and how to research and develop solutions to handle its challenges.

## **Course Director**

**Audrey Erbes, Ph.D.**, is a global life-science business development and marketing consultant, industry blogger at [www.AudreysNetwork.com](http://www.AudreysNetwork.com), organization leader, public speaker and developer of customized executive education. She is known for her industry blog publications on [Audreysnetwork.com](http://Audreysnetwork.com). She had 25 years of corporate managerial experience in the biopharmaceutical industry including Executive Vice President and Cofounder of Kowa Research Institute, a biopharmaceutical licensing and investment subsidiary of Kowa Company Ltd., Japan. Before that she held both U.S. and international management positions at Syntex Corp. (acquired by Roche) in market research, product management, strategic marketing, and business development with a special emphasis on Europe and Asia/Pacific/Canada.

## **Guest Speakers and Their Topics**

**Joyce L Chiarenza**, Chiarenza Consulting, L.L.C. is a regulatory affairs, labeling expert and clinical compliance certified professional with over 40 years of pharmaceutical and biotech experience. She held managerial positions in quality control, quality assurance, compliance and regulatory affairs. After more than 16 years at Genentech, Inc., she became a regulatory affairs consultant, specializing in labeling, advertising and promotion, and clinical compliance. Prior to Genentech she worked in quality with Abbott Laboratories and for three years worked in area of vitamins, food supplements and cosmetics.

Joyce holds a B.S. degree in Child Psychology and Special Education Credentials from California State University at Northridge. In 2010, she received her certification as a Clinical Compliance Professional. Topic: "Operating in the U.S. Regulatory Environment: Is Product Approvable"

**Linda L. Schock** is the Director of Commercial Compliance & Government Programs at Compliance Implementation Services (CIS) and responsible for opening the CIS West Coast office in Burlingame, California. Ms. Schock brings over 20 years of industry experience ranging from distribution, pricing, Commercial and Government contracting, reimbursement and Patient Support Programs. Prior to joining CIS, Ms. Schock worked at NeurogesX as Director, Commercial Operations from 2009-2011 and CV Therapeutics from 2005-2009. From 2001 to 2005 Ms. Schock was Associate Director, Distribution and Reimbursement within Commercial Operations at Actelion Pharmaceuticals where she was involved in the launch of Tracleer<sup>®</sup> and the risk management program *T.A.P.* Ms. Schock began her career at Genentech, Inc. where she worked in Commercial Operation positions of increasing responsibility from 1987 to 2001. Topic: "Building Effective & Compliant Commercial and Government Contracting Operations: A Case Study"

**Stanley Skrzypczak, M.S., M.B.A.**, Senior Director, Commercial Development was previously Senior Director of Oncotype Marketing and Director of Managed Care Marketing, at Genomic Health. He has over 25 years of successful biotech and pharmaceutical sales and marketing experience, including product, managed care, clinical marketing and sales management. In his last position at Genentech, he was the Senior Product Manager for Xolair Marketing. Stan initially built a career in field sales and management for 7 years at Searle Pharmaceuticals, prior to joining Genentech where he worked for 18 years. Topic: "The Impact of U.S. Health Care System on Marketing Biotech Products"

**Julie Tompkins, MBA**, is Sr. Vice President at Timely Data Resources (TDR), a healthcare market research and consulting firm. She has more than 30 years experience in the pharmaceutical and biotech arenas, including 12 years in industry and more than 20 years in market research consulting, and has worked with pharmaceuticals, diagnostics, and drug delivery systems. At Syntex (acquired by Roche), Julie worked in both R&D and Marketing, including positions as Analytical Chemist, Market Research Analyst, Manager of New Product Planning, and Manager of Market Analysis. She spent most of her time in Marketing as the primary liaison between Marketing and R&D, serving as a key member on multi-disciplinary project teams and strategic planning committees. After leaving Syntex, Julie was President and Founder of MedSearch, a primary market research company that merged with TDR in January 2000. She holds a B.A. in Human Biology from Stanford University and an MBA from Santa Clara University. Topic: "The Role of Market Research in Product Planning, Development and Marketing"

### **Course Content Outline**

#### The Discipline of Marketing in the Bioscience Industry

- Unique bioscience industry marketing characteristics
- The core marketing functions
- Pivotal documents associated with marketing functions
- The critical role of marketing at all stages of a product's development

#### Marketing Research and Analysis

- Use of market research to optimize product planning, development and marketing
- Role of market research throughout development of company and product
- Defining the objectives, planning and implementation of the research
- Types of market research and methodologies

#### Impact of Managed Care System on Marketing Bioscience Products

- Review healthcare industry trends/data that impact cost and reimbursement
- Define "who/what is the U.S. healthcare system" and how it influences the commercialization process
- Define reimbursement from Managed Care perspective

#### Success Parameters for Products and Companies

#### Dealing with regulatory Environment and Product's Approvability

#### The Role, Function, Objective of Selected Major Marketing Functions

- Business Development and Licensing Process, Contract and Terms
- Product/Technology Opportunity Assessment Research and Recommendation
- Strategic Planning and Strategic Plan
- Product Management and Product Marketing Plan

- Sales and Distribution

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**CACO-PBSS Workshop, Friday Afternoon, April 12, 2013**

Topic: "Translational PKPD in drug discovery and early drug development: theory and case studies (jointly with BAPKPD Network)"

Speakers: L. Roskos (MedImmune), J. Gibbs (Amgen), J.Y. Jin (Genentech), D. Bourdet (Theravance)

If you plan to attend, please register at [www.CACO-PBSS.org](http://www.CACO-PBSS.org) before it is closed (it may close BEFORE the deadline if the seating capacity is reached early).

Date and Time: Friday, April 12, 2013, 12:45-17:30

Location: SF Bay Area: Foster City Crowne Plaza

Fees: Registration fee: Regular: \$80; For vendor-show reps: \$0; For unemployed: \$0; Webcast - for San Diego members: \$80; Webcast - for Boston members: \$80; Webcast: \$225;

Registration: <http://www.PBSS.org>

Further Information: A joint workshop with BAPKPD Network

Registration deadline: 4/4/2013 (it will close sooner if the seating cap is reached)

Topic Description

Translational pharmacokinetic and pharmacodynamic studies provide bridges between animal research and subsequent clinical development. The goal of this workshop is to provide an overview of the fundamental theories of translational PKPD, along with case studies from different disease areas highlighting how preclinical data is integrated and used to predict clinical outcomes.

Workshop agenda:

- Introduction to key concepts – theory of translational pharmacokinetics and pharmacodynamics
- Biologics case studies
- Cardiovascular case studies
- Oncology case studies
- Transporter related case studies
- Panel Discussion

Speaker Bios

Dr. Lorin Roskos serves as Vice President of MedImmune Clinical Pharmacology and DMPK. His group is responsible for systems pharmacology, translational pharmacokinetics and pharmacodynamics (PK-PD), pharmacometrics, bioanalytics including PK, immunogenicity and PD biomarker assays, and clinical sample and data management. The group supports MedImmune's biopharmaceutical portfolio at all stages of R&D and for all therapeutic areas. Lorin is a member of several senior committees at MedImmune and AZ, including the Human Exposure Limit Committee, Safety Monitoring Committee, Senior Clinical Review, and Protocol Review Committee. Lorin joined AstraZeneca/MedImmune in 2006. Previously, Lorin spent six years at Abgenix, as the head of pharmacokinetics and toxicology, and he has prior experience in pharmacokinetics and drug metabolism at Amgen and Eli Lilly, where he worked on the development of large and small molecule drugs. Lorin received a PhD in pharmaceuticals from the University of Washington in 1994. He has published over 50

research articles, reviews, and book chapters on topics of PK-PD modeling, translational science, PD biomarker development, and immunogenicity testing.

Dr. John Gibbs (Amgen): Dr. Gibbs is currently Scientific Director at Amgen. John earned his Ph.D. in Pharmaceutics from the University of Washington in Seattle, WA in 1998. He worked at Pfizer in Groton CT and his area of focus was in drug discovery and the application of PK/PD in CNS and oncology. In 2006, John joined Amgen in the Department of Pharmacokinetics and Drug Metabolism in Seattle, WA. His current role as Scientific Director involves pharmacometric support for development programs in the inflammation, diabetes, and cardiovascular therapeutic areas. Current areas of research include use of modeling and simulation for decision making along the drug development continuum.

Dr. Jin Yan Jin (Genentech): Dr. Jin Yan Jin is currently the Modeling and Simulation Lead for Oncology and Neuroscience at Genentech in Clinical Pharmacology. In this role, she is responsible for overseeing the clinical modeling and simulation for all small molecules and biologics in these therapeutic areas. She has extensive experience on the application of modeling and simulation for trial design, decision making, and regulatory interactions at various phases of drug development. Her areas of expertise include mechanistic PK/PD modeling, PBPK, population analysis, trial simulation, disease modeling, and literature meta-analysis. In addition to her responsibility at Genentech, Dr. Jin also serves on the Editorial Board of CPT: Pharmacometrics and System Pharmacology and is a member of the Simcyp Consortium. Dr. Jin completed her PhD and post-doc on PKPD with Dr. Bill Jusko at the State University of New York at Buffalo. Prior to join Genentech, Jin was at Eli Lilly where she served as the PKPD lead on projects at various development stages in the areas of metabolic diseases and neuroscience.

Dr. David Bourdet (Theravance): Dr. Bourdet is currently Associate Director in the Drug Metabolism and Pharmacokinetics department at Theravance, Inc. David supports multiple drug discovery and development projects at Theravance and leads a group of scientists focused on clinical pharmacokinetics and development-stage drug metabolism. Prior to joining Theravance, David held positions of increasing responsibility in DMPK at Roche Palo Alto and Chiron/Novartis. David received his Ph.D. from the School of Pharmacy at the University of North Carolina at Chapel Hill where his research focused on mechanisms of drug absorption and intestinal drug transport.

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### **Life Science Foundation, Monday Evening, April 15, 2013**

Topic: "The Centaur and the Whale: Chiron, Cetus and the Emergence of Biotech"

Speakers: Bill Rutter, Frank McCormick, Ed Penhoet, Hollings Renton, Tom White, and Pablo Valenzuela

Date and Time: Monday, April 15, 2013 from 5:30 PM to 7:30 PM (PDT)

Location: UCSF Mission Bay Campus Fisher Banquet Room, 1675 Owens Street, San Francisco, CA 94158

Free

Register at

[https://www.eventbrite.com/register?orderid=149032552376&client\\_token=6b1beaa021074df2ad0fe6bad6bafcb5&eid=5444263940](https://www.eventbrite.com/register?orderid=149032552376&client_token=6b1beaa021074df2ad0fe6bad6bafcb5&eid=5444263940)

#### Topic Description

During this one-hour talk, you will hear from the founders and leaders of Cetus and Chiron, two of the pioneering and most successful biotechnology companies of the 1970s and early 1980s responsible for creating PCR, sequencing the HIV genome, and discovering the hepatitis C virus. The discussion will focus on their first 10 – 15 years of operation, before

these two great Bay Area companies merged. Hear about their successes, mistakes, and lessons that have helped inform how we define biotech success today. Moderated by Ed Penhoet, former CEO of Chiron. Panelists include Chiron co-founders Bill Rutter and Pablo Valenzuela, former Cetus President Hollings Renton, and former Cetus Vice Presidents of Research Frank McCormick and Tom White.

Cetus and Chiron were early and influential Bay Area biotechnology companies responsible for creating PCR, sequencing the HIV genome, and discovering the hepatitis C virus. Please join us as Bill Rutter, Frank McCormick, Ed Penhoet, Hollings Renton, Tom White, and Pablo Valenzuela reflect on their successes, failures, and the lessons learned in the first decade of these two companies.

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### **HBA, Wednesday Evening, April 17, 2013**

Topic: "Connecting the Mind, Body and Action- Translating Neuroscience into Leadership"

Speaker: Charlotte Milliner, CEO and President of The Center for Professional Development, Inc.

Date and Time: Wednesday, April 17, 5:30-8:15pm

Location: Golden Gate University, University Center (536 Mission Street, SF, CA 94105)

Registration: Please visit [hbanet.org](http://hbanet.org) for additional information and to register for the event.

Fee: Member: \$40\*; Nonmember: \$50\*; Student: \$15\* (\*after April 1, fees increase \$5)

#### Topic Description

An evening discussion with a focus on social cognitive and affective neuroscience and practical application to leadership. Charlotte Milliner, CEO and President of The Center for Professional Development, Inc., will speak about the intersection of neuroscience with leadership. In this dynamic discussion, Charlotte will share insights within the field of social cognitive and affective neuroscience and their application to leadership. She will focus on how to effectively collaborate and influence others.

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### **Baybio And Drinkerbiddle, Thursday Mid Day, April 18, 2013**

Event: Baybio Lunch & Learn: Preparing For The Sunshine Act: Don't Be Left In The Dark  
Speaker: Robyn Shapiro, *Partner, Drinker Biddle*

Date and Time: April 18, 2013

11:00am – 11:30am: Registration and Networking

11:30am – 12:30pm: Program

Location: HCP/BayBio Event Center, 250 East Grand Avenue, Suite 26, South San Francisco, CA 94080

Cost: Members: Free; Non-members, \$20

Register at <https://m360.baybio.org/event/registration/login.aspx?eventID=75061>

#### Topic Description

A Final Rule to implement The Sunshine Act, intended to enhance transparency of financial arrangements between industry and healthcare providers, was issued February 1, 2013.

In this Lunch and Learn session, we will address The Act's requirement of "applicable manufacturers" of drugs, devices, biologicals and medical supplies to report to HHS certain payments or transfers of value to physicians and teaching hospitals, as well as information about ownership or investment interests held by physicians in such manufacturers, and posting of submitted payment and ownership information on a public website. This session will also address issues that those involved in clinical research should consider, including:

- Will payments to physician researchers for early-stage development work be reportable?
- How will appropriate contextual information about research payments be included on the website?
- How will the Act impact early co-development work involving start-ups and established "applicable manufacturers"?
- How will provisions in contracts between industry research sponsors and contract research organizations, and between contract research organizations and research sites change?
- How will disputes about reported payments between industry research sponsors and teaching hospitals and physicians be resolved?
- How will Sunshine reports be reconciled with other requirements governing the collection and reporting of similar information(e.g., the NIH Final Rule on conflicts of interest, and state reporting laws)?
- Will the payment reports achieve the Act's goal of reducing risks of inappropriate financial incentives interfering with medical judgment and patient care?

Early registration is highly advised as space is limited to 20 attendees and there will be no on-site registration.

- Late arrivals will not be admitted after 11:30AM.
- Pre-registered attendees will receive an immediate receipt/confirmation after submission.
- Please print this receipt/confirmation and bring it with you to receive your conference credentials.
- Photo ID (driver's license or passport) will be required at check-in.
- All sales are final.

Please mail your event-related questions to: [registration@baybio.org](mailto:registration@baybio.org) or you can contact us via phone: 650-871-3257.

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### **BioDesign, Tuesday Evening, April 23, 2013**

Event: "From the Innovators Workbench"

Speaker: Omar Ishrak, CEO, Medtronic

Date and Time: Tuesday, April 23, 2013, 5:30 -7:00 pm

Location: Li Ka Shing Berg Hall, Stanford University

Fee: Public \$45 advanced, \$60 at the door; Stanford Alumni \$35 adv, \$40 door; Biodesign Alumni Fellows \$25

Stanford students, faculty, staff Free but please register

Register at <http://biodesign.stanford.edu/bdn/networking/workbench.jsp>

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### **Recap Alllicense 2013, Monday and Tuesday, April 29-30, 2013**

Conference: "Alllicense 2013"

Date and Time: Monday – Tuesday, April 29-30, 2013

Location: Palance Hotel, San Francisco, CA

Register now at the Early Bird rate of \$1,706. Expires on Feb. 1  
General Rate: \$2,275  
Early Bird: \$1,706 (*ends Feb 1*)  
Academic/Non-Profit: \$1,137  
Team Discount: 30% off additional registrants from the same company

Registration includes two days of conference sessions, continental breakfasts, seated luncheons, and attendance to the Breakthrough Alliance Award™ dinner on April 29. For further details and registration, go to <http://www.recap.com/allicense/2013/index.html>

#### Conference Description

The Deloitte Recap ALLICENSE™ meeting brings together leading biopharma dealmakers and industry leaders in an open, collaborative forum designed to encourage debate and tackle the significant challenges facing dealmaking teams today. Celebrating its 17th year, ALLICENSE has become a landmark partnering conference for sharing cutting-edge insights that help shape the future of biopharma business development.

This year's agenda includes:

- Venture Capital Trends, Jonathan Norris, Managing Director, SVB Capital
- Public Markets - A CEO's Perspective, Kleanthis Xanthopoulos, CEO, Regulus Therapeutics
- How Price (Drug) Affects Price (Deal), Roger Longman, CEO, Real Endpoints LLC
- Special Lunch Keynote - Innovation: From University to Corporation, Dr. Susan Desmond-Hellmann MD, MPH, Chancellor, UCSF Medical School
- Trends in Dealmaking, Jennifer Doyle, Senior Biopharma Deals Analyst, Deloitte Recap LLC
- Option Deals and M&A Trends, Chris Dokomajilar, Manager and Senior Biopharma Analyst, Deloitte Recap LLC

#### Panel Discussions

- Big Pharma Dealmaking Leaders Shaping the Next Era of Licensing
- A Fresh Perspective in Company Building, The Versant Approach
- Old vs. New: Venture Capital Model
- Corporate Venturing and Deals Coming Together

#### Breakthrough Alliance Award Dinner

A special dinner announcing the award winner and celebrating the most innovative deals of 2012.

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#### **RAPS San Francisco Chapter, Friday, May 17, 2013**

Topic: "QA/RA Organizational Interfaces in the Medical Device Supply Chain"

- Speakers: Chris Devine, president, Devine Guidance International Inc.
- Connie Hoy, vice president, RA/QA, Cutera Inc.
- Roger Stern, president, Stellartech Research Corporation
- Michael A. Swit, JD, special counsel FDA Law, Duane Morris LLP

Date and Time: Friday, May 17, 2013, 8:00 am – 4:45 pm

8:00–8:45 am - Registration, check-in, networking and continental breakfast

8:45 am–12:00 pm - Morning sessions

12:00–1:15 pm - Luncheon

1:15–4:15 pm - Afternoon sessions

4:15–4:45 pm - Panel discussion and close

Location: Biltmore Hotel & Suites, 2151 Laurelwood Road, Santa Clara, CA 95054

Event Description

Join your quality and regulatory colleagues from ASQ Northern California Biomedical and the RAPS San Francisco Bay Area Chapter for a lively and informative one-day workshop addressing the best practices and lessons learned for successfully managing complex QA/RA interfaces between global medical device organizations and their partners. Take away useful tools and new insights into managing critical relationships for quality and regulatory success in a changing medical device environment.

Topics include:

- Outsourced Manufacturing: Domestic and International  
Chris Devine, president, Devine Guidance International Inc.
- Establishing Distributor Contracts and Agreements  
Connie Hoy, vice president, RA/QA, Cutera Inc.
- Managing Quality and Regulatory Relationships in a Virtual World  
Roger Stern, president, Stellartech Research Corporation
- Unique Quality and Regulatory Challenges of Combination Products  
Michael A. Swit, JD, special counsel FDA Law, Duane Morris LLP

Local Contacts: RAPS: Kiran Gulati - [Kiran.gulati@comcast.net](mailto:Kiran.gulati@comcast.net) and Michelle Ragozzino - [mmragozzino@gmail.com](mailto:mmragozzino@gmail.com)  
ASQ: George Marcel - [gjmarcel@gmail.com](mailto:gjmarcel@gmail.com)

RAPS Wesley Carr, +1 301 770 2920

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**UC Berkeley Extension Free Information Session, Wed. Evening, May 22, 2013**

Topic: "Free Information Session: All Life Science Industries Professional Certificates and Specialized Programs of Study"

Date and Time: Wednesday, May 22, 2013, 6-8 pm

Location: Room 804, UC Berkeley Extension Downtown Center, 425 Market St., 8th Floor (enter on Fremont St.), San Francisco, CA

No fee (EDP 406330)

<https://enroll.unex.berkeley.edu/cgi-bin/free/free.cgi?course=406330> or phone (510) 642-4111.

Event Description

Attend a free, no-obligation event to learn about the wide variety of biomedical sciences programs available at UC Berkeley Extension. Meet instructors who can answer your questions about how these programs can help you in your biotech career. For details, visit the Sciences, Biotechnology & Mathematics department at <http://extension.berkeley.edu/sciences/>.

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**BayBio/BioCom CALBIO 2013, June 12-14, 2013**

Event Title: "CALBIO 2013: Success Redefined"

Dates and Times: June 12-14, 2013, 7:00 am – 5:00 pm

Location: San Diego Convention Center, 111 West Harbor Drive, San Diego, California 92101

Cost: \*For a very limited time, we are offering an incredible discounted registration price of \$600. This offer is only good through Tuesday, January 15<sup>th</sup>. Trust us, you will be glad you registered early!

To receive this special price, please use the code TRUSTUS.

If you are a BIOCUM member, register at <http://biocom.org/event/777/>. BAYBIO members register at <https://m360.baybio.org/event/registration/login.aspx?eventID=67497>.

#### Topic Description

California. The birthplace of the biotechnology industry and home to the largest and most productive concentration of life science companies in the world. Over the years, our focus has remained constant – discover the next great thing and turn it into reality. While capital sources, scientific insights and models inevitably evolve and cycle, with the world’s experts in life sciences, California innovates, adapts and continuously redefines the business models, technologies, targets, and development and commercial strategies that drive success. Today, these innovations and the skills needed to move them forward, our changing faster than ever and California is setting the pace. CALBIO 2013 offers highly unique, one of a kind programming so join us, the experts, and learn how we are doing ‘IT’ today, not tomorrow.

The conference is scheduled for June 12-14, 2013 at the San Diego Convention Center.

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#### **BioDesign, Monday Evening, June 17, 2013**

Event: “From the Innovators Workbench”

Speaker: John Dineen, Chief Executive Officer and President of GE Healthcare Ltd. and GE Medical Systems, Inc.

Date and Time: Tuesday, June 17, 2013, 5:30 -7:00 pm

Location: Li Ka Shing Berg Hall, Stanford University

Fee: Public \$45 advanced, \$60 at the door; Stanford Alumni \$35 adv, \$40 door; Biodesign Alumni Fellows \$25

Stanford students, faculty, staff Free but please register

Register at <http://biodesign.stanford.edu/bdn/networking/workbench.jsp>