Audrey's Life Science Meeting Picks for Jan. 22, 2018 through April 2018
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PBSS, Monday, Jan. 22, 2018

Event: Workshop: Preclinical development & IND/CTA Filing
Speakers: Tracy Chen, Jim Zhang, Peter Staehr, Anne Bonneville, Xingrong Liu
Date and Time: 1/22/2018, 8:30-17:00
Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (USD): Regular: $195; Academic: $125; For unemployed or students: $30;
Registration: http://www.PBSS.org
Registration deadline:1/22/2018 (it will close sooner if the seating cap is reached)
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Bio2Device Group, Tuesday Morning, Jan. 23, 2018

Topic: "The Promise and Peril of Agile for Medical Devices"
Speaker: Aaron Joseph, Sr. Medical Devices Consultant, Consensia, Inc.
Date and Time: Tuesday, Jan. 23, 2018, 8:30am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
No charge or registration required for morning meetings.

Topic Description
Agile methods promise faster development of medical devices but at the peril of jeopardizing regulatory compliance. Learn about the four key rules to follow to ensure you don't sacrifice compliance in order to take advantage of agile methods. This presentation will describe how agile methods can lower risks, improve quality, and shorten time to market for medical device development. The presentation will cover the basic principles behind agile and lean methods and important adaptations needed for the particular needs of medical device companies. We will illustrate the methods with a comparison of two product development teams—one following a traditional approach and the other following an agile-lean approach. The presentation will conclude with a discussion of how to modify design controls, risk management, and other quality system procedures to support agile-lean product development.

Speaker Bio
Aaron has 20 years of experience in medical device development over a wide range of products: surgical robotics system, digital x-ray fluoroscopy system, heart-lung bypass machine, robotic catheter system, drug inhaler devices, x-ray catheter for brachytherapy, laser eye surgery system, and endoscopy instrument with RF ablation.
Aaron is an avid promoter of lean and agile methods for medical device development and helps clients implement requirements management tools for streamlined compliance. He works closely with product development teams in performing risk analyses, managing testing for software and hardware, managing product requirements, refining design control procedures, and training R&D staff. Aaron is an expert at medical device design verification and validation, including software, hardware, and system testing. He is able to apply design controls efficiently and rigorously to a broad range of products and adapt them to small and large organizations.
Aaron has a BS in Electrical Engineering from Rice University and an MS in Bioengineering from the University of Washington.

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Precision Medicine World Conference (PMWC) Silicon Valley 2018, Jan. 22-24, 2018

Event: Medical Conference
Date and Time: January 22, 2018, 8:00am to January 24, 2018 5:00pm
Location: Computer History Museum, 1401 N Shoreline Blvd, Mountain View, California, 94043
Cost: $1350 by December 13th, 2017
Registration:3-Day Access to Talks, Exhibition & Reception:
Learn more at: http://www.pmwcintl.com/2018sv-info/

Event Description:
Precision Medicine World Conference (PMWC) Silicon Valley is organized by Precision Medicine World Conference (PMWC) and will be held during Jan 22 - 24, 2018 at Computer History Museum, Mountain View, California, United States Of America.
The preeminent Precision Medicine World Conference (PMWC) series is recognized as a vital cornerstone for all constituents of the healthcare and biotechnology community and considered an exceptional forum for the exchange of information about the latest advances and topics in technology, clinical implementation, research, and the regulatory and reimbursement sectors. Learn first-hand from the experts in precision medicine: recognized leaders and innovators, top researchers, medical professionals, and more, catalyzing cross-functional fertilization and collaboration.
PMWC 2018 SV, co-hosted by Stanford Health Care, UCSF, Intermountain Healthcare, Duke Health, and Duke University will cover all facets of Precision Medicine including current hot topics like immunotherapy, the Precision Medicine Initiative (All of US), liquid biopsy, the human microbiome, big data, and cancer & companion diagnostics.
Session Themes :
• Metabolomics Proteomics Applications
• Medical Health Apps
• Cancer Immunology, Immunotherapy
• Patient Recruitment for Clinical Trials
• Cancer Stem Cells
• Infectious Disease Monitoring, Pathogen Identification
• The Economics and Financial Impact of Bringing PM to the Clinic
• Addressing Disparities and Public Health
• Reimbursement - the Payer Perspective
• Liquid Biopsies
• Biobanking
• Telemedicine
• Large-scale integrated genomics, phenotype, and clinical data analysis
• Data Sharing
• Interoperability in Healthcare.
Speakers:

- Sir John Bell, Regius Professor of Medicine, Oxford University
- Dame Sally Davies, Chief Medical Officer, Department of Health, UK Government
- Elizabeth Blackburn, Nobel Laureate, President, Salk Institute for Biological Studies
- George Sledge, Professor, Division Chief, Stanford University Medical Center
- Jeffrey Bluestone, CEO and President, Parker Institute for Cancer Immunotherapy
- Christopher Ianelli, Founder and Chief Executive Officer, iSpecimen
- Kenneth J. Pienta, Director, Brady Urological Institute, Johns Hopkins Medicine
- Roy Beveridge, Senior Vice President & Chief Medical Officer, Humana

- Kimberly Blackwell, Professor of Medicine, Assistant Prof. of Radiation Oncology, Duke Cancer Institute
- Joshua Denny, Professor of Biomedical Informatics & Medicine, Vanderbilt University Medical Center
- Edward S. Kim, Chair, Solid Tumor and Investigational Therapeutics, Levine Cancer Institute
- Howard L. McLeod, Medical Director, Personalized Medicine Institute, Moffitt Cancer Center
- Lee Newcomer, SVP, UnitedHealthcare Oncology and Genetics
- Vinod Khosla, Partner and Founder of Khosla Ventures
- Troy Brennan, Executive VP & CMO, CVS Health
- Ira Mellman,VP, Cancer Immunology, Genentech

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WIB Webinar, Wednesday Mid-Day, Jan. 24, 2018

Event: WIB-National Webinar "Speak up and Succeed! How to Find and Use Your Voice to Deliver Impact"
Date and Time: January 24, 2018, 3:00 p.m. – 4:00 p.m. EST; noon-1:00 pm PT
Contact: Women In Bio, info@WomenInBio.org
Pricing: Members free, nonmembers- $30
Online registration is available until: 1/24/2018
« Go to Upcoming Event List
Register at https://www.womeninbio.org/events/unable_to_register.asp?id=1048355

Event Description
As an organizational leader, there are many opportunities to have a positive impact, but to do so, you need to speak up and be heard. During this webinar Kristin Backstrom, Ph.D., will share strategies to manage yourself, your voice, and your message. Wouldn't you like to be in full control of yourself and your message so you know you are heard? Wouldn't you like to overcome anxiety related to sharing your ideas and input? And deliver effective, impactful feedback or input? Learn how to find and use your voice so that you are able to build rapport with others, insert value, and get credit for your own ideas.

Speaker Bio
Kristin Backstrom, Ph.D., helps rising executives and seasoned leaders take on new challenges and succeed. With a Ph.D. in business psychology, a masters degree in marketing, and years of experience aligning human capital motivation with business objectives, Kristin helps her clients advance in their career paths through improved self-management, strategic thinking, collaboration, personal resilience, and assertiveness. As an applied research practitioner, her methods are derived from what research says works to create and sustain positive change in people and the places they work.

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

Pricing Information
Members: Free
Non-Members: $30
* - Registrants will be sent a specific GoToMeeting link to access the webinar. Please be sure to click on the link before the webinar to ensure the program is properly installed on your computer.

Registration Deadline

January 16, 2018

Event Date/Time
Wednesday, January 24, 2018
3:00 p.m. – 4:00 p.m. (noon – 1:00 pm PT)
*- Please note this webinar's time is listed in Eastern Standard Time.

Venue
Webinar link to be provided in confirmation email

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ASQ, Biomedical Division, Northern California Discussion Group, Wednesday Evening, Jan. 24, 2018

Topic: Effective Training:Implementing Ideas to Improve Competencies
Featured Speaker: Barry Craner and Moderator: Bill Kurani
Date and Time: Wednesday, January 24, 2018, 7:00 to 9:00 pm
Topic:
ASQ NCDG will be discussing the cGMP's (21CFR820) implementation this year, with training (FDA 21CFR820.25 and ISO 13485:2016 6.2) as a baseline competency for the Medical Device Industry and every company's performance effectiveness.

In Barry's talk, he will cover several relevant topics:

- Training Tools and Learning Management System
- Ten Tips by experts on effective training.
- Training Deliveries and Techniques.
- Supervisor and one-to-one training.
- Training a group face-to-face
- Synchronous training – Webinar with engaged distant participants.
- Asynchronous training – Voice-over PowerPoint and how to make it successful.
- Testing – Effective methods and questions and how to ensure questions are effective.

We will have several brief workshops/discussions during this session in order to ensure attendees have a chance to share their own experiences and learn from others.

Speaker and Moderator Bios
Barry Craner (MS+, MBA, FASQ, RAC, CQE, CRE, CQA, CBA) was QA/RA Vice President for Stellartech Research Corporation, Past Chairs ASQ Biomedical Division and San Diego Section, three times Past Chair ASQ NCDG, and for 10 years, has taught Risk Management at two Universities (Adjunct Professor CSU & Instructor UCSC). Barry's many awards include the Los Angeles ASQ Section Simon Collier Quality Award (2008), on MDDI list of "100 Notable People in the Medical Device Industry" (2008), the ASQ Biomedical Division Marvin Rosenbaum Distinguished Service Award (2010) and creation of the Barrett C. Craner scholarship for young QA practitioners (2015). In October, 2017, Barry taught two Risk Management seminars to the FDA at their headquarters in Silver Springs, MD.

Bill Kurani is a very active member of the NCDG Planning Committee, has extensive experience in the area of medical device regulatory affairs and quality assurance, is a sought-after speaker for the NCDG, ITU, Silicon Valley Section, and UCSC Extension, and earned his MSRA at San Diego State University, MSEE at LSU, and Biomedical Certificate at Stanford University

Registration Link: NCDGJAN2018.eventbrite.com
Register online early for discount & save.
Only Credit Card accepted at door (via Eventbrite)

Location: Stellartech Research Corporation, 560 Cottonwood Dr., Milpitas, CA 95035
Food: Snacks equivalent to a light meal and beverages are provided at each event at no additional cost.
Email: To be added to or removed from our email list, contact George Marcel: gjmarcel@gmail.com
Questions: For information about this session, contact Barry Craner: CranerASQ@gmail.com
Formal discussion and questions will end between 8:30 - 8:40 pm to allow time for networking.
Materials: Presentation & workshop sheets provided for onsite attendees only.
Please limit distribution to attendees: personal professional use only.

Webinar Remote Access (no cost):
https://attendee.gotowebinar.com/rt/6376324503535979521

--- Applicable References ---

ISO 13485:2016

6.2 Human resources

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience.
The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization shall:
a) determine the necessary competence for personnel performing work affecting product quality;
b) provide training or take other actions to achieve or maintain the necessary competence;
c) evaluate the effectiveness of the actions taken;
d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
e) maintain appropriate records of education, training, skills and experience (see 4.2.5).

NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H--MEDICAL DEVICES

PART 820 -- QUALITY SYSTEM REGULATION
Subpart B--Quality System Requirements

Sec. 820.25 Personnel.
(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.
(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.
(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.
(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.
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JLABS, Thursday Morning, Jan. 25, 2018

Topic: "Who's Who in 2018: A Strong Finish to 2017 Healthcare Investing?"
Speaker: Jonathan Norris | Managing Director, Silicon Valley Bank
Date and Time: Thursday, January 25, 2018 from 8:00 AM to 10:00 AM (PST)
Agenda:
8:00 AM | Registration, Breakfast & Networking
8:30 AM | Presentation - Q&A
9:30 AM | Networking
10:00 AM | Program Close
Location:
JLABS @ SSF
329 Oyster Point Blvd - 3rd Floor
South San Francisco, CA
Fees:
$12 | General Public
$8 | Student/Academic
$25 | At the door
Details and registration at https://www.eventbrite.com/e/whos-who-in-2018-a-strong-finish-to-2017-healthcare-investing-tickets-36706212269?aff=weekly

Event Details
2017 saw a banner first half, driven in part by advancements in artificial intelligence and machine learning for healthcare applications and a surge in Series A investments. With 2017 in the review mirror, Jon Norris takes a look at – and makes sense of – the past trends to provide an informed look into 2018.

As the 2018 investment market takes shape, what can we expect for the IPO and M&A markets? Jon will share his expertise and provide insight into:
How the 2017 healthcare landscape compares to previous years
Current and total healthcare and sector investments
Which Biopharma indications attracted the most funds
Which venture firms are most active
Changes in the past crossover phenomenon
Exits: the trends in IPOs and M&A's

At the end of this talk you should be informed as to who is investing, and the type of deals and exits that are likely to be executed in 2018.

Presenter's Biography:
Jonathan Norris | Managing Director, Silicon Valley Bank

Jon Norris is a managing director for SVB's Healthcare practice. Norris oversees business development efforts for banking and lending opportunities as well as spearheading strategic relationships with many healthcare venture capital firms. He also helps SVB Capital through sourcing and advising on direct equity co-investment and limited partnership allocations.

In addition, he has authored numerous thought leadership pieces examining the flow of capital into healthcare, including detailed analysis of venture-backed M&A and IPOs. Norris has more than thirteen years of banking experience working with life science companies and venture capital firms.
Norris earned a bachelor's degree in business administration from the University of California, Riverside and a juris doctorate from Santa Clara University.
About Jon Norris spends most of his non-banking time with his family in Los Altos, attending and coaching many youth sports. An avid baseball fan, he still plays baseball in a men's baseball league in San Jose.

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SBIR Workshops, Winter 2018, Available at UC Berkeley and UCSF

Class: "Get non-dilutive funding for your startup. Take the QB3 SBIR workshop."
Available at UC Berkeley and UCSF
UCSF: Six sessions, on Thursdays
Dates: Starts Feb. 1, ends Mar. 29
Location: Genentech Hall, UCSF Mission Bay

See the individual workshop pages for details.
Instructors
Shauna Farr-Jones, PhD, UCSF/QB3 grant writer
Ioana Aanei, PhD, Entrepreneurship Program Manager, QB3
Kaspar Mossman, PhD, Director of Marketing & Communications, QB3

Fee Structure
General Admission: $750
Startup in a Box members: $150

Note: Startup in a Box fee for UC founder: $250, non-UC founder: $350. More information on the program is available here.
Register at https://www.eventbrite.com/e/qb3-sbir-workshop-at-ucsf-spring-2018-tickets-41020922684?mc_cid=c26b42b0f4&mc_eid=cb4c38a44a

Email Ioana Aanei with any questions.
About the Instructor

Shauna Farr-Jones, Ph.D., has a record of writing successful government grant and contract proposals on diverse life science topics, providing strategic input on both research and business plans. She has helped companies secure over $200 million in grant and contract funding from numerous government and philanthropic organizations, including BARDA, NIH, DTRA, USDA, DARPA and the Bill and Melinda Gates Foundation. For 17 years, she has consulted for life science companies and universities, identifying funding opportunities, preparing research plans, marketing plans, technical reports INDs, NDAs, white papers and proposals. She is also the Project Manager of the Antibody Technology Research Center at UCSF. Previously,

she was Senior Writer at BioCentury Publications, where she analyzed and wrote about the biotechnology industry. She was a post-doctoral fellow at UCSF and has a Ph.D. in Biochemistry from Tufts University.

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UC Berkeley: Four sessions, on Wednesdays
Dates: Starts Feb. 14, ends Mar. 14
Location: Stanley Hall, UC Berkeley

For entrepreneurs looking for non-dilutive federal funding to get life science startups off the ground. Small Business Innovation Research (SBIR) grants from US federal agencies can provide up to $225k (Phase I) or $1.5M (Phase II) for startup R&D. But applying can be a complex, frustrating affair if you are not ready for it. We get you ready. Our instructors walk you through your NSF or NIH SBIR grant application to ensure you complete everything properly and submit by the April NIH or June NSF deadlines.

Did you know that entrepreneurs applying through the QB3 workshop are 3x more likely than the nationwide average to get funded?

Location is 177 Stanley Hall, UC Berkeley. All classes are on Wednesdays. Class dates: Feb. 14, Feb. 21, Mar. 7, Mar. 14

The chances of your SBIR getting funded are vastly improved if your proposal is well written and packaged. In fact, many great ideas fail to get funded simply because of poor "grantsmanship." In addition, first-time applicants are often daunted by the intricacies of the grant submission and review process, and unsure about how to interact with funding agency staff.

This workshop will help you develop a compelling, well-organized research plan, and to explain your ideas in clear, engaging writing that will win over your reviewers. We will focus on the Research Plan sections of NIH and NSF SBIR proposals, and one full session will be devoted to helping you craft your Specific Aims (the most important section of your application). We will also provide guidance on filling out your budget, Biosketch and other forms, and tips on how to most effectively navigate the NIH and NSF application and review processes.

The workshop will consist of four 2.5 to 3 hour sessions. Specific topics to be covered will include:

- Introduction to the NIH and NSF SBIR funding processes
- Identifying funding opportunities
- Developing a logical, compelling Research Plan
- Facing and conquering the blank page
- Writing for your reviewers
- Instructor and peer feedback on your Specific Aims
- Making the most of graphics
- Electronic registration and submission

- Communicating with NIH and NSF staff

This class is designed for applicants planning to submit for the April 5, 2018 NIH and/or the June 2018 NSF deadline. The science writing skills taught in this class will serve you well in writing not only grant applications, but also manuscripts and public relations materials.

Fee Structure
General Admission: $750
Startup in a Box members: $150

Note: Startup in a Box fee for UC founder: $250, non-UC founder: $350. More information on the program is available here.
Register at https://www.eventbrite.com/e/qb3-sbir-workshop-at-berkeley-spring-2018-tickets-41022444235?mc_cid=c26b42b0f4&mc_eid=cb4c38a44a

Email Ioana Aanei with any questions.
About the Instructor
Gabrielle G. Leblanc, Ph.D. is a grant consultant and science writer with over 15 years of previous experience as both an NIH grant program director and an NIH- and NSF-funded PI. She has worked with numerous grant applicants in both academia and biotech, and as a science writer for NIH institutes, non-profit foundations, and the popular press. She has a B.A. in Biology from Harvard University and a Ph.D. in Neuroscience from Stanford University.

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JLABS, Thursday Morning, Feb. 2, 2018

Event: "Meet With...Versant Ventures"
Speakers: Graham G. Walmsley | Investment Professional, Versant Ventures and Lev Osherovich | Director of Innovation Sourcing, Versant Ventures
Date and Time: Thursday, February 1, 2018 from 10:30 AM to 1:00 PM (PST)
Agenda:
10:30AM | Registration and Networking
11:00 AM | Presentation and Q&A
12:00 PM | Networking Lunch
1:00-5:15 PM | One-on-One Meeting* (30 - minute meetings)

*Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due January 4, 2018. Apply Here.
Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor South San Francisco, CA
Fees:
Presentation
$25 | General Public

$35 | Onsite
Details and registration at https://www.eventbrite.com/e/meet-withversant-ventures-tickets-36705327623?aff=weekly

One-on-One Meeting
FREE | Application
FREE | Accepted Companies
Apply to meet one-on-one with Graham Walmsley of Versant Ventures. Your application will be reviewed and you will be notified of acceptance on Wednesday, January 18th, 2018. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.

Event Details
Committed to transforming the healthcare landscape through innovation, Versant Ventures is eager to help you make an impact in healthcare. Graham Walmsley, MD, Ph.D. and Lev Osherovich, Ph.D. of Versant Ventures will be visiting JLABS @ SSF on February 1, 2018 to provide an overview of Versant's unique investment strategies and meet 1-on-1 with pre-selected companies.

*The one-on-one application process is separate from the event registration process. Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due by January 4th. Apply Here.

Program Overview:
Versant Ventures is a leading healthcare investment firm committed to helping exceptional entrepreneurs who are building the next generation of great healthcare companies. The firm invests across the healthcare sector and at all stages of company development, with an emphasis on the discovery and development of novel therapeutics. With $2.3 billion under management and offices in North America and Europe, Versant has built a team with deep investment, operating, and scientific expertise that enables a hands-on approach to company building. Since the firm's founding in 1999, nearly 70 Versant companies have achieved successful acquisitions or IPOs.
Graham Walmsley, MD, Ph.D. and Lev Osherovich, Ph.D. will be in attendance to provide an overview presentation of their firm's area of interest. They will be on hand to meet with a handful of applicants 1-on-1 after the presentation. To be considered for a 1-on-1 meeting complete the information required here. Applications due by January 4, 2018.

Speakers' Biographies:

Graham G. Walmsley | Investment Professional, Versant Ventures

Graham G. Walmsley, M.D., Ph.D. is an Investment Professional at Versant Ventures focused on biotechnology and healthcare investments. Graham joined Versant after completing his training as a Physician Scientist Fellow at Stanford University School of Medicine. At Versant, Graham helped build and launch BlueRock Therapeutics, a regenerative medicine company formed in collaboration with Bayer through one of the largest series A investments ($225M) in biotech history.

Graham received his M.D. and Ph.D. in Stem Cell Biology and Regenerative Medicine from Stanford University and earned his B.A. in Molecular and Cell Biology with

summa cum laude honors from the University of California, Berkeley. He conducted his thesis work in the laboratories of Irving Weissman and Michael Longaker with a focus on regenerative medicine, stem cells, and therapeutic approaches to fibrosis. This work was featured in TIME Magazine and resulted in several patents as well as over 60 peer-reviewed publications in journals such as Science and Cell.

Lev Osherovich | Director of Innovation Sourcing, Versant Ventures

Lev Osherovich, Ph.D. is Director of Innovation Sourcing at Versant Ventures, where he focuses on early stage therapeutic investment. Lev trained in Molecular and Cell Biology at UC Berkeley (undergraduate) and in Biochemistry at UCSF, and completed postdoctoral training at University of Kent at Canterbury and UCSF. After leaving academia, he worked as a biotech industry analyst and science journalist at BioCentury and Nature Publishing Group. Since 2014, Lev has worked at Versant and its discovery engine, Inception Sciences, to evaluate academic research with translational potential and to create new portfolio companies.
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JLABS, Tuesday Morning, Feb. 6, 2018

Topic: "The Art and Science of Productive FDA Meetings"
Speaker: Ron Farkas, MD PhD, Vice President, Technical, PAREXEL Consulting
Tuesday, February 6, 2018 from 10:30 AM to 1:00 PM (PST)
Agenda:
10:30 AM | Registration & Networking
11:00 AM | Presentation
11:40 AM | Q&A
12:00 PM | Networking Lunch
1:00 PM | Program Close
Location: JLABS @ SSF,329 Oyster Point Blvd - 3rd Floor, South San Francisco, CA
Fees:
$25 | General Public
$10 | Student/Academic
$35 | At the door
Details and registration at https://www.eventbrite.com/e/the-art-and-science-of-productive-fda-meetings-tickets-37017978771?aff=weekly

Event Details
Getting solutions to patients can be a long and complicated process. Working with the FDA is a key part of the sequence. Preparing for and understanding the FDA's needs is essential to smooth the way and shorten your time to approval.

Johnson & Johnson Innovation, JLABS is happy to be hosting Ron Farkas, MD PhD, Vice President, Technical, PAREXEL Consulting, to discuss the ins and outs of FDA meetings. Ron will pull from his vast experience which includes a decade plus run at the FDA to help guide us through these vital interactions. Topics will include:
Understanding the FDA's position; not just what it wants but why
What to agree on now and later; What does agreement mean?
The key to proceed
Understanding the dynamics within the FDA
Flexibility and norms and what they mean
Experts, Patients and Advocates at Meetings

Meeting minutes and follow up

Understanding the process will help you better prepare for your meetings and build confidence in and ability to adjust your own plan. Come prepared with your questions!

Speaker Bio
Ron Farkas | Vice President, Technical, PAREXEL Consulting
Dr. Ronald Farkas is a senior regulatory professional with over 15 years of experience in all phases of drug development from preclinical development through marketing application, advisory committee meetings, labeling negotiations, and the post-approval period. Dr. Farkas has in-depth cross-disciplinary expertise in clinical safety and efficacy, clinical pharmacology and pharmacogenomics, preclinical development, statistical analysis, and biomarker/surrogate endpoint development and utilization.

Dr. Farkas uses his extensive scientific, drug development and regulatory experience to assist clients in negotiating with regulatory authorities across the entire product life cycle to achieve their company objectives.

Prior to joining PAREXEL, Dr. Farkas was a Cross-Disciplinary Team Leader at FDA in CDER's Division of Neurology Products, with prior assignments to the Office of New Drugs Guidance and Policy Team and the CDRH Office of Device Evaluation. Prior to joining the FDA, Dr. Farkas was an assistant professor and attending surgeon at the Johns Hopkins University Wilmer Ophthalmic Institute.

Dr. Farkas completed residency training in ophthalmology at the Harvard University School of Medicine Massachusetts Eye and Ear Infirmary, subsequent to earning dual MD and PhD degrees in neuroanatomy and neuropharmacology from the University of Illinois at Chicago School of Medicine.
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PBSS, Thursday, Feb. 22, 2018

Event: Workshop Metabolite Detection Identification and Qualification for Drug Development
Speakers: S. Cyrus Khojasteh, Bill Fitch, Shichang Miao, Ryan Takahashi, Raju Subramanian, Shuguang Ma
Date and Time: 2/22/2018, 8:30-17:00
Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (USD): Regular: $195; Academic: $125; For unemployed or students: $30; For vendor-show rep: $35; For major-sponsor rep (incl lunch): $0;
Registration deadline:2/22/2018 (it will close sooner if the seating cap is reached)
Register at http://www.pbss.org/aspx/login01.aspx?iURL=
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PBSS Workshop, Monday, March 12, 2018

Topic: "Clinical Trials Essentials: An Intensive One-Week Course (register for the full week or half day sessions)"
Speakers: Edward Rozhon, Mike Huston, Narinder Singh, Gerri O'Riordan, Pete Shabe, Savita Sinha, Clarisa Tate, Frances Ann McKenney
Date and Time: 3/12/2018, 8:30-17:30
Registration fee (USD): One-week full course: $1865; Mon AM: Drug Development Process: $200; Mon PM: Science of Clinical Trials Design: $200; Tue AM: GCP & ICH Investigator & Clinical Research Site: $200; Tue PM: Global Clinical Trials Perspective

& Applied Statistics in Clinical Trials: $200; Wed AM: Monitoring Clinical Trials: $200; Wed PM: Medical Devices: $200; Thur AM: Clinical Data Management: $200; Thur PM: Clinical QA/Compliance Audits and the FDA: $200; Fri AM: Good Manufacturing Practices and the Transition to Full Scale Manufacturing: $200; Fri PM: Business of Clinical Research; Study Site Perspective: $200;
Location: SF Bay Area: Foster City Crowne Plaza
Registration: http://www.PBSS.org
Registration deadline:3/9/2018 (it will close sooner if the seating cap is reached)

Topic Description
Clinical Trials Essentials: An Intensive One-Week Course
A joint course between UCSC Extension Silicon Valley and Pharmaceutical and Bio ScienceSociety -- San Francisco

Monday March 12, 2018 – 8:30 am—12:30 pm

Drug Development Process 4 hours – Edward Rozhon

Major players in drug development
Assay development and discovery of new medical entities
Non clinical and clinical development of new drugs
History and regulatory oversight of FDA
Structure of Phase I, II, & III clinical trials
FDA review of New Drug Application.
Monday March 12, 2018 – 1:30 pm—5:30 pm

Science of Clinical Trials Design 4 hours – Mike Huston

Phases of drug development
Objectives of clinical studies
Basic clinical trials designs
Underlying science for clinical trials designs.
Tuesday March 13, 2018 – 8:30 am—12:30 pm

GCP & ICH Investigator & Clinical Research Site 4 hours – Narinder Singh

Historical and legislative roads to Good Clinical Practices (GCP)
Principles of GCP and the research-care conflict
Role of various stakeholders in Clinical Trials
Elements of informed consent.
Tuesday March 13, 2018 – 1:30—3:00 pm

Study Site Perspective 1.5 hours – Gerri O'Riordan

Translational research in an academic center: fundamental strengths and weaknesses
Research Process and Operations management as the success of a trial
Essential conversations between academia, biomedical and pharmaceutical companies, venture capitalists and consultants
Data Integrity and well-supported metrics (Case Studies).
Tuesday March 13, 2018 – 3:15 pm—5:30 pm

Applied Statistics in Clinical Trials 2.25 hours – Pete Shabe

The role statistics plays in clinical research
Basic data summarization techniques
Estimation and Hypothesis Testing Introduction
Estimation and Confidence Intervals
Statistical Hypothesis Testing.
Wednesday March 14, 2018 – 8:30 am—12:30 pm

Monitoring Clinical Trials 4 hours – Savita Sinha

Review the basic regulatory requirements of monitoring a clinical research study
Describe the tasks that should be performed before, during, and after a monitoring visit
Learn how to track all key parameters involved in monitoring a site
Know how to complete visit reports and follow-up on action items after each site visit.
Wednesday March 14, 2018 – 1:30 pm—5:30 pm

Medical Devices, An Overview 4 hours – Clarisa Tate

What is a medical device, a general overview of regulations
Medical devices regulatory pathways: 510(k), PMA, and HDE
Medical device clinical trials: Focus on Investigational Device Exemptions
Post-market surveillance: Focus on 522, complaints, and recalls
Globalization and changing regulatory environment.
Thursday March 15, 2018 – 8:30 am—12:30 pm

Clinical Data Management 4 hours – Instructor TBA

Key data management activities for study startup, conduct, and closeout
Regulations applicable to data management activities
Clinical data management systems and electronic data capture (EDC)
Working with contract research organizations (CROs) for data management.
Thursday March 15, 2018 – 1:30 pm—5:30 pm

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

Qualifications needed for GXP auditors and FDA Inspectors
Objectives of sponsor audits and regulatory inspections
Similarities and differences between sponsor audits and regulatory inspections
General approach to hosting an audit or inspection
Types of findings that cause concern for auditors or inspectors.
Friday March 16, 2018 – 8:30 am—12:30 pm

Good Manufacturing Practices and regulatory trends 4 hours – Narinder Singh

Good Manufacturing Practices (GMP) for drugs
GMP for biologics and related products, including Good Tissue Practices
Considerations for Quality Systems.
Friday March 16, 2018 – 1:30 pm—3:00 pm

Global Clinical Trials Perspective 1.5 hour – Narinder Singh

Trends in global clinical trials.

Role of FDA and local regulatory culture.
Friday March 16, 2018 – 3:15 pm—5:30 pm

Business of Clinical Research 2 hours – Mike Huston

The Market Players – Pharma, Biotech, Contract Research Organizations (CROs)
Cost of Doing Business – Cost of conducting clinical research
Outsourcing and CROs – It costs money to make money
Innovative Ways to Reduce Cost – Business Strategies and Process Innovations.
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JLABS, Thursday Mid Day, March 29, 2018

Event: Meet With... Frazier Healthcare Partners
Speakers: James W. Brush, M.D. | Senior Associate, Frazier Healthcare Partners and Patrick Heron, MBA | Managing General Partner, Frazier Healthcare Partners
Date and Time: Thursday, March 29, 2018 from 10:30 AM to 1:00 PM (PDT)
Agenda:
10:30AM | Registration and Networking
11:00 AM | Presentation and Q&A
12:00 PM | Networking Lunch
1:00-5:15 PM | One-on-One Meeting* (30 - minute meetings)

*Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due February 22,, 2018. Apply Here.
Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Fees:
Presentation
$25 | General Public
$35 | Onsite

One-on-One Meeting
FREE | Application
FREE | Accepted Companies
Apply to meet one-on-one with Jamie Brush of Frazier Healthcare Partners. Your application will be reviewed and you will be notified of acceptance on March 13th. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.
Details and registration at https://www.eventbrite.com/e/meet-with-frazier-healthcare-partners-tickets-36705859213?aff=weekly

Event Description
With over 26 years of exclusively investing in over 170 healthcare companies, Frazier Healthcare Partners has a great deal of experience building successful life science businesses. On March 29, 2018, Jamie Brush MD, and Patrick Heron, MBA will be visiting JLABS @ SSF to provide an overview of Frazier Healthcare Partners' unique investment strategies and meet 1-on-1 with pre-selected companies.

*The one-on-one application process is separate from the event registration process. Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due by February 22nd. Apply Here.

Program Overview:
Frazier Healthcare Partners is committed to helping great healthcare companies who are working hard to make a difference in the future of life sciences. The firm has partnered with exceptional entrepreneurs at all stages and focuses on therapeutic development. With $3 billion under management, investments in over 170 companies and 35 IPOs, Frazier Healthcare Partners has built a team with deep knowledge and scientific expertise that enables company building.
Jamie Brush, MD and Patrick Heron, MBA will be in attendance to provide an overview presentation of the firm's areas of interest. They will be on hand to meet with a handful of applicants 1-on-1 after the presentation. To be considered for a 1-on-1 meeting, please complete the information required here. Applications due by Feb 22, 2018.

Speakers' Biographies:

James W. Brush, M.D. | Senior Associate, Frazier Healthcare Partners
Jamie joined Frazier Healthcare Partners in 2016 and focuses on investment identification, due diligence, and deal closing.

Before joining Frazier, Jamie was a management consultant with the Boston Consulting Group, where he was a core member of the Healthcare Practice. In this capacity, he led projects involving Biotechnology mergers and acquisitions, R&D, manufacturing and business development strategy.

Jamie received his M.D. from the University of Southern California, where he was inducted into Alpha Omega Alpha honors society, and his B.A. from Middlebury College. He completed his postgraduate training in Internal Medicine at Beth Israel Deaconess Medical Center in Boston. He has co-authored several papers in top-tier journals on genomic instability and its role in cancer, and is a member of the board of directors of Longwood Symphony Orchestra.

Patrick Heron, MBA| Managing General Partner, Frazier Healthcare Partners

Patrick is a Managing General Partner of Frazier's Life Sciences team. He joined the firm in 1999 and opened Frazier's Menlo Park office in 2003. Throughout his 12 years as General Partner, Patrick has led or co-led investments across nearly 20 companies.

Patrick has successfully partnered with entrepreneurs across a range of company types and stages, from early – stage anti-infectives companies to >$100M commercial-stage dermatology companies. Patrick has also been active in company formation around both early – and later – stage assets. He has led and served as director for many successful Frazier Life Sciences investments, including Tobira Therapeutics (acquired by Valeant), MedPointe (acquired by Meda), and Collegium (NASDAQ: COLL). He currently serves on the boards of Imago BioSciences, Iterum Therapeutics, Silvergate Pharmaceuticals, SutroVax and Zavante Therapeutics.

Prior to joining Frazier, Patrick helped develop McKinsey & Company's West Coast biotechnology consulting practices, where he led projects involving mergers and acquisitions, product launches, sales force optimization, corporate partnering, and research prioritization.

Patrick received his M.B.A. from Harvard Business School. He also holds a B.A. from the University of North Carolina at Chapel Hill, where he is a Phi Betta Kappa graduate and Morehead Scholar.
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PBSS Workshop, Tuesday Afternoon, April 24, 2018

Topic: "Regulatory Authority Inspection Preparation and Outcomes"
Speakers: Kim Burson (Achaogen)
Date and Time: Tuesday, 4/24/2018, 12:30-17:00
Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (USD): Regular: $125; Academic: $75; For unemployed or students: $25; For vendor-show reps: $25; For major-sponsor rep (incl lunch): $0;
Registration: http://www.PBSS.org
Registration deadline:4/24/2018 (it will close sooner if the seating cap is reached)
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PBSS, Tuesday, May 22, 2018

Workshop : Understanding and Overcoming High Clearance and Poor Bioavailability: Fundamentals, Investigations and Strategies for Drug Discovery
Speakers: Matthew Wright (Genentech) et al
Organizers: Matthew Wright (Genentech)
Date and Time: 5/22/2018, 8:45-17:00
Registration fee (USD): Regular: $195; Academic: $125; For unemployed or students: $30; For vendor-show rep: $35; For major-sponsor rep (incl lunch): $0;
Location: SF Bay Area: Foster City Crowne Plaza
Major Sponsor: (1)Worldwide Clinical Trials;(Major Sponsorship - afternoon session still open)
Vendor show vendors registered to date: (1)Pion Inc.
Registration: http://www.PBSS.org
Registration deadline:5/21/2018 (it will close sooner if the seating cap is reached)

Topic Description
Poor exposure following oral administration is a common challenge facing discovery programs and consequently a frequent focus for DMPK scientists. Frequently, potent compounds cannot be further developed due to less-than-ideal ADME (absorption, distribution, metabolism, and excretion) properties that prevent the compounds to be available following oral administration. Beyond the discovery phase the importance of understanding and optimizing oral exposure continues in the preclinical and ultimately clinical phases of drug development. Inadequate oral exposure could be due to suboptimal physicochemical properties, or problems in absorption from the gut, or first-pass metabolism in the gut and liver, or high intrinsic clearance of the compounds.

The focus of this workshop/symposium is on: 1) to identify and learn about the issues that contribute to low oral exposure, 2) to discuss approaches that one could use to overcome those challenges, 3) to present additional methodologies that can aid in solving exposure problems and 4) to provide suggestions on how to work with partners in Medicinal Chemistry and Biological Sciences within Project Teams.

This workshop/symposium will cover the following topics:

Pharmacokinetic concepts – absorption, bioavailability, and clearance factors contributing to low oral exposure

Physiological factors that affect oral exposure
Physicochemical factors that influence oral exposure
Metabolism-based issues that give rise to poor oral exposure
Transporter-based issues that give rise to poor oral exposure
How to identify the source of problem in oral exposure – properties of the molecules or conditions of the experiment?
Biopharmaceutical Aspects of oral drug exposure
Approaches to overcome oral exposure issues, including case studies
Enabling Exposure of ADME Challenged compounds
What do Medicinal Chemists/Biologists want and how can we work with them
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