

**Audrey's Life Science Meeting Picks for Aug. 23, 2015 – Dec., 2015
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Aug.23, 2015**

Biodesign Innovation Fellowship, Application Due August 31, 2015

- Features of the Fellowship
- Program Timeline
- Frequently Asked Questions
- Application Instructions

Webinar Date:

- Aug 19 at 6pm (PDT) - register
- Recording of July 30 webinar

The Biodesign Innovation Fellowship teaches a proven, hands-on, project-based approach to identifying important unmet medical needs, developing innovative diagnostic, device, or other medical technology (medtech) interventions to address them, and preparing to bring those products into patient care through start-up, corporate, or other implementation channels. [PLEASE NOTE: This is not the Stanford-India Biodesign fellowship, which is no longer offered.]

The fellowship is a launch pad for initiating, redirecting, or turbo-charging a career in medical technology. Graduates from the program apply their talents to:

- Catalyzing innovation inside major medtech corporations
- Building their own medtech start-up companies
- Teaching and/or leading translational research projects for world-class universities
- Driving innovation initiatives within academic or private medical centers
- Becoming specialists in design, investing, or other aspects of the medtech innovation ecosystem

Individuals with a background in medicine, biosciences, engineering, computer science, product design, or business are encouraged to apply. Masters, medical, or doctorate degrees preferred. Candidate will be selected based on their experience, as well as their potential to become leaders in the medtech field. We encourage persons from all countries to apply.

Fellows become a member of the Stanford Biodesign team at the James H Clark Center on the Stanford University campus. Clinical Immersion is held at Stanford Hospital as well as nearby healthcare venues.

The fellowship is a full-time, intensive experience that runs from the beginning of August through early June each year. Fellows receive a monthly stipend and health benefits during the fellowship period.

Applications for 2016-17 are due on August 31, 2015. To be considered, please complete our online application. For those selected, interviews will be held on the Stanford campus November 12 and 13. More information about the application process and timing is provided with our application instructions and FAQs.

Golden Gate Polymer Forum, Monday Evening, August 24, 2015

Topic: "Computationally Inexpensive Simulation and Modeling for Future Lithography Processes"

Speaker: Prof. Hayden Taylor, Dept. of Mechanical Engineering, U.C. Berkeley

Date and Time: Monday, August 24, 2015, 6:00 pm

6:00 PM social hour

7:00 PM dinner

8:00 PM presentation

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

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 (full-price) registration Monday, Aug. 17, 11:59 PM

End of regular (full-price) registration Friday, Aug. 21, 5:00 PM

Register at www.GGPF.org<<http://www.GGPF.org>>

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:

Eveleen Tang

etang@amaranthmedical.com<<mailto:etang@amaranthmedical.com>>

650-965-3831 ext 228

You should receive confirmation of your registration; if not, please contact us again.

Topic Description

Nanoimprint lithography (NIL) - in which a thermoplastic film or ultraviolet-curing resin is mechanically nanopatterned in contact with a solid template - offers sub-10 nm patterning resolution with lower capital costs than competing technologies such as extreme ultraviolet lithography (EUV). To be adopted widely in data storage and semiconductor manufacturing, NIL's throughput needs to increase and its defect rate needs to fall. One way of improving NIL's throughput and yield is to develop comprehensive models of the process that can guide its optimization.

Over the last six years we have developed a computationally inexpensive simulation technique for NIL. The technique captures the deformation behavior of an imprinted polymeric film or droplet pattern using its mechanical impulse response, and describes elastic deformations of the patterned imprinting mask/template via a point-load response. We have developed the technique to simulate the imprinting of chip-scale patterns containing many millions of features, and to model the imprinting of both thermoplastic resists and ultraviolet-curing resins. I will describe the simulation technique and how we have applied it to: (i) optimize process parameters; (ii) select materials for the template; and (iii) guide the design of the imprinted pattern itself.

We have also applied the model to the manufacturing of polymeric microfluidic devices, and have extended the model for roller-based imprinting on continuous substrates, capturing substrate-speed and roller-load dependencies. By considering viscoelasticity of the imprinted material, we argue that there is an optimal substrate speed that maximizes the fidelity of imprinted patterns. Finally, we introduce recent work to model efficiently the directional spreading and coalescence of tens of thousands of picoliter-

volume droplets of resist beneath a patterned imprint template.

Speaker Bio

Hayden Taylor is an Assistant Professor in the Department of Mechanical Engineering, UC Berkeley. He received his B.A. and M.Eng. degrees in Electrical and Electronic Engineering from Cambridge University in 2004, and a Ph.D. in Electrical Engineering and Computer Science from MIT in 2009. He is a member of the IEEE, the Institution of Engineering and Technology, and the Institute of Physics.

<http://www.me.berkeley.edu/faculty/taylor/>

Bio2Device Group, Tuesday Morning, Aug. 25, 2015

Topic: "MALDI TOF MS: An Ongoing Revolution in Microbe Identification and Characterization"

Speaker: Dr. Gongyi Shi, Director of Scientific Affairs, Bruker Corporation

Date and time: Tuesday, Aug. 25, 2015, 8:30 am

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

There is no charge or registration required for morning meetings.

Topic Description

Microbe identification and classification is widely applicable in many areas including food/consumer product quality control, environmental research, and veterinary and clinical diagnostics. Ideally, accurate microorganism identity should be obtained in an rapid and cost effective manner. Especially in clinical applications, characterization pathogens in a timely manner is the foundation for appropriate antimicrobial therapy and patient management. However, traditional identification methods, which are based on morphological and biochemical traits of microorganisms, could take up to 16 to 24 hours and are with limited in reliability. The introduction of MALDI-TOF MS (matrix assisted laser desorption/ionization mass spectrometry) based whole cell proteomic fingerprinting revolutionized the field by its speed, accuracy and cost effectiveness. Here, fundamentals of this technology platform as well as its applications, impact on patient care will be discussed in the talk.

Speaker Bio

Dr. Gongyi Shi is the Director of Scientific Affairs at Bruker Corporation. Dr. Shi has over ten-years' experience in translational research in areas of biomarker discovery and clinical proteomics. Prior joining Bruker, Dr. Shi was a research faculty at Stanford University and senior research scientist at CIPHERGEN Biosystems Inc. Dr. Shi received his Ph.D in biochemistry and cell biology from State University of New York, Stony Brook.

BioScience Forum, Wednesday Evening, August 26, 2015

Topic: "Oncology Meets Immunology: Revolution of the Cancer-Immunity Cycle"

Speaker: Daniel Chen, M.D., Ph.D., Cancer Immunotherapy Franchise Head, Product Development, Oncology, Genentech

Date and Time: Wednesday, August 26, 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, August 24th, 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, August 20th
If paying with check, do not complete online registration with Cvent
Register at www.biosf.org

Topic Description

The genetic and cellular alterations that define cancer provide the immune system with the means to generate T cell responses that recognize and eradicate cancer cells. However, elimination of cancer by T cells is only one step in the Cancer-Immunity Cycle, which manages the delicate balance between the recognition of nonself and the prevention of autoimmunity. Identification of cancer cell T cell inhibitory signals, including PD-L1, has prompted the development of a new class of cancer immunotherapy that specifically hinders immune effector inhibition, reinvigorating and potentially expanding preexisting anticancer immune responses.

The presence of suppressive factors in the tumor microenvironment may explain the limited activity observed with previous immune-based therapies and why these therapies may be more effective in combination with agents that target other steps of the cycle. Emerging nonclinical and clinical data suggesting that cancer immunotherapy is becoming a key part of the clinical management of cancer will be discussed.

Speaker Biography

Daniel S. Chen, MD, PhD, is the Cancer Immunotherapy Franchise Head in Product Development at Genentech/Roche and Adjunct Faculty in Medical Oncology at Stanford University. He received a BS degree in Biology from the Massachusetts Institute of Technology (1990), a PhD in Microbiology & Immunology (1996) and MD (1998) from the University of Southern California. Daniel completed an Internal Medicine Residency and Medical Oncology Fellowship at Stanford University (2003). He went on to complete a Post-doctoral fellowship with Mark Davis in Immunology, where he was a Howard Hughes Medical Institute Associate. He also ran the metastatic melanoma clinic at the Stanford Cancer Center from 2003-2006, where he continues to care for melanoma patients. In that time, he studied human anti-cancer immune responses pre- and post- cancer vaccination and cytokine administration to determine why anti-tumor immune responses were not more clinically effective. He received a U19 grant to develop better immunologic tools to interrogate human immune responses and ultimately patented the MHC cellular microarray to detect and functionally characterize antigen-specific T cell states.

Since joining Genentech in 2006, Daniel has focused on the clinical development of anti-angiogenic and immune modulatory targeted therapies in both early and late development, as well as the diagnostic tools to aid their development. He is a reviewer for Clinical Cancer Research and gave the keynote presentation at the AACR NCI EORTC Annual Meeting 2014. He has continued to publish with academic and Genentech collaborators in the field of cancer immunotherapy.

WIB Webinar, Wednesday Morning, Sept. 2, 2015

Topic: Best Practices for Sharing IP Rights in the Life Sciences

Speakers: Julie Watson, Special Counsel at Marshall Gerstein & Borun, LLP; Kate Murashige, Senior Of Counsel at Morrison & Foerster and Dawn Matthews, co-founder of Abiant, Inc., a 50% parent of ADMdx

Date and Time: Wednesday, Sept. 2, 2015, 11:00 AM TO 12:15 PM

Wednesday, September 2, 2015 (times listed below for each time zone)

11:00 a. m. - 12:15 p.m. PST

1:00 p.m. - 2:15 p.m. CST

2:00 p.m. - 3:15 p.m. EST

Fee: Free to members and nonmembers

Register at <http://www.womeninbio.org/eventdetails.aspx?EventId=26074>

Topic Description

A panel of experienced professional women will discuss best practices and potential pitfalls associated with sharing intellectual property (IP) rights. An IP strategy is crucial for a company driven by technological innovation. Our expert panel will share their thoughts on how to effectively share IP, analyze potential collaborations, avoid pitfalls, and maximize an invention's ROI. This is a great opportunity to gain legal perspective and wisdom from industry leaders.

See below for speaker biographies.

Speaker Bios

- **About Julie Watson:** Julie Watson is Special Counsel at Marshall Gerstein & Borun, LLP, a Chicago-based intellectual property law firm. A licensing professional with over 25 years' experience in structuring and negotiating complex deals, Julie concentrates her practice on intellectual property transactions with a particular emphasis in technology startups and university technology transfer. Julie's prior work includes managing nonprofit intellectual property licensing programs including the Wake Forest Institute for Regenerative Medicine and the American Medical Association. Julie received her law degree from Wake Forest University Law School and is admitted to practice law in Illinois, North Carolina and before the USPTO. She also holds a master's degree from Johns Hopkins University and is a Certified Licensing Professional.
- **About Kate Murashige:** Kate is the Senior Of Counsel at Morrison & Foerster and has been doing patent prosecution, opinions, and due diligence for 35 years. She worked as an in-house patent attorney for Syntex and Genentech before going into private practice. Kate has a Ph.D. in organic/biochemistry and did "next case" practice before turning to patents. Additionally, she was awarded Chamber's lifetime achievement recognition and has been consistently listed in Best Lawyers in America.
- **About Dawn Matthews:** Ms. Matthews has over 25 years of management experience in the life sciences industry, with more than half of those focused on imaging for drug development and disease detection. She is a co-founder of Abiant, Inc., a 50% parent of ADMdx, where she has directed the optimization of quality control, processing, and analysis methods for amyloid and FDG PET image data, the development of novel methods to classify dementias, and the successful implementation of clinical trials. She previously served as CEO of MIICRO, Inc., a medical imaging technology company, and as Director of Business Development for Motorola BioChip Systems. She was a co-founder of Aksys, Ltd., where she served as Vice President and Acting CFO during multiple private financings and the company's Initial Public Offering in 1996, and earlier was a Senior Principal Engineer at Baxter Healthcare.

JLABS, Wednesday, Sept. 9, 2015

Topic: "Meet with ...Astellas Venture Management"

AVM Participating Representatives:

Sakae Asanuma MBA, CFA | President & CEO, Astellas Venture Management

Takashi Futami | Associate Investment Director, Astellas Venture Management

Taro Masunaga, Ph.D. | Senior Investment Director, Astellas Venture Management

Hideaki Matsuoka, Ph.D. | Associate Investment Director, Astellas Venture Management

Nobuaki Shindoh, Ph.D. | Associate Investment Director, Astellas Venture Management

Date and Time: Wednesday, Sept. 9, 2015, 10:30 am – 12:30 pm

Agenda:

10:30am | Registration Opens and Networking

11:00am | Presentation and Q&A

12:00pm | Networking Lunch

12:30-5:00pm | One-on-one Meetings*

*Companies must have applied for a one-on-one meeting ahead of time and be approved. The application period ends on August 5th.

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

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 September 8th (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 August 5th. Your application will be reviewed and you will be notified of acceptance by August 21, 2015. 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-astellas-venture-management-tickets-17393910655?aff=weekly>

Event Description

Investing in opportunities to improve health through innovation is a key driver of solutions for today's most difficult healthcare problems. Astellas Venture Management (AVM) /Innovation Management ("AIM") are interested in supporting early stage opportunities to advance the creation of human therapeutics. AVM/AIM will be presenting at Johnson and Johnson Innovation, JLABS on September 9th, 2015.

AVM is the venture group within one of Japan's second largest pharmaceutical company, Astellas Pharma Inc. You may be familiar with some of AVM's successful,

local portfolio companies including eFFECTOR Therapeutics and Fate Therapeutics. With hundreds of millions in an evergreen fund, AVM is looking to invest in more private companies in the early stage drug discovery and platform technology across several therapeutic areas, including:

- Immunology and Inflammation, Urology, Oncology, Nephrology and Neuroscience
- Ophthalmology, Hearing Loss, Muscle disorder and Regenerative Medicine.

Also, AVM has another mission by AIM to execute early stage innovative collaborations with Academia and biotech companies. Recent collaboration deals include MD Anderson Cancer Center (oncology drug discovery), Potenza (Immune oncology drug discovery) and Kanyos Therapeutics (Autoimmune drug discovery). AVM/AIM will provide equity and non-dilutive capitals to our portfolios and partners while actively looking for innovative new opportunities.

Representatives from AVM/AIM will be in attendance to give an overview presentation on the company's key areas of interest and best practices when seeking funding. Following the presentation, don't miss this opportunity to network with fellow attendees and the AVM/AIM representatives during lunch. For those companies who apply online and receive approval, one-on-one meetings with AVM will provide a private forum to discuss your company.

AVM Representatives' Bios

Sakae Asanuma MBA, CFA | President & CEO, Astellas Venture Management
Mr. Sakae Asanuma joined AVM in June 2011. Prior to joining AVM, he served as Director at Yasuda Enterprise Development America, Japan's major VC firm with \$800M under management, from 2000 to 2011 and originated Yasuda's biotech investment activities in the US. Based in Bay Area since 2000, he has invested in 30+ US biotech venture companies and deeply involved in the business development discussions with Japanese pharmaceutical companies on behalf of his portfolios. To date, his portfolio companies successfully achieved 9 IPOs and 8 M&As. Prior to Yasuda, he was venture capitalist and buy-side equity analyst from 1988 to 1999, managing \$20B+ equity portfolios for Meiji-Yasuda Life Insurance Company (one of the largest life insurance companies in Japan). He holds Master of Business Administration from Carnegie Mellon University.

Takashi Futami | Associate Investment Director, Astellas Venture Management
Mr. Futami joined Astellas Venture Management in Oct 2013. Prior to joining AVM, he worked as a Senior Researcher at Astellas Pharma Inc. He served as a team leader at Oncology Labs of Astellas Pharma, and led a drug discovery research and preclinical development of kinase inhibitor programs in oncology therapeutics area. He also has experiences of collaboration with several institution like The University of Tokyo Hospital, Metabolex Inc. etc.

Taro Masunaga, Ph.D. | Senior Investment Director, Astellas Venture Management
Dr. Masunaga joined Astellas Venture Management in Oct 2013. He has more than 25 years experience of drug discovery research from target discovery to development mainly in Immunology area including transplantation and autoimmune. From 2007 to 2012, he served as associate director to start up the Astellas Research Institute of America (ARIA) which is engaging early drug discovery (target identification, Hit/Lead generation and therapeutic strategy) in transplantation. Prior to joining AVM, he worked as a head of Advanced Drug Discovery (ADD) group in Pharmacology

Research Laboratories taking a responsibility for early drug discovery of small molecules for every single focused therapeutic area, Urology, Oncology, Immunology, CNS, Kidney diseases and Frontier diseases.

Hideaki Matsuoka, Ph.D. | Associate Investment Director, Astellas Venture Management

Dr. Matsuoka joined AVM in October 2014. He has more than 14 years experiences of drug discovery research in the field of immunology, cell biology, and molecular biology at Astellas Pharma Inc., and served as a principal scientist at Astellas Research Institute of America (ARIA) from 2007 to 2010 specifically focusing on early drug discovery (target identification, Hit/Lead generation and therapeutic strategy development) in transplantation. Prior to joining AVM, he served as a senior manager in charge of scientific evaluation at Astellas Innovation Management (AIM) and has a significant track record of leading several partnering deals.

Nobuaki Shindoh, Ph.D. | Associate Investment Director, Astellas Venture Management

Dr. Shindoh joined AVM in November 2014. He has 18 years experiences of drug discovery research in the field of Oncology, Urology and renal disease at Astellas Pharma Inc. and covers broad range of drug discovery from target identification to clinical development with successful experience in oncology. From 2011-2012, he worked at the Dana-Farber Cancer Institute as a visiting scientist to identify novel drug targets. Since Oct 2013, he served as associate director of Astellas Innovation Management (AIM) in charge of scientific evaluation in the oncology disease area and led the partnering with CRUK.

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, Wednesday Afternoon, Sept. 19, 2015

Event: "CABS Science and Technology Workshop: New Frontiers in Peripheal 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

Over the past few years, there have been remarkable advances in DNA detection and sequencing technologies that enabled faster and better diagnostics developed for liquid biopsies. Liquid biopsies have now emerged as promising tools that are safer and cheaper than traditional tissue biopsies to survey health and disease state. For the first time, we are now able to obtain a wealth of information from blood and urine derived circulating DNA fragments that could revolutionize research and patient care. Began with prenatal screening, these technologies now allow physicians to make early disease diagnosis, monitor progression, and predict treatment benefits. This workshop will be led by founders and leaders of many prominent companies which have pioneered the frontiers of peripheral

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.

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

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.

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 start-ups 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.

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.

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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.

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.