

Audrey's Life Science Meeting Picks for Sept. 27, 2015 – Dec., 2015
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Sept. 27, 2015

Bio2Device Group, Tuesday Morning, Sept. 29, 2015

Topic: "The Business Side of Regulatory Affairs "

Speaker: Patrick Lee, Senior Consultant, Navigant Consulting

Date and Time: Tuesday, Sept. 29, 2015, 8:30 am

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

There is no registration or fee for morning meetings.

Topic Description

Regardless of your background, this presentation on regulatory affairs could provide useful and critical insights to your company and your personal career. The regulatory affairs function in business planning and operations have often been overlooked or underestimated, a position that can have disastrous outcome for an emerging medical product company. As a regulatory consultant, we often see the effects of companies failing to meet regulations and falls into non-compliance and finally FDA sanctions. And on the opposite end, when a company fails to receive timely approval of its product by all the appropriate competent authorities, the delay in time is a direct loss to the company in the form of opportunity costs. Understanding regulations and compliance is a critical step to forming a successful business strategy.

This presentation will present basic concepts and terminology in regulatory affairs, followed by a discussion on regulatory strategies. Discussion will include the topics of how to refine indications-for-use statement, developing a meaningful partnership strategy, understanding market expectations, and others. There are significant factors regulatory can make or break a business' strategy. The presentation will be interactive and audience participation and questions are welcomed.

Speaker Bio

Patrick S. Lee is a Senior Regulatory Scientific Advisor in Navigant Consulting's Healthcare and Life Sciences Disputes, Regulatory, Compliance, and Investigations (HLS DRCI) practice, focusing on FDA regulatory matters.

Patrick has over 20 years of experience in FDA-regulated products spaces including regulatory & quality affairs and product development in medical devices. He has broad experience with QSR and MDD requirements, and has managed and secured over 100 global clearances (e.g., 510(k), CE Mark, Health Canada license). Patrick has experience with cardiovascular, endovascular, and neurovascular devices; cerebral implants; ophthalmic implants; stem cell and biologic products; regenerative medicine; and laser, radio-frequency, intense-pulse-light, and ultrasonic devices, many of which are electronic (IEC compliant) and software-driven. He has been deeply involved in design control, risk assessment, verification and validation tests, quality audits, and many functional aspects of the transfer of process from R&D to manufacturing. Patrick holds a RAC (US) from RAPS, is a professional engineer in the states of California and New Jersey, holds two U.S. patents, and is an instructor with the Silicon Valley Chapter of the ASQ and RAPS.

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 <<http://www.slotdies.com/>>.

Palo Alto AWIS, Tuesday Evening, Sept. 29, 2015

Event: Networking Event

Date and Time: Tuesday, Sept. 29, 6-8 pm

Location: Tootsies at The Stanford Barn

700 Welch Rd, Palo Alto, CA 94305

Cost: Hors-d'oeuvre will be served; bar will be no host.

Palo Alto AWIS Members: FREE

Pre-registered Non-Members: \$10

Fee at Door: \$15

Register at <http://www.brownpapertickets.com/event/2245248>

Event description

Networking is essential to establishing professional relationships and to informing yourself about the ever-changing landscape of companies in the STEM fields.

Access to up-to-date information gives you an advantage in every stage of your career development. You need only to plug into a professional network. Finding like-minded professionals, however, can be a challenge.

AWIS is hosting a social event to introduce you to other motivated professionals in the STEM fields. You will build your network, sense the pulse of companies in the SF Bay Area, and plan your next career move.

BVS SF Biotech Community, Wednesday Evening, Sept. 30, 2015

Event: BVS SF Biotech Community Event
Date: Wednesday, Sept. 30, 2015, 5:00 pm-8:00 pm
Location: Dominic’s Oyster Point, □ 360 Oyster Point Blvd
South San Francisco, CA 94080

Free
Register at <http://www.bvsweb.com/php/register.php?ShNbr=3053>

Event Description

BVS SF Biotech Community Event – Weds, September 30th – Dominic's Oyster Point – 5:00 pm – 8:00 pm. This fun event will provide a wonderful way for fellow scientists and entrepreneurs to connect and network, hear a great scientific talk, visit with the best suppliers in the industry along with having some great food, beer and wine!

xTalks Free Webinar, Thursday, Oct. 1, 2015

Topic: “Talent Management Solutions to the CRA Shortage: Investing in a Global Talent Pool”
Speakers: John Avender, Associate Director, Clinical Performance, inVentiv Health Clinical; Michael L. Jimmink, Vice President, Strategic Resourcing, inVentiv Health Clinical; Joe Mills, Senior Director, Global Recruitment Center, inVentiv Health Clinical
Date and Time: Thursday, October 1, 2015, 8am PT (*Duration: 60 minutes*)
Cost: Free webinar
Register at <https://attendee.gotowebinar.com/register/3750806165651136002>

Topic Description

The global shortage of Clinical Research Associates (CRAs) to monitor investigational trials is having a significant impact across the pharmaceutical industry, driving higher costs and extending drug development timelines.

This webinar explores the pragmatic solution of accessing clinical research talent and creating an avenue for developing CRAs through a comprehensive training program. Key elements of success include rigorous screening of candidates and robust structured support from mentors, trainers, and peers.

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BioPharma Consortium and French BioBay, Thursday Evening, Oct. 1, 2015

Event: "2015 Fall Fling Mixer"
Date and Time: Thursday, October 1, 2015, 6:00-8:30 PM
Location: Porterhouse Restaurant
60 E. Third Ave.
San Mateo, CA
Pricing: \$20, if pre-registered by Sunday, September 27
\$30 walk-in (cash only)
Register: <http://bpcoc2015.eventzilla.net/>

Event Description

It's not too late to expand your network in 2015...Make new professional connections and deepen existing ones!

Join us in the bar and lounge for an evening of delicious appetizers and free-flowing networking. Cash bar.

Enjoy a relaxed evening out socializing and catching up on the latest industry buzz with your fellow professionals in biotech.

Contact: <http://www.biopharmaconsortium.com/contact/>

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) meeting 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

Medtech Frontiers, Thursday Evening, Oct. 1, 2015

Topic: "Digital Pathology: Perspective of a Practicing Pathologist"

Date and Time: Thursday, Oct. 1, 2015, 6:00 – 9:00 pm

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

Register at

<https://events.r20.constantcontact.com/register/eventReg?oeidk=a07ebjgs4km48b3fc4a&seq=&c=&ch=>

Topic Description

Digital pathology has been promised for nearly 40 years, but has not yet been put into routine clinical practice. The FDA has still not approved digital pathology for primary diagnosis, while at the same time the interpretation of digital images has been central to radiology for decades. While the return on investment for radiology was compelling and drove digital technologies for the radiologists, the same is not yet clear for pathologists, who are still "pushing glass" as they did 150 years ago. It is the perspective of the speaker that the key technological breakthrough for this field will be eliminating the need to produce glass slides altogether, and instead, capture a diagnostic-quality digital image directly from the tissue specimen. This will produce a dramatic reduction in technical costs for the specialty and help drive digitization of the professional component.

Speaker Bio

Dr. Russell Kerschmann, is an M.D. pathologist with 30 years experience in clinical practice and pathology research. Dr. Kerschmann's undergraduate education centered on electrical engineering and neurosciences. He earned his medical degree from the University of Massachusetts, with residency training at Massachusetts General Hospital in Boston. During his career Dr. Kerschmann has served on the pathology faculties of Harvard Medical School, the University of Massachusetts, and the University of California at San Francisco. From 2004 to 2009, he was executive manager of the Space Biosciences Division at NASA Ames Research Center, where he initiated programs in radiation biology and toxicology. Dr. Kerschmann continues to practice pathology in Silicon Valley and serves as a consultant to multiple clinical laboratories, as well as the NASA Engineering and Safety center where he co-initiated a program in nature-inspired design.

Bio2Device Group, Tuesday Morning, Oct. 6, 2015

Topic: "Redeveloping Old Antibiotics for Use: European Initiative"

Speaker: Ursula Theuretzbacher, Ph. D., Founder and Principal, Center for Anti-Infective Agents

Date and Time: Tuesday, Oct. 6, 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

Dr. Theuretzbacher will talk about the interesting initiative in Europe to overcome critical shortage worldwide of effective antibiotics due to the development of resistance to modern antibiotic drugs resulting from medical misuse and overuse as well as other market place practices. The Initiative includes the multinational collaborative EU-funded project AIDA (Re-developing old antibiotics) and the multinational public-private partnership project DRIVE-AB (Incentivizing antibacterial drug R&D, funded by the EU Innovative Medicines Initiative=IMI).

Speaker Bio

Dr. Ursula Theuretzbacher is founder and principal of the Center for Anti-Infective Agents in Vienna, Austria, since 1988. A microbiologist by training, she dedicated her professional life to antibacterial and antifungal drug R&D as well as appropriate and optimized usage of these drugs. She focuses on resistance and dosing issues from the early development phase to the use of old and new drugs in clinical practice.

Dr. Theuretzbacher is currently "work package leader" in the multinational collaborative EU-funded project AIDA (Re-developing old antibiotics) and in the multinational public-private partnership project DRIVE-AB (Incentivizing antibacterial drug R&D, funded by the EU Innovative Medicines Initiative=IMI) and partner in the IMI project COMBACTE-MAGNET (Developing new molecules against Gram-Negative Infections). Dr. Theuretzbacher is currently President of the Society of Anti-Infective Pharmacology (ISAP) and Past and Founding President of the ESCMID (European Society of Clinical Microbiology and Infectious Diseases) PK/PD of Anti-Infectives Study Group (EPASG). She is chair of a policy and scientific study group of the International Society of Chemotherapy (ISC), Council Member of the International Society of Infectious Diseases (ISID) and member of the ECCMID Programme Committee. She has published widely read text books on clinical microbiology and authored and/or co-authored reviews, book chapters, research papers on resistance, PK/PD, and antibacterial and antifungal agents.

ShareVault Webinar, Tuesday Oct. 6, 2015

Event: "What's Hot & What's Not in Immuno-Oncology Licensing"

Panelists:

- Linda Pullan, Ph.D | Pullan Consulting
- Jeff Bockman, Ph.D | Defined Health
- Ferran Prat, Ph.D | MD Anderson
- Axel Hoos, MD, Ph.D | GlaxoSmithKline
- Nate Sanburn, MS | Eli Lilly & Company

Date and Time: Tuesday, October 6, 2015, 2:00-3:15pm EDT / 11:00am-12:15pm PDT US
Cost: Free

Register at <http://resources.sharevault.com/webpanel-immuno-oncology-licensing?hsCtaTracking=4cfff13a-8f96-4c80-ba46-dc4035c0c731%7C48f93b98-2813-4fde-b84e->

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Event Description

Join us for a live web panel, hosted by ShareVault, Defined Health, Pullan Consulting and the Biotechnology Industry Organization (BIO), discussing what's exciting and not so

exciting in immuno-oncology drug development, and why.

For the live event, [biotech licensing and pharmaceutical business development consultant Linda Pullan](#) will be joined by four panelists who are business development experts from global pharmaceutical companies, a leading academic cancer center, and a top business development consulting firm. The panelists will discuss whether it is too late to get into PD1 and other checkpoint inhibitors, how they judge immuno-oncology combinations, if CAR-T can go into solid tumors, the impact of business models on cell therapy, winning strategies for deals in immuno-oncology licensing, and more.

The panelists will also respond to questions from the audience.

If you are developing an immuno-oncology drug or working toward in- or out-licensing one, you will want to hear these perspectives.

Panelist Bios

Linda Pullan, PhD

[Pullan Consulting](#)

Linda offers biotech and pharmaceutical companies consulting in all aspects of partnering. Linda has a Ph.D. in Biochemistry, a B.S. in Chemistry, and more than twenty years of drug industry experience.

Jeff Bockman, PhD

Vice President, Defined Health

Jeff leads the Oncology and Virology practices at Defined Health. Previously, he was a Senior Research Scientist in the commercial development of therapeutics for viral diseases and cancer at Inovir Laboratories.

Ferran Prat, PhD

VP of Strategic Industry Ventures, MD Anderson

Ferran helps the faculty and researchers at MD Anderson develop collaborative opportunities with pharmaceutical, biotech, diagnostics, imaging, laboratory medicine and other industry partners.

About Axel Hoos, MD, PhD

Vice President, Oncology R&D and Head of Immuno-Oncology at GlaxoSmithKline Pharmaceuticals (GSK)

Axel builds the immuno-oncology portfolio of GSK across the modalities of antibodies, small molecules, bispecific molecules and cell & gene therapies, for which he directs clinical and discovery research.

About Nate Sanburn, MS

Director- Strategy and Business Development - Oncology, Eli Lilly & Company

Nathan Sanburn currently serves as the Strategy and Business Development Director for the Oncology Business Unit at Lilly. He is a molecular biologist by training, with over 19 years of experience across R&D, clinical trials, and business transactions.

xTalks Free Webinar, Wednesday Morning, Oct. 7, 2015

Topic: "Building the Evidence Generation Roadmap:
The Role of Real World Data in Drug Development"

Speaker: Alex Exuzides, PhD,
Director, Health Economics & Epidemiology, ICON Commercialisation & Outcomes
Date and Time: Wednesday, Oct. 7, 2015, 8:00 am PT
Cost: Free
Register at <https://attendee.gotowebinar.com/register/114786083872176385>

Topic Description

This webinar will include topics such as understanding the development of an effective strategy that incorporates epidemiology, health economics and outcome research, and uses already available Real World data. When such data are not available, learn how to develop the data to support an effective evidence generation plan.

Clinovo, Friday Evening, Oct. 8, 2015

Topic: eClinical Integration: Challenges and Best Practices
Date and Time: October 8th, 2015 – 6pm – 8pm PST
Location: HP Palo Alto Campus, 3000 Hanover St, Building 20 Auditorium, Palo Alto, CA 94304
Cost: Free
Register at <http://www.clinovo.com/register-11th-biotalks>

Topic Description

*What are the industry trends changing the systems integration landscape?
What are the challenges and drawbacks to integrating systems?
What are the key principles for successful clinical systems integration?*

The use of electronic data collection in clinical trials has been increasing rapidly over the last few years, prompting a rise in the demand for integrated systems. The topic of “systems integration” is widely discussed, but its adoption remains slower than expected. Whether you choose EDC & CTMS, eTMF & Safety, or EMR integration, there is no one-stop-shop solution.

For example, CTMS solutions such as Advanced Clinical Software’s StudyManager have been installed at over 2,000 sites but there are still no defined metadata and communication standards that allow CTMS and EDC solutions to share data. A common issue with EDC-CTMS integration occurs when there are complex investigative site business practices. Most EDC systems only capture clinical trial data through eCRFs that lack CTMS information. Another issue is that some EDCs may lack timeline planning features such as reaching target subject recruitment milestones, for instance. As for eTMF & Safety integration, common issue here is the lack of real-time inspection and ICH/GCP compliance.

With increased regulatory requirements and the trend towards personalized medicine, sponsor companies and CROs need to access more specific solutions to meet their need, making systems integration an increasing necessity for a successful clinical trial. In addition, risk management of the product’s life cycle includes investigators, regulators and patients. This is where systems integration comes in; ensuring data is more accurate and consistent. If data were integrated from the start, it would be easily accessible at any point making the data review and cleaning process faster and higher quality.

However, this is easier said than done, as implementing systems integration is estimated to cost about \$500K and take as much as 3-6 months, which can come up to nearly 10% of the research budget. Such decisions usually come from investors or the company board, which adds extra approval steps for CROs to go through. While the medical and technical staff know the value of data integration, it needs to outweigh some of the drawbacks of the integration process, seen as time-consuming and a costly investment.

Collaboration and consolidation among front-end and back-end systems, as well as the emergence of advanced eClinical systems or modules, shows that the value of integrating will grow as users see the efficiency in storing and viewing their data on a single interface. Panelists would address questions such as: What are the key principle for a successful outcome? What are the new trends and players in place that are tackling the high cost of integrated solutions? Why are eClinical systems vendors and CROs instrumental in making progress and how can they accelerate this process?

HBS, Thursday Evening, Oct. 8, 2015

Topic: "Courage and Leadership Discussion"

Speakers: Jennifer Cook, EU Head, Roche Pharmaceuticals. and Wendy White, senior VP at Dohmen Life Sciences

Date and Time: Thursday, Oct 8, 2015: 5:30 PM - 8:00 PM

5:30 PM - 6:15 PM Networking and reception

6:15 PM - 6:30 PM HBA SF chapter president's remarks

6:30 PM - 7:30 PM Keynote discussion on courage and leadership

7:30 PM - 7:45 PM President elect close

Location: Genentech (Gateway Campus), Genentech (Bldg 82), 651 Gateway Blvd, 15th Floor, South San Francisco, CA 94080, 650-225-1000

Registration information

Event is open to: HBA members and nonmembers

Online registration deadline: October 2, 2015

Onsite (walk-in) registration: Is allowed

Member rate:

\$35 until September 30, 2015

\$40 after September 30, 2015

Nonmember rate:

\$45 until September 30, 2015

\$50 after September 30, 2015

Genentech employee rate:

\$25 until September 30, 2015

\$30 after September 30, 2015

Space is limited to 60 registrants.

Register at <https://my.hbanet.org/MyHBA/EventDetails.aspx?MeetingID=7D7C3385-093A-E511-B471-0050569C00A7>

Event description

Join the HBA San Francisco chapter for a memorable evening of networking and seeing firsthand the impact women leaders can have on our community. Rebecca Vermuelen, past president of the HBA SF chapter, will moderate a panel discussion on courage and leadership in healthcare with current HBA president Wendy White, senior VP at Dohmen Life Sciences, and Jennifer Cook, EU Head, Roche Pharmaceuticals. Together, they will hold an interactive discussion with the audience on what it takes to be courageous in today's leadership landscape and how it can help increase your impact and advancement potential.

Program fees include: food and beverage (alcoholic and non-alcoholic), panel discussion and networking with HBA leaders.

Learning objectives

1. Evaluate the importance of courage and leadership to optimal team and company success
2. Enhance ways to accelerate your professional and personal growth

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.cbaf.org and use the Event link on the right side to pay. Non-CBA members please use the bottom PayNow button at www.cbaf.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.cbaf.org. Please mark down your calendar and register the conference online to experience another fascinating event from CBA on Oct 10!

Bio2Device Group, Tuesday Evening, Oct. 13, 2015

Topic: To be announced

Speaker: Caleb Bell, CEO and Founder, Bell Biosystems

Date and Time: Tuesday, Oct. 13, 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

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 <http://www.eventbrite.com/e/meet-with-orbimed-tickets-17394113261>

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 apply online 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.

WIB, Thursday Evening, Oct. 15, 2015

Topic "Companion Diagnostics: A How-To, and Their Role in the Personalized Medicine Movement"

Date and Time: Thursday, October 15, 2015, 6:00 p.m. – 8:30 p.m. PST

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

Location: Genomic Health, 301 Penobscot Drive, Redwood City, CA 94063

Pricing

- Members: \$35
- Non-Members: \$65
- Students: The first 10 students to register receive \$10 off registration using code SanFran101515student
- Event volunteers with discount code: \$25
- Genomic Health employees: \$35

Register at <http://www.womeninbio.org/eventdetails.aspx?EventId=26526>

Registration Deadline

October 14, 2015

Topic Description

Companion diagnostics play a supporting role in the story of health care, but for this evening they are the stars. Hear diagnostics experts from companies, including Veracyte and Roche, discuss the trials and tribulations of companion diagnostic development, regulation, and marketing as well as their role in the personalized medicine movement. Come be part of the discussion!

NATEA, Sunday Mid Day, Oct. 18, 2015

Event: NATEA 2015 Fall BBQ

Date and Time: Sunday, Oct. 18, 2015, 11:00 am – 3:00 pm

Location: Ortega Park Picnic Site #2, 636 Harrow Way, Sunnyvale, CA 94088-3707

Admission: With RSVP: \$5.00 / pp for NATEA member, spouse and family member; Free for child under age of 11 ; Free for VIPs; Without RSVP: \$10 / pp for NATEA member, spouse and family member

Register by Oct. 17 at <http://sv.natea.org/events/register.php?ev=294>

Description

Activities: Come and share with us the summer fun in the big NATEA family!

Entertainment:

Bio2Device Group, Tuesday Morning, Oct. 20, 2015

Topic: "MedDevice Digital Marketing Nirvana: Monetizing 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 [EndoGastric Solutions](#). Previously, she was a Director of Marketing at [Avantis Medical Systems](#) and established a robust digital foundation for Third Eye Colonoscopy. At [Intuitive Surgical](#) she was the Senior Manager focused on market development programs and e-marketing initiatives supporting Gynecology and Oncology surgery specialties. In addition, she has 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 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 \(IABC-SV\)](#).

QB3, Monday Afternoons, Oct. 22, 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

10/22 (Thurs) 1:00-4:30 pm BH-212

11/19 (Thurs) 1:00-4:30 pm BH-212

12/10 (Thurs) 1:00-3:30 pm BH-212

12/17 (Thurs) 1:00-4:30 pm BH-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 hour sessions on NSF submissions. Starting Thursday, September 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.

Bio2Device Group, Tuesday Morning, Oct. 27, 2015

Topic: TBA

Speaker: Ming Tan, Founder and CEO, Wainamics, Inc.

Date and Time: Tuesday, Oct. 27, 2015, 8:30 am

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

No fee or registration required for morning meetings.

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: www.HealthTechConference.com

Conference Description

Check out our updated [agenda](#) and impressive list of [thought leaders speaking](#) at the [HealthTech Conference!](#)

Join us on October 27-28, 2015 as the [HealthTech Conference](#) heads to a new venue at the [Santa Clara Convention Center](#) 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 [HealthTech Conference](#) 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 famous "Deep Dive Panels" 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 Clercq, Partner, Norwest Venture Partners
Jack Young, General Partner, Qualcomm and dRx Capital
Tom Rodgers, Managing Director, McKesson Ventures

2. The "Match Making" meetings 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 Economics, 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 Fraczekiewicz, 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 <http://www.pbss.org/asp/homeSF.aspx>

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 Fraczekiewicz, 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, [BiosciDB](#), 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, [BiosciBD](#), 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 [AcelRx](#) and [Calibr](#) 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: 3rd 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—\$1,295.00; Academic/Govt 2nd 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 15th 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.

JLABS, Tuesday Morning, Jan. 26, 2015

Event: Meet with...Canaan Partners

Speaker: Wende Hutton | General Partner, Canaan Partners

Date and Time: Tuesday, Jan. 26, 2015, 10:30 am – 1:00 pm

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Fees:

Presentation & Lunch

\$25 | General Public

\$35 | General Public Onsite

Includes presentation, Q&A, and lunch. All attendees must pay this fee, regardless of one-on-one meeting status. Registration to attend the presentation, Q&A, and lunch will remain open until January 25th, 2016 (or sold out).

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 December 1st, 2015. Your application will be reviewed and you will be notified of acceptance by January 5th, 2016. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.

Register at <http://www.eventbrite.com/e/meet-with-canaan-partners-tickets-18496128418?aff=blast#s1>

Event Description

Canaan Partners is a global venture capital firm that invests in entrepreneurs with visionary ideas. With \$4.2 billion under management and over 180 exits to date, Canaan has funded some of the world's leading technology companies including LendingClub, Ebates, PrimeSense, and Skybox Imaging as well as healthcare stars like Chimerix, Durata, Labrys Biologics, and Civitas Therapeutics. Canaan recently announced Fund X, a \$675 million fund focused on early stage IT and healthcare startups. The fund's healthcare focus inclu

Wende Hutton, General Partner, will be in attendance on January 26th to provide an overview presentation of Canaan's areas of interest and best practices when applying for funding. Following the presentation, don't miss this opportunity to introduce yourself to Wende during the networking lunch. And finally, for those companies who apply online and

are approved, one-on-one meetings with Wende will provide a forum to discuss your company.

Speaker Bio

Wende Hutton | General Partner, Canaan Partners

Healthcare investor Wende Hutton brings 20 years of experience to identifying, investing in and building companies that are changing the practice of medicine. She has facilitated bringing over a dozen medical devices and drugs to market, and currently sits on the boards of Butterfly Health, Chrono Therapeutics, Dermira, Glooko, ReVision Optics, Theraclone Sciences and Transcend Medical. Prior investments include BiPar Sciences (acquired by Sanofi-aventis), Chimerix (CMRX), and Labrys Biologics (acquired by Teva Pharmaceutical). Wende was recognized among Fierce Biotech's 2014 "Fierce 15" women in biotech and honored as one of The Most Influential Women in Bay Area Business 2015 by The San Francisco Business Times. Wende joined Canaan in 2004, and her life sciences track record includes seven IPOs and five acquisitions. She began her venture career at Mayfield Fund in 1993, where she worked closely with the founding teams of Heartstream (HPQ) and Northstar Neuroscience (NSTR). Earlier in her career, Wende held senior operational management positions at GenPharm International and Nellcor in business development and marketing. Wende holds an AB in human biology from Stanford University and an MBA from Harvard Business School, where she was a Baker Scholar. She is active with several community service groups including serving on the board of FACE AIDS.

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.pmwintl.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!
