# Audrey's Life Science Meeting Picks for Sept. 13, 2015 – Dec., 2015 Complimentary Service of AudreysNetwork.com Sept. 13, 2015

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# Bio2Device Group, Tuesday Morning, Sept. 15, 2015

Topic: "How Early-Stage and Growth Companies Can Protect their Intellectual Property" Speakers: Seth Northrop, Principal & Technology Attorney, Robins Kaplan LLP, and Li Zhu, technology attorney and registered patent agen, Robins Kaplan LLP

Date and Time: Tuesday, Sept. 15, 2015, 8:30 am

Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA No fee or registration required for morning meetings.

#### Topic Description

Medtech and biotech companies have sophisticated needs when it comes to intellectual property. The industry is experiencing explosive growth, while IP law has undergone significant changes in recent years, creating unique challenges for early-stage and growth companies. Seth and Li will discuss key pitfalls to avoid when growing your business and securing future investment, and how you can best protect your intellectual property in the current landscape.

#### Speaker Bios

Seth Northrop is a principal and technology attorney at Robins Kaplan LLP. He is a former entrepreneur who leverages his background in business, technology, and the law to solve his clients' most complicated problems. Prior to attending law school, Seth worked as an engineer and successfully co-founded his own company.

Now as an attorney, Seth focuses his practice on providing strategic advice for large and small companies along with handling large-scale disputes involving a variety of technologies.

Li Zhu is a technology attorney and registered patent agent at Robins Kaplan LLP. Prior to law school, Li worked in a research lab at The Scripps Research Institute. His background provides an intimate understanding of the intersection between technology and science and the process by which technologies travel from the workbench to the courtroom. As an attorney, Li counsels his clients in a broad range of industries, including Medtech, biotech, and life sciences.

# San Francisco WIB, Tuesday Evening, Sept. 15, 2015

Topic: "Tapping into the Modern Financial Landscape in Biotech"

- Panelists: Lindy Fishburne
- Una Ryan
- Phyllis Whiteley
- Nancy Stagliano

Date and Time: Tuesday, September 15, 2015, 6:00 p.m. - 8.30 p.m. PST Program

6:00 p.m. – 6:30 p.m. Registration and Networking

6:30 p.m. – 6:45 p.m. WIB Welcome and Event Introduction

6:45 p.m. - 7:45 p.m. Panel Discussion

7:45 p.m. - 8:00 p.m. Q&A

8:00 p.m. - 8:30 p.m. Networking and Wrap Up

**Pricing Information** 

Location: Cooley LLP, 3175 Hanover Street, Palo Alto, CA 94304

Walk-Ins Accepted?

Walk-ins are not accepted – be sure to register early!

Members: \$35 Non-Members: \$65 Students\*: \$35

\* - The first ten students to register will receive the \$35 student rate by using the discount code SanFranstudent91515 on the Non-Member rate.

# Topic Description

In today's financial climate, companies often need to use creative and/or alternative funding strategies to stay funded. In this panel, we will discuss current financing options, including venture capital, angel investing, philanthropies, crowd funding, and more. Learn about approaches companies can take to be successful in today's market.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# ACRP, Thursday Evening, Sept. 17, 2015

#### REGISTRATION IS NOW OPEN!!

South Bay Educational Event

Topic: "eConsents - The Why, How & Watch-outs"

Speaker: Timothy J. Kelly, MS, MBS, Director, Standard Register Healthcare

Date and Time: Thursday, Sept. 17, 2015, 6:00 - 8:30 PM

Agenda:

6:00 – 6:45 PM Registration, Networking, & Dinner Buffet 6:45 – 7:15 PM President's Welcome, Raffle, Open Mic

7:15 – 8:15 PM Educational Presentation 8:15 – 8:30 PM Networking 1:1 with speaker

Location: Cepheid, 1315 Chesapeake Terrace (Bldg. 5), Sunnyvale, CA 94089

F	
F666.	

NCC ACRP member	\$ 5
ACRP member	\$25
Non-member/public	\$30
1 ACRP, CBRN, and CME CONTACT	T HOURS are approved
Purchase with online registration or	up to 14 days after event
CHAPTER MEMBERS	FREE – included in your online
CHAI TER MEMBERS	registration
ACRP member	\$15
Non -member/public	\$30

Bring your email confirmation to the event. Please notify Event Manager of cancellation. No refunds or transfers.

To receive contact hours: Purchase the contact hours online only with registration or up to 14 days after the event, sign-in at event registration, and attend the program. Go to <a href="http://www.acrpnet.org/">http://www.acrpnet.org/</a>, logon as member or guest, go to "My Tests, Evaluations, and Certificates" (TEC) 1-30 days after the event, complete the evaluation and receive the certificate.

ACRP online registration/contact hour purchase questions: <a href="mailto:chapters@acrpnet.org">chapters@acrpnet.org</a>
NCC Event questions: Caroline Cooper cqc1117@gmail.com

Register at EVENT REGISTRATION closes Thursday, September 10 2015, 11:59 PM Pacific Time

Online register **NOW** to assure admission

Walk-in registration: if seats available, add \$5 to below registration fee, cash or check only <a href="http://www.acrpnet.org/GetInfoFor/USChapters/NorthernCalifornia/Upcoming-Chapter-Events.aspx">http://www.acrpnet.org/GetInfoFor/USChapters/NorthernCalifornia/Upcoming-Chapter-Events.aspx</a>

# Topic Description

Healthcare is going electronic. Reimbursement is being provided for EHRs. Informed consent for surgical procedures has become automated. It is thus inevitable that use of eConsents for research studies and clinical trials will develop and expand.

This session will review the benefits of eConsents. The potential of eConsents to reduce the risk of errors and eliminate the costs inherent to paper-based processes will be explored. Different mechanisms for implementing an eConsent process will be discussed, including: leveraging an EHR, employing forms software and utilizing an informed consent application. Potential watch-outs exist when deploying an eConsent process. Areas of attention include: maintaining the privacy and security of electronic documentation, ensuring compliance with applicable FDA requirements, confirming subject understanding of all key study aspects and addressing potential concerns of the IRB.

# Target Audience:

- Clinical Research Professionals
- Sponsors
- Study Sites, Physicians, Nurses
- Students
- Vendors/Service Providers/CROs, Consultants
- Institutional Review Boards
- Related-Clinical Quality Assurance, Project Management, Account Rep, HR, Recruiters/Staffing, Finance, Biometrics, Regulatory

#### Learning Objectives:

- Discuss the benefits of automating the process of obtaining informed consent for clinical trials and research studies
- Identify three different approaches to designing and deploying an e-consent system
- Analyze the potential challenges associated with deploying an electronic system for facilitating the research consent process

### Speaker Bio

Tim Kelly has 25 years' experience in the medical device/software industry including 17 years working with two different divisions of C.R. Bard, Inc. – a large medical device firm and study sponsor where his responsibilities included managing a Phase III clinical trial of a novel anti-infective medical device. Recently Tim completed work on a prospective, randomized, multicenter study evaluating the impact of "repeat-back" during the informed consent process.

Tim is a member of ACRP, HIMSS and ASHRM. He has presented at the ACRP Global Conference, including the current presentation at the 2014 Conference. Additionally, Tim holds two U.S. patents.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# Sharevault, Thursday Morning, Sept. 17, 2015

Free Webinar: M&A Negotiations: Are You As Good As You Could Be?

Speaker: Brian Moriarty, Provider of Outsourced Corporate Development Services

Date and Time: Thursday, Sept. 17, 2015, 11am-12 pm PDT

Cost: Free

Register at http://resources.sharevault.com/webinar-ma-

negotiations?utm\_source=hs\_email&utm\_medium=email&utm\_content=21914473&\_hsenc =p2ANqtz-8zTPsaQ-

Oad\_gzUUrXefYh1G4FNbVf2STzIPU5undrBy5YIwbzT569rO5NTC3zFR0h8sI0\_PuEmbiuAtZ4LIkJYXCS0Q&\_hsmi=21914473

#### Webinar Description

Most business people believe they are good negotiators. But over many years of participating in M&A negotiations on behalf of Sun Microsystems and Hewlett-Packard, Brian Moriarty has observed that very intelligent business people don't always employ negotiation best practices. In many cases, they could have significantly improved their position by implementing the findings of academics and other experts who have identified the most effective negotiation techniques.

Negotiation isn't innate for most people; it is a skill that can be learned. You can either learn to negotiate effectively through experience, which can be very expensive, or you can learn by studying the findings of negotiation researchers.

#### Speaker Bio

Brian Moriarty has negotiated more than \$50B in M&A transactions in his career as an investment banker and corporate development professional.

Brian currently provides outsourced corporate development services (both M&A and integration) to mid-market companies.

Prior to his current role, Brian was a Vice President at Hewlett-Packard where he led the HR group responsible for M&A and outsourcing, and supported HP's separation into two publicly traded companies (the largest such separation in history).

Prior to HP, Brian led the M&A and acquisition integration group at Sun Microsystems where he led 17 acquisitions and supported the company's sale to Oracle Corporation.

Over his long career in investment banking and corporate development, Brian has closed virtually all types of business combinations including mergers, acquisitions, divestitures, joint ventures and venture investing.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

### **PBSS, Friday, Sept. 18, 2015**

Topic of Workshop: "Conducting a Successful End-of-Phase2 Meeting with the FDA:

Overview, Strategies, and Perspectives from the FDA and Industry"

Speakers: Azin Shahzamani, Yaning Wang, Mike Eldon, Terry Sweeney, Ramani Raghavan, Detlef Albrecht

Date and Time: Friday, September 18, 2015; 8:45-17:00

Location: SF Bay Area: Foster City Crowne Plaza

Registration fee (US\$): Regular: \$195; For major-sponsor rep (incl lunch): \$0; For vendor-show rep: \$35; For unemployed & students: \$30; Webcast: \$350; For others, details available upon online login.

Registration deadline: 9/17/2015 (it will close sooner if the seating cap is reached) Topic Description

An End-of-Phase 2 (EOP2) meetings is a meeting between the US FDA and the sponsor of a clinical development program after the completion of the Phase 2 study and prior to the start of the Phase 3 study. It is most useful to the sponsor and should be held before major efforts and resources are committed to specific Phase 3 studies. The purpose of an EOP2 meeting is to determine sufficient safety prior to Phase 3, to evaluate the Phase 3 plan and protocols, the adequacy of current studies and plans to assess pediatric safety and

effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

This workshop is intended to address the important topics for an effective discussion at an EOP2 meeting and to provide an overview of a successful meeting preparation. Regulatory aspects will be provided from the FDA and the industry perspective. For clinical pharmacology the progress of PK study data and additionally needed studies will be reviewed. The preclinical safety and toxicology as it relates to dose, duration & route of administration will be discussed. In the CMC area the approach to specifications and test methods as well as the formulation to be used in clinical trials and "to be marketed" formulation will be addressed. In the clinical discussion at an EOP2 meeting, agreement needs to be reached with FDA on pivotal study designs, dose selection, patient population and the safety and efficacy endpoints for Phase 3 studies. Topics:

- Regulatory Overview of End of Phase 2 meeting What to consider? Industry perspective - Azin Shahzamani (Genentech/Roche)
- The FDA perspective of a successful EoP2 meeting, how to avoid the common mistakes; and Phase 3 dose selection aspects Yaning Wang (FDA)
- Nonclinical safety and toxicology aspects and strategy Terry Sweeney (Nektar)
- CMC aspects and strategy Ramani Raghavan (Genentech/Roche)
- Clinical aspects and strategy Detlef Albrecht

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# CABS, Saturday Afternoon, Sept. 19, 2015

Event: "CABS Science and Technology Workshop: New Frontiers in Peripheral Monitoring"

# Agenda:

1:00 - 1:25 pm	Registration, networking, workshop introduction
1:25 - 1:50 pm	Mike Schwartz, Co-founder and VP of Marketing, Fluxion Biosciences
	Liquid biopsy innovations for oncology using sequencing of circulating tumor cells
1:50 - 2:15 pm	Shengrong Lin and Paul Tang, Co-founders, AccuraGen
	Title tbd
2:15 - 2:40 pm	Mojgan Haddad, former Sr. Director, Bioinformatics and Analytics, Health Tell
	HIV Drug Resistance Diagnostics: Path of Discovery to Clinical Application
2:40 - 3:00 pm	Break
3:00 - 3:25 pm	John Waldeisen, Co-founder and CEO, DiAssess
	My Life as an Entrepreneur
3:25 - 4:50 pm	Nikolay Sergeev, R & D leader, Natera
	Applications of Massively-Multiplexed PCR for Liquid Biopsy
4:50 - 5:00 pm	Wrap-up

# \* Lunch will be provided.

Location: Hanqi Investment Inc., 1633 Bayshore Highway Suite 280 Burlingame, CA 94010

Registration Requirement:

Online registration is strongly encouraged.

Online: \$10 for CABS members, \$15 for non-members

Onsite: \$20

Register at http://www.cabsweb.org/CABSweb/feventslist.jsp?id=1120

#### Topic Description

# Bio2Device Group, Tuesday Morning, Sept. 22, 2015

Topic: "Life Science Careers: Your Place in Midst of Dramatic Industry Shifts" Speakers: Audrey S. Erbes, Ph.D., Audrey S. Erbes, Ph.D., Industry Blogger,

www.AudreysNetwork.com and Principal, Erbes & Associates

Date and Time: Tuesday, Sept. 22, 2015, 8:30 am

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

No fee or registration required for morning meetings.

#### Topic Description

Audrey will provide current industry employment data and discuss dramatic shifts by sector. She will provide her take on impact on the careers of current and future life science professionals. She will share tips on how to redefine where you best fit

#### Speaker Bio

Audrey Erbes, Ph.D., an international life-science business development and marketing professional and industry blogger at www.AudreysNetwork.com, has over 25 years corporate biopharmaceutical management and 12 years small company consulting experience. In her last corporate position, she was co-founder and Executive VP of Kowa Research Institute, a U.S. subsidiary of Kowa of Japan. Previously, she held management positions at Syntex, an international pharmaceutical company acquired by Roche, where she was involved in both U.S. and global product management, business development, and marketing research for 20 years.

She developed and taught three courses for working professionals—Life Science Marketing, Business Development and Product Management—for 12 years at UC Berkeley and UC Santa Cruz Extensions. She continues as Board VP of the Bio2Device Group —Servicing Pharma, Biotech, Diagnostics and Medical Device professionals from all functions and levels. She supports career professionals each week with a current list of upcoming Bay Area Industry Events and comments on the industry on her website.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# AWIS, Tuesday, Sept. 22, 2015

Event: "2015 National Summit On Innovation And Entrepreneurship: A Roadmap For

Inclusion"

Keynote Speaker: Janet Napolitano

Date and Time: Tuesday, September 22, 2015, 10:00 am - 2:00 pm; networking reception

1 – 3 pm

Location: Oakland Marriott City Center | Oakland, CA

Registration fee: \$50 members, \$125 general registration.

Register at https://awis.site-ym.com/events/register.aspx?id=666640&itemid=07945d5e-

0d68-4ebc-b53f-b357820e9c3c

# **Event Description**

In partnership with the University of California and the California Life Sciences Association, we are pleased to invite you to join us in Oakland, CA on September 22, 2015 for the National Summit on Entrepreneurship and Innovation.

Building upon our inaugural Summit which was held in partnership with The Ohio State University, this meeting will focus on how we, as a society, can develop inclusive, fiscally-responsive systems to drive research excellence, feed long-term economic growth, and fuel innovative solutions to global challenges facing all our citizens. Janet Napolitano, President of the University of California, will serve as the keynote speaker.

# A NATIONAL DIALOGUE ON GENDER AT THE NEXUS OF INNOVATION AND ENTREPRENEURSHIP

A full day of sessions, keynote address from Janet Napolitano, President of the University of California, plus networking reception provide a forum for the exchange of advanced knowledge on gender at the nexus of innovation and entrepreneurship.

Expert speakers: The National Summit engages panelists and participants in evidence-based and thought-provoking discussions.

Networking: Connect with experienced innovation professionals who represent the science, technology, engineering, and mathematics (STEM) community from corporate, academic, and government agencies.

Tickets are going fast. Registration is open to you first as a valued member of AWIS. Reserve your \$50 member-only ticket today before general registration opens on August 11th. This event is expected to sell out.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

### QB3, Tuesday Afternoon, Sept. 22, 2015

Event: UCSF Innovation and Entrepreneurship Summit

Date and Time: Tuesday afternoon, September 22<sup>nd</sup>, 3-5PM, Summit with 5-6PM

social hour

Location: Byers Hall 212, UCSF Mission Bay

Fee: Free

Register at https://www.eventbrite.com/e/ucsf-innovation-and-entrepreneurship-

summit-tickets-18313913408?mc\_cid=14ef2f6677&mc\_eid=cb4c38a44a

Organizer: crystal.nyitray@gb3.org

#### **Event Description**

What do you need to transform your concept into reality in a commercial or academic setting? UCSF has an amazing array of resources available for entrepreneurial scientists. We've brought them all together in a first-ever UCSF-wide innovation gathering! Join us on September 22<sup>nd</sup> to meet and hear from representatives from the Helen Diller Family Comprehensive Cancer Center, the Center for Digital Health and Innovation, CTSI, QB3, the Small Molecule Discovery Center, Surgical Innovations, and, from the Office of Innovation, Technology & Alliances, the Entrepreneurship Center and Technology Management.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# BioScience Forum, Wednesday Evening, September 23, 2015

Topic: "From Bench to Bedside: Targeting Key Stem Cell Pathways in Cancer"Speaker: Jakob Dupont, M.D., Senior Vice President & Chief Medical Officer, OncoMed

Pharmaceuticals Inc.

Date and Time: Wednesday, Sept. 23, 2015, 6:00 PM - 9:00 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, California 94080, USA

Cost:

Event Registration (\$3 service fee will apply)

Pre-Registration \$50.00
On-Site Registration \$60.00
Pre-Registration ends Monday, Sept. 21st, at 9 pm
Cash or check accepted on the day of the event
\$10 discount for full-time students

Or you can pay with a check made out to "BioScience Forum" and sent to: BioScience Forum
1442A Walnut Street, #308
Berkeley, CA 94709-1405
Please do not mail checks later than Thursday, Sept. 17th
If paying with check, do not complete online registration with Cvent
Register at www.biosf.org

# Topic Description

Heterogeneous cell types within solid tumors include a sub-population of cells, termed cancer stem cells (CSCs), that underlie the growth, proliferation, and metastatic potential of the tumor: this hypothesis is supported by numerous lines of evidence. This evidence also supports the concept that CSCs are preferentially resistant to many conventional therapies and thus mediate tumor recurrence. Experimental data demonstrating the presence of CSCs has been derived for many distinct tumor types including breast, colon, lung, pancreas, prostate, ovarian, melanoma, and glioblastoma. Consequently, therapeutic strategies aimed at reducing CSC frequency within solid tumors offer the promise of limiting disease progression and, in some instances, possibly providing durable clinical benefit.

Two key signaling cascades governing cell fate during development, the Notch and Wnt pathways, have been shown to be involved in CSC function in a variety of disease settings. As these pathways are frequently deregulated in cancer, they have long been recognized as

potentially oncogenic. However, efforts to generate therapeutics have been hindered by the challenges of achieving effective and selective targeting in these complex pathways characterized by numerous signaling components, often with overlapping or redundant functions. OncoMed Pharmaceuticals has developed seven large molecule drug candidates, targeting various components of the Notch and Wnt pathways, that are advancing in the clinic in seventeen ongoing clinical trials. Data from these clinical trials is beginning to show the potential and promise of targeting this novel therapeutic area in oncology. Emerging non-clinical and clinical data will be presented.

#### Speaker Bio

Jakob Dupont, MD, is Chief Medical Officer and Senior Vice President of OncoMed Pharmaceuticals Inc. and Adjunct Faculty in Medical Oncology at Stanford University. He received his AB in Philosophy from Vassar College; his MA in Philosophy from New York University; and his MD from the Weill Medical College of Cornell University.

Dr. Dupont has extensive academic and pharmaceutical oncology drug development experience. He joined OncoMed Pharmaceuticals from Genentech, where he was Global Medical Director for Avastin® (bevacizumab) overseeing the global medical strategy and late-stage medical program from Basel Switzerland.

He held leadership positions at all stages of oncology drug development from Phase 1 through Phase IV and was instrumental in the development and approval of Avastin for patients with breast cancer and gynecologic cancers such as ovarian cancer and cervical cancer. He also held a leadership position in the Oncology Exploratory Clinical Development group overseeing the development activities of the oncology angiogenesis pipeline at Genentech. Previously, he oversaw a Phase 1 solid tumor and gynecologic oncology clinic and led a tumor immunology laboratory as a faculty member at Memorial Sloan Kettering Cancer Center. In his academic work, Dr. Dupont helped develop key oncology drugs including: Zaltrap® (ziv-aflibercept); ALIMTA® (pemetrexed); XyotaxT (paclitaxel poliglumex); VELCADE® (bortezomib); and several other new molecular oncologic entities.

Dr. Dupont has been Chief Medical Officer at OncoMed since 2011. OncoMed currently has seven drug candidates in the clinic targeting critical cancer stem cell pathways. His team oversees seventeen ongoing clinical trials, from Phase 1 to Phase 2, in diverse solid and hematologic tumor indications. OncoMed completed an Initial Public Offering in 2012 and has three major collaborations with GlaxoSmithKline, Bayer, and Celgene. Dr. Dupont has received numerous grants and awards, has authored more than forty peer-review publications and is a co-inventor on over ten patents. He continues to care for gynecologic oncology patients and teach as an Adjunct Clinical Faculty at Stanford University Medical Center.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

### QB3, Monday Afternoons, Sept. 24, 2015

Workshop: QB3 NIH/NSF SBIR WORKSHOP FALL 2015

Instructors:

Shauna Farr-Jones, PhD, UCSF/QB3 grant writer

Crystal Nyitray, PhD, Entrepreneurship Program Manager

Dates: Sept. 24 - Dec. 17

Schedule

9/24 (Thurs) 1:00-4:30 pmMH-1401 10/22 (Thurs)1:00-4:30 pmBH-212 11/19 (Thurs)1:00-4:30 pmBH-212 12/10 (Thurs)1:00-3:30 pmBH-212 12/17 (Thurs) 1:00-4:30 pmBH-212

Location: UCSF Mission Bay

Fee: Standard rate for the entire 14-hour workshop: \$750 per company; Discounted rate for UC affiliates, QB3 Startup in a Box Members, and QB3 Accelerator Members: \$250 for entire course per company

#### Workshop Description

Five two-and-a-half hour SBIR classes, with two additional one-hour sessions on Phase 2 submissions and resubmissions, and two additional one hours sessions on NSF submissions. Starting Thursday, Sepember 24th and concluding Thursday, December 17th.

There are a limited number of seats, so please sign up as soon as possible by registering here on Eventbrite and also filling out the online application form (\*must be completed by 9/18/2015\*).

This five-session workshop will take you through all the steps necessary to successfully file a well-written SBIR/STTR grant application for the January 5th, 2015 NIH SBIR deadline and the December NSF deadline. This course will focus on crafting a well-structured research plan, getting persuasive letters of support, crafting an efficient budget, and helping you anticipate reviewers' comments. We will help you speed through the application instructions, saving you hours of time. The course culminates in a submission clinic that will ensure your application is correctly filed.

One or more team members from the company should be prepared to attend every session. Remember to bring your laptop; these will be working sessions.

#### Course includes

- Five 2.5-hour working sessions
- One 1-hour resubmission working session
- One 1-hour Phase 2 working session
- Two 1-hour NSF working sessions
- Pre-submission review of specific aims by our course instructors

#### Topics include

- Understanding the requirements of an SBIR
- Preparing to apply for an SBIR (company formation, registration at all required websites, identifying the best PI)
- Assembling all the necessary parts of the application (letters of support, sub-contract quotes and letters, facilities to execute the grant, and research plan)
- Composing a competitive research plan
- Understanding and assembling a budget and justification
- Documentation required to use human samples, vertebrate animals, select agents, resources
- Composing competitive innovation and significance sections as well as specific aims
- Searching for program announcements and finding opportunities
- Assembling and filing (completing the 424 correctly and filing on time)

Startup in a box membership fee for new members includes this workshop. If you fall under this category, you may register for free (ask Crystal Nyitray for the code).

A light snack and coffee is included for all sessions.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

### QB3, Thursday Afternoon, Sept. 24, 2015

Topic: "Learn what it takes to launch and run a genomics startup"

Date and Time: Thursday, September 24, 4:30-6:30 pm

Location: UCSF Mission Bay Fee: General admission --\$10 Register at https://www.eventbrite.com/e/qed-panel-from-the-illumina-accelerator-lessons-learned-for-genomics-entrepreneurs-tickets-18403121231?mc\_cid=14ef2f6677&mc\_eid=cb4c38a44a

#### **Event Description**

Three genomics startups will discuss their adventures in launching a startup, building a team, and refining their business models to unlock the power of the genome. On the panel: Poornima Parameswaran, PathoGn; Alberto Acedo, Biome Makers; Trevor Levin, Urology Diagnostics. The Illumina Accelerator is helping reduce the barriers to entry in creating genomics startups. Amanda Cashin, Head of the Illumina Accelerator, will provide perspective and tips for success. An informal Q&A session will follow the panel.

#### CLSA, Thursday Lunch, Sept. 24, 2015

Event: Lunch & Learn | Merger, Collaboration Deal of IPO: Getting Your IP House in Order

Speaker: Mika Reiner Mayer, Partner, Morrison & Foerster LLP

Topic Description

Date and Time: Thursday, September 24, 2015, 11:00 AM: Doors open

11:30 AM – 12:30 PM: Program 12:30 – 1:00 PM: Networking

Location: Morrison & Foerster, 755 Page Mill Rd., Palo Alto, CA 94306

Cost: Members: Free Non-members: \$75

• Early registration is highly advised as space is limited 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: <a href="mailto:registration@califesciences.org">registration@califesciences.org</a> or you can contact us via phone: 650-871-3257.

#### Topic Description

The driving force behind vast majority of mergers is the acquirer's desire to obtain the target's intellectual property assets. IP has come to dominate, both in volume and in value, not only merger transactions but also funding events, partnering deals and, increasingly, IPOs. Having a weak IP position can kill a deal, lower a valuation, and allow savvy competitors to steal market share. During this presentation you'll learn what it means to have a "strong" or "weak" IP position, how to prepare for an IP due diligence and what investors want to know about your IP. This session will provide a perspective on how to increase the value of the company, evaluate where your IP stacks up and how to make a deal go more smoothly while keeping competition out.

# QB3, Thursday Afternoon, Sept. 24, 2015

Topic: Lessons Learned For Genomics Entrepreneurs

Speakers: Amanda Cashin, Head, Illumina Accelerator; Alberto Acedo,

Co-Founder & CSO, Biome Makers; Trevor Levin, CEO, Urology Diagnostics; and Poornima Parameswaran, Co-Founder, PathoGn

Date and Time: Thursday, September 24, 4:30 to 6:00 pm

Room 212, Byers Hall, UCSF Mission Bay

General Admission: \$10

Register at https://www.eventbrite.com/e/qed-panel-from-the-illumina-accelerator-lessons-

learned-for-genomics-entrepreneurs-tickets-

18403121231?mc cid=78f992b242&mc eid=cb4c38a44a

#### Topic Description

Three genomics startups will discuss their adventures in launching a startup, building a team, and refining their business models to unlock the power of the genome. The Illumina Accelerator is helping reduce the barriers to entry in creating genomics startups. Amanda Cashin, Ph.D., head of the Accelerator, will provide perspective and tips for success. An informal Q&A session will follow the panel.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### QB3, UC Startup Competition Deadline, Sept. 25, 2015

Event: UC startup competition: Compete for \$300,000 in awards

Application Deadline September 25, 2015

We'd like to invite you to apply for the new UC-wide startup competition that we've <u>just launched</u> from the UC Office of the President. The first primeUC event, focusing on identifying and fostering life science startups emerging from the 10 UC campuses and 3 National Labs, will be held August-December 2015. Any startup that has a UC alum founder (students or staff), faculty advisor, or is resident in a UC incubator can apply, as long as they haven't raised >\$1M in private capital (excluding grants).

The application process will lead to an event on December 2nd where 20 finalists will be invited to a day-long program to pitch their company and network with active seed investors and partners. The day will culminate in announcement of the winners of a \$150K grant prize and three \$50K runner-up awards across the Pharmaceutical, Medical Devices, and Consumer Health sectors. Prizes are no-strings-attached awards sponsored by Johnson & Johnson Innovation.

Learn more about the primeUC program, review official rules and apply at www.primeuc.org.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# UCSF-Stanford Center of Excellence in Regulatory Science and Innovation, Friday Morning, Sept. 25, 2015

Topic: "Regulatory Science Forum: Next Generation Sequencing" Date and Time: Friday, September 25, 2015, 8:30 AM - 11:30 AM

8:30 - 9:00 AM Breakfast

Welcome and introductions

9:00 - 9:10 AM Russ Altman, MD, PhD (Stanford, Professor and UCSF-Stanford CERSI

Co-Director)

Key issues for regulation in next generation sequencing

9:10 - 9:40 AM David Litwack, PhD (FDA, Policy Advisor, Office of In Vitro Diagnostics

and Radiological Health)

9:40 - 10:10 AM Standards for characterizing whole-genome sequencing

Marc Salit, PhD (NIST, Leader of Genome Scale Measurements Group)

10:10 - 10:20AM Break

Panel on unmet regulatory science needs for establishing standardsbased oversight of NGS diagnostics

Russ Altman, MD, PhD (Stanford, Professor and UCSF-Stanford CERSI Co-Director)

Katherine Donigan, PhD (FDA, Staff Fellow, Office of In Vitro Diagnostics and Radiological Health)

10:20-11:30AM

Eunice Lee, PhD (FDA, Acting Branch Chief, Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health) Elizabeth Mansfield, PhD (FDA, Deputy Office Director for Personalized Medicine)

Sharon Liang, MD, PhD (FDA, Expert Scientific Reviewer, Division of Molecular Genetics and Pathology, Office of In Vitro Diagnostics and Radiological Health)

Zivana Tezak, PhD (FDA, Associate Director for Science and Technology, Office of In Vitro Diagnostics and Radiological Health)

Location: Stanford University, Mackenzie Room, Huang Engineering Center, 475 Via Ortega,

Rm 300, Stanford, CA 94305

Cost: Free

Please join us for this for this event by signing up

here: <a href="https://www.eventbrite.com/e/regulatory-science-forum-next-generation-sequencing-">https://www.eventbrite.com/e/regulatory-science-forum-next-generation-sequencing-</a>

tickets-18419270534

# Topic Description

Direct to consumer marketing of DNA tests, warning letters from the FDA, and a host of issues have confused the public and the scientific community about how DNA testing, and particularly diagnostics, which rely on Next Generation Sequencing (NGS) will be regulated. In this exciting symposium, scientists from the U.S. Food and Drug Administration, the National Institutes of Standards and Technology and academia will engage in a panel discussion regarding unmet needs in regulatory science as it pertains to diagnostics that use NGS technologies. Participants will also hear from FDA and NIST speakers as they discuss key issues in regulation of NGS and of current progress in the development of standards for whole-genome sequencing.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### GGPF, Tuesday Evening, Sept. 29, 2015

Topic: "Slot Die Coating Technology & How Precision Fluid Coating Impacts Optical and

**Energy Storage Products**"

Speaker: Mark Miller, Co-Owner, Coating Tech Slot Dies

Date and Time: Tuesday Evening, Sept. 28, 2015

6:00 PM social hour 7:00 PM dinner 8:00 PM presentation

Location: Michael's at Shoreline, 2960 N Shoreline Blvd, Mountain View, CA

Cost:

Employed/postdocs: \$30 early registration, \$35 regular registration

Unemployed/retired/students: \$15 early registration, \$20 regular registration

Free if you attend just the lectures at 8:00 PM (but please let us know for headcount) After deadline:

Registration not guaranteed, so contact us
Late fee applies if space available -- \$40 regular/employed, \$25
unemployed/student/retired

Deadlines for registration:

End of discounted advance registration Monday, Sept. 21, 11:59 PM End of regular (full-price) registration Monday, Sept. 28, 5:00 PM

Because we must pay the restaurant for the ordered meal, we must ask no-shows to pay for their reservation.

However, penalty-free cancellations are allowed up until the deadline for reservations (5PM Monday, Sept. 28)

PLEASE NOTE:

We accept cash or checks at the door, but are unable to accept payment by credit card at the event.

You may pay at the door.

Checks may be made to "GGPF"

Please register on the web page

Or, if necessary, contact:

Claudia Allison

callison1117@gmail.com<mailto:callison1117@gmail.com> 408-394-4000

You should receive confirmation of your registration; if not, please contact us again. Register on website at http://www.GGPF.org

### Topic Description

When you look at a roll of tape, there are two parts - the plastic substrate and the adhesive. The plastic substrate is produced via an extrusion die and the adhesive is coated via slot die. But adhesive tapes are only one of the plethora of products that utilize slot die coating technology to place a fluid onto a substrate.

Slot die coating technology is a function of the coating process, auxiliary system, and fundamental technique. The decision to utilize a coating technology needs to be analyzed against these functions to determine best fit. In the era of clean, thin, and precise converting operations, a customized coating system is necessary to have a technical edge. Building the system from the material up to the process sets the stage for a high precision tool designed around the process needs.

This material-up building process begins with the rheology of the fluid. Rheology is the study of flow. When you talk about squeezing, spreading, or lubricating a fluid, you are talking rheology. When you apply a force that causes a fluid to move, rupture, or flow you are describing a rheological force. Understanding rheology is fundamental to building fluid coating processes and in particular a slot die coating head.

The dramatic increase in the expectations of coated products, in areas as diverse as optical films to battery technology, has put substantial pressure on the systems used to produce the next generation of coated products. With increased speeds, thinner coatings and increased functional performance, awareness of coating techniques and technologies is required. The world is changing and new tools are needed to compete in the changing world markets.

An awareness of coating techniques, technologies, and systems allow for novel adaptations and application to new market opportunities. Rheological understanding and an application to slot die technology provides innovative tools that will help coating companies

improve precision, tackle new markets, and develop new processes.

# Speaker Bio

Mark Miller's first introduction to the world of slot die coating was in 1996, when he was learning the technology at 3M company. Today, Mark and Tim Marion own and operate the slot die manufacturing company Coating Tech Slot Dies. Coating Tech Slot Dies supplies precision equipment to the finest coating companies around the globe. They also operate Coating Tech Institute, a user conference designed for engineers and operators to learn slot die technology for immediate implementation at their site. In addition, Mark also operates Coating Tech Service, a slot die consulting company that has helped start-up companies and established businesses improve efficiencies and increase capability. He has presented papers at AIMCAL, PSTC, CONVERTECH, AWA, and countless other conferences held for the converting industry. More information can be found at www.slotdies.com

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### PBSS, Thursday, Oct. 1, 2015

Topic: "Cancer Immunotherapy: A Game Changer for Cancer Treatment - Breakthroughs in Science, Translational Medicine, Clinical Development &

Latest Trends in Oncology Practice and Business Partnerships"

Date and Time: Thursday, Oct. 1, 2015, 8:45 - 5:00

Location: Foster City Crowne Plaza

Register at http://pbss.org/

#### Topic Description

An End-of-Phase 2 (EOP2) meetings is a meeting between the US FDA and the sponsor of a clinical development program after the completion of the Phase 2 study and prior to the start of the Phase 3 study. It is most useful to the sponsor and should be held before major efforts and resources are committed to specific Phase 3 studies. The purpose of an EOP2 meeting is to determine sufficient safety prior to Phase 3, to evaluate the Phase 3 plan and protocols, the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

This workshop is intended to address the important topics for an effective discussion at an EOP2 meeting and to provide an overview of a successful meeting preparation. Regulatory aspects will be provided from the FDA and the industry perspective. For clinical pharmacology the progress of PK study data and additionally needed studies will be reviewed. The preclinical safety and toxicology as it relates to dose, duration & route of administration will be discussed. In the CMC area the approach to specifications and test methods as well as the formulation to be used in clinical trials and "to be marketed" formulation will be addressed. In the clinical discussion at an EOP2 meeting, agreement needs to be reached with FDA on pivotal study designs, dose selection, patient population and the safety and efficacy endpoints for Phase 3 studies.

#### Topics and Speakers:

- Regulatory Overview of End of Phase 2 meeting What to consider? Industry perspective - Azin Shahzamani (Genentech/Roche)
- The FDA perspective of a successful EoP2 meeting, how to avoid the common mistakes; and Phase 3 dose selection aspects Yaning Wang (FDA)
- Nonclinical safety and toxicology aspects and strategy Terry Sweeney (Nektar)
- DMPK issues & Clinical pharmacology (Mike Eldon)
- CMC aspects and strategy Ramani Raghavan (Genentech/Roche)

Clinical aspects and strategy - Detlef Albrecht

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# CBA Annual Conference, Saturday, Oct. 10, 2015

Conference Topic: "Future of the Life Science Industry - Innovation and Opportunities" Confirmed Speakers:

- Dr. Peter Yu, ASCO President Keynote speaker
- Dr. Lennart Mucke, Director of the Gladstone Institute of Neurological Disease
- Dr. Tim Hoey, Sr. Vice President from OncoMed
- Dr. Radoje (Rade) Drmanac, CSO at Complete Genomics
- Dr. Jacqueline Law, Senior Director at Genentech
- Dr. Janet Xiao, Partner at Morrison Foerster
- Dr. Scott Liu, CEO at Henlius Biotech
- Dr. Hiromitsu Nakauchi, Professor of Genetics at Stanford
- Dr. Mary Vincent, Co-founder & CTO, SK Telecom Americas Innopartners, Lifetime MD
- Dr. Xi Zhao-Wilson, CEO at BioMarker Pharmaceuticals
- Dr. Licen Xu, Senior Director, Thermo Fisher Scientific
- Dr. Ruhong Jiang, CEO of Applied Stem Cell

Date and Time: Saturday, Oct. 10, 2015

Location: Crown Plaza, Foster City, CA

Register at CBA website. See instructions below. Registration (including banquet style lunch) open. CBA members please login first at www.cbasf.org and use the Event link on the right side to pay. Non-CBA members please use the bottom PayNow button at www.cbasf.org home page to pay.

- Early Registration online (by Sept 15th, 2015), CBA member \$10, Non-CBA member \$30. Lunch included.
- Regular Registration online (Sept 16th to Oct 5th, 2015), CBA member \$20, Non-CBA member \$40. Lunch included.
- Onsite Registration: CBA member \$30, Non-CBA member \$50. Lunch not guaranteed.

#### Conference Description

The next CBA event, the 18th Annual Conference, will be held at to share the latest research results and success stories. Registrations are open at the CBA website: www.cbasf.org. Please mark down your calendar and register the conference online to experience another fascinating event from CBA on Oct 10!

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### JLABS, Wednesday Mid Day, Oct. 14, 2015

Topic: "Meet with...OrbiMed

Speaker: Peter Thompson, M.D. | Private Equity Partner, OrbiMed

Date and Time: Oct. 14, 2015, 11:00 am - 1:30 pm 11:00 AM | Registration, Lunch, and Networking

11:30 AM | Presentation

12:15 PM | Discussion and Q&A

12:30 PM | Audience Pitches and Critique

1:30 PM | Program Close

\*Companies must have applied for a one-on-one meeting ahead of time and be approved. The application period ends on September 11th.

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd - 3rd Floor,

South San Francisco, California

Fees:

Presentation & Lunch

Fees:

\$35 | General Public

\$20 | Student/Academic

\$45 | At the door

One-on-One Meeting

FREE | Application

FREE | Accepted Companies

Companies must have applied for a one-on-one meeting ahead of time. The one-on-one application period ends on September 11th. Your application will be reviewed and you will be notified of acceptance by September 25, 2015. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.

Details and registration at <a href="http://www.eventbrite.com/e/meet-with-orbimed-tickets-17394113261">http://www.eventbrite.com/e/meet-with-orbimed-tickets-17394113261</a>

#### Topic Description

Can you provide healthcare innovation that will help humanity live healthier, longer and more productive lives? Then OrbiMed wants to talk to you.

OrbiMed is the world's largest life sciences-dedicated investor with specific interests in biopharma, diagnostics, med tech and healthcare services. They've helped to nurture and commercialize some of today's most successful healthcare companies focused on creating healthier, longer and more productive lives around the globe. OrbiMed is seeking novel healthcare innovations across biopharma, devices, diagnostics and healthcare IT at any stage of development in both public and private companies.

A representative from OrbiMed will be in attendance to give an overview presentation about the company's key areas of interest and best practices when seeking funding. Following the presentation, don't miss this opportunity to introduce yourself to Peter Thompson during the networking lunch. And finally, for those companies who <u>apply online</u> and are approved, one-on-one meetings with OrbiMed will provide a forum to discuss your company.

#### About the Meet with... Series:

The purpose of the Meet with Series events sponsored by JLABS is to help start-up entrepreneurs, as well as the academic community, connect with potential partners, such as big pharma or other investment corporations, through one-on-one meetings. It is also a chance for the featured corporation to outline their specific business development goals and clarify what types of products or research they are interested in and how best to approach them to get the partnering process started. Past participants include the Wellcome Trust, Bill & Melinda Gates Foundation, MedImmune Ventures, NCI, Mercury Fund, DARPA's Biological Technologies Office, Correlation Ventures, Breakout Labs, New Enterprise Associates, Canaan Partners, Thomas McNerney & Partners, NCATS, NINDS, Johnson & Johnson Innovation, Poliwogg, California Institute for Regenerative Medicine, Astellas Venture Management, and OrbiMed.

OrbiMed Participating Representative Bio Peter Thompson, M.D. | Private Equity Partner, OrbiMed Peter Thompson is currently a Private Equity Partner with OrbiMed who brings over 20 years of industry experience. He co-founded and was CEO of Trubion Pharmaceuticals, co-founded Cleave BioSciences, serves on the Boards of Cleave, Anthera, Methylgene, Principia Biopharma, and Response Biomedical, and was an executive of Chiron Corporation and Becton Dickinson. Dr. Thompson is an Ernst & Young Entrepreneur of the Year awardee, an Affiliate Professor of Neurosurgery at the University of Washington, an inventor on numerous patents, and a board-certified internist and oncologist. He was on staff at the National Cancer Institute following his internal medicine training at Yale University.

# Bio2Device Group, Tuesday Morning, Sept. 22, 2015

Topic: "MedDevice Digital Marketing Nirvana: Monitizing Patient-Facing Websites" Speakers: Debbie Donovan, Director of Communications and Corporate Identity,

**EndoGastric Solutions** 

Date and Time: Tuesday, Oct. 20, 2015, 8:30 am

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

No fee or registration required for morning meetings.

# Topic Description

The time has come and it doesn't cost much. You can determine return-on-investment for patient-facing websites. Build the right foundation and marketing nirvana can be yours.

#### Speaker Bio

Debbie Donovan is a medical device digital marketer (eGold Solutions consultant) and an original Wise Dame. She's focused on developing revenue-generating digital marketing programs for medical technology companies that include the integration of social media strategy.

Currently, Debbie is the Director of Communications and Corporate Identity at <a href="EndoGastric Solutions">EndoGastric Solutions</a>. Previously, she was a Director of Marketing at <a href="Avantis Medical Systems">Avantis Medical Systems</a> and established a robust digital foundation for Third Eye Colonoscopy. At <a href="Intuitive Surgical">Intuitive</a> Surgical she was the Senior Manager focused on market development programs and emarketing initiatives supporting Gynecology and Oncology surgery specialties. In addition, she has experience serving Ob/Gyn, Orthopedics/Spine and ENT physicians at <a href="Conceptus">Conceptus</a>, <a href="Kyphon">Kyphon</a> and <a href="Somnus">Somnus</a>. 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 marketing communications and public relations agencies. She holds a BA degree in public relations journalism from the University of Southern California. She also lectures at UC Extension courses and is an active member of Medtech Women and International Association of Business Communicators, Silicon Valley Chapter (IABC-SV).

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

### HealthTech Conference, Tuesday - Wednesday, Oct. 27-28, 2015

Conference Topic: Moving the Needle in HealthTech Date and Time: Tuesday – Wednesday, Oct. 27-28, 2015 Registration before 8/31: \$750 vs \$1,295 (at the door)

Date: October 27-28, 2015

Location: Santa Clara Convention Center, Silicon Valley, CA

Web: <u>www.HealthTechConference.com</u>

Conference Description

Check out our updated <u>agenda</u> and impressive list of <u>thought leaders speaking</u> at the HealthTech Conference!

Join us on October 27-28, 2015 as the <u>HealthTech Conference</u> heads to a new venue at the <u>Santa Clara Convention Center</u> where we will share important stories and ideas on how we have, and will continue to move the needle in healthcare during this time of dramatic change.

Since 2011, the <u>HealthTech Conference</u> has sold out every year and is focusing on *How to Build Sustainable HealthTech Companies* to change the business of healthcare delivery. This year, in addition to enabling deep dive discussions with existing stakeholders, we will focus on encouraging Match Making with potential customers and business partners.

This year, the 4th HealthTech Conference theme is "Moving the Needle in HealthTech" and will encourage leading providers, payers, and healthcare corporations to share how they implemented innovative solutions and validated their impact. The agenda will include:

1. Our <u>famous "Deep Dive Panels"</u> with leading healthcare players discussing their HealthTech transformation experiences:

Serial Entrepreneurs: Secrets to Success Jeff Margolis, CEO, Welltok Glenn Tullman, CEO, Livongo Health

What are the unmet needs of Providers?
Rich Roth, VP Strategic Innovation, Dignity Health
Amir Rubin, CEO, Stanford Health
Molly Coye, Network for Excellence in Health Innovation (NEHI)
Thomas Thornton, SVP, North Shore-LIJ Health System

How are Employers driving healthcare changes? Kyu Rhee, VP & Chief Health Officer, IBM Corp Derek Newell, CEO, Jiff

Is Digital Mental Health finally here? Ravi Hariprasad, Head of Clinical Programs, Ginger i.o. Eve Philips, CEO, Empower Interactive Alon Matas, CEO, BetterHelp/Teladoc Seth Feuerstein, VP Innovation, Magellan Health

How will Value Care change healthcare delivery? David Sayen, Regional Administrator, Centers for Medicare & Medicaid Services Jeff Rideout, CEO, Integrated Healthcare Association Sam Glick, Partner, Oliver Wyman

Are Digital Therapeutics the next unicorns? Alan Levy, CEO, Chrono Therapy Mike Payne, Chief Commercial Officer, Omada Health Rick Altinger, CEO, Glooko

Who will be the 2015 Most Promising HealthTech Company? Renee Ryan, VP venture investment, JJDC Casper de Clercg, Partner, Norwest Venture Partners Jack Young, General Partner, Qualcomm and dRx Capital Tom Rodgers, Managing Director, McKesson Ventures

# <u>2. The "Match Making" meetings</u> between pre-vetted exhibiting companies and potential customer or business partners:

Leading healthcare delivery systems:

Stanford Health, Kaiser, Dignity, UCSD, North Shore, Magellan Health

Established healthcare companies: Genentech, GE, Philips

Payers and Employers: CMS, Humana

Leading investors: dRx, Canaan, Merck Global Health, CHCF

# 3. The "Business Building Workshops

How to build the Right Team: (Employees + Board)

Glenn Tullman, CEO, Livongo Health

Wende Hutton, Managing Director, Canaan Partners

Michael O'Donnell, Partner, Morrison Foerster

Gale Richards, Partner, Bioquest

Building successful corporate partnership

Noah Lewis, Managing Director, GE ventures

Joel Krikston, Managing Director, Merck Global Health Innovations Fund

# Selling to Healthcare Delivery Systems

Rick Altinger, CEO, Glooko

Seth Frazier, Chief Transformation Officer, Evolent Health

Robin Cisneros, National Director, Medical Technology Assessment and Products, Kaiser Permanente

### 4. The "Move the Needle Exhibitor Pavilion"

Reception on October 27 and open for 2 days during lunch and breaks

#### \*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### JLABS, Tuesday Mid Day, Nov. 3, 2015

Topic: "It Must be Witchcraft"

Speaker: John Bates | Chief Executive Officer, Executive Speaking Success & Business

Coaching

Date and Time: Tuesday, Nov. 3, 2015, 11:00 am - 1:30 pm

Agenda:

11:00 AM | Registration, Lunch, and Networking

11:30 AM | Presentation

12:15 PM | Discussion and Q&A

12:30 PM | Audience Pitches and Critique

1:30 PM | Program Close

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor,

South San Francisco, CA

Fees:

\$35 | General Public

\$20 | Student/Academic

\$45 | At the door

Details and registration at http://www.eventbrite.com/e/it-must-be-pitchcraft-

tickets-17169625813

#### Who Should Attend:

Life science industry executives, founders, CEOs, and marketing managers of startups and other private companies.

Details and registration at http://www.eventbrite.com/e/it-must-be-pitchcraft-tickets-17169625813?aff=weekly

#### Program Description

Have you ever wondered why you didn't get the investment? The potential funders loved the idea. They loved the team. They thought the market would be receptive... But, they wanted to think about it a little longer.

In this enlightening session with world renowned Communications & Leadership Expert, John Bates, you will learn the secrets behind pitches that succeed. You will leave ready to apply the secrets of PitchCraft to all of your pitches. From internal presentations to fundraising and client pitches you will learn not only what works, but why it works.

John has trained teams to take pitches from disaster to success that have raised hundreds of millions of dollars. In preparing PitchCraft John enhanced his own extensive experience by interviewing many top funders in the Healthcare ecosystem. From leading grant reviewers and high stakes venture fund managers to startup founders, John has gathered and distilled the principles, practices and gems no one ever discusses.

Even though you have a great idea, a great product, and a great team, you need to be able to communicate that well or it can languish while an inferior idea, product and team rise to prominence. Make sure your pitch skills are worthy of your idea, product and team. Make sure you are skilled in the art of PitchCraft.

The "How to... Workshop" series is dedicated to giving you the keys to a successful business, from creation to exit. As with all our events, the "How to... Workshop" is interactive and informal so bring your questions with you!

#### Speaker Bio

John Bates | Chief Executive Officer, Executive Speaking Success & Business Coaching

John fell in love with the Internet the moment it dawned on him what it would do for communication. Since then he has worked with early stage companies as a founder or early employee and has been instrumental in raising hundreds of millions of dollars in Venture Capital. He co-founded BIGWORDS.com, a dotcom darling which ended up going bust in the dotcom bomb of 2000 and he was the first employee and is a part owner of Goldstar.com. John has been asked to speak and teach all over the world at events ranging from Web Attack to the St Gallen B-School World Leaders Symposium, the Leiden Veerstichting conference for Global Leaders, TEDActive twice, and many TEDx's. Most recently he taught groups of entrepreneurs and business owners in Bratislava, Slovakia via the University of Ekonomics, American Chamber of Commerce and the American Embassy. These days John loves bringing the ideas of others to life.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# PBSS, Tuesday, November 10, 2015

Topic: " Effects of Food and pH on Drug Absorption and Pharmacokinetics: Fundamentals,

Investigation, Prediction, and Formulation Remedies"

Speakers: Matt Wright, Mark Ratain, Joe Ware, Grazyna Fraczkiewicz, Jan Wahlstrom, Atik

Rahman, Charles Yang

Date and Time: Tuesday, Nov. 10, 2015, 8:45 - 17:00

Location: SF Bay Area: Foster City Crowne Plaza

Registration at <a href="http://www.pbss.org/aspx/homeSF.aspx">http://www.pbss.org/aspx/homeSF.aspx</a>

Registration deadline: 11/9/2015 (it will close sooner if the seating cap is reached) Topic Description

- Review of Human GI Physiology and Responses to Food Physicochemical and BCS Class Considerations (Matt Wright, Genentech)
- Food effect: Clinical Lesson Learned in Oncology: Where we have been and where we are going (Mark Ratain, University of Chicago)
- pH-dependent drug-drug interactions (Joe Ware, Genentech)
- PBPK modeling to predict and learn from food effect and pH-dependent interactions (bottom-up/top down approaches) Grazyna Fraczkiewicz, Simulations Plus
- Case study and Lessons Learned (Jan Wahlstrom, Amgen)
- FDA speaker on food effect and pH-dependent Drug-Drug Interactions (Atik Rahman, FDA)
- To Eat or Not to Eat? Contemplating a Nobler Formulation to Address Food Effect (Charles Yang, Genentech)

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# Bio2Device Group, Tuesday Evening, Nov. 10, 2015

Topic: "TBA"

Speaker: Mark G. Edwards, Managing Director, BioSci Advisors

Date and Time: Tuesday, Nov. 10, 2015, 6:00pm

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

Cost: \$6 - Students/In-transition - Members only ; \$11 - Early-bird Registration - Members

only; \$20 - Late Registration and Non-Members Register on website www.Bio2DeviceGroup.org

#### Speaker Bio

Mark Edwards has over two decades of experience in negotiating and analyzing biopharma alliances. As founder and managing director of Recombinant Capital (Recap) from 1988 until its sale to Deloitte in 2008, Mr. Edwards supervised the creation and maintenance of several databases relating to the development and commercialization of pharmaceutical products, including the Recap Corporate Alliances Database. Over this period, Mr. Edwards and Recap was retained by more than 50 companies to assist in the negotiation of biopharma alliances. His consulting clients have included Abbott, Amgen, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, Millennium, Merck, Pfizer, PTC Therapeutics, Roche and Tularik. In 2008, Mr. Edwards was awarded a Lifetime Achievement Award by the American Liver Foundation for "two decades of leadership, thoughtful insights and detailed analysis of the biotechnology industry."

From 2008 through 2010, Mr. Edwards was the managing director of Deloitte Recap LLC, a wholly-owned subsidiary of Deloitte LLP. In this capacity, he ran Deloitte Recap and consulted on behalf of Deloitte on a variety of client engagements.

In January 2011, Mr. Edwards founded Bioscience Advisors, Inc. (Biosci), a consulting and database firm focused on biopharma alliances. Biosci has created a database, <u>BiosciDB</u>, that contains copies of over 12,000 license, development, co-development, joint venture, distribution, asset purchase and other arm's-length agreements that have been publicly filed

with the U.S. Securities and Exchange Commission (SEC). Biosci analysts have obtained unredacted copies of approximately 8,500 of these agreements, with the majority obtained via Freedom of Information Act (FOIA) requests.

Biosci also launched a public discussion forum, <u>BiosciBD</u>, where biopharma licensing professional and other interested parties can share and enhance best practice in negotiating, structuring and managing alliances.

Mr. Edwards is a charter Certified Licensing Professional as established by the Licensing Executive Society. He is on the board of directors of <u>AcelRx</u> and <u>Calibr</u> and has previously served on the boards of Allos Therapeutics, CombiMatrix and Ontogen. He holds a Bachelor of Arts degree in Political Science and Economics and an MBA, both from Stanford University.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

# Chief Medical Officer West, Monday - Tuesday, Nov. 9-10, 2015

Event: 2<sup>nd</sup> Chief Medical Officer West Conference

Speakers: CMOW is delighted to welcome back members of our distinguished faculty and also welcomes aboard new speakers from Kite Pharma, Kearney Venture Partners, Sorrento Therapeutics, Sunesis Pharmaceuticals, Apricus Biosciences, Skyline Ventures, Tocagen, Roche Venture, NGM Biopharmaceuticals, Relypsa, Nevro, EddingPharm, Bay City Capital and Vivo Capital.

Date and Time: Monday - Tuesday, Nov. 9-10, 2015

Location: Hilton San Francisco Airport Bayfront, Burlingame, CA

Price: Standard 2nd Early Bird, through 9/12—S1,295.00; Academic/Govt 2<sup>nd</sup> Early Bird

Through 9/12--\$647.50 through 9/12 **10% Discount with Code TEML** Register at https://theconferenceforum.org/events/cmo-west-2014-2/

#### **Event Description**

The 2015 CMOW program is the only conference of its kind dedicated to addressing the unique challenges faced by CMOs in emerging biotechs. The program is designed with input from CMOs and our lead advisor, Dr. Pamela Palmer, CMO & Co-founder, AcelRX. It is an R&D leadership event unique to the CMO.

#### New Novel Topic Discussions

New topics including, CMO / Investor Joint Interview; Selling the Buy-side: Interacting with Healthcare Hedge Funds; Think Globally: Gaining EU Approvals & Navigating the EU Market; Separation vs Collaboration of Medical and Commercial Roles in Biotech; Latest Clinical Development Approaches for CMOs; and much more!

# Networking & Benchmarking Opportunities

Meet other CMOs facing similar challenges and exchange ideas and best practices. Opportunities to get a comprehensive update on helpful technologies and other services for smaller pharma are in the exhibit area.

See agenda at http://theconferenceforum.org/conferences/cmo-summit-west/agenda/

# JLABS, Thursday Mid Day, Nov. 12, 2015

Topic: "ABCs of the FDA - How to... Set a Preclinical Roadmap"

Speaker:

Michael Kelley, VMD, Ph.D., DABT | Senior Scientific Director, Janssen Research &

Development

Date and Time: Thursday, 11:30 am - 1:00 pm

Agenda:

11:30am | Registration, Networking and Lunch

12:00pm | Presentation

12:30pm | Q&A 1:00pm | Close

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor,

South San Francisco, CA

Fees:

\$35 General Public

\$20 Student/Academic

\$45 At the door

Details and registration at http://www.eventbrite.com/e/abcs-of-the-fda-how-to-set-a-preclinical-roadmap-tickets-17169970845

#### Topic Description

Moving a program from Discovery through Development is an arduous task. Key among these challenges is designing a safe and druggable molecule that can withstand the rigors of preclinical testing in support of First in Human (FIH) trials, human Proof of Concept (POC), and finally global drug registration. This session will highlight design considerations to optimize drug disposition and safety characteristics in the Discovery phase, to ensure the preclinical road in Development is a smooth one. In addition, you will learn what startups need to know about preclinical requirements and resources to support early clinical trials through Human POC. This workshop is geared towards pharmaceutical and biotech startups.

#### Topics will include:

- Key drug metabolism, pharmacokinetic and toxicology characteristics that should be considered in molecule design
  - Preclinical requirements to support FIH trials and POC
  - Evaluating preclinical resources (consultants and CROs) to support your program
  - Hiring your first Preclinical FTE

The workshop will feature Michael Kelley, VMD, PhD, DABT, Senior Scientific Director with Janssen Research & Development. Mike has over 25 years of industry experience and has held leadership positions in both small and large biopharmaceutical companies.

The "How to... Workshop" series is dedicated to giving you the keys to a successful business, from creation to exit. As with all our events, the "How to... Workshop" is interactive and informal so bring your questions with you!

Speaker Bio

Michael Kelley, VMD, Ph.D., DABT | Senior Scientific Director, Janssen Research & Development

Mike is currently Senior Scientific Director/Head of Preclinical Projects & Submissions

at the Janssen R&D site in Spring House, PA. As part of this role, he is responsible for a portfolio of discovery and development projects in the Oncology, Cardiovascular and Metabolism therapeutic areas. Mike is also the Janssen R&D preclinical scientific liaison to the Johnson & Johnson Boston Innovation Center. Mike has more than 25 years of preclinical experience working for small and large biopharmaceutical companies. He is a full member of the Society of Toxicology, Past-President of the Mid-Atlantic Chapter of the Society of Toxicology, and a Diplomate of the American Board of Toxicology. Mike received his BA and VMD degrees from the University of Pennsylvania, and his PhD in toxicology from Texas A&M University.

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*

#### PBSS Workshop, Friday Afternoon, Dec. 4, 2015

Topic: Getting your IP House in Order: Patent Fundamentals, Strategies, and Case Studies for Life Science Professionals

Speakers: Janet Xiao (Morrison & Foerster LLP), Jen Liu (Orrick, Herrington & Sutcliffe LLP), Vandana

Date and Time: Friday, December 04, 2015, 12:45-17:30

Location: SF Bay Area: Foster City Crowne Plaza

Registration fee (US\$): Regular: \$125; For unemployed & students: \$20; For major-sponsor rep (incl lunch): \$0; For vendor-show reps: \$25; For others, details available upon online login.

Registration: http://www.PBSS.org

Further Information:

Registration deadline: 12/3/2015 (it will close sooner if the seating cap is reached)

#### About the Topic

This workshop aims to help life science professionals gain good understanding on the business values of patents and the process of building a strong patent portfolio. The workshop will begin with an overview of key factors for building a strong patent portfolio in the life science industry. Basic legal requirements for patentability, as well as recent changes in patent law that impact patent strategic considerations will then be covered. With this groundwork, we will then discuss the process and key considerations for obtaining patent protection from the inception of the ideas to the preparation of a patent application and working with the patent office to obtain a patent. The workshop will conclude with an overview of the key considerations during IP due diligence as well as practice tips on how to best prepare life science companies for IP due diligence by investors and collaborators. Real-life case studies will be presented throughout the workshop.

Key topics to be covered:

- Business values of a strong IP portfolio; what constitutes a strong IP portfolio and how to build one
- Legal requirements for patentability and recent changes in patent law impacting patent strategic considerations
- Overview and key considerations of the patent application process
- IP due diligence practice and practice tips on how best to prepare for IP due diligence

# Speaker Bios

Dr. Janet Xiao is a partner in Morrison & Foerster's Life Science Group primarily representing clients in the biotechnology and pharmaceutical industries in their world-wide patent procurement, patent portfolio management, and strategic planning. Dr. Xiao advises biopharmaceutical companies and research institutions on patent matters relating to various technologies including antibody therapeutics, nanomedicine, personalized medicine, drug delivery systems, drug screening platforms, diagnostics, and nutraceuticals. She also represents many start-up biopharmaceutical companies to help them build a strong IP

position from inception. In both 2014 and 2015 Dr. Xiao was listed in Chambers Global as a leading IP expert in the U.S. and a leading IP lawyer in China as an expert based abroad. Ms. Zheng (Jen) Liu, Of Counsel in the Silicon Valley office of Orrick, Herrington, & Sutcliffe LLP, is a member of her firm's Intellectual Property Group. Ms. Liu's practice focuses on patent, trade secrets, and unfair competition litigation, intellectual property counseling, due diligence and technology transactions across a broad range of industries, including biotechnology, pharmaceutical, medical devices, Internet and telecommunications. Ms. Liu has also been the lead member for many patent infringement and commercial litigation cases and has argued important issues such as claim construction and examined witnesses in federal courts.

# Bio2Device Group, Tuesday Evening, Dec. 8, 2015

Topic: "Vaccines, Canaries and Coalmines: What lessons for Biopharma from the Oldest

Class of Biologics?"

Speaker: Piers Whitehead, Special Advisor to the CEO, Acquisitions, PaxVax

Date and Time: Tuesday, Dec. 8, 2015, 6:00 pm

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

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

#### Topic Description

Since at least the 15<sup>th</sup> Century, people have been vaccinating against infectious disease. As the most "mature" biopharma sector, what can we learn from it about broader biopharma trends, such as industry concentration, the role of developing country producers, achieving global access, industry cycles and more?

#### Speaker Bio

Mr. Whitehead joined PaxVax in early 2013 and brings 20 years of experience in the vaccines and biopharmaceutical industries. He previously served as Vice President of Corporate Development for Paris-based Neovacs. Prior to that, he was Vice President of Corporate and Business Development for vaccine company, VaxGen. At VaxGen, he negotiated several important partnerships and led the company's commercial strategy, resulting in the award of a nearly one billion dollar Project Bioshield Act contract. He also spent 10 years at Mercer Management Consulting, where he headed the San Francisco office and led marketing, strategy, and manufacturing projects for clients including the Global Alliance for Vaccines and Immunization (GAVI), UNICEF, and several private-sector pharmaceutical and biopharmaceutical companies. Mr. Whitehead has published extensively on the vaccine industry and related public policy matters and holds an A.B. from Oriel College, Oxford University, England.

### PMWC, Monday - Wednesday, Jan. 24-27, 2015

Event: Personalized Medicine World Conference

Date and Time: Monday, January 25, 2016 at 7:00 AM -Wednesday, January 27,

2016 at 5:00 PM (PST)

Location: Computer History Museum 1401 N Shoreline Blvd

Mountain View, CA 94043

See program details at http://2016sv.pmwcintl.com/all/

Price: \$950 prior to Sept. 30 and then \$2,500 through Jan. 24, 2015

Register at https://www.eventbrite.com/e/pmwc-2016-sv-attendees-tickets-

14926919819

# **Event Description**

The Personalized Medicine World Conference (PMWC) is the only fully integrated conference to examine the advances and challenges of Personalized Medicine through a practical lens. PMWC brings together the thought-leaders of business, government, healthcare-delivery, research and technology into one information-rich, two-day conference.

Tickets are not refundable!

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*