

Audrey's Life Science Meeting Picks for January-March 2012
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(Jan. 21, 2012 Edition)

**BioCentury TV Today, See the Webcast Sunday, Jan. 22, 2012 www.biocenturytv.com,
Continuously available starting at 9:00 a.m. EDT**

Topic: "Curtain Raiser"

Speaker:

Norm Coleman, former Republican Senator from Minnesota and Senior Governmental Advisor at the law firm Hogan Lovells

Byron Dorgan, former Democratic Senator from North Dakota and Senior Policy Advisor to the law firm Arent Fox

Dr. Judy Feder, Professor of Public Policy at Georgetown University and former Principal Deputy Assistant Secretary of HHS in the Clinton Administration

Gene Grabowski, EVP at Levick Strategic Communications

Date: Sunday, Jan. 22, 2012

Watch the Broadcast
8:30 - 9:00 a.m. EDT
WUSA Channel 9
in Washington, D.C.

Watch on the Web
www.biocenturytv.com
Continuously available
starting at 9:00 a.m.

Topic Description

As President Barack Obama delivers his fourth State of the Union address next Tuesday, the U.S. Supreme Court is preparing to hear challenges to his landmark Affordable Care Act. On Sunday, Jan. 22, *BioCentury This Week* offers a vigorous debate on the future of healthcare reform, featuring a panel of Washington insiders and political communications specialists. They will debate the prospects for "repeal" or "reform" of the Affordable Care Act. Assess the impact of political gridlock and budget sequestration on the biopharma agenda. And provide advice on where the political classes should be connecting with the American public.

Personalized Medicine World Conference 2012, (PMWC), Mon.-Tues., Jan. 23-24, 2012

Date: January 23-24, 2012

Location: Computer History Museum, 1401 N Shoreline Blvd, Mountain View, CA 94043 Mountain View, California

Contact Information: registration@pmwcintl.com

Cost: \$1,400 or table of 10 for \$7,500

Register to attend: <http://pmwc2012.eventbrite.com> You can see a nicer version of this email with pictures at: <http://pmwc2012.com/email/industry/index3.html>

Register today to start connecting with companies. A new website for attendees enables networking before, during and after the Conference.

Current PMWC 2012 Speakers (see details at <http://pmwc2012.com/speakers.php>):

Brian Druker M.D., Director [Oregon Health & Science University Knight Cancer Institute](#)

Amir Dan Rubin, President & CEO [Stanford Hospital and Clinics](#)

Naomi Aronson Ph.D., Exec. Direction [Blue Cross Blue Shield](#)

Mara Aspinall, President [Ventana Medical Systems](#)

Joffre B. Baker Ph.D., CSO [Genomic Health](#)

Barrett Bready, President & CEO [NABsys](#)

Alexis Borisy, Chairman and Co-Founder [Foundation Medicine](#)

Pierre Cassigneul, President & CEO [XDx Cardio](#)

William Dalton Ph.D., M.D., President, CEO & Dir. [Moffitt Cancer Center](#)

Brett Davis, Sr. Dir. [Oracle Health Sciences](#)

Laura Esserman M.D., MBA, Dir. Carol Franc Buck Breast Care Center & Professor [UCSF](#)
Steven Finkbeiner M.D., Ph.D., Assoc. Dir. [Gladstone Institute of Neurological Disease](#)
Felix Frueh Ph.D., VP and R&D [Medco Health Solutions, Inc.](#)
David Galas Sr., Ph.D., VP [Institute for Systems Biology](#)
Evian Gordon BSc, Ph.D., MBBCH, Chairman & CEO [Brain Resource](#)
Pat Groody Ph.D., Divisional VP, R&D [Abbott Diagnostics](#)
Marc Hellerstein M.D., Ph.D., Co-Founder [KineMed](#)
James Heywood, Co-Founder & Chairman [PatientsLikeMe](#)
Andrea Klemes DO, FACE Medical Dir. [MDVIP](#)
Jon Kobashigawa M.D., Assoc. Dir. [Cedars-Sinai Heart Institute](#)
Walter Koch Ph.D., VP & Head of Global Research [Roche Molecular Systems](#)
Jean-Pierre Kocher Ph.D., Bioinformatics Core Dir., Health Sciences Research [Mayo Clinic](#)
C. Ola Landgren M.D., Sr. Investigator [National Cancer Institute](#)
David H. Ledbetter Ph.D., FACMG, Exec. VP & CSO [Geisinger Health Systems](#)
Lawrence Lesko Ph.D., Professor College of Pharmaceutics, [University of Florida](#)
Ronald Levy M.D., Ph.D., Chief Division of Oncology [Stanford Medical School](#)
Elizabeth Mansfield Ph.D., Dir. of Personalized Medicine [FDA](#)
David Parkinson M.D., CEO [Nodality](#)
Scott Patterson Ph.D., Exec. Dir. [Amgen Molecular Sciences](#)
Michael J. Pellini M.D., President & CEO [Foundation Medicine](#)
Michael Phelps Ph.D., Dir. of Institute for Molecular Medicine [School of Medicine UCLA](#)
Bruce Quinn M.D., Sr. Health Policy Specialist [Foley Hoag](#)
Ron Ribitzky M.D., CEO R&D [Ribitzky](#)
Stefan Roever, CEO [Genia Technologies, Inc.](#)
Michael Shuster Ph.D., IP Partner & Life Sciences Group Co-Chair [Fenwick & West LLP](#)
Ralph Snyderman M.D., Chancellor Emeritus [Duke University](#)
Sharon Terry, President & CEO [Genetic Alliance](#)
Chris Toumazou Ph.D., Biomedical Engineering [Imperial College London](#), CEO [DNA Electronics](#)
Peter Yu M.D., Dir. of Cancer Research [Palo Alto Medical Foundation](#)
Steven Bartz Ph.D., Dir. of Worldwide Licensing [Merck & Co., Inc.](#)
Paul Beresford Ph.D., VP of Business Development [Biodesix](#)
Flavia Borellini Ph.D., Life Cycle Leader for [Zelboraf Genentech](#)
James S. Burns, President & CEO [AssureRx](#)
Atul Butte M.D., Ph.D., Pediatric Bioinformatics [Lucile Packard Children's Hospital](#)
Ashley Dombkowski Ph.D., Chief Business Officer [23andMe](#)
Jill Hagenkord M.D., CMO [Complete Genomics](#)
Mary Haak-Frendscho Ph.D., President & CSO [Takeda Pharmaceuticals San Francisco](#)
Ann Kapoun Ph.D., VP of Translational Medicine [OncoMed Pharmaceuticals](#)
Andrew Kurtz Ph.D., Program Dir., SBIR Development Center [National Cancer Institute](#)
Lousie Perkins, Ph.D., Chief Scientific Officer [Multiple Myeloma Research Foundation \(MMRF\)](#)
Jessica Melin Ph.D., MBA, Sr. Business Development Biosciences [Sony DADC](#)
Robert Michel, Editor in Chief [The Dark Report](#)
C. Douglas Monroe, RPh, MS, FCSHP Bio & Pharma Tech [Kaiser Permanente](#)
Hakan Sakul Ph.D., Sr. Dir. & Global Head of Diagnostics & Oncology [Pfizer](#)
Andrew Schorr, Founder [Patient Power](#)
Stephen Quake Ph.D., Professor [Bioengineering Stanford University](#)
Elizabeth Worthey Ph.D., Assistant Professor [Medical College of Wisconsin](#)
Gerald McDougall, Partner [PricewaterhouseCoopers](#)
Andre de Fusco, CEO [Cynvenio Biosystems](#)
Mark Blumenkranz M.D., CEO [Digsight Network](#)
Robert Gould Ph.D., President & CEO [Epizyme](#)
Casey Eitner, President and CEO [Expression Pathology](#)
Ken Fang M.D., CMO [Integrated Diagnostics](#)
David Fineman Ph.D., President & CEO [Kinemed](#)
Michael Paul Ph.D., CEO [Lineagen](#)
Zachary Antovich, Founder & CEO [Linkage Biosciences](#)
Paul Rhodes Ph.D., CEO [Metabolomx](#)
Peter Leigh, CEO [Microsonic Systems](#)

Ilya Kupershmidt Ph.D.c, Co-Founder & VP of Products [NextBio Enterprise](#)
Gil Blander Ph.D., Founder & President & CEO [Segterra](#)
Richard Gould Ph.D., CEO [Station X](#)
Peter Payne, CBO [TcLand Expression](#)
Calvin Harley Ph.D., President & CSO [Telome Health](#)
Robert Booth Ph.D., CEO [Virobay](#)
Alan Nelson Ph.D., CEO & Founder [Visiongate](#)
Jim Kean, CEO [WellnessFX](#)

Some topics to be discussed:

- How good are today's cancer therapies and how much should we pay for them?
- What can EMRs tell us about drug responses and interactions?
- Do clinical trial results reflect real-world efficacy?
- How do we integrate "-omics" into an entrenched health care system?
- Can personalized medicine impact neurodegenerative disease?

Program Structure:

Main Track - Emerging Technologies, Into The Clinic, Evolving Regulation, Economics, Rx/Dx Opportunities, NextGen Health IT

Track 1 - Opens with tutorials followed by emerging companies presenting to win Award

Track 2 - Established companies, clinicians, and researchers present their technologies & platforms

Exhibition Floor - Includes professional booths showcasing companies' latest products

PMWC Connect - enables attendees and speakers to connect with each other

View the latest program at: <http://pmwc2012.com/program>

Bio2Device Group, Tuesday Morning, Jan. 24, 2012

Topic: "FDA's 21 CFR 11 Inspection Assignments"

Speaker: Angela Bazigos, CEO, Touchstone Technologies

Date and Time: Tuesday, Jan. 24, 2012, 8:30- 10:30 am

Location: Sunnyvale City Council Chambers, 456 W. Olive, Sunnyvale, CA (across the street from Sunnyvale Public Library)

Cost: Free

Park in Street and in NOVA and library parking lots across the street.

Topic Description

In December 2010 the FDA changed the way it does audits to include 21 CFR 11 add-on inspections. Very little is known about this, yet the FDA has already issued citations on the subject. This Webinar will present the current status of 21 CFR 11, the latest on FDA thinking (with slides directly from the FDA's Office of Compliance), discuss how these inspections will impact both your company and the industry, and provide guidance on how your company can ensure that they have a successful inspection.

Speaker Bio

Angela Bazigos is the CEO of Touchstone Technologies Silicon Valley, Inc. "Your Outsourced FDA Compliance Department". She has almost 30 years experience in the Lifesciences industry and has applied for patents aimed at speeding up Software Compliance. She is a member of the SQA CVIC (Society of Quality Assurance Computer Validation Initiative Committee), DIA and RAPS and works consults to Pharma / Biotech / Medical Device and CRO industry on compliance matters, including strategy, submissions, quality assurance and remediations following action by the FDA. She taught classes on Compliance, 21 CFR 11, Computer Systems Validation, and Project Management. More recently, Ms. Bazigos was selected to co-author Computerized Systems In Clinical Research / Current Data Quality and Data Integrity Concepts with FDA, DIA

and Academia. She is also on the board for UC Berkeley's Business School for Executive Education in Life Sciences and on the Stanford Registry for Women's Who's Who.

QB3 Seminars, Wednesday Lunch Time, Jan. 25, 2012

Topic: Exploiting a More Polar Property Space in the Design of Brain Penetrant Molecules

Speaker: Anabella Villalobos, PhD, Vice-President, Neuroscience and Antibody Drug Conjugate Medicinal Chemistry, Pfizer

Date and Time: Wednesday, Jan. 25, 2012, noon to 1:00 pm (Lunch will be served)

Location: Genentech Hall N-114, UCSF Mission Bay

Cost: Free

Register at

https://www.eventbrite.com/register?orderid=66281572969&ebtv=C&eid=2736367549&client_token=180049490ad7484aab9ac19068e354c

Topic Description

In our efforts to increase the survival of drug candidates, we undertook a detailed study of the chemical space for Central Nervous System (CNS) molecules. Ultimately, we were interested in optimizing the number of design cycles and in vivo toxicology testing needed to advance candidates from idea to proof of concept clinical studies. We focused on understanding the relationships between physicochemical properties, in vitro absorption, distribution, metabolism, and excretion (ADME) and safety attributes, and binding efficiencies for over 200 marketed CNS drugs and Pfizer CNS candidates. This analysis together with medicinal chemistry knowledge was used to create and validate a prospective design tool which used an overall desirability score for drug-likeness. The novel CNS multi-parameter optimization desirability (CNS MPO Desirability) algorithm, based on six physicochemical parameters, showed that 74% of marketed CNS drugs displayed a high desirability score (>4, using a scale of 0-6). In addition, a relationship between an increasing desirability score and alignment of key in vitro ADME and safety attributes was seen in the marketed CNS drug set, the Pfizer candidate set, and a Pfizer proprietary diversity set. The CNS MPO Desirability score is thus an algorithm in the medicinal chemistry toolbox that may be used prospectively at the design stage to accelerate the identification of compounds with increased probability of success. Furthermore, application of this tool to new clinical drug candidates has challenged the long-held notion that CNS molecules need to be highly lipophilic with low polar surface area, moving the CNS design field in a new direction.

Speaker Bio

Anabella Villalobos is currently the head of Neuroscience and Antibody Directed Conjugate Medicinal Chemistry at Pfizer Worldwide Research and Development, Groton Laboratories. Anabella obtained her B.S. in Chemistry at the University of Panama and her Ph.D. in Medicinal Chemistry at the University of Kansas where she was a Fulbright-Hayes fellow. After two years as a National Institutes of Health Postdoctoral Fellow at Yale University in synthetic organic chemistry, Anabella joined the Groton Laboratories at Pfizer in 1989. Among Anabella's accomplishments are her contributions to the Acetylcholinesterase Inhibitor program leading to the design and discovery of CP-118,954 (icopezil) which was advanced to Phase II clinical trials in Alzheimer's disease. This candidate became part of the agreement that led to the successful co-promotion of Aricept by Pfizer and Eisai. Anabella has significant drug discovery and development experience and has led multidisciplinary teams that have taken development candidates into Phase I and Phase II studies for Alzheimer's disease, stroke, and sleep disorders. She is the author of multiple publications and patents.

Palo Alto AWIS, Wednesday Evening, Jan. 25, 2012

Topic: "Starting Your Own Company; Making a Difference: The Potential of Nanotechnology for Life Sciences and Biotechnology"

Speaker: Aihua Fu, Ph.D., CEO Nvigen

Date and Time: Wednesday, January 25, 2012, 7-9 PM

Schedule: 7:00-7:30 pm Networking Dinner 7:30-7:45 pm Announcements 7:45-9:00 pm Seminar Dinner will be served prior to the event, so join us for networking!
Location: Xerox PARC Auditorium, 3333 Coyote Hill Rd. Palo Alto, CA
Cost: \$5 Students/Members; \$10 Others
RSVP: <http://bit.ly/tObnBU>
Flyer: http://pa-awis.org/flyers/AWIS_Flyer_Jan2012.pdf

Topic Description

Dr. Aihua Fu, CEO of NVIGEN will share with you my experience in the founding of NVIGEN, which should reinforce the image of Silicon Valley that is uniquely suited for scientists to pursue their dreams under the strong innovative atmosphere created by many entrepreneurs, technologists, investors and technological innovations. Additionally she will discuss opportunities to leverage unique properties of nanoparticles for biomedical innovations, from the general perspective and with some specific examples of the nanoparticle reagents developed at NVIGEN Inc. Bio:

Speaker Bio

Dr. Aihua Fu, CEO of NVIGEN studied chemistry as an undergraduate at Beijing University of Chemical Technology. She then moved to the United States, graduated with a M.S. degree from Rutgers and received her Ph.D. degree from UC Berkeley. Her doctoral research focused on developing new nanoprobe from semiconductor quantum dots and gold nanoparticles help her built a solid foundation for understanding the unique properties and potentials of nanoparticles for biological applications. She conducted her postdoctoral research at Stanford, working on engineering nanoparticles with enhanced properties for in vitro diagnostics and in vivo cancer imaging and targeting applications in the Molecular Imaging Program and Radiology Department. In 2011, with strong determination to promote the use of nanotechnology and help realize its full potential for biomedical innovations, she founded NVIGEN Inc with support from local biotechnologists, entrepreneurs and investors. She has won many awards and honors including Dow Chemical Award, Du Pont Award, the Materials Research Society Graduate Student Award and the NIH Pathway to Independence Award.

You don't need to be a member to attend. All scientists, students, and their friends are all welcome. Men too! Members pay \$5 and non-members pay \$10 at the door.

BayBio Life Science Series, Thursday Morning, Jan. 26, 2012

Topic: "Fundraising in Troubled Times: Alternatives to the Traditional Forms of Funding"

Moderator: Michael Benjamin, Shareholder, Audit Burr Pilger Mayer, Inc.

Speakers:

- Kim Tsuchimoto, Chief Financial Officer, Treasurer and Secretary Raptor Pharmaceutical Corporation
- Bruce W. Jenett, Partner and Co-Chair, Global Life Sciences Sector DLA Piper

Date and Time: Thursday, Jan. 26, 2012, 8:00-10:30 am

Registration: 8:00AM – 9:00AM

Breakfast, Networking: 8:00AM – 8:30AM

Program: 8:30AM – 9:30AM

Networking: 9:30AM – 10:30AM

Location: DLA Piper, 2000 University Avenue, East Palo Alto, California 94303

Cost: Pre-registration through January 25-\$20 BayBio Members, \$40 Non-Members

On-site registration on January 26- \$40 BayBio Members, \$75 Non-Members

Topic Description

For life science companies facing lengthy, high-cost R&D cycles, government approvals, and difficult clinical trials, funding is their lifeblood. Of course, there's less money to go around these days with the IPO market essentially having grinded to a halt and the competition for VC funding fierce. Fortunately, there are other sources.

This panel discussion will cover some of the lesser-known funding options available in today's marketplace. Accounting, finance, and legal considerations surrounding these alternatives will be discussed in detail. In addition, experts working at venture capital and Super Angel firms, to provide their perspectives and BayBio Life Science Series, Thursday Morning, Jan. 26, 2012

East Bay Association for Women In Science, Thursday Evening, Jan. 26, 2012

Event: "An Evening of Networking"

Date and Time: Thursday, January 26, 2012, 6:30 – 9:00 pm

Agenda

- Light Dinner and Networking at 6:30 pm
- Structured Program at 7:00 pm

NOTE: Registering w/ Eventbrite will say free; however, fee will be collected at the door

Location: Novartis, 5400 Hollis St, Building X-310 Emeryville, CA

Parking is in front of the Building

Fee: \$5 for members, \$10 for non-members.

Register at <http://www.eventbrite.com/event/2639220981>

Event Description

An entire Chapter meeting devoted to networking! Our venue will guide you through a review of networking strategies; then, effective networking games that introduce you to many people will offer you the opportunity to-

- v Meet scientists as well as professionals interested in an affiliated career if you are job searching
- v Enhance your contacts if you are established in your present position
- v Polish presentation skills before the interview
- v Gather invaluable feedback about yourself in a friendly, fun, and informal environment

VC Taskforce, Thursday Evening, Jan. 26, 2012

Topic: "Trends in Life Science Funding"

Moderator: Meredith L. Warshaw, PhD, CSO, Molecular Image and Chair, VC Taskforce Life Sciences

Life Sciences Money Tree Overview: Steve Bengston, Director, PwC (Pricewaterhouse Coopers)

Panelists:

Doug Foster, Longitude Capital

Mike Powell, PhD, Sofinova Ventures

Jonathan Norris, SVB (Silicon Valley Bank)

Steve Bengston, PWC (Pricewaterhouse Coopers)

Philip Ottinger, WSGR (Wilson Sonsini Goodrich & Rosati)

Roger Flugel PhD, Sanderling Ventures

Date and Time: January 26, 2012 | 6:00-8:30 PM |

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

Agenda:

Doors open and networking: 6 PM

Program: 6:30-8:30 PM

Hors d'oeuvres and beverages will be served.

Registration:

\$45 VC Taskforce Members

\$55 Affiliate Organization Members (Applicable to those members of AudreysNetwork.com and

Bio2Device Group)

\$75 General

(If space is available, door registration is an additional \$10)

Register at http://vctaskforce.site-ym.com/events/event_details.asp?id=201023

Topic Description

This program is for investors and entrepreneurs both venture backed and those looking for initial funding, as well as anyone interested in the life science space. We'll explore the Life Science funding ecosystem; its many facets and issues. Funding in life science is not what it used to be. Find out:

- How investors see the life science investment environment in Silicon Valley, across the country and abroad.
- What venture capitalists need to do to get financing
- What startup companies need to do to get their companies funded
- About the 510(k) process and FDA regulation
- How the FDA is influencing life science investments
- About benefits/implications of clinical trials abroad vs US

Our panel discussions are exciting, informative and interactive. Get the real story about what's happening in today's market and how to make it work for you. Hear first-hand what it takes to raise capital in the Life Science arena. Come prepared with questions you've always wanted to ask.

VC Taskforce and the Wilson, Sonsini, Goodrich and Rosati law firm have partnered to bring to you this program series. The evening will prove to be very informative. We look forward to your participation.

The discussion will be followed by a Networking Opportunity to meet the panel and your fellow colleagues.

Health Technology Meetup, Thursday Evening, Jan. 26, 2012

Topic: "Health Research: Ripe for Disruption - Health Technology Meetup"

Speakers: Greg Biggers, Chief Instigator & CEO of Genomera; Kate Schafer, Senior Technology Executive and Independent Consultant

Thursday, January 26, 6:00 PM (networking time and speakers)

Location: Pillsbury Winthrop Shaw & Pittman, 2475 Hanover St., Palo Alto, CA 94304

Cost: No cost to attend event or join group but you need to register through the Meetup website at this link. just click "join us"

http://www.meetup.com/HealthTechnology/events/47735762/?a=me1.1p_grp&rv=me1.1p

Two Topics Description

Topic 1: Health Research: Ripe for Disruption.

This talk will compare the status quo with new developments in crowdsourcing, e-patients, participatory medicine, clinical trial recruiting, citizen science, and more. You will hear about challenges, opportunities, and developments that show us what is possible.

Topic 2: HIPAA Compliance DeMystified.

While HIPAA must be taken very seriously and is in fact a very big deal, HIPAA compliance is achievable. Learn more about HIPAA regulations specific to software vendors and corresponding Business Associates.

Speaker Bios

Greg Biggers

A 20 year industry veteran with a track record commercializing innovation, Greg Biggers is combining the potential of faster medical research with activated consumers and Internet distribution. An Internet and software multiprenuer, he brings a fresh perspective to

how we meet the health challenges of this decade and catalyze more healing for the world.

Kate Schafer

Kate Schafer is a senior technology executive and independent consultant with more than 20 years experience spanning software engineering to senior management. Her expertise is in technology strategy, with an emphasis on Healthcare IT and regulatory compliance. Kate most recently served as SVP of Engineering and HIPAA Compliance Officer at Epocrates, where she was responsible for leading mobile and web product development . As HIPAA Compliance Officer, Kate designed and implemented the internal controls, policies and procedures to ensure HIPAA compliance.

Kate's credentials include Certified HIPAA Professional (CHP) and Certified Security Compliance Specialist (CSCS). She is a member of the Healthcare Compliance Association (HCCA) and the Information Systems Security Association (ISSA).

Bio2Device Group, Tuesday Morning, Jan. 31, 2012

Topic: "Everything you always wanted to know about patents but were afraid to ask"

Speaker: Dr. Nusrat Khaleeli, Of counsel at TechLaw, LLP

Date and Time: Tuesday, Jan. 31, 2012, 8:30- 10:30 am

Location: Sunnyvale City Council Chambers, 456 W. Olive, Sunnyvale, CA (across the street from Sunnyvale Public Library)

Cost: Free

Park in Street and in NOVA and library parking lots across the street.

Topic Description

Like you, technology expert and patent attorney Nusrat Khaleeli has heard patent basics explained in numerous ways over the years. Some seminars are about the nuts and bolts of applying for patents and getting them issued and others are about patent statutes, patent cases or even patent reform. This one is different. In this presentation, Nusrat has asked you what you want to know about patents and has answered your real-life questions.

Speaker Bio

Dr. Nusrat Khaleeli, of counsel at TechLaw, LLP, specializes in representing bioscience, biotechnology, pharmaceutical, and life sciences clients with a focus on patent prosecution and due diligence matters.

Nusrat graduated from Oberlin College with a B.A. in Chemistry and Biochemistry, focusing primarily on protein chemistry. Nusrat also holds a Ph.D. in Chemistry from The Johns Hopkins University, where her research included elucidation of the biosynthetic pathway for the Streptomyces natural product, clavulanic acid, a component of a commercially available antibiotic. Research techniques included site-directed mutagenesis, cloning, protein overexpression, purification, characterization, assay development, enzyme substrate synthesis and small molecule purification from fermentation culture. Nusrat has three years experience as a drug discovery research scientist. In industry, she gained expertise in drug target identification, automated liquid handling instrumentation, high throughput screening of small molecule libraries for lead identification and validation. Nusrat has technical expertise in areas ranging from drug discovery research, protein chemistry, small molecules, liquid separations, molecular biology, instrumentation and pharmacogenomics.

Nusrat holds a J. D. from Santa Clara University School of Law where she served as a Technical Editor for the Computer and High Technology Law Journal and received a High tech Law Certificate.

Medtech Frontiers, Thursday Evening, February 2, 2012

Topic: "The Internet of Living Things"

Date and Time: Thursday, Feb. 2, 2012, 6:00 pm

Location: Triple Ring Technologies, 39655 Eureka Dr., Newark, CA 94560

Cost: Free A limited number of on-site registrations are available. If you received this invitation from a colleague, send a note to mtf@tripleringtech.com to receive your own invitation and RSVP.

Topic Description

Welcome to the exciting field of synthetic biology, where cells are computers, genomes are operating systems, and viruses are "apps". Founded on the most powerful yet inexpensive technologies humanity ever developed – digital computing, DNA sequencing, and DNA synthesis – synthetic biology has been building up a head of steam for the last decade. Making a biotechnology company used to take a roomful of brilliant PhDs, state-of-the-art labs, millions of dollars, and a decade of R&D to reach market. Not anymore. With synthetic biology, anyone with a copy of Biology for Dummies, a laptop, and a credit card can give it a go. What does the future hold? Andrew Hessel, geneticist turned futurist, will walk you through some of the startling possibilities.

Speaker Bio

Andrew Hessel, is a consulting biologist and visionary in synthetic biology and open source biology. His efforts to raise awareness of the benefits in this field have been supported by the University of Oklahoma, the University of Toronto, MIT, and most recently, the Alberta Ingenuity Fund. Andrew is the co-founder of the Pink Army Cooperative, the world's first cooperative biotechnology company and co-chairs the Biotechnology and Bioinformatics track at the Singularity University. He has been responsible for program development for iGEMS, the international Genetically Engineered Machines synthetic biology training program. Andrew earned his MSc. in bacterial genomics from the University of Calgary.

East Bay-AWIS Winter Career Workshop, Saturday, Feb. 4, 2012

Topic: "Build Flexibility and Energy into your Career"

Date and Time: Saturday, February 4, 2012, 9:00am- 2:00pm

Location: Bio-Rad, 225 Linus Pauling, Suite D, Hercules, CA 94547

Please dress comfortably to participate in Dr. Susan Bernstein's Tai Chi exercises.

Fee: \$45 members, \$55 non-members until 1.31.2012, \$60 after 1.31.2012 and at the door.

REGISTRATION FEE INCLUDES BREAKFAST, LUNCH, AND A COMPLEMENTARY COPY OF DR.

JOANN DAHLKOETTER'S BESTSELLER YOUR PERFORMING EDGE

Space is limited so please register early.

Register at <http://ebawisfebruaryperformance.eventbrite.com/>

Parking is in front of the Building

"Future Proof Your Career"

Susan Bernstein, PhD, [Work From Within](#)

Future Proof Your Career: Building Flexibility to Navigate Changes

Learn how to navigate the future of work and create the calm, clarity, confidence and connection needed to thrive in the new economy. Prepare yourself for the inevitable changes in your professional career. Our world is changing quickly and familiar jobs are becoming obsolete. Now, instead of going to work, work often comes to us. The Millennial Generation grew up on technology, and is forcing us to use it more wisely and creatively. At the same time, we're living

in a time when the environment is increasingly polluted and resource-depleted. With all these changes, what do you need to know to make your career a success?

- The five major trends that will dictate your professional future
- Three conflicts that will have tremendous impact on your work — and your family/personal life
- Four key strategies you can adopt right now to be future-proof and flexible
- Techniques for creating calm, clarity, confidence and connection

“OLYMPIC THINKING” Strategies for High Energy, Productivity, and Balance

Dr. JoAnn Dahlkoetter, PhD, [Peak Performance Plan](#)

This program, “Your Performing Edge “will give you a complete system with mindset tools and results-driven solutions to increase your energy, drive productivity, and enhance your performance under pressure. You will walk away with a powerful experience along with tools and resources for managing daily demands and strengthening your mind and body to be more resilient, to perform well, and to create inner balance under the most highly demanding work conditions. Learn leadership skills you can apply immediately:

- Your Gold Medal Mindset for Success – Olympic Thinking Tools
- Your Performing Edge – 3 P’s: Positive images, Power words, Present focus
- How to Build a Healthy, Balanced Lifestyle Professionally and Personally
- Visualize to Energize: Confidence and Focus to Break through Barriers to Success

Bio2Device Group, Tuesday Morning, Feb. 7, 2012

Topic: “Children’s Global Health Initiative - A highlight of how researchers and clinicians at a local organizations are healing globally”

Speaker: Seema Handu, Ph.D., Managing Director, & Dr. Desiree LeBeaud, MD, M.S., assistant scientist at CHORI and a clinician at the Children’s Hospital in the Pediatric Infectious Disease, respectively, Children's Global Health Initiative

Date and Time: Tuesday, Feb. 7, 2012, 8:30- 10:30 am

Location: Sunnyvale City Council Chambers, 456 W. Olive, Sunnyvale, CA (across the street from Sunnyvale Public Library)

Cost: Free

Park in Street and in NOVA and library parking lots across the street.

Topic Description

Health care has become a global issue not only because of increasing worldwide travel but also because of the impact on global economies. Our children are the most vulnerable population on the planet and represent the greatest challenge to improving health and decreasing mortality – over 10,000,000 children under the age of 5 years die of diarrhea, lung infections, malaria and measles each year, many complicated by malnutrition and most are preventable! Other diseases such as sickle cell anemia, cancer, and AIDS also take their toll on morbidity and mortality rates. With this backdrop, we developed the Children’s Global Health Initiative.

The Children's Global Health Initiative (CGHI) represents the collaborative efforts of researchers and clinicians from Children's Hospital Oakland Research Institute (CHORI), the research arm of Children's Hospital & Research Center Oakland. CGHI collaborates with other non-profits, universities, institutes and biotechnology companies to provide a venue for the medical and scientific world to collaborate to develop and implement cures for childhood and adult diseases globally. We have an active program of providing medical care tied with hands-on training at a number of hospitals/clinics in developing countries. This includes the bilateral exchange of physicians, scientists, postdoctoral fellows, medical students, graduate students and undergraduate students for training in appropriate medical and basic science technology and education. We also have ongoing translational research projects on specific topics relevant to individual countries as well as other topics for improving the global health of children and individuals of all ages. In addition, we have three Focused Country Programs in Vietnam, Ecuador and Uganda that include capacity building, clinical service, education, training and research. As part of capacity building, we promote country-appropriate medical and research technologies for these low-resource settings.

CGHI's mission is to enable sustainable global health for children and their communities through education, training, clinical care and translational research.

We create sustainable programs specifically by collaborating with local in-country clinics and institutions where we are invited so that the knowledge, training and education we provide persists within local resources long after we have left.

Today's discussion will showcase two of our projects in Vietnam and in Kenya. The difficulty of diagnosing mosquito borne viral infections in the field will be presented to generate discussion among and collaboration with the B2DG.

Speaker Bios

Seema Handu, PhD, Managing Director of CGHI, is responsible for leading the organization's team to run sustainable health programs for children in the developing world. Prior to CGHI, Dr. Handu was the founder, President & CEO of PharmQuest, a regulatory software company for the drug development industry. She led the standardization efforts by the FDA in collaboration with the industry for the Standard for Exchange of Nonclinical Data (SEND). In 2005, Bio-IT World Magazine identified her as a Bio-IT Champion for her leadership in the convergence of Biotechnology and Information Technology. Dr. Handu also served on the Industry Advisory Board of Clinical Data Interchange Standards Consortium (CDISC) from 2002 to 2006.

Dr. Handu also serves on the Board of the Cardea Center for Women, and is a Mentor at Fresh Lifelines for Youth (FLY). She is a founder of the Enterprising Pharmaceutical Professionals from the Indian subContinent (EPPIC) which promotes networking and entrepreneurial mentoring for professionals in the pharmaceutical, biotechnology and related industries.

Dr. Handu holds a Ph.D. in Pharmaceutical Sciences from the University of Iowa. She is a graduate of the NextGen CEO program sponsored by the Forum for Women Entrepreneurs (FWE).

Angelle Desiree LaBeaud, MD, MS is an assistant scientist at CHORI and a clinician at the Children's Hospital in the Pediatric Infectious Disease department. Her area of research is arboviral epidemiology, the study of arthropod- (or mosquito-) borne viruses. Commonly known arboviruses include St. Louis encephalitis virus and West Nile virus. In particular, Dr. LaBeaud investigates Rift Valley fever virus in Kenya, where outbreaks cause fever, retinitis, encephalitis, and hemorrhagic fever.

Dr. LaBeaud's main research questions focus on the risk factors for arboviral infections, the development of diagnostic tests that can be administered in the field to quickly determine what kind of arboviral infection a person has, and the genetic and immunologic investigation of why different people respond differently to the same infection.

Dr. LaBeaud's long-term goals are to contribute to a deeper understanding of arboviral infections and their long-term health consequences and to optimize control strategies to prevent these emerging infections.

Bio2Device Group, Tuesday Evening, Feb. 14, 2012

Topic: "Challenges and Tips for Expanding Your Business into China"

Speaker: Matt Levy, President, 55 Star Ventures

Date and Time: Tuesday Evening, Feb. 14, 2012, 6:00-9:00 pm

Location: Wilson Sonsini Goodrich & Rosati-- 650 Page Mill Road, Palo Alto, CA 94306

Register at www.bio2devicegroup.org week prior to meeting

Cost:

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

\$11 - Early-bird Registration - Members only

\$20 - Late Registration and Non-Members

\$25 - Walk-ins

Topic Description

Matt will provide an overview of his experience working and living in China managing a business unit for various life science and diagnostic companies. Some of the topics will include choosing a legal entity, cultural differences, sales and marketing challenges as well as common pitfalls to avoid.

Speaker Bio

Matt Levy is a 10-year industry veteran heading his specialty firm, 55 Star Ventures, to sell and market life science and diagnostic products in China.

Previously, as Sr. Director International Market Development for Akonni Biosystems, he led their international expansion into new geographic markets. Prior to joining Akonni, Matt was Director, International Market Development at Luminex Corporation where he successfully launched operations into Asia. He obtained his initial experience operating in Asia while he was at Applied Biosystems (Life Technologies) where he managed the Protein & Small Molecule business unit while residing in China. In addition to his international experience, Matt spent several years in the IBM Life Sciences group where he was responsible for developing and commercializing partner based solutions in various fields such as medical imaging, bioinformatics and protein analysis.

Matt has a BS, Business Administration and MS, Computer Information Systems & Quantitative Business Methods from California State University, East Bay. In addition, he has a MBA from Carnegie Mellon University with concentrations in Strategy, Finance and Entrepreneurship.

UC Berkeley Extension, Thursday Evenings, Feb. 16, 23, March 1, 8, 15 and 29, 2012

Course: "Life Science Product Marketing: It's All in the Plan"

Instructor: Audrey S. Erbes, Ph.D.;

Guest Instructors (See bios and topics below):

- Naina Shehzeen Ahmad, Senior Consultant, Simon Kucher
- Richard Clark, Sr. Director, Biopharma Strategy at Medtronic
- Deb Donovan, Director of Marketing at Avantis Medical Systems
- Charles Versaggi, President, Versaggi Biocommunications
- Steven Wong, Senior Consultant, Plan A

Date and Time: Feb. 16, 23, March 1, 8, 15 and 29, 2012; 6:00 – 9:00 pm

Location: New Belmont Center, UC Berkeley Extension, Room 3B, 1301 Shoreway Road, Suite 400, Belmont, CA 94002

Fee: \$695

See more details and register at <http://extension.berkeley.edu/catalog/course135.html>

Course Description

This science product marketing course introduces industry-relevant product planning knowledge and skills required for successfully marketing life science products and, specifically, explores the development of strategic and tactical marketing programs for their launch. Topics include learning about different market research approaches; information resources critical for developing a successful plan, product strategy and positioning with differentiated claims; and how to identify the most lucrative target audience. Course activities include a team-developed preliminary marketing plan.

The course is appropriate for professionals at all levels in life science marketing research, product planning and management, product sales, promotion, business development and licensing, public and corporate relations, as well as other company functions involved in the development and commercialization of a product and its labeling, including clinical and regulatory.

Course participants will learn about the development of a marketing strategy, product positioning, differentiated claim structure and selection of target audience as members of a class-based product team that replicates a company-based team. They will understand what goes into successful tactical marketing and promotional programs and gain insights into what it takes to gain management approval and resources for implementation.

Course Content Outline

Strategic Marketing Research, Analysis and Creativity

- Marketing plan outline
- Market research tasks and methodology for implementation
- Analysis of market research results for input to planning
- Development of market strategy
- Selection of best market segment and target audience focus
- Development of product positioning and claim structure

The Marketing Program

- Development of tactical marketing program: steps and content
- Development of information about the product and its competitive market needed for hiring vendors and providing direction that would assist in selection and implementation of tactical programs
- Selection of tactical marketing activities and programs for plan implementation

Writing the Product Marketing and Sales Plan

- Putting all the elements together in draft plan
- Writing final preliminary plan for implementation
- Selling the plan and obtaining prospective “company commitment” to proposed plan, marketing programs and related budget with guest Marketing Committee

Presentation of Team Marketing Plans

Bios

Lead Instructor

Audrey Erbes, Ph.D., Principal, Erbes & Associates and www.audreysnetwork.com, is a life-science business development and marketing consultant and developer of customized executive education. With more than 30 years of managerial experience in the biotech and pharmaceutical industry, she was Executive Vice President and cofounder of Kowa Research Institute, a biopharmaceutical licensing and investment subsidiary of Kowa Company Ltd., Japan and before that held U.S. and global management positions at Syntex Corp. (acquired by Roche) in market research, product management, strategic marketing and planning, and business development.

Guest Speakers:

Naina Shehzeen Ahmad, M.S., a Senior Consultant specializing in the Life Science division of Simon-Kucher & Partners in San Francisco, has professional focus which includes strategic development, value and market access planning, pricing and value positioning strategies, and reimbursement strategies, including innovative contracting, for pharmaceuticals, biotech and med tech products, and high-value molecular diagnostics. Since joining SKP, Ms. Ahmad has led pricing research in international and domestic markets, including the US, EU-5, Canada, Australia, Latin America and APAC countries, in a broad range of therapeutic areas. *“Role of Pricing and Reimbursement in Product Management Strategic Planning”*

Debbie Donovan, B.A., an expert in medical device marketing, is focused on developing digital marketing programs for medical technology companies—including the integration of social media channels. Currently, Debbie is the Director of Marketing at Avantis Medical Systems supporting market adoption of Third Eye® Retroscope. Previously, she was a Senior Manager at Intuitive Surgical and, in addition, had experience serving Ob/Gyn, Orthopedics/Spine and ENT physicians at Conceptus, Kyphon and Somnus. Her expertise is in developing effective strategies and leading teams in marketing communications, public relations and event

programs. Before heading to the client side, Debbie began her career at a medical advertising and public relations agency. *"e-Marketing: Connecting with Providers and Patients"*

Richard Clark, Sr. Director, Biopharma Strategy at Medtronic working to integrate Medtronic technology into drug development, has extensive cross-functional biotech experience in large and small companies with a focus on managing all aspects of commercial/ product development, including target product profile and value proposition development, forecasting, portfolio management, and clinical trial enrollment strategy. Richard was previously Senior Director, commercial at ARYx Therapeutics where he served on the joint steering committee with Proctor and Gamble developing a gastroenterology program. Richard worked for many years in commercial organization at Genentech. *"Product Management 101- Developing/Executing The Tactical Plan."*

Charles S. Versaggi, Ph.D., is President, Versaggi Biocommunications®, a marketing consultancy specializing in corporate and marketing communications for the global life-science industry. Based in the San Francisco Bay Area, the firm serves clients in every stage of development — from seed funding through research and development, clinical trials, regulatory approval and worldwide product marketing. With nearly 30 years of strategic marketing and communications experience, Dr. Versaggi has directed marketing and communications initiatives for life science companies ranging from startups to Fortune—100 global leaders. These include the launch of the first genetically engineered vaccine and genomic disease management products, and the first applications of minimally invasive surgery. *"Building Value through Strategic Marketing Planning and Communications."*

Steven Wong, B.A., is a Senior Consultant at Plan A, a strategic marketing consulting firm servicing biotechnology and pharmaceutical companies. He specializes in developing patient-based forecast models and prioritizing marketing opportunities in therapeutic areas such as oncology and infectious diseases. At Plan A, he has directed numerous consulting engagements, including opportunity assessments, complex population modeling, and therapeutic area strategy. Additionally, Mr. Wong co-authored several editions of Plan A's *ONCOSight* and *Innovations in Anticancer Drugs* multiclient report series. *"Market Research Information Resources."*

CACO, Thursday Afternoon, February 16, 2012

Topic: The IND Development of Monoclonal Antibodies (MAbs)
Speakers: Ben Marafino Jr. and Kathy Meyer Date and Time: Thursday, Feb. 16, 2012, 1245-1730
Location: SF Bay Area: Foster City Crowne Plaza
Event fee: Below cost of course materials for unemployed; For others, details available upon online login.
Online registration and further details: <http://www.caco-pbs.org>
Registration deadline: 2/15/2012 (it will close sooner if the seating cap is reached)

Bio2Device Group, Tuesday Morning, February 21, 2012

Topic: "Survive and Thrive: A Medical Imaging Device Start-Up Story"
Speaker: Kendall Waters, Silicon Valley Medical Instruments (SVMI)
Location: Mountain View, Silicon Valley Center, 801 California Street, Mountain View, CA 94041
Cost: Free, no need to register
Two-hour parking is available in the lot adjacent to Bryant Street intersection with California.

The venue is also 4 blocks from the Mountain View Caltrain station.

Topic Description

Silicon Valley Medical Instruments (SVMI) is a development-stage medical device start-up focused on innovative, catheter-based solutions for cardiovascular diseases where integrated image guidance is a key enabling technology. SVMI's first product is a high-definition intravascular ultrasound imaging system and catheter that will be operated by interventional cardiologists during treatment of patients with coronary artery disease. This talk will cover the stages of development of SVMI from founding through impending commercial launch. SVMI has experienced triumphs as well as setbacks and continues to look forward as it transitions from an engineering-focused company to a company with strong operations, sales, and marketing components.

Speaker Bio

Kendall R. Waters is manager of intellectual property (IP) and technology development at SVMI. He manages in-house IP activities, strategic research collaborations, and licensing activities related to minimally invasive image guidance for cardiovascular interventions. Prior to joining SVMI in 2008, Kendall was with Volcano Corp (Cleveland, OH) as technical lead of VH-IVUS, a real-time atherosclerotic mapping technology. Kendall has held medical ultrasound research positions at the National Institute of Standards and Technology (Boulder, CO), the Ecole Supérieure de Physique et de Chimie Industrielles (Paris, France), and the Centre National de la Recherche Scientifique (Paris, France). Kendall holds a PhD in Physics from Washington University in St. Louis. He also holds a BS Physics / BA Mathematics from the University of Texas at Austin.

Kendall is currently Chair of the IEEE Consultants' Network of Silicon Valley. He is also a member of the Medical Ultrasonics Technical Program Committee of the IEEE Ultrasonics, Ferroelectrics, and Frequency Control Society.

CACO Workshop, Feb. 24, 2012

Topic: Metabolic activation and potential drug toxicity: the knowns and unknowns, the sense and non-sense

Speaker: Professor Alan Buckpitt, University of California, Davis

Date and Time: Friday luncheon workshop, 11:00 am – 1:30 pm

Location: SF Bay Area: Foster City Crowne Plaza

Event fee: Below cost of course materials for unemployed; For others, details available upon online login.

Online registration and further details not posted as yet. See details at <http://www.caco-pbs.org/asp/sfchemists.aspx>

Bio2Device Group, Tuesday Morning, Feb. 28, 2012

Topic: "Developing Innovative Biotherapeutics driven by Unmet Medical Needs"

Speaker: Xiaodong Yang, M.D., President, CEO and Member of Board, Apexigen

Date and Time: Tuesday, Feb. 28, 2012, 8:30- 10:30 am

Topic: "Survive and Thrive: A Medical Imaging Device Start-Up Story"

Speaker: Kendall Waters, Silicon Valley Medical Instruments (SVMI)

Location: Fenwick & West, Silicon Valley Center, 801 California Street, Mountain View, CA 94041

Cost: Free, no need to register

Two-hour parking is available in the lot adjacent to Bryant Street intersection with California.

The venue is also 4 blocks from the Mountain View Caltrain station.

Topic Description

In the current economic, financial and regulatory environment, it has become increasingly challenging to develop innovative biotherapeutics such as novel antibody-based therapeutics. Apexigen is a start-up biopharma company focusing on discovery and development of best-in-class antibody therapeutics for the treatment of cancer and inflammation. At Apexigen, we believe innovation in drug discovery and development must be driven by the needs of patients. This presentation will illustrate and discuss the opportunities and hurdles facing biopharma companies in growing their businesses and achieving the ultimate goal of delivering innovative medicines to patients.

Speaker Bio

Dr. Xiaodong Yang is President and Chief Executive Officer of Apexigen which is a biopharma company focusing on development of antibody therapeutics. He has over 15 years of experience in the research and development of antibody and siRNA therapeutics. Prior to joining Apexigen, Dr. Yang was Vice President of Research and Preclinical Development at Intradigm Corporation (now Silence Therapeutics). In this role, he was responsible for overseeing the progress of company's discovery and preclinical development of RNAi-based therapeutics. Dr. Yang began his career as a founding scientist at Abgenix (now Amgen). He was Senior Director and the head of the Oncology Therapeutic Program Team responsible for setting strategy and managing the company's oncology portfolio. Dr. Yang was the project team leader for Vectibix® (panitumumab) and played a key role in discovery, development and BLA approval for Vectibix®. He was also in charge of managing the company's partnerships on a number of therapeutic antibody collaboration programs. He was an American Diabetes Association and Juvenile Diabetes Foundation postdoctoral fellow at Stanford University School of Medicine in Microbiology and Immunology, and was also trained as a research fellow at Novartis. Dr. Yang received his medical degree from Beijing Medical University and was awarded his doctorate in Immunology from University of Bern in Switzerland.

QB3 Quadrant Speaker Series, Tuesday Noon, Feb. 28, 2012

Topic: "The Future of Diagnostics—Detecting, Preventing, and Predicting Disease"

Speaker: Eric Whitters, Global Head of Research and Development, Novartis Diagnostics

Date and Time: Tuesday, Feb. 28, 2012, noon-1:00 pm (Lunch will be served)

Location: Genentech Hall N-114, UCSF Mission Bay, San Francisco

Topic Description

Diagnostics inform decision making across the entire healthcare spectrum. Yet although they may influence as much as 60-70 percent of health care decision-making, they comprise less than 5 percent of total hospital and Medicare costs. Eric Whitters, VP of Global R&D at Novartis Diagnostics, based in Emeryville, will discuss where diagnostics are heading, and how tools that detect, prevent, and predict disease impact clinical decision-making. Some of the areas where Eric will focus include:

- Major forces contributing to advancement of diagnostics such as access to genomic information, understanding of biological pathways, demand for rational data, and need for cost-effective treatments.
- Evolution of diagnostics in the areas of immunoassays, molecular diagnostics, and cell biology.

- Role of emerging technologies in reshaping the medical field including allergy diagnostics, serology testing, and electronic biosensors for near-patient testing for blood screening and vaccines.

Speaker Bio

Eric Whitters serves as the global head of research and development at Novartis Diagnostics. He leads a dynamic research team responsible for current investigations in neurodegenerative diseases, infectious disease immunochemistry and vaccine development. His current focus is the identification of emerging technologies and unique biomarkers that will foster the growth of Novartis Diagnostics. Eric also oversees the development of new diagnostic tests in the areas of infectious disease, prenatal health, and transfusion medicine that build on Novartis Diagnostics' expertise in blood screening. Eric joined Novartis Vaccines and Diagnostics after 13 years within the diagnostics industry where he held increasing roles in research & development for Diagnostic Product Corporation and later the Siemens Healthcare business. During this time, Eric led a multifaceted team responsible for the launch of over 100 new diagnostic products on the IMMULITE platform into the clinical world. After a successful R&D career, Eric explored additional opportunities in the Siemens Healthcare world, serving in the management of Clinical Affairs, Regulatory Affairs and Technical Operations. During this time he led a team that successfully validated, submitted and registered several PMA assays in the United States as well as multiple 510(k) assays. Eric received his Ph.D. in Microbiology from the University of Illinois at Champaign.

Bio2Device Group, Tuesday Morning, March 20, 2012

Topic: Tentative Reimbursement topic
 Speaker: Ellen Licking, Senior Editor and Analyst, Value & Innovation LLC, a subsidiary of Real Endpoints
 Date and Time: Tuesday, March 20, 2011, 8:30-10:30 am
 Location: Sunnyvale City Council Chambers, 456 W. Olive, Sunnyvale, CA (across the street from Sunnyvale Public Library)
 Cost: Free
 Park in Street and in NOVA and library parking lots across the street.

Topic Description
 Ellen will provide interesting discussion of what makes reimbursement "tick."

Speaker Bio

Ellen has covered the medical industry for more than 10 years, as a reporter at BusinessWeek, then at Windhover Information, and since it's acquisition by Elsevier, as business bureau chief and executive editor for the pharma group, where she has been responsible for both IN VIVO and Start-Up, among other duties. Ellen holds a BA in Biochemistry from Swarthmore College, an M. Phil. in Biochemistry from Cambridge University, and an MS in Biochemistry from Stanford University. (www.valueandinnovation.net)

CACO Workshop, Monday Afternoon, March 26, 2012

Topic: Large molecule bioanalytical: immunoassays and LCMS methods

Speakers: Surinder Kaur (Genentech), Binod DeSilva (BMS), Keyang Xu (Genentech),
Montserrat Carasco

Date and Time: Monday, March 26; 12:45 pm – 5:30 pm

Location: SF Bay Area: Foster City Crowne Plaza

Cost: Free

Register at <http://www.caco-pbs.org/asp/login01.aspx> (requires registration to site)

Topic Description

Protein biotherapeutics, especially monoclonal antibodies, are now the standard of care in several critical disease areas such as oncology and immune disorders. Given the complex interaction of target expression, mechanisms of disease and drug clearance that ultimately impact the pharmacokinetics (PK) of large molecule biotherapeutics, PK studies are critical to guide the appropriate dosing strategies in the clinic. Well-designed bioanalytical strategies that take into consideration the complexity of potential molecular interactions with endogenous proteins are important to assess PK. Ligand binding assays are typically used to measure large molecule concentrations in serum. Appropriate validation is required to obtain robust PK data. As binding interactions in ligand binding assays may have many subtle variables, there are efforts for global harmonization of assay parameters assessed during validation, to ensure industry-wide consistency. More recently, mass spectrometry has emerged as a new technology platform for measuring large molecule concentrations in serum and plasma and offers an alternative approach for measuring PK. In order to assess the potential immunogenicity of therapeutic proteins, appropriate methods must be deployed in a systematic manner in well-designed clinical studies, so that clinical events can be correlated with laboratory test results. It is important to determine ATA responses to protein biotherapeutics for a better understanding of the PK, safety and efficacy relationships.

This workshop will cover the following topics:

- Overview of large-molecule therapeutics: Molecular characteristics, PK properties and bioanalytical technologies (Kaur)
- Ligand binding PK assays: Key considerations, Validation and regulatory guidelines, Overview of the global harmonization efforts (DeSilva)
- Mass Spectrometry Technologies for large molecule PK assays: Rationale for large molecule LC-MS/MS PK assays, Case studies comparing ligand binding and LC-MS/MS data (Xu)
- Immunogenicity of Therapeutic Antibodies: Strategies used in acquisition & interpretation of immunogenicity data from clinical trials (Carrasco)
- Case studies showing the importance of interpreting ATA results in the context of safety, efficacy, pharmacokinetic and pharmacodynamic aspects of protein therapeutics.

UC Berkeley Extension Course, Thursday and Friday, April 19-20, 2012

Topic: "Life Science Business and Marketing: Their Integral Role"

Instructor: Audrey S. Erbes, Ph.D.; Guest Speakers: Don Holsten, Pharm. D., Bev Hudson, M.B.A., Julie Tompkins, M.B.A.

Date and Time: Thursday and Friday, April 19-20, 2012; 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; X442.4 (1 semester unit in Business Administration)

Register at <http://extension.berkeley.edu/catalog/course190.html>

Course Description

Course includes two days of intensive classroom work, Thursday and Friday, April 19-20, 2012 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 addition to the instructor's lectures there are three industry expert speakers covering specialized topics that include: (1) the impact of the health care system and reimbursement issues on business and marketing functions; (2) in depth exposure to methodologies and examples how to carry out primary market research, and (3) detailed overview of regulatory requirements across life science industry sectors. Students will complete business investment analysis of a company and its technology/products of their choice for term project.

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.

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

Bios

Lead Instructor

Audrey Erbes, Ph.D., is a global life-science business development and marketing consultant, industry educator, organization leader and public speaker who originated several bioscience business development and marketing courses at the UCB and UCSC Extensions. She is known for her industry blog publications on Audreysnetwork.com. She has 25 years of 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. Previously, she held both U.S. and

international management positions at Syntex Corp. in market research, product management, strategic marketing, and business development, with a special emphasis on Europe and Asia/Pacific/Canada.

Guest Lecturer Bios and Topics

Donald Holsten, Pharm D., a regulatory consultant and educator with over 20 years of national and international experience as a senior regulatory affairs and quality assurance executive, has expertise in food, drug/biopharmaceutical, medical device and cosmetic products. He has an intimate knowledge of the FDA approval cycle and has helped prepare numerous biotechnology and pharmaceutical companies for FDA interactions and panel reviews. Don has held management positions at several companies, including Liposome Technology, Inc and Oclassen Pharmaceuticals, Inc. where he was Director of Regulatory Affairs/Quality Assurance and Director of Regulatory Affairs, respectively. Earlier in his career he held a senior level position as Assistant Chief, Food and Drug Branch, Department of Health Services for the State of California. (See detailed biography at end of lecture notes.)

Bev Hudson, MBA, is the Senior Vice President, Business Development, Omnicomm Systems, Inc., a Web-based electronic data capture (EDC) and eClinical (eClinical) software and services company with products that streamline the clinical research process. Previously, she was VP and General Manager of Clinical Research Services at MedPoint Communications, Inc. and earlier ran sales and operations for Mayo Clinical Trial Services. She spent eleven years at Genentech in sales and marketing management roles. 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 (now 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"

CACO Workshop, Tuesday Afternoon, April 24, 2012

Topic: "Getting the Most from Your CRO Collaboration: in vitro/in vivo studies and analytical/bioanalytical assays"

Speakers: Steven Smith (Consultant), Kenjie Amemiya (Genentech), Dave Toman (Elan)

Date and Time: Tuesday Afternoon, April 24, 2012; 12:45 pm – 5:30 pm

Location: SF Bay Area: Foster City Crowne Plaza

Cost: Free

Register at <http://www.caco-pbs.org/asp/login01.aspx>

Topic Description

Outsourcing projects to Contract Research Organizations (CROs) has become common practice in the pharmaceutical industry in recent years. This brings new challenges to project and resource management as compared to in-house studies, including differences in

skill sets and work experience, instrumentation, communication style, time zones, and cultural norms (for foreign CROs), etc. In this half-day workshop, the presentations will experiences and best practices from outsourcing single laboratory to complete studies. The areas covered will include analytical and bioanalytical assays as well as in-life and cell culture studies.

This workshop will cover:

- Advantages and disadvantages of using CROs.
- How to identify a CRO that can do what you need.
- Define the scope of work and set up agreements.
- Transfer of methods between in-house laboratories and CROs.
- Ongoing management, communication and interaction with CROs to minimize relationship risks.
- When things go wrong.
- A perspective from the CRO.

CACO Seminar Luncheon, Friday, May 11, 2012

Topic: Clinical Development of Peptide Therapeutics

Speaker: Chris Rhodes (ex-Amylin)

Date and Time: Friday, May 11, 2012; 11:30 am-1:30 pm

Location: SF Bay Area: Foster City Crowne Plaza

Cost: Free

Register at <http://www.caco-pbs.org/asp/login01.aspx>

Topic Description

Overview of peptides nearing commercialization and in preclinical and clinical development with insights on the evolving peptide therapeutic market place.

UC Berkeley Extension Course, Thursday and Friday, June 21-22, 2012

Course: Life Science Business Development

Dates and Time: Thursday and Friday, June 21-22, 2012; 8:30 am – 5:00 pm for classroom intensive and balance of term for working on term project

Location: Downtown University of California, Berkeley Extension, 425 Market St., 8th Floor, San Francisco, CA 94105

Cost: Summer term—fee: \$895. Course will be posted for registration in April, 2012.

Course Description

This intensive course including two days of classroom and balance of term for individual research is designed to provide participants with an understanding of the critical role business development and licensing functions play in the commercialization of new products or technology and to the development of a successful life science company. The term assignment is designed to give students the opportunity to put the knowledge and materials from class to immediate and practical use with resulting document for inclusion in their portfolio.

Upon successful completion of the course, participants will:

- Understand the various aspects of the business development function in the life science industry and appreciate the skills required to be effective in business development and licensing roles
- Appreciate types of deals and their role in commercialization strategies and funding of a company
- Understand importance of IP status and patent life cycle planning

Who Will Benefit from This Course

This course is suitable for marketing and business development professionals as well as scientific professionals working in bioscience companies, especially those considering a career move into BD. Licensing, potential entrepreneurs, scientific, clinical, regulatory financial, legal and auxiliary personnel will also benefit from insights gained in the course. Although there are no format prerequisites, those who have been exposed to the life science industry and/or the Drug Development Process course will most benefit from the course.

Deliverables

Lectures, discussion, and guest expert lecturers will address business development topics and issues. Student will be exposed to templates and primers for major business development documents and offered mentoring by instructor in researching and developing their term project. They will have access to two major industry databases for use in researching their project during the term. An extensive reader, including lecture slides and a sizable online accessible reference list, will be prepared and distributed by the instructor for use by students during and after class.

Course Instructor

Audrey Erbes, Ph.D., is a global life-science business development and marketing consultant, industry educator, organization leader and public speaker who originated several bioscience business development and marketing courses at the UCB and UCSC Extensions. She is known for her industry blog publications on Audreysnetwork.com. She has 25 years of managerial experience in the biopharmaceutical industry including Executive Vice President and Co-founder of Kowa Research Institute, a biopharmaceutical licensing and investment subsidiary of Kowa Company Ltd., Japan. Previously, she held both U.S. and international management positions at Syntex Corp. 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

Thomas L. Gutshall, Chairman as well as Co-Founder of Cepheid in 1996, was the company's first CEO. He also served as President and COO for CV Therapeutics from 1994-96. Previously, he was the Executive Vice President for Syntex Corporation and a member of its Pharmaceutical Executive Committee. Tom serves on the board of directors for PROFUSA. He graduated from the University of Delaware with a BS in Chemical Engineering and completed the Executive Marketing Program at Harvard University. He serves the University of Delaware as a member of the Chemical Engineering Advisory Council and was named to the Delaware Alumni Wall of Fame in 2001. Topic: *"Cepheid: How to Build Your Own Biotech Company"*

Harold (Hal) Etterman, MBA, CEO, Knight Financial Plans & Services, LLC has over twenty-five years experience in Finance, Operations and Information Technology, including over ten years serving as a CFO, COO and interim CEO. Hal's extensive international and domestic experience includes medical devices, software development, medical information publishing, Internet/data security and Homeland security systems. Hal had earlier worked for Siemens Medical Systems for nearly 17 years in Manufacturing Operations, Divisional Sales and Service, Corporate Finance and Information Systems. After Siemens, Hal was the CFO/COO for a medical laser manufacturer and has served as a financial planning consultant for 3 medical device businesses. Most recently he has just completed four major Sarbanes-Oxley projects where he successfully helped his client firms through their internal audits resulting in SOX certified SEC filings. Topic: *"Financial Planning and Funding for a Bioscience Venture: New, Emerging and Growing Entities"*

Carolyn Feamster, MBA, a business strategy and analysis consultant, has over 25 years experience in the pharmaceutical and biotech therapeutics, diagnostics and drug delivery systems. She has broad expertise across numerous therapeutic areas, including oncology, CNS, transplantation, autoimmune disease, women's health and urology. Carolyn worked in R&D and pharmaceutical marketing at Syntex, where her responsibilities included the major brands Naprosyn and Cellcept. In 1995, Carolyn joined ALZA Corporation as Senior Director of New Product Marketing with commercial responsibility for building and managing the pipeline products. She shepherded three products onto the market and was instrumental in evolving the three ALZA therapeutic franchises: urology, CNS and oncology. Carolyn was VP of New Product Planning at Corixa Corporation and, most recently, Vice President of Business Strategy and Analysis at Clearview Projects. Topic: *"Preparing for and Planning Deals for Maximum Strategic Impact"*

Gilbert R. Mintz, Ph.D., President of GRM Associates, a biotechnology business development, licensing, strategic planning consulting firm, has expertise in building early-stage companies by focusing their strategic planning and licensing activities, and raising money through venture capitalists. His 20-plus years in the biotechnology industry include general and laboratory management and executive level business development roles. He has executed technology platform, corporate and academic collaborations; in/out licensing of late-stage products for partnerships in the US, Europe and Japan; as well as analyzed and managed intellectual property activities. He has consulted with Affymetrix and other biotechnology companies; served as the President and CEO, Director of an early-stage cancer company; and provided transactional and strategic planning advice to numerous pre-IPO biotechnology companies. He has held senior management positions at Genelabs Technologies, Anergen (Corixa), Cygnus and Trega Biosciences. Topic: *"Working Your Way through the Bioscience Licensing Process: Negotiating and Writing Deal Contract"*

Ginger Dreger, J.D., M.S., partner in Arnold & Porter LLP's intellectual property practice group, concentrates her practice on counseling and providing strategic advice to emerging and established public companies in the biotechnology, medical device, and pharmaceutical industries. She advises clients on domestic and international patent matters, including worldwide patent protection and enforcement strategies; freedom-to-operate issues; intellectual property due diligence; and analysis of third-party patents. Corporate experience included role with Genentech's in-house legal department. Topic: *"What you Need to Know about Patents Working in Business Development"*

Chris Dokomajilar serves as a senior Biopharma Analyst at Deloitte Recap LLC. He provides advisory services to clients in the Life Sciences, including Biotech and Pharmaceutical companies, and Legal and Venture Capital firms. His focus areas include alliances, M&A, financing, and pharmaceutical manufacturing. Prior to joining Recap, Chris managed international labs and clinical trials at the University of California San Francisco. His research on trends in infectious diseases has been published in medical and scientific journals. Before transitioning into science, Chris held finance positions at Bank of America. Chris holds a bachelor's degrees from the University of California Berkeley in Molecular and Cell Biology and in Integrative Biology. Topic: *"BioPharma Alliances: Trends in the Marketplace"*

Course Content Outline

The Function of Business Development In A Bioscience Company

- How a discovery product becomes identified as potential commercial product
- Assessing commercial potential of a life science discovery product
- Development of business model and plan
- Typical activities of BD function

Financing The Development And Commercialization Process Of Life Science Products And Technologies

- Preparing financials and marketing company for getting funding from banks, individual investors, angel investors, VCs, bridge loans, and finance rounds
- Discuss various financial vehicles for funding and maintaining a company

Developing And Protecting The Product's Intellectual Property Status

- Role of patents in business development function and alliances
- Filing for patents worldwide—the process
- Due diligence of developing IP estate needed to successfully commercialize the product
- Developing legal resources to protect the patent
- Life science IP life cycle planning: U.S. and international patent issues

Licensing Process

- Working through the licensing process
- Intellectual property as corporate assets
- Contractual terms and provisions
- Financial and strategic variables of contracts
- Specific collaborations and licenses
- Strategic alliance and alliance management
- Preparing for and planning deals for maximum strategic impact
- Academic licensing and offices of technology transfer

Business development from the entrepreneurial perspective

- Developing the business model and plan for a start up company
- Building the management team
- Financing and staffing to IPO
- Implementation of business plan
- Building valuation and meeting the payroll

Alliance Deals: Trends in the Marketplace

- Environment of dynamic macro level in which deals happen
- Status quo and trends
- Analysis of deals and what it tells us
- Changing business models as reflected in deals