Audrey's Life Science Meeting Picks for Sept. 10, 2017 – Oct. 2017
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JLABS, Monday-Tuesday, Sept. 11-12, 2017

Join the Janssen Human Microbiome Institute, JLABS @ SSF, Stanford Medicine, and Seventure for the 2017 West Coast Microbiome Forum, a 2-day event exploring key aspects of microbiome research. **Note - There is separate registration for each day.

September 11: Bioinformatics for the Microbiome, hosted by Stanford Medicine. Details/Register with Stanford here (Link will redirect you to a non-J&J Innovation website)
September 12: Bugs, Drugs & Beyond: Translational Approaches to the Mircrobiome, hosted by JHMI and JLABS.

Bugs, Drugs & Beyond: Translational Approaches will explore the ways in which innovators from San Francisco and beyond are harnessing the human microbiome and advancing novel therapeutics, diagnostics and other health products. During this event, we'll hear from entrepreneurs, academics, investors, and biotech and pharma companies about a variety of product development approaches and the organizations pursuing them.
Agenda:
10:00am | Registration
10:15am | The Microbiome: A New Paradigm for Health Solutions
10:30am | Insights from the Front Lines of Microbiome Innovation
11:00am | QuickFire Challenge, Part I
12:00pm | Lunch and Gallery Walk
1:15pm | Panel Discussion: From Validation to Regulation: Breaking Down Barriers to Microbiome Progress
2:15pm | QuickFire Challenge, Part II
3:15pm | Networking Reception and QuickFire Challenge Winner Announced
4:30pm | Program Close
Location: Quadrus Conference Center & Catering, 2400 Sand Hill Rd., Menlo Park, CA 94025
Registration at https://www.eventbrite.com/e/bugs-drugs-beyond-translational-approaches-to-the-microbiome-tickets-34552212598?aff=weekly

Interactive sessions will highlight:
Challenges in advancing to market, from IP protection to commercialization
Potential solutions and pathways currently being pursued across the field
Opportunities for collaboration
The Bugs, Drugs & Beyond QuickFire Challenge:
Are you a game-changing early-stage microbiome company? The Bugs, Drugs & Beyond QuickFire Challenge is officially open! We encourage innovators with promising ideas or research with the potential to impact patients to apply now. The winner will be awarded a customized package of support from the JHMI and JLABS, and will be announced at the event of the event on September 12. Applications for the Bugs, Drugs, & Beyond QuickFire Challenge will remain open until July 14, 2017. Apply online today!

Speakers:
Miguel Barbosa | Chief Scientific Officer -Microbiome, Assembly Biosciences ;
Colleen Cutcliffe, CEO, Whole Biome Inc.; Dirk Gevers. Global Head, Janssen Human Microbiome Institute, Janssen R&D Denise Kelly, Investment Advisor, Seventure;
Justin Sonnenburg, Principal Investigator, Stanford University
[Moderator] Stephanie Roberston, Sr Director of Consumer Science Innovation, Johnson & Johnson Innovation
Location: Quadrus Conference Center, Menlo Park, CA 94025
Fees:
$40 | General Public
$20 | Student/Academic
$45 | At the door
Details and registration at https://www.eventbrite.com/e/bugs-drugs-beyond-translational-approaches-to-the-microbiome-tickets-34552212598?aff=weekly

Speakers' Biographies:
Miguel Barbosa, Chief Scientific Officer -Microbiome, Assembly Biosciences
Dr. Barbosa has more than two decades of experience leading drug discovery and development programs at major pharmaceutical and biotechnology companies. Until 2015, Dr. Barbosa was Global Head and Vice President of Immunology Research and External Innovation at Janssen Research & Development, where he oversaw immunology R&D and new program initiatives, including establishing the foundation for, and then leading, Johnson & Johnson's new microbiome enterprise. Earlier in his career, Dr. Barbosa held positions of increasing responsibility managing new drug R&D programs at prominent biopharmaceutical firms, including Centocor, Signal Pharmaceuticals, TRL USA, Chugai Biopharma and Mirna Therapeutics. Dr. Barbosa received a BS degree from the University of California, Davis and a PhD from the University of California, Los Angeles. He completed a post-doctoral fellowship at the National Cancer Institute..

Joseph Petrosino Colleen Cutcliffe, CEO and Co-founder, Whole Biome, Inc.
Colleen Cutcliffe is the CEO and Co-Founder of Whole Biome Inc. She has over 15 years of experience leading and managing biology teams in academia, pharmaceuticals and biotechnology. Prior to starting Whole Biome, Colleen was the Senior Manager of Biology at Pacific Biosciences and a Scientist at Elan Pharmaceuticals. Colleen received her Ph.D. in Biochemistry and Molecular Biology from Johns Hopkins University and her B.A. in Biochemistry from Wellesley College..
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Stephanie Robertson Dirk Gevers, Global Head, Janssen Human Microbiome Institute, Janssen R&D
Dirk Gevers, Ph.D., is Global Head of the Janssen Human Microbiome Institute (JHMI), where he leads efforts to expand scientific understanding and capabilities in this emerging area of science. Previously, Dirk was Senior Group Leader of Microbial Systems and Communities at the Broad Institute of MIT and Harvard, serving as a scientific liaison among various organizational components, including the institute's data generation platforms and both clinical and analytical collaborators on microbiome-related projects. Dirk's research included the characterization of the microbial imbalance associated with diseases such as Crohn's disease, type 1 diabetes and colorectal cancer. He was also involved with the National Institutes of Health Human Microbiome Project, holding a leading role in the Data Analysis Working Group. Dirk received his Ph.D. in biochemistry from Ghent University (UGent), Belgium, and completed postdoctoral training at UGent and the

Massachusetts Institute of Technology in bioinformatics, comparative and evolutionary genome analysis and microbial ecology.
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Justin Sonnenburg Denise Kelly, Investment Advisor, Seventure
Denise joined Seventure in September 2015 as an investment Advisor to the Life Sciences Team for microbiome field. Her focus is in Human Microbiome Research and her time is dedicated to coverage of scientific and academic community on behalf of Seventure, and to prospect new investment opportunities in the specific field of microbiome. Denise is currently based in Aberdeen, Scotland. Prior to joining Seventure, Denise was Head of her Research team at the World-renowned Rowett Institute, University of Aberdeen, where she acquired over 20 years experience in gut microbiology and immunology. She was the (former) Founder Director, CEO and CSO of GT Biologics Ltd, one of the first translational spinouts, developing Innovative Microbiome-based Therapies.

Denise Kelly Justin Sonnenburg, Principal Investigator, Stanford University
Justin Sonnenburg conducted his Ph.D. in Biomedical Sciences at the University of California, San Diego. His graduate studies in the laboratory of Ajit Varki focused on the biological roles of glycosylation, performing comparative studies on sialic acids and their receptors in humans and great apes, to shed light on the molecular evolutionary history of humans. In 2003, Justin moved to Washington University in Saint Louis, Missouri to join the laboratory of Jeffrey Gordon, where he applied his background in glycobiology to study host-microbial interactions within the gastrointestinal tract. During his post-doc, Justin investigated model microbial communities living within the gut of gnotobiotic mice to define the basic principles that govern interactions within the microbiota and between the microbiota and the host. In 2008, Justin moved back to California and is currently Assistant Professor in the Department of Microbiology and Immunology at the Stanford University School of Medicine. In 2009 Justin was the recipient of an NIH Director's New Innovator Award. In 2011 he received the Burroughs Wellcome Fund Investigators in Pathogenesis of Infectious Disease Award. He and Erica Sonnenburg, PhD, are the authors of the forthcoming book The Good Gut: Taking Control of Your Weight, Your Mood, and Your Long Term Health.

The Sonnenburg lab is currently focused on understanding basic principles that govern interactions within the intestinal microbiota and between the microbiota and the host. To pursue these aims, his lab colonizes germ-free (gnotobiotic) mice with simplified, model microbial communities, applies systems approaches (e.g. functional genomics), and uses genetic tools for the host and microbes to gain mechanistic insight into emergent properties of the host-microbial super-organism.
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Migeul Barbosa Stephanie Roberston, Sr Director of Consumer Science Innovation, Johnson & Johnson Innovation
Stephanie is part of the New Ventures Team at J&J Innovation. As part of her role at J&J Innovation, she works closely with the Janssen Human Microbiome Institute and with J&J Consumer Emerging Sciences to create collaborations with academic experts and biotech companies with a goal of accelerating the translation of microbiome research into breakthrough solutions that promote health. Previously Stephanie was at the University of California, San Francisco UCSF where she helped to establish and

grow translational efforts on campus including her role as Program Director for the Sandler Center for Drug Discovery, and for the Grand Multiple Myeloma Translational Initiative. She later took on the role of Director, Strategic Alliances where she led business development and alliance management activities for the campus. Prior to joining UCSF, Stephanie worked for over a decade at Exelixis, Inc, where she held diverse leadership roles including leading a computational biology team and acting as scientific project leader for numerous drug discovery programs in cancer, cardiovascular disease and metabolism as well as managing early oncology clinical programs and alliances for several programmatic collaborations with large pharma.

Stephanie earned an undergraduate degree in chemistry (Honors) at the University of Michigan, Ann Arbor, and a Ph.D. in chemistry at the University of California, Berkeley.

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Bio2Device Group, Tuesday Evening, Sept. 12, 2017

Topic: "Behavioral Design for Wearables and Health-IT: Pitfalls and Promises"
Speaker: Sunil Maulik, Innovator, Educator, Entrepeneur
Date and Time: Tuesday, Sept. 12, 2017, 6:00 pm
Location: Wilson Sonsini Goodrich & Rosati - 650 Page Mill Road, Palo Alto
Cost:
$6 - Students/In-transition - Members only
$11 - Early-bird Registration - Members only
$20 - Late Registration and Non-Members
$25 - Walk-ins
Register at Bio2Device Group website www.Bio2DeviceGroup.org

Speaker Bio
Sunil Maulik has over twenty-five years of experience in Silicon Valley. He teaches workshops on product design for long-term behavior change in the technology and healthcare industries. He has given keynote speeches at Triple Ring Technologies, Product Realization Group, Genentech, Perkins-Coie, Alterra, Roche, Health2.0 and numerous other organizations. He has been a mentor and advisor to over 50 startups. Sunil helped start five companies (two IPOs (OXMOL; TRPS), two acquisitions (Moneta, 500Friends), one spectacular failure (Pangea Systems!) He co-founded and ran GeneEd, the first e-learning company focused on long-term behavior change for providers and patients. (Acquired by InVentiv Health in 2008.) Sunil is an advisor at The Innovation Center Denmark, a Danish government-funded design and innovation agency with offices in eight countries. He has guest-lectured at the Stanford d-school, U.C. Berkeley, and at the University of Amsterdam (THNQ.) Sunil has held management positions at Pangea Systems, Tripos (NASDAQ:TRPS), Hoffmann-La Roche (NYSE: ROCHE), Oxford Molecular (LSE: OXMOL), and IntelliGenetics. Sunil's thesis research on mathematical methods for 3-D image reconstruction of biological assemblies was published on the cover of the scientific journal Nature. His book "Molecular Biotechnology" (J. Wiley & Sons) sold over 4000 copies and was used in four university courses. He holds patents in fields as diverse as gene sequence pattern-matching, e-learning and e-mail analytics. Sunil worked with the Nobel-prize winners Maurice Wilkins and Aaron Klug as an undergraduate, and Sir Tom Blundell and Donald Caspar as a graduate student. He holds degrees in Physics (B.Sc.), Biology (B.Sc.), X-ray Crystallography (M.Sc.) and Biophysics (Ph.D.) After graduate school, he participated in AI research at Bionet™ with Drs. Peter Friedland, Doug Brutlag, Russ Altman and Ed Feigenbaum of Stanford.

Sunil participates in several non-profit ventures dedicated to health and wellness in sustainable communities, including the Pacific AIDS Education Center and Project Ahimsa. He is enthralled by the opportunity to help extend wellness across the globe by bringing the power of informatics to everyday users.

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WIB-San Francisco YWIB, Tuesday Evening, Sept. 12, 2017

Topic: "STEM CELLS… All the cool girls are discovering them!"
Date and Time: Tuesday, September 12, 2017, 4:00 p.m. - 7:00 p.m. PST
Program
4:00 p.m. – 4:30 p.m.
Check In and Welcome
4:30 p.m. – 5:15 p.m.
What are Stem Cells?
5:15 p.m. – 6:00 p.m.
Professionals in Science Panel
6:00 p.m. – 7:00 p.m.
Women in Science Activity and Dinner
Location: California Institute for Regenerative Medicine, 1999 Harrison Street, Suite 1650 Oakland, CA, 94612
Parking Information
The Lake Merritt Plaza parking garage is open to the public Monday through Friday from 5:00 a.m. - 7:00 p.m.
Public Transit Information
Easily accessible from the 19th St. Oakland BART station
Pricing Information
Members: Free
Non-Members: Free
Details and registration at http://womeninbio.org/eventdetails.aspx?EventId=31771
Registration Deadline
September 7, 2017

Maximum Capacity
40

Event Description:
Come join WIB-San Francisco Bay Area Young Women In Bio and California's Stem Cell Agency on September 12 to learn what stem cells are, ask questions of science professionals, and become a spokeswoman for girls in science!

Please read the YWIB permission forms located here.

YWIB Participant Age Range
9th through 12th grade

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

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QB3 Rosenman Institute D-Series, Tuesday Evening, Sept. 12, 2017

Event: An Interview with Justin Klein of New Enterprise Associates

Date and Time: Tue, September 12, 2017, 5:00 PM – 7:00 PM PDT
Location: Byers Hall, Room 212, 1700 4th Street, UCSF Mission Bay, San Francisco, CA 94158
Admission: Free for QB3 and UC Affiliates; $10 for general admission
Refunds up to 1 day before event
Details and registration at https://www.eventbrite.com/e/an-interview-with-justin-klein-of-new-enterprise-associates-tickets-37067803799?mc_cid=5316113df7&mc_eid=cb4c38a44a

Event Description
Join us Tuesday, September 12, when venture capitalist Justin Klein of New Enterprise Associates (NEA) will give us an inside view on the current state of healthcare investing. Christine Winoto, director of the Rosenman Institute, will interview Justin.

Speaker Bio
Justin Klein joined NEA in 2006 and is a Partner on the healthcare team. He focuses on medical device, healthcare technology, and biopharmaceutical company investments. He serves as a director of Advanced Cardiac Therapeutics, Cartiva, ChromaCode, FIRE1, Intact Vascular, Personal Genome Diagnostics, PhaseBio Pharmaceuticals, Relievant Medsystems, Senseonics (NYSE: SENS), VertiFlex, Vesper Medical, and VytronUS. Justin's past board memberships and investments include CV Ingenuity (acquired by Covidien), Nevro (NYSE: NVRO), Topera (acquired by Abbott), TriVascular (NASDAQ: TRIV), and Ulthera (acquired by Merz). He is also a member of the advisory boards for the National Venture Capital Association's Medical Industry Group and its Medical Innovation and Competitiveness Coalition (MedIC), as well as a member of AdvaMed's Business Development Committee.

Prior to NEA, Justin worked for the Duke University Health System—reporting directly to the hospital CEO on health system strategy, finance and clinical service unit operations—as Duke built one of the nation's first and largest healthcare integrated delivery systems. Justin concurrently earned his MD from the Duke University School of Medicine and his JD from Harvard Law School. He has also served as a member of the Board of Trustees of Duke University, where he earned his AB in Economics and his BS in Biological Anthropology and Anatomy.

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PBSS, Wednesday Seminar Luncheon, Sept. 13, 2017

Topic: "Unique Clinical Pharmacology & Biopharmaceutics Properties of Vyxeos: Development of a Nano-scale Fixed-ratio Cytarabine/Daunorubicin Liposomal Formulation for Acute Myeloid Leukemia"
Speaker: Jackie Gibbons, Ph.D, Jazz Pharmaceuticals
Organizer: Tracy Chen
Date and Time: 9/13/2017, 11:00-13:30
Registration deadline: 9/12/2017 Registration fee (USD): ;
Location: SF Bay Area: Foster City Crowne Plaza
Registration: http://www.PBSS.org

Speaker Bio
Jackie Gibbons, Ph.D, is currently Head of Clinical Pharmacology at Jazz Pharmaceuticals, an international biopharmaceutical company with marketed products and development

programs in the areas of sleep and hematology/oncology. She earned a BS in Biology from UC Berkeley and a PhD in Toxicology at Cornell University, where she studied cytochrome P-450 enzyme systems. Jackie has worked in the field of drug metabolism and pharmacokinetics for more than 25 years, and her former companies include Chiron, Bayer, and Medivation. She will be speaking on Vyxeos, a nano-scale liposomal formulation of a fixed 5:1 molar ratio of the antineoplastic agents, cytarabine and daunorubicin. In 2016, FDA granted breakthrough therapy designation for the use of Vyxeos in treating of acute myeloid leukemia, and Jazz submitted an NDA in March 2017. Jackie led the clinical pharmacology and biopharmaceutics portions of the NDA and will describe how the unique biopharmaceutics properties of Vyxeos affect its tissue distribution, pharmacokinetics, and exposure-response.

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Bio2Device Group, Tuesday Morning, Sept. 19, 2017

Topic: "CardioConnect (tm), teleHealth, Heart health tracking"
Speaker: Steve Stephansen,CEO, LifeWave Biomedical
Date and Time: Tuesday, Sept. 19, 2017 – 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale

Topic Description
LifeWave Biomedical is developing a digital health product in value-based care, called the CardioConnect(tm) system, that improves the management of patients diagnosed with congestive heart failure (CHF) and respiratory/lung diseases in hospital, ambulatory, and home settings.
The solution consists of a small non-invasive sensor that will deliver accurate and absolute measurement of lung fluids and cardiorespiratory parameters with a brief daily assessment. The data is uploaded to a smartphone/tablet application and integrated with the patient's drug regimen and other measured physiologic parameters to provide hospitalization decision support and to enhance patient self-management.
The CardioConnect integrates with artificial intelligence driven analytics and the development of a population health database. The clinical and economic benefits of the CardioConnect system are the improvement of patient quality-of-life, the potential extension of life expectancy, and the reduction of health care cost associated with initial hospital admissions and re-admissions.

Speaker Bio
Steve is the CEO of LifeWave Biomedical. Steve has 30 years of experience in the high tech industry, with a record of achievement in the commercialization of innovative technology products. His domain experience spans a number of areas, including semiconductor solutions for high-speed computing and signal processing, Internet video capture systems, and mobile application software.
He was previously CEO of WebV2, Inc. and Agoura Technologies. He held the position of VP of Marketing & Sales at Information Storage Devices and served in several senior marketing and sales positions at Advanced Micro Devices (AMD), including VP of Strategic Marketing for the $1B flash memory division.
He holds an MS in Management from the Stanford GSB, an MBA from Santa Clara University, an MSEE from Rensselaer Polytechnic Institute, and a BSEE from Lehigh University.
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QB3 Seminars for Life Science Entrepreneurs, Tuesday Mid-Day, Sept. 19, 2017

Topic: "CSO: Point of the Innovation Spear"
Speaker: Zach Serber, Chief Science Officer and Vice President of Development, Zymerge
Date and Time: Tue, September 19, 2017,12:00 PM – 1:00 PM PDT
Location: Room 160, Helen Diller Bldg., 1450 3rd Street, San Francisco, CA 94158
Cost: Free for QB3 and UC Affiliates; $10 for regular admission
Registration and details at https://www.eventbrite.com/e/zach-serber-zymergen-cso-point-of-the-innovation-spear-tickets-37071407578?aff=erelpanelorg#tickets

Topic Description
Maintaining a competitive edge in technology is key to startup success. The chief technology or science officer keeps that edge sharp by conceiving and developing new innovations, often managing a team of scientists and engineers. So what's it like to have that responsibility? Join us on September 19 to find out. We'll hear from Zach Serber, CSO at Zymergen, which was recently profiled by Science for its application of robotics and machine learning to the refinement of industrial microbes.

Speaker Bio
Dr. Zach Serber is a scientist and entrepreneur devoted to using bioengineering to drive the next industrial revolution. In 2013, Dr. Serber co-founded Zymergen, a technology company unlocking the power of biology by combining biology with technology such as robotics and machine learning. Today, he is the company's Chief Science Officer and Vice President of Development overseeing scientific direction, new products, and development teams.

Dr. Serber was previously the Director of Biology at Amyris where he worked on manufacturing bio-derived transportation fuels, on lowering the cost of the antimalarial drug, Artemisinin, and on developing advanced tools for engineering biology. He has been PI on multiple DARPA contracts including an $8M contract devoted to improving the genome engineering cycle and, currently, a $31M contract to develop 360 microbes, each producing a novel molecule with the potential to generate innovative polymers and materials.

Dr. Serber has 17 peer-reviewed publications in journals such as Cell and Science, multiple patents, and has worked as a research fellow at Stanford University Medical School. He has a PhD in Biophysics from University of California San Francisco, a MSc in Neuroscience from the University of Edinburgh, and a BA from Columbia University.

Zach lives with his wife, two children, and dog on a sailboat in Sausalito, CA.

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EMBS, Wednesday Evening, Sept. 20, 2017

Topic: kV X-ray Digital Tomosynthesis Image Tracking of Respiratory Motion During The Delivery of MV Radiotherapy Treatment of Cancer.
Speaker: Larry Partain, Director of Clinical Research, TeleSecurity Sciences, Silicon Valley Operations,Los Altos, CA
Date and Time: Wednesday, September 20, 2017, 7:30 PM
Location: Room M-114 of the Alway Bldg., Stanford University School of Medicine (see campus map at link below).

Optional dinner location: Stanford Hospital cafeteria, 6:15 PM (no host, no reservations, self-serve)

The Stanford campus map is at: https://campus-map.stanford.edu/
Parking is usually free after 5 PM at Roth Way Garage, which is at the corner of Roth Way and Campus Drive on the map. The Stanford Hospital Cafeteria is across Campus Drive from Roth Way Garage and near the Emergency entrance. The meeting is in Room M-114 of the Alway Building, which is also across Campus Drive from Roth Way Garage, and Room M114 is accessible from outside the Alway Building.

Topic Description
External beam radiotherapy, widely applied in the treatment of cancer, directs a constantly re-shaped beam of gamma rays (i.e. MeV photons) from outside a patient to non-surgically enter the patient's body to destroy a malignant lesion, as this focused treatment beam circles the patient's body, for a lesion positioned near the center of rotation. A priority early application is treatment of lung cancer in free breathing patients where the cancer lesion can easily move up and down a cm or more during respiratory cycles (every 4 to 6 sec.) for continuous treatments that can typically last a minute or more. Since real time viewing of respiratory motion of objects has not usually been available during radiotherapy, the standard protocol delivers this lethal dose over the total volume traversed by the lesion during multiple breathing cycles. Unfortunately this directly kills about 2% of the patients treated and seriously injures a larger fraction due to the radiation damage to healthy surrounding lung tissues, the heart, the spinal cord and other "organs at risk" including the ribs. The success of this x-ray tomosynthesis tracking technology has the potential to significantly reduce the magnitude of such collateral damage.
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JLABS, Thursday Afternoon, Sept. 21, 2017

Topic: "From Chemical to Drug: The Path to a Small Molecule IND"
Speakers
Anders Brunmark | Sr Director, External Innovation, Discovery Sciences, Janssen R&D
Mark Krook | Sr. Scientific Director, Portfolio Management, Janssen R&D
Sandra Snook | Sr. Director, Preclinical Development & Safety, Janssen R&D
Jan de Jong | Scientific Director, Clinical Pharmacology, Janssen R&D
Katherine Tsokas | Regulatory Head, Regenerative Medicine & Advanced Therapy, Janssen R&D
Date and Time: Thursday, September 21, 2017, 12:30- 5:00 pm
Agenda
12:30 PM | Registration, Lunch, and Networking

1:00 PM | Janssen Research & Development - your partner of choice

1:30 PM | Preclinical Development Strategies
- Pharmacokinetics, distribution and metabolism in Discovery and Early Development
- picking the right molecule
- Preclinical toxicology evaluations before and during GLP toxicology
- Considerations for typical FIH Program
- Case study

2:15 PM | Chemistry, Manufacturing and Controls Strategies
- Optimizing manufacture of your API
- Drug product formulations for FIH

3:00 PM | Break

3:15 PM | Clinical Pharmacology
- Designing FIH trials
- Understanding PK/PD
- Biomarkers of safety and efficacy
- Case study

4:00 PM | Regulatory - Satisfy Statutory Legal Requirements for Testing in Humans
- Regulatory Strategy
- Data requirements: CMC, safety, clinical plan
- eCTD
- Pre-IND meetings
- Case study

4:45 PM | Discussion and Q&A

5:00 PM | Program Close
Location: Byers Hall Auditorium, University California San Francisco, 600 16th St., San Francisco, CA
Fees:
$35 | General public
Free | UCI students/staff
$20 | Other student/academic
$35 | At the door
Register at https://www.eventbrite.com/e/from-chemical-to-drug-the-path-to-a-small-molecule-ind-tickets-34888361027?aff=blast

Program overview

Topic Description
Do you have a solid plan to achieve IND acceptance? Filing an Investigational New Drug (IND) application might be the next step in advancing your company's early-stage drug development program. Johnson & Johnson Innovation, JLABS and Janssen Discovery Sciences invite you to an in-depth look into the process of filing an IND.

Whether your goal is to develop a pipeline through commercial launch or partner as early as possible, submitting an IND is a critical early milestone for every biotech company. With big Pharma and VC firms competing for the most promising compounds, startups are expected to demonstrate a clear blueprint for IND approval, and we want you to be ready.

Join us for a series of short presentations exploring the basic requirements and considerations necessary to achieve a successful small molecule IND submission.

The presentations will highlight the following:

Janssen Research & Development - a brief overview

Preclinical Development strategies for pharmacokinetics, drug metabolism and toxicology
Key CMC strategies to balance cost, time and quality risks
Designing First-in-Human trials to highlight the qualities of your molecule
Regulatory strategy, IND requirements, and Pre-IND meetings

Speakers Bios

Anders Brunmark, Ph.D. | External Innovation, Discovery Sciences, Janssen R&D

Anders Brunmark obtained his undergraduate in chemistry at University of Lund and completed his PhD on quinones and free radical biochemistry at University of Linköping, Sweden. He held a faculty position at this University between 1988 and 1992. He did postdoctoral work on immune recognition at the Department of Immunology at The Scripps Research Institute in La Jolla, CA between 1990 and 1994. Anders Brunmark joined J&J's Pharmaceutical R&D organization in 1994 as group leader for protein expression and held a group leader position in Immunology Discovery 1999-2004. In 2004 Anders established an enabling technology team at the La Jolla, California R&D site, comprising DMPK, Pharm Sci/formulations, Genomics, Compound Logistics, and High Throughput Screening functions. In 2012 he took a job as Scientific Director in Integrated Systems Biology. Since 2014 he is Director in External Innovation in Janssen R&D Discovery Sciences with primary responsibility for Western US and Canada. He is an author on 48 papers, 3 book chapters, and inventor on 5 patents. Anders Brunmark's research interests include development and application of new techniques for studying disease mechanisms and drug action both in vitro and in vivo.

Jan de Jong, Ph.D. | Scientific Director, Clinical Pharmacology, Janssen R&D

Jan has over 20 years experience in drug development, with a focus on small molecule pharmacokinetics and metabolism. He is currently a Clinical Pharmacology Leader in the Global Clinical Pharmacology department. He holds a master's degree in Pharmacochemistry from the Vrije Universiteit (VU) Amsterdam, the Netherlands, and a doctorate from the same university. Following a temporary Assistant Professorship at the VU, Jan joined the Drug Metabolism & Kinetics department at Organon, the Netherlands. He started at Janssen R&D in Belgium in 2000 as Head of Bioanalysis, and later relocated to the US where he joined the San Diego, CA site and became a preclinical project lead. He transitioned to clinical development to become the ClinPharm Oncology lead for ibrutinib, a first-in-class BTK inhibitor jointly developed and marketed with Pharmacyclics. He has worked on IND packages for several early development projects across various therapeutic areas.

Mark Krook, Ph.D. | Head, Global Portfolio Management - Small Molecules, Janssen R&D

Mark has over 30 years of drug development experience in the pharmaceutical industry. He began his career at The Upjohn Company (eventually becoming Pfizer) as a process chemist working on API process development for clinical and commercial needs, eventually moving into the leadership of global, multi-site chemical process R&D organizations with responsibilities for both laboratory and pilot plant facilities. From there he transitioned to portfolio management, providing broad technical, strategic and governance oversight for cross-functional CMC activities within a diversified portfolio of development projects.

Mark joined Janssen in 2007 as the leader of the ChemPharm API Development group in the US. In 2010, he moved into the PDMS Portfolio Management function where he

is currently leading a group of CMC Leaders with responsibility for CMC activities across the entire small molecule development spectrum (pre-clinical to life cycle management).

He earned a B.A. in Chemistry from the College of St. Thomas (now University of St. Thomas) and completed a Ph.D. in Organic Chemistry from the University of Notre Dame

Katherine Tsokas, J.D. | Regulatory Head of Regenerative Medicine & Advanced Therapy, Janssen R&D Director Regenerative Medicine & Advanced Therapy Network, Johnson & Johnson
Katherine has 26 years of progressive global regulatory experience in small and large sized Pharma companies. She has worked on products at various stages of development, from early through to filing, approval and commercialization. Currently, her responsibilities include providing strategic regulatory oversight to advanced therapy projects in several therapeutic areas by ensuring regulatory strategies contribute to and support the development plans for the products and that all opportunities for collaboration internally and externally are utilized. Further, through the RMAT Network, Katherine leads J&J cross-sector efforts to enhance awareness and connectivity for the development of processes that enable assessing, partnering, and developing safe and effective advanced therapies globally. In addition, she represents Global Regulatory Affairs on the J&J First in Human Committee. Katherine received her Bachelor of Science Biology from Temple University, Juris Doctorate from Widener University Law School, and is admitted to the practice of law in Pennsylvania and New Jersey.

Sandra Snook | Sr. Director, Preclinical Development & Safety, Janssen R&D
Sandra has been supporting the preclinical development of small molecules for 25 years. She is a DVM and board certified Veterinary Pathologist and after a stint leading an academic research group at The University of Chicago, she moved to GD Searle/Pharmacia where she worked for 11 years supporting projects from late discovery through full development. In 2003 she took on the mission to form a nascent Preclinical Development & Safety group for Janssen's La Jolla site. During her career, Sandra has worked across platforms including synthetic peptides, and small and large molecule pharmaceuticals. She has worked across therapeutic areas including infectious diseases, metabolic and cardiovascular diseases, immunology, neuroscience and oncology. Additionally, she has lead staff supporting toxicology and DMPK project support as well as laboratory animal medicine, investigative toxicology and molecular pathology. She and her team have extensive experience supporting innovative compound development from lead optimization through global registration; including managing the preclinical portion of external alliances and partnerships. Her team is frequently called upon to participate in critical due diligence reviews of potential licenses and acquisitions. For the last few years Sandra has also lead the Janssen Imbruvica preclinical development team 9a partnership with Pharmacyclics), one of the first drugs to successfully navigate the Breakthrough Drug designation at the FDA. Sandra received her AB degree from The University of Chicago, a DVM from Iowa State University and served as a post-doctoral fellow in Comparative Pathology at Harvard University. She served on the faculty of The University of Chicago where she had independent research funding (NIDA) and ran a comparative pathology diagnostic laboratory supporting the LAMS organization in addition to the Lincoln Park Zoo and Shedd Aquarium. Over the years Sandra has been active in both the ACVP and STP. She is an author on 26 papers and 33 posters/presentations.

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PBSS Webcast, Thursday, Sept. 21, 2017

Workshop Webcast: Conducting Clinical Trials in China – Regulatory and Clinical Challenges and Recent Developments for Drug and Device Development; Lessons for US-based Companies Entering the China Market
Speakers: Lan Huang, PhD, BeyondSpring (Co-founder & CEO), John Mao, PhD, Foresee Pharma (SVP), Vivian Mao, MD, Abbott Vascular (Associate Director, Clinical Science), Honggang Bi, PhD, Covance China (Corporate Vice President and General Manager), Guobin Wang, PhD, PPD China (Director, Project Management)
Date and Time: Thursday, Sept. 21, 14:00-16:30
Location: Online Webcast ONLY
Registration: http://www.PBSS.org
Registration deadline:9/20/2017 (it will close sooner if the seating cap is reached)

Topic Description
Pharmaceutical and Medical Device companies today face a growing demand to expand their clinical trial programs into China in order to access the vast pool of patients. While there are clear benefits for conducting clinical trials in China, there are significant operational and regulatory challenges, which need to be addressed before overseas companies plan to conduct trials in China, either as a trial conducted solely in China or as part of a multinational trial involving Chinese patients. It is important that appropriate measures are put in place to satisfy the ever evolving Chinese clinical trial and approvability standards. In the meantime, the China FDA (CFA) has initiated a major effort to harmonize the regulatory and clinical practices with the developed world and has implemented a number of policies that have profound impact on the clinical and regulatory practices in China.

This workshop aims at discussing some of the regulatory and operational challenges when conducting clinical trials in China, in both, the Pharma and Medical device arena. The presenters who are industry leaders with deep experience with drug and device development in China will review some of the recent regulations for the Pharma and Device development in China and suggest ways to approach China's FDA (CFDA). It will discuss challenges and solutions when conducting national or multinational device trials in China from the perspectives of a local Chinese CRO as well as global CROs with affiliates in China. The workshop will provide examples for early strategies to include China in the development as part of a global development plan. A case example will demonstrate how a global clinical Phase 3 trial would suffice for a US FDA and China FDA approval.

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QB3 SBIR Workshop, Starting Tuesday, Sept. 26, 2017

Classes offered at UCSF

UCSF: Six sessions, on Tuesdays. Starts Sept. 26, last one Dec. 19
Location: 212 Byers Hall, UCSF Mission Bay. http://qb3.us5.list-manage.com/track/click?u=61b2598b3587bfbe0c0972994&id=9f2fca1ac4&e=cb4c38a44a

Workshop Description

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 $250k (Phase I) or $1M (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 December NSF or January NIH deadlines.

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

See the individual registration pages for details.
Faculty includes:

Shauna Farr-Jones
Grant Writer,
UCSF/QB3
Shauna's LinkedIn profile

Ioana Aanei
Entrepreneurship
Program Manager,
QB3

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Rosenman Institute, Wednesday, Sept. 27, 2017

Event: Get Help on Device Regulatory Issues from Rosenman Fellow Kevin MacDonald
Kevin is holding office hours at UCSF on Wednesday, September 27. It's free. Sign up for a half hour session.
Date and Time: Wednesday, September 27, 11:00 am to 4:00 pm
Location: UCSF Mission Bay, Byers Hall, Room 212
Space is very limited. Click the link to reserve a timeslot.
Free
Register at http://qb3.us5.list-manage.com/track/click?u=61b2598b3587bfbe0c0972994&id=093deda515&e=cb4c38a44a

Session Description
Regulatory issues can get in the way of commercializing medical devices. Need help with your company or product? Sign up for office hours with Rosenman Fellow Kevin MacDonald.
1) Click the link and reserve a timeslot
2) Email Christine Winoto a brief description of the issue that you need help with. This information will be held confidential.

Bio for Speaker
Kevin MacDonald is currently a regulatory, clinical, and quality consultant working with small medical device startup companies. Kevin has more than 25 years of experience and a successful track record with achieving regulatory market clearances/approvals in the United States and abroad. Prior to his consulting role, Kevin's recent experience includes Vice President positions at NeoTract and Concentric Medical. Earlier in his career, Kevin held various RA/CA/QA positions with Fox Hollow Technologies, Heartport, Cordis, Boston Scientific Corporation, and CR Bard. Kevin graduated with a B.S. in biology from Framingham State College
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JLABS, Thursday Morning, Sept. 28, 2017

Topic: "The Race to Market: Building an Efficient Discovery Engine"
Speakers: David Malwitz| Manager, Bioresearch Quality & Compliance, Janssen R&D; Lynn Young | Sr. Research Manager, Alliance Business & Portfolio Managements, Janssen R&D; Jackie Benson| VP Immunology SCI Innocation, Research Admin, Johnson & Johnson Innovation
Date and Time: Thursday, September 28, 2017 from 8:30 AM to 11:15 AM (PDT)
Agenda:
8:30 AM | Registration and Networking Breakfast
9:00 AM | A roadmap for bringing a drug to market
Drug discovery process
Internal and external stakeholders
Opportunities and challenges
9:15 AM | Dilemmas in discovery - a workshop
An interactive session focusing on potential data handling dilemmas and their associated risks
10:00 AM | Discovery data integrity – a quality approach for Janssen R&D
Sponsorship and support
Training approach
Risk-based monitoring
Phase appropriate solutions
11:00 AM | Discussion and Q&A
11:15AM | Program Close
Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California
Fees:
$25 | General Public
$15 | Student/Academic
$45 | At the door
Details and registration at https://www.eventbrite.com/e/the-race-to-market-building-an-efficient-di...

Topic Description
Are you confident in the integrity of your data? Every day, hundreds of scientists are forming the basis of drug discovery. Laboratory data forms the building blocks of the scientific work, and its quality is paramount to crucial business decisions and long term success. Take an in-depth look into potential quality risks and inefficiencies in research and explore measures to improve data quality in the drug discovery processes. Johnson & Johnson Innovation, JLABS (JLABS) and Janssen R&D invite you to an interactive workshop where attendees will work in groups to think about data handling dilemmas and their possible risks..

[This is an interactive workshop including small working groups during the day, therefore space is limited]
Presentations will cover the following topics:
A roadmap for bringing a drug to market
Dilemmas in discovery – a workshop
Reproducibility in research
A quality approach within Janssen R&D

Speaker Bios
David Malwitz | Manager, Bioresearch Quality & Compliance, Janssen R&D
David is responsible for the planning and execution of external strategy in the Non-regulated QA domain of Bioresearch Quality & Compliance. This includes implementing key systems and processes needed to establish a risk-based audit program, operationalizing strategic quality and compliance capabilities, and recruiting the right team and network across global R&D sites to enable a successful portfolio. In addition, David supports the internal quality maintenance program by leading internal and external assessments across multiple therapeutic areas and has led compliance integration efforts to ensure the successful alignment of acquired assets into the Janssen R&D organization. David began his career as a research scientist at Wyeth Research and Amgen. He has a M.S. in Organic Chemistry from Wright State University and B.S. in Chemistry from Cedarville University.

Lynn Young | Sr. Research Manager, Alliance Business & Portfolio Managements; Janssen R&D
Lynn enables the "business of science" for Discovery Immunology team at Janssen Research & Development. Her focus areas include driving the end-to-end contracts process, ensuring Healthcare Compliance for contracts, monitoring records management and promoting Discovery Data Integrity (DDI) practices. Lynn is a protein biochemist and began her career in the pharmaceutical industry at Tanabe Research Laboratories USA focusing on integrin targets. From there she moved to the RW Johnson Pharmaceutical Research Institute to support drug discovery in the Virology, Infectious Diseases and later the Immunology departments. In 2010, she transitioned to a strategy and operations team supporting the business needs within Research Immunology. Lynn has a M.S. in Biology from the University of California at Irvine and a B.A. in Biochemistry and Cell Biology from University of California at San Diego.

Jackie Benson | VP IMMUNOLOGY SCI INNOVATION, Research Admin Johnson & Johnson Innovation
Jackie is responsible for creating and implementing an external innovation plan focused on developing an industry-leading portfolio of Immunology Therapeutic Area investment opportunities on the West Coast. This work will help solidify Janssen as the partner of choice in a highly competitive landscape, and identify and deliver the best opportunities for value-generating collaborations supporting our Immunology scientific strategy.
In her previous role, Jackie launched and led the Estrela Venture within the Janssen Incubator, advancing innovative treatments for systemic lupus erythematosus (SLE). Jackie led the Estrela Venture to a number of key milestones, including the declaration of two new molecular entities, one of which recently achieved first patient dosed in SLE patients.
Jackie joined the Janssen Pharmaceutical Companies of Johnson & Johnson as a Senior Research Scientist in 2001, playing an instrumental role in the research and discovery of several flagship programs, including STELARA® (ustekinumab), for which she earned a Johnson Medal, and guselkumab. She received her B.S. in Biology from The Ohio State University, followed by her Ph.D. in Immunology from the College of Medicine at The Ohio State University, and was awarded a National Multiple Sclerosis Society postdoctoral fellowship at Stanford University School of Medicine.

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WIB-San Francisco, Thursday Evening, Sept. 28, 2017

Topic: "Redefining Healthcare"
Our panel includes moderator, Michelle Zeman, PhD (Clinical Genomics Scientist at Invitae) and the following experts, who will touch upon various aspects of the rapidly growing field of digital health:

- Deborah Kilpatrick, PhD (CEO, Evidation Health)
- Ida Shum, JD (Sr. Manager, Business Development at Samsung)
- Ruchita Sinha (Sr. Director Investments, Sanofi Ventures
- Lucia Soares (VP, Healthcare Technology Programs & Delivery, Johnson & Johnson)

Date and Time: Thursday, September 28, 2017, 5:15 p.m. – 8:30 p.m. PST
5:15 p.m. - 6:15 p.m. Registration and Networking
6:15 p.m. - 6:30 p.m. Welcome Remarks
6:30 p.m. - 8:00 p.m. Panel Discussion and Q&A
8:00 p.m. - 8:30 p.m. Networking and Wrap Up
Location: Foley and Lardner, 975 Page Mill Road, Palo Alto, CA 94304
Price: Members: $20
Non-Members: $50
Students: $10*
* - Students, please email sanfrancisco@womeninbio.org to obtain the discount code to receive student pricing. Also, note that only 6 tickets are available at the discounted student price.

Details and registration available at
http://www.womeninbio.org/events/EventDetails.aspx?id=1007455&group=

Registration Deadline
September 26, 2017

Topic Description
Digital health is at the forefront of disrupting and positively transforming the current healthcare system. This convergence of traditional pharmaceutical science and technology is progressing toward fundamentally shifting how we track and manage health to improve patient outcomes and promote wellness. Join the San Francisco Bay Area chapter of Women In Bio on September 28 to hear about:

- How and why digital health is transformative
- Where is the money? What interests digital health investors
- What are the recent breakthrough technologies and who are the rising stars in digital health
- Where are the employment opportunities

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JLABS, Tuesday Morning, Oct. 3, 2017

Event: Meet with... Novo Ventures
Speaker: Peter Moldt, Ph.D., Partner, Novo Ventures
Participating representatives
Peter Moldt | Partner, Novo Ventures

Kenneth Harrison | Sr Associate, Novo Ventures
Date and Time: Tuesday, October 3, 2017, 10:30 am
Agenda
10:30 AM | Registration and Networking
11:00 AM | Presentation and Q&A
11:45 AM | Networking Lunch
1:00 PM | Program Close
1:00-5:00 PM | One-on-one Meetings*

*Companies must apply for a one-on-one meeting ahead of time and be approved. The application period ends on September 6th.

Location: JLABS @ SSF, 329 Oyster Point Blvd, 3rd Floor, South San Francisco, CA
Fees $25 | Presentation & Lunch
FREE | 1-on-1 Application

Program overview
Do you want to meet with one of the most active Life Science investors in the World? Novo Ventures is the venture investment vehicle for Novo A/S – a holding and investment company that manages ~$45B of assets on behalf of the Novo Nordisk Foundation.

Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due September 6th. Apply Here.

http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1_uEwZB6HmF8Y-GoeWGrHvynXUOlzxCtra1HLXnby75b_FnZwyd7pQI87Jxs2qahhnJkcE1Kkgy6fxExtreaKox4rcqv8OpC3JT24izkU2u3oyD7n9ut2Vg06FOSYMUz4xfKCfZky3xUIN6MYktmk07ZSjQtkaZ2vj2Wlxplu6fTZvrHcQ3zKJP_bUxMWjGTLJcEK76qxH1vEhHdB7Sr_iyPOS-8Suak-Ub8bNULkb16heaZmjRswHZZ5kSeqNMgr5dmJ&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re_w==&ch=U55Vv8DstNx5o7FGRomWV_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==
http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1_uEwZB6HmF8Y-GoeWGrHvynXUPZldooFkfGQ_eQ6kik64Gop6fbw1r5yKjdxJ59BRGl7pPdRjgRd81yJWU4AYdds3ozLR8TS84dM0aWOAZgI1hE_1USOZFgJg8pomY0nh0nZq6YthoTWGa5PGaqbH-RHadUy_m_E1rox&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re_w==&ch=U55Vv8DstNx5o7FGRomWV_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==

Novo Ventures is structured as an evergreen fund with an annual total of $350M to invest in private and public life science companies in North America and Europe. Their team identifies opportunities by leveraging a local presence in leading global biotech hubs and typically co-invests with other life sciences funds as either a lead or co-lead investor.

Novo Ventures has a strong focus on pre-commercial therapeutics and commercial med-tech companies, with opportunistic investments in diagnostics and research tools. Their team of professionals in Boston, Copenhagen, London and San Francisco has an active portfolio of more than 50 companies and has invested in more than 140 companies since 2000.

Peter Moldt, Ph.D., Partner and Kenneth Harrison, Ph.D., Senior Associate with Novo Ventures, will be in attendance to provide an overview presentation on Novo

Ventures' key areas of interest and venture investment philosophy. Novo Ventures will also be meeting one-on-one with selected companies.

Speaker spotlight
Peter joined Novo Ventures in San Francisco, California in 2012. He is Chairman of the Board of Directors of Allakos and a member of the Board of Directors of Corvus Pharmaceuticals, Bolt Therapeutics, E-Scape Bio, Spruce Biosciences and Tioma Therapeutics. Previously, he was a board member of Cytochroma, HemoFocus, Neurokey and Orphazyme. In 2004, Peter co-founded Curalogic A/S, served as CEO until 2009 and took the company public in 2006. From 2000-2004, he was Chief Operating Officer of 7TM Pharma A/S, which he also co-founded. Previously, he worked for 11 years with NeuroSearch A/S, where he was responsible for all aspects of pre-clinical and clinical drug development. Peter holds a Ph.D. in medicinal chemistry from the Royal Danish School of Pharmacy. He has also been a post doc with Yale University's department of organic chemistry.

http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1_uEwZB6HmF8Y-GoeWGrHvynXUKsoSrsU0nwnKV8xCh-7lkLTVF3jVmjJarxl5BNBPTWwKfLECT2TnfouEhIUc8YOjx6Ipkp7QsCWPKQGoka9s7Jo0Fbc2blgfvO96TaZKyoYqajQauVk8UL5fRCPSVhgYHrfSx5Fe5WUgBEUZba4c0g=&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re_w==&ch=U55Vv8DstNx5o7FGRomWV_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==

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JLABS, Wednesday Morning, Oct. 4, 2017

Topic: "Let's Talk Legal Workshop | Protecting and Leveraging your Intellectual Property"
Speakers: Stuart Wilks | Assistant General Council, Johnson & Johnson,Megan R. Baca | Partner, Ropes & Gray and Melissa S. Rones | Partner , Ropes & Gray
Date and Time: Wednesday, October 4, 2017 from 10:30 AM to 1:00 PM (PDT)
Agenda:
10:30 AM - 11:00 AM | Registration & Networking
11:00 AM - 11:45 AM | Presentation
11:45 AM - 12:00 PM | Q&A
12:00 PM - 1:00 PM | Lunch and Networking
1:00 PM | Program Close
Location: JLABS @ SSF, 329 Oyster Point Blvd. Floor 3, South San Francisco, CA 94080
Fees:
$25 | General Public
$10 | Student/Academic
$35 | At the door
** Please note: fees do not go to the presenting lawyers, they cover only a portion of catering and event costs
Register at https://www.eventbrite.com/e/lets-talk-legal-workshop-protecting-and-leveraging-your-intellectual-property-tickets-35577694843?aff=weekly

Join us for "Let's Talk Legal Workshop I Protecting your Intellectual Property" – a workshop designed to help entrepreneurs demystify the legal landscape and fill in the blanks. The program is interactive and informal so bring your questions with you!

Program Overview
Science and technology both play a key part in your life sciences business. You have technology or information that no one else does. You want to share the secret sauce, but only on your terms. How do you make this happen?

This practical session will focus on how intellectual property (IP) can be used in your life science business, including:
Identifying the types of IP relevant to your business
Protecting and managing IP of your business
Leveraging your IP through collaborations and licensing
What investors look for in IP due diligence and how to avoid common pitfalls

This event is brought to you by Johnson & Johnson's law department working in close partnership with Ropes & Gray LLP, a preeminent global law firm with deep expertise in life sciences. The lawyers presenting these workshops have extensive experience working with life sciences companies ranging from very early-stage ventures through to global companies.

Speaker Bios

Stuart Wilks | Assistant General Counsel, Johnson & Johnson
Stuart is Assistant General Counsel at Johnson & Johnson resident at the Johnson & Johnson Innovation Center in Menlo, Park California. In this role, Stuart provides general legal advice to the Innovation Center team in California, participates directly as legal counsel in Innovation Center transactions, and/or coordinates with colleagues in the Johnson & Johnson Law Department to support Innovation Center matters.

During his nearly fifteen years with Johnson & Johnson, in addition to the California Innovation Center, Stuart has supported a diverse group of Johnson & Johnson operating companies and units, such as Alza, BabyCenter, Janssen Health Innovation, Janssen Research & Development, Janssen Supply Chain, Johnson & Johnson Innovation – JJDC, Inc., Noramco, and Scios in a broad range of business and contractual matters. Prior to joining Johnson & Johnson, Stuart was corporate counsel at Scios, Inc. in Fremont, California, corporate counsel at COR Therapeutics, Inc. in South San Francisco, California and an associate in the corporate and life sciences practice groups of the Palo Alto office of Cooley LLP.

Megan R. Baca | Partner, Ropes & Gray
Megan is a partner in Ropes & Gray's intellectual property transactions, life sciences, and technology, media & telecommunications practice groups. Megan advises public and private companies, investors, and universities in strategic transactions where technology or IP assets are the key drivers. These transactions include technology licensing and transfer, development collaborations, joint ventures, and arrangements for supply, distribution, promotion, outsourcing, and other strategic relationships. Megan also represents private equity firms and other companies in technology-focused mergers and acquisitions, and represents venture-backed companies in financings and ongoing matters. Megan also advises clients on data use, digital health, social media, and advertising issues.

With a background in computer science, Megan works with companies in a broad range of industries including technology, software, advertising, gaming, branded products, media, pharmaceutical, biotechnology, medical device, and finance.

Connect with Megan: Connect on LinkedIn

Melissa S. Rones | Partner, Ropes & Gray
Melissa counsels life sciences clients on a wide range of intellectual property issues, including patent portfolio strategy and life cycle management, licensing and monetization strategy, and the risks associated with third party intellectual property. She also performs due diligence investigations and advises clients on strengths, weaknesses, and opportunities to mitigate risk and remedy issues related to intellectual property in the context of a range of transactions, including private financings and capital markets transactions, license agreements, collaborations, joint ventures, and mergers and acquisitions.

Prior to joining the firm, Melissa completed a Ph.D. in cell and developmental biology from Harvard University. Her graduate work focused on examining signaling events involved during the patterning of tissues to generate complex organs and helped define specific roles for Notch signaling in both cardiogenesis and nephrogenesis.
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QB3 SBIR Workshop At Berkeley, Starting Oct. 4, 2017

Description
"The Art, Science, and Politics of Writing a Successful SBIR Proposal"
Schedule (all classes are on Wednesdays. Location is 177 Stanley Hall, UC Berkeley)
Oct. 4, 2 - 5 pm
Oct. 11, 2 - 5 pm
Oct. 25, 2 - 5 pm
Nov. 1, 2 - 5 pm
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 December 2017 NSF deadline, the January 5 2018 NIH deadline, or later deadlines. 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.
Details and registration at https://www.eventbrite.com/e/qb3-sbir-workshop-at-berkeley-fall-2017-tickets-37132418062?aff=erellivmlt
Fee Structure
General Admission: $750
Startup in a Box members: $100

Note: Startup in a Box fee for UC founder: $250, non-UC founder: $350. More information on the program is availablehere.

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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PBSS, Wednesday, Oct. 11, 2017

Minisymposium Topic: "Immunogenicity of Biologic Therapeutics"
Speakers: TBA
Organizers:
Date and Time: 10/11/2017, 8:45-17:00
Registration fee (USD): Regular: $195; Academic: $125; Students & Unemployed: $35;
Location: Crowne Plaza, Foster City, CA
Major Sponsor:
Vendor show vendors registered to date: (2)AIT Bioscience; Science Exchange
Registration: http://www.PBSS.org
Registration deadline:10/9/2017 (it will close sooner if the seating cap is reached)

About the Topic

Outline:

Introduction to Immunogenicity
Overview of the Immune System
Innate vs Adaptive
Cellular vs Humoral
Antibody classes
Types of Cellular Immune Responses
Immunogenicity Risk Assessment
Route of administration
Correlation of ADAs with safety, PK, efficacy
Association of ADAs with genotype, protein function, CRIM status
Clinical Implications
The Complement System and Pathways
Immune Complexes
Hypersensitivity Reactions
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PBSS, Tuesday Morning, Oct. 24, 2017

PBSS-San Francisco Bay Workshop "Good Laboratory Practices (GLPs): Fundamentals, Regulatory Trends and Best Practices"
Speaker: Lisa Helmonds, Vice President, MWA Consulting, Inc.
Date and Time: Tuesday, 10/24/2017, 8:30-12:30
8:45-9 am PBSS Welcome & Workshop Overview
9-9:30 am History of GLP Regulations
9:30-9:45 am Areas Covered by GLPs
9:45-10 am Key Definitions
10-10:15 am Break & Vendor Show
10:15-11:15 am Important Aspects of GLPs

- Subpart A: General Provisions
- Subpart B: Organization and Personnel
- Subparts C & D: Facilities and Equipment
- Subpart E: Testing Facilities Operations
- Subpart F: Test and Control Articles
- Subpart G: Protocol
- Subpart J: Records and Reports
- Subpart K: Disqualification

11:15 -11:30 am FDA Actions and Misconduct
11:30-12 pm Q & A
Registration fee (US$): Regular: $125; Academic: $75; For unemployed or students: $25; For major-sponsor rep (incl lunch): $0; For vendor-show reps: $25; For others, details available upon online login.
Location: SF Bay Area: Foster City Crowne Plaza
Registration deadline: 10/20/2017 (it will close sooner if the seating cap is reached)
Details and registration at http://www.pbss.org/aspx/eventInfo.aspx?eID=546

Workshop Topic
This workshop will include a discussion on the history of Good Laboratory Practices (GLP) regulations, the importance of the regulations, key definitions, areas covered by the GLPs, a review of the regulations, examples of misconduct and, potential FDA actions. After completing this workshop, participants should be able to understand the origin, purpose, and expectations of the GLP regulations.

Speaker Bio
Lisa Helmonds has over 30 years of experience in Manufacturing and Quality Assurance in the pharmaceutical, biotechnology and medical device industries. She has extensive GXP knowledge, has held positions as a manufacturing chemist and QA manager/director as an FTE and as a consultant with several startups and large companies such as Syva, Syntex, Roche Bioscience, Alza, Shire, Gilead, along with many others and she understands the challenges facing the industry. She holds a BS in Zoology and minor in Chemistry from the University of Rhode Island and an MBA from Santa Clara University. She is currently Vice President of MWA Consulting, Inc. where she provides the highest quality of consulting services to MWA clients.

support@PBSS.org
www.PBSS.org
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JLABS, Tuesday Morning, Oct. 24, 2017

Topic: "Excited About Your Story: Tell it Like a TED Pro
Date and Time: Tuesday Morning, October 24, 2017
9:30am |
Location: JLABS @ SSF, 329 Oyster Point Blvd, 3rd Floor, South San Francisco, CA
Fees
$35 | General Public
$20 | Student/Academic

Program overview
Great leaders tell great stories. Stories have the power to touch people's deepest emotions. And emotions are the wellspring of loyalty, trust, co-operation and action. You will succeed more often, more quickly and more completely as you master the power of stories. And, as a human being, you are a natural born storyteller with full access and rights to the best that story has to offer. In this excellent session, you will learn how to unleash your own innate powers and have others be "Excited About Your Story."
Details and registration at
http://r20.rs6.net/tn.jsp?f=0014Vr7KTt4HYkT3ScXChii0DLMeywI5tsIFrkMhpfXuJjexrFY8BrCk_kKNhlCbbCnfqMPvnCMxDxk1rOIjtf9lfmMagWmdpvkbdiM-XnTE3uTdHlZi3uuAR91jppKvEnmh3XzmhIYHlg0TtoT5BRGJDZO-4dbC8kb6iLGvPmpwzttgCxDrACTSf3vN0NsCYl6&c=7IK8faFTT1QFfDnYW1Mb11LS7Gp0-hKzr_4fgrwwOiV46KxBRm-4HA==&ch=oY7vJfNs5oKhHHtZVSAzOqpbDDvrpkwodW-igkScTVk8Y4RKQ0x-jw==

Topic Description
Topics covered in the session will include:
Why the ability to tell a compelling story is essential for startups
5 elements of a strategic story
Strategies for pitching in front of various audiences: clinical vs. non-clinical vs. investors
How to embed storytelling into all aspects of your business and pitches
Join John Bates, TED speaker, Leadership & Communications Coach, and storyteller extraordinaire. My, does he have some stories to tell you!

Speaker Bio

John Bates has spoken, hosted, and coached for over 30 different worldwide TED and TEDx events. His group trainings are world famous and executives from companies like Johnson & Johnson Innovation Labs, Accenture, NASA, IBM, and more, recommend him to their colleagues as the best communications and leadership trainer working today. Long ago 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, has been instrumental in raising hundreds of millions of dollars in Venture Capital and has always earned the title Chief Evangelist. 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 current Internet powerhouse Goldstar.com. John is a co-author of World Class Speaking in Action, an Amazon best-seller, and loves making a difference for those who make a difference.