Audrey's Life Science Meeting Picks for August 13, 2017 – Oct. 2017
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Bio2Device Group, Tuesday Morning, August 15, 2017

Topic: "Japan's Rapidly Aging Society: How to Innovate for This"
Date and Time: Tuesday, August 15, 2017, 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
Speaker: Fumiaki Ikeno, M.D., Program Director (U.S.) Japan Biodesign, Stanford Biodesign Medical Director/Research Associate, Experimental Interventional Laboratory, Division of Cardiology, Stanford University
No registration or fees for morning meetings.

Event Details:
Japan is facing a rapidly aging population and is currently the country aging at the highest rate in the world. At the same time, the younger population is becoming smaller year by year due to low birth rate. We have to think of some smart way to maintain health of this aging society. "To predict the future is to create it." From my experiences in Silicon Valley, I would like to introduce the process of medical device innovation and also some other technologies for achieving this.

Speaker Bio
Dr. Ikeno is currently serving as Program Director (U.S.) of Japan Biodesign at Stanford Biodesign. Previously he served as the Global PDP Liaison at Stanford Biodesign, and in 2013 he accepted a position as Chief Medical Officer at Medventure Partners, Inc. In 2009 he began serving as a member of the Working Group 1 Committee in the Japan-U.S. "Harmonization By Doing" (HBD) Pilot Program Initiative. After completing a Postdoctoral Research Fellowship in 2004 at the Stanford Division of Cardiovascular Medicine, he was appointed Medical Director/Research Associate in Experimental Interventional Cardiology at Stanford. His education includes an M.D. received at Jichi Medical University in Japan, after which he passed his National Board Examination. This was followed by a Residency at Shizuoka Prefecture General Hospital, and a Clinical Fellowship in Cardiology at Yaizu Municipal Hospital in Yaizu, Japan. He subsequently served for four years on the Medical Staff in Internal Medicine at Sakuma Hospital in Shizuoka, Japan.
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Syntex Syva Alumni Summer Picnic , Thursday Evening, August 17, 2017

Event: Annual Picnic for former employees of Syntex and Syva
Date and Time: Thursday, August 17, 2017, 4-8 pm
Buffet from 5:30 to 7:00 PM
Raffle at 7:00 PM
Location: Cuesta Park Group Picnic Area accessed on Castro Street driveway and parking lot near intersection of Cuesta and Grant Rd.
Cost: $25 per person (includes food and drinks)
Download event calendar and registration form at
http://www.syntexsyvaalumni.org/picnicflyer17.pdf
Send registration and check for $25 made out to SSAA as follows:
SYNTEX SYVA ALUMNI ASSOCIATION, P. O. BOX 1857, LOS ALTOS, CA 94023-1857
The deadline for reservations into the mailbox is Thursday, August 10, 2017
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Bio2Device Group, Tuesday Morning, Aug. 22, 2017

Topic: Fist Assist: The first renal failure medical wearable
Speaker: Tej M. Singh, MD, MBA, CEO and President, Fist Assist Devices, LLC
Date and Time: Tuesday, Aug. 22, 2017 - 8:30am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There are no fees and no required registration for morning meetings.
Topic Description
Dr. Tej Singh, the creator of the Fist Assist device, will share his novel, external device to help mature fistulas for hemodialysis. The presentation will focus on the clinical problem, basic science research and development of the Fist Assist device as a simple, cost-saving renal failure wearable.
Speaker Bio
Dr. Tej Singh has researched arterial hemodynamics in response to increased and decreased flow over the last 30 years. He is boarded in both General and Vascular Surgery through the American Board of Surgery and over the last 15 years has been Founder and Chief of Vascular Surgery for 3 large multi-disciplinary vascular programs in Silicon Valley: Palo Alto Medical Foundation, El Camino Hospital, and Santa Clara Valley Medical Center. Throughout his career Dr. Singh has developed a vast knowledge of renal failure and vascular access procedures. Most recently he has also been focusing on his startup, Fist Assist Devices, LLC, to help improve fistula maturation via non-invasive external methods revolving around novel intellectual property on vein maturation.
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ASQ Biomedical Discussion Group, Wednesday Evening, Aug. 23, 2017

Topic: "Data Integrity – Beyond "Good Documentation Practices" A small company view to creating a culture of compliance"
Speaker: George J. Marcel, Director of Quality Assurance at TheraNova LLC
Date and Time: Wednesday, Aug. 23, 2017, 7:00 pm to 9:00 pm
Location: Stellartech in Milpitas, CA
To register and full details - go to: ncdgaug2017.eventbrite.com

Topic Description
21CFR11.3(b5) requires that "the integrity of the data can be verified".
21CFR820 has 10 references to "data"
21CFR820.180 requires data "made readily available…legible...stored to minimize deterioration and loss…backed up".
ISO 13485(2016) has new requirements for "data analysis", to "protect" "confidential…information"
Data, whether captured in paper or electronic format, is the basis for product assumptions and decisions from the manufacturing floor to the boardroom to the offices of regulators and notified bodies. Medical Device companies, especially small start-ups, often limit discussions of data integrity to "Good Documentation Practices". GDP is a set of widely accepted, unwritten rules, dealing with the collection of data during design and manufacture of a product, mostly focused on paper based systems, where "data integrity" refers to the completeness, consistency, and accuracy of all data. Validations of electronic systems that collect and store data and management of paper-based systems can be daunting to resource-constrained companies. Before the protocols, quality professionals should start with a "culture of compliance" based on ensuring a common understanding of the significance of managing and maintaining product and design data at all stages of the product lifecycle.

Speaker Bio

Brian McCollum, Vice President, Quality, Apama Medical, BS Aerospace Engineering, MBA, CQA, CQE. Brian has over 20 years experience in Medical Device Quality Management ranging from large multinational commercial organizations to small pre-clinical start-ups. Brian was one of the long-term members of the Northern California Biomedical Discussion Group in the years 1998-2010, and served in various roles, including Communications, and Arrangements.
https://www.eventbrite.com/e/data-integrity-beyond-good-documentation-pr...
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Bio2Device Group, Tuesday Morning, Aug. 29, 2017

Topic: "Specifics of Pharmaceutical development for global clinical trials"
Speaker: Chitra Sharma, Founder, gCompliance, Inc.
Date and Time: Tuesday, Aug. 29, 2017 – 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There is no registration or cost for morning meetings.

Event Description
The globalization of clinical trials has been a regulatory strategy to increase patient participation, awareness in the medical community, cost savings and a single point of data collection to get global approvals from regulators worldwide. The semantics dictate that these applications themselves be split into NDA, MAA and such but the data can be utilized to foster drug approvals for the entire population, all at once.
Execution of any regulatory strategy or one that involves multiple countries i.e. multiple regulators does bring in many challenges and opportunities to evolve currently run practices or processes. Even simple events like enrolment rate or the number of patients per country is data. Manufacturing is complex for these trials. Packaging and labeling has a whole different set of rules that are needed to be processes along the trial. This talk will attempt to touch upon the various factors that one needs to be taking into account and attributes of drug development that need to be understood for execution of a global clinical trial successfully. Actual cases without identity disclosure to be discussed.

Speaker Bio
Chitra Sharma has over 15 years of experience in pharmaceutical development of small and large molecules. Chitra founded gCompliance, Inc., with a vision to execute projects in pharmaceutical development to commercialization. She takes on projects that have process scale up / optimization needs and engages from start to finish i.e., from development to commercial product launch readiness. Her consulting firm strengthens internal resources in client organizations and provides product specific needs to create complete product portfolios. gCompliance, Inc. has clients ranging from virtual biotech to large pharmaceutical firms. Chitra previously worked at Vivus, Genentech, Cor Therapeutics, Roche BioSciences and Boehringer Ingelheim. She holds a MS in Pharmaceutical Sciences from the University of Connecticut, Storrs, CT.

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Bio2Device Group, Tuesday Morning, Sept. 5, 2017

Topic: "The Journey to Mars: The Next Giant Leap for All Mankind"
Speaker: Elizabeth Keller, Science Manager, Space Biology Project, NASA
Date and Time: Tuesday, Sept. 5, 2017 – 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There is no registration or cost for morning meetings.

Topic Description

Since we first landed on the moon in 1969, the world has been captivated by the exploration of this last frontier and the promising new discoveries that await. Sending robotic probes and roving satellites into space has captured fascinating new finds that delight and inspire, but nothing quite captures the imagination as the notion of sending humans into the inhospitable vastness of space. The Journey to Mars is an enormous undertaking that involves thousands of experts in science, engineering, and technology working collaboratively to identify and solve seemingly impossible challenges, configure, test and build pioneering new technologies, and eventually take a giant calculated leap of faith into the Great Beyond. Many doubt it will be possible, many more question the value of trying, but those of us involved in the effort are thrilled with the opportunity to tread where no one has gone before and create advances in medicine and technology that will benefit all of humanity."

Speaker Bio
Elizabeth has had a colorful career working as a scientist, in technology, as a business owner, and an award-winning author. She started her career in science as a graduate student at Ames Research Center working in Aerospace Human Factors conducting research on astronauts working in low earth orbit. She soon after went to work in the Space Life Sciences Payloads Office where she worked supporting science payload operations on the Space Shuttle. She is the creator, author and producer of ExtremeScience.com, an online destination that established a new standard for approachable and engaging science education. Her success with Extreme Science got her noticed by the National Geographic Society, which later offered her a book contract. She's been back at Ames Research Center since 2012 as a Senior Scientist supporting the Space Biology project office, where she is a science manager supporting strategic planning for life sciences research in space. Elizabeth enjoys engaging the public on NASA's missions and inspiring the next generation.

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JLABS, Thursday Morning, Sept. 7, 2017

Event: Meet with...NCI and NHLBI
Speakers:
Kurt Marek, Ph.D. | Deputy Director, National Heart, Lung, and Blood Institute read bio»
Greg Evans Ph.D. | Supervisory HSA and Team Leader, Cancer Imaging/ Biology/ Control , SBIR Development Center, National Cancer Institute read bio»
Date and Time: Friday September 8th, 10:00AM to 4:00PM | 1-on-1 meetings *30 minutes each
Agenda:
Thursday September 7th
10:00AM | Registration and Networking
10:30 AM | Presentation and Q&A
11:45 AM | Networking Lunch
1:00-5:15 PM | One-on-One Meeting*
*Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due August 17th. Apply Here.
Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor, South San Francisco, CA
Fees:
Presentation
$25 | General Public
$35 | Onsite

Includes presentation, Q&A, and lunch. All attendees must pay this fee, regardless of one-on-one meeting status. Pre-registration to attend the presentation, Q&A, and lunch will remain open until noon on September 6th (or sold out).

One-on-One Meeting
FREE | Application
FREE | Accepted Companies
Apply to meet one-on-one with representatives from NCI and NHLBI Your application will be reviewed and you will be notified of acceptance on Thursday, August 24th 2017. 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-withnci-and-nhlbi-tickets-35582432012?aff=weekly

Event Description
The National Cancer Institute Small Business Innovation Research (NCI SBIR) is returning to the Bay Area. This year they will be joined by representatives from the National Heart, Lung, and Blood Institute(NHLBI), Division of Cardiovascular Sciences. The joint presentation will be held on September 7th with 1-on-1* meetings, for accepted companies, scheduled on September 7th and 8th.

*Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due by August 18th. Apply Here.

On Thursday, September 7th, Greg Evans, NCI SBIR and Kurt Marek, NHLBI will highlight funding opportunities and other resources for startups in the cancer and cardiovascular sciences.

Program Overview:
NCI and NHLBI Present Current and New Funding Opportunities
The representatives will discuss the exciting new non-dilutive targeted funding opportunities in cancer and cardiovascular focused technology development. They will explain the application and review process at the NIH to help small businesses submit stronger applications. The team will discuss key requirements, timelines, important contacts as well as the best practices for successful applications. Additionally, the presentation will touch on the I-Corps at NIH program and other initiatives to facilitate the success of SBIR companies. .
Following the presentation on Thursday afternoon, September 7th and Friday September 8th, the NCI and NHLBI will meet with selected companies for 1-on-1 meetings. To be considered for a one-on-one meeting, please apply here, by August 17th.
Kurt Marek, Ph.D. | Deputy Director, National Institutes of Health/NHLBI Office of Translational Alliances and Coordination
Office of Translational Alliances and Coordination Dr. Marek is the Deputy Director of the Office of Translational Alliances and Coordination (OTAC) at the National Heart, Lung, and Blood Institute (NHLBI). OTAC is charged with developing trans-NHLBI programs to foster the translation of early stage discoveries into commercial products. The Office coordinates the NIH Centers of Accelerated Innovations and the Institute's small business program. Dr. Marek is the Program Director for the NIH Research and Commercialization Hubs program and oversees the Institute's efforts to support small businesses performing research and development on innovative biomedical products and to facilitate partnerships between small businesses, investors and strategic partners. Dr. Marek has received numerous awards over the

course of his government service, and has served as an organizer of and speaker at national conferences.
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Greg Evans Ph.D. | Supervisory HSA and Team Leader, Cancer Imaging/ Biology/ Control , SBIR Development Center, National Cancer Institute
Dr. Greg Evans is a molecular biologist/biochemist by training who has worked at NIH for 26 years. He has 19 years experience as an NIH Program Director managing early-stage, bench-to-bedside (Translation I) research projects. Since June of 2008, Dr. Evans has served as a Team Leader and Program Director within the National Cancer Institute (NCI) SBIR Development Center, an office created in 2007 to centralize management of all NCI SBIR/STTR funding, to increase marketing efforts in the small business and biotechnology investment communities, and to raise the bar for commercialization of cancer-related products and services by small businesses. As a Team Leader and Supervisor, Dr. Evans leads a group of 5 Program Directors responsible for small business projects in the imaging, cancer biology, and behavioral medicine areas. As a Program Director, he is responsible for a technically diverse portfolio that includes projects focused on imaging devices, drug development, diagnostics, basic cancer biology, and population-based cancer prevention.

Prior to coming to the NCI SDC, Dr. Evans worked from 1998-2008 as a Program Director for research on hemoglobin disorders within the Blood Division of the National Heart, Lung, and Blood Institute (NHLBI) at NIH. In that capacity, he managed for five years the Comprehensive Sickle Cell Centers Clinical Trials Consortium, a 20-institution academic collaborative group funded to develop and implement collaborative Phase I-II clinical studies in sickle cell disease. Dr. Evans played a lead role coordinating and facilitating the development of 7 collaborative clinical studies. He also managed a joint NHLBI-Pfizer project for a Phase II/III contract clinical trial of Sildenafil (Viagra) for pulmonary hypertension secondary to sickle cell disease. In that effort, he played a key role in the development of an Independent Research Grant Agreement with Pfizer that covered donation of the study medication and matched placebo, as well as Pfizer's special requirements for adverse event reporting. In addition, while with NHLBI Dr. Evans managed three projects under the NIH RAID (Rapid Access to Intervention Development) program, all of which involved both academic and commercial stakeholders. Lastly, he served on NHLBI-wide programs focused on translational research (e.g. Programs of Excellence in Gene Therapy, 2000-2005; Programs for Genomic Applications, 2000-2008).

Prior to moving to NHLBI to take a research administration position, Dr. Evans was a Senior Staff Fellow from 1995-1998 at the National Human Genome Research Institute at NIH, where he studied and published on gene therapy for the blood clotting disorder Hemophilia A. Before that, he served from 1991-1995 as a American Cancer Society postdoctoral fellow, and an intramural research and training fellow at the NCI, where he studied and published on MDR1-mediated multidrug resistance in cancer.

Dr. Evans received a Ph.D. in Biochemistry in 1991 from the UCLA, and a B.A. in Biochemistry from UC Berkeley in 1982. He is a native of Santa Rosa, California.

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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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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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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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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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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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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.