Audrey's Life Science Meeting Picks for June 26, 2017 – Oct. 2017
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Bio2Device Group, Tuesday Morning, June 27, 2017

Topic: "Recent Advances in Addressing Recruitment, Enrollment and Retention of Women In Cardiovascular Medical Device Clinical Trials"
Speaker: Tami Shipman , Director of Clinical Affairs, Vascular Dynamics
Date and Time: Tuesday, June 27, 2017, 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There is no cost or registration required for morning meetings

Topic Description
While there has been some progress, gender bias and under-representation of women in cardiovascular medical device trials continues to be a challenging issue. The reasons for this under-representation are multi-factorial and include physician screening of trial subjects, gender gaps in the diagnosis of women with cardiovascular disease, misconceptions on the incidence of cardiovascular disease in women and trial designs that fail to appropriately capture women. The medical device industry has recently partnered with the FDA , advocacy groups, and physicians to develop strategies to address this long-standing issue. An update on the progress to date and current thinking on this topic will be discussed.

Speaker Bio
Tamara (Tami) Shipman is an RN and clinical researcher with extensive experience from both the Investigator and Sponsor side for over 25 years. She has participated in and managed numerous studies in cardiology and electrophysiology. Tami is the Director of Clinical at Vascular Dynamics and is currently active in the Clinical Trials Group and the Ad Hoc Women's Group at AdvaMed, a trade organization for the medical device industry.
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PBSS MiniSymposium, Wednesday, June 28, 2017

Event: "Immuno-Oncology: Advances in Translating from Bench to Clinic"
Organizers: Snow Ge (Nektar), Deborah Charych (Nektar), Wenfeng Xu (Genentech)
Date and Time: Wednesday, June 28, 2017, 8:30-17:00
Location: Crowne Plaza, Foster City, CA
Registration fee (USD): Regular: $195; Academic: $125; Students & Unemployed: $35;
Registration: http://www.PBSS.org
Registration deadline:6/27/2017 (it will close sooner if the seating cap is reached)

Tentative List of Speakers/topics:
Willem Overwijk (MDAnderson): Cancer Vaccines in the era of checkpoint blockade
Lewis (Rusty) Williams (Five Prime Therapeutics)
Speaker from Nektar
Brian Wong (FLX Bio)
Juan Jaen (Founder and President of Arcus Biosciences and PACT Pharma): "Small Molecules, Antibodies, and Cell-based Therapies in the Fight Against Cancer"
Tara Arvedson (Amgen) - "Blincyto and BiTE® Antibody Platform for Cancer Therapy"
Jason DeVoss (Amgen) - T-VEC and oncolytic therapy
Lelia Delamarre (Genentech) - Personalized Cancer Vaccine
Cheng Liu (Eureka CEO) - CAR-T
Ravi Majeti (Stanford) - Pre-Clinical Development of a Humanized Anti-CD47 Antibody

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ASQ Biomedical Division, Wednesday Evening, June 28, 2017

Event: Roundtable - Update on Software Regulations: FDA's 21st Century Cures Act, and the EU's Medical Device Regulation (MDR)
Speaker: Tim Stein
Moderator: Barry Craner, former Vice President of Quality and Regulatory, Stellartech Research Corporation, FASQ.
Date and Time: Wednesday, June 28, 2017, 7:00 -9:00 pm
Location: Stellartech Research Corporation 560 Cottonwood Drive Milpitas, CA 95035
Registration Link: ncdgjun2017.eventbrite.com ONLY Check or Credit Card accepted at door
Questions: For information about this session, contact Barry Craner (CranerASQ@gmail.com)
Formal discussion and questions will end between 8:30 - 8:45 pm to allow time for networking after the roundtable presentation.
Materials: Handouts provided. Please limit distribution to immediate personal professional use only.

Event Description

"The 21st Century Cures Act," 2016, codifies the FDA's positions on when software is a medical device, and when it isn't, that have been published in guidance documents. This presentation will review Section 3060, "Clarifying Medical Software Regulation." In addition, Tim will review the more extensive requirements for software in the MRD. The playing field and rules are changing in the domestic and international arenas! Learn about the changes in time to meet the new requirements as part of your development process, and not after development is complete. This is the best chance this year to learn what those new rules are.
Presentation outline:
When software is considered to be a medical device by the FDA
MDR new requirements for software with respect to: compatibility, interoperability, IT environment, repeatability, reliability and performance, mobile platforms, IT security, verification and validation, UDI, labeling, and classification.

Speaker Bio

Tim founded Business Performance Associates, Inc., a consulting firm located in Cupertino, California in 1994. Tim has consulted with over 130 companies in software development regulatory compliance, quality systems, software submissions, and software validation. Tim has helped numerous companies achieve compliance with IEC 62304 through the development of procedures, audits, gap analyses, training and implementation support.
Tim was the Director of Software Validation and Quality Assurance at Genomic Health. He is the author of the: The Computer System Risk Management and Validation Lifecycle, 2006. Tim has made over 40 presentations at professional meetings and conferences and as well as webinars. He is a past chair of the Northern California Biomedical Discussion Group, and an ASQ Fellow.

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BioScience Forum, Wednesday Evening, June 28, 2017

Topic: "Turning Tumor Mutations into Personalized Cancer Therapies"
Speaker: Karin Jooss, Ph.D., Executive Vice President of Research and Chief Scientific Office, Gritstone Oncology, Inc.
Date and Time: Wednesday, June 28, 2017 6:00 PM - 9:00 PM
6 pm - 7 pm networking
7 pm - 8 pm dinner
8 pm - 9 pm presentation
Location: The Holiday Inn, 275 S Airport Blvd, South San Francisco, California 94080, USA
Event Registration ($3 service fee will apply)
Pre-Registration
$50.00
On-Site Registration
$60.00
Pre-Registration ends Monday, June 26th, at 9 pm
Cash or check accepted on the day of the event
$10 discount for full-time students
Details and registration at http://biosf.org/

Or you can pay with a check made out to "BioScience Forum" and sent to:
BioScience Forum
1442A Walnut Street, #308
Berkeley, CA 94709-1405
Please do not mail checks later than Thursday, June 22nd
If paying with check, do not complete online registration with Cvent

Topic Description
Genetic instability is a hallmark of cancer and, consequently, each cancer patient's tumor genome (i.e., the DNA of the tumor cell) is different from their normal cells. This DNA difference leads to the creation of new protein antigens that are specific to tumor cells. These new antigens, known as tumor-specific neo-antigens (TSNAs), can be recognized and targeted by the immune system. This inherent vulnerability of tumor cells is being exploited at Gritstone by identifying a patient's unique set of tumor antigens and deploying them in a therapeutic immunization strategy. Current public approaches to TSNA prediction from sequence data alone lack specificity and sensitivity.

To build a best-in-class TSNA prediction model, large numbers of human tumors were collected (initial focus on NSCLC) and characterized by next-generation DNA sequencing and RNA analysis, together with HLA immuno-peptidomics to measure presented peptides. These data were used to build a neural network-based TSNA prediction model that performs with high positive predictive value and offers broad HLA allelic coverage. The selected TSNA will be delivered in the context of a potent personalized cancer vaccine. The proximal goal of a highly potent TSNA specific cancer vaccine is the induction of hi-titer, polyfunctional and durable CD4+ and CD8+ T-cell responses. This has been demonstrated in humans with viral vector based vaccines such as replication deficient adenoviral vectors delivering viral antigens.

Gritstone is pairing an adenoviral prime vaccination with an RNA based boost vaccination to keep the TSNA specific T-cells at high titers long term. The personalized vaccine is delivered in combination with immune checkpoint blockade, to keep TSNA-induced T-cells active in the immunosuppressive tumor

microenvironment. Data will be presented supporting this novel approach to TSNA identification through integrated tumor tissue analysis and deep learning, in the context of the potential impact for the development of personalized cancer immunotherapy.

Speaker Bio
Karin Jooss serves as Chief Scientific Officer of Gritstone Oncology. Dr. Jooss joined Gritstone from Pfizer, where she served as head of Cancer Immunotherapeutics within the Vaccine Immunotherapeutics department for seven years. While at Pfizer, she built and led immuno-oncology teams, was a member of the Vaccine Immunotherapeutics leadership team and served as the head of the Immunophamacology team. Her duties included overseeing the assessment of all cancer vaccine in-licensing opportunities, and developing and launching Pfizer's first clinical cancer vaccine program deploying a variety of vaccine platforms and immune modulators to build a multi-component vaccine-based immunotherapy regimen. Prior to joining Pfizer, Jooss served as vice president of Research at Cell Genesys, Inc. where she oversaw all research activities related to the company's cancer vaccine and oncolytic virotherapy programs.

Jooss received her Ph.D. in Molecular Biology from the University of Marburg in Germany and performed postgraduate work in gene therapy and immunology at the University of Pennsylvania. She is on the editorial board of Molecular Therapy and Journal of Gene Medicine and is a member of the immunology and educational committee for the American Society of Gene Therapy as well as the Industry Task Force of the Society for Immunotherapy of Cancer (SITC).

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MedTech Frontiers, Thursday Evening, July 6, 2017

Topic: "AI in the MedTech and Healthcare Enterprise"
Speaker: Stephen Pratt, CEO, Noodle.ai
Date and Time: Thursday, July 6, 2017, 6:00 - 9:00 pm, presentation begins at 6:45 pm
Location: Triple Ring Technologies, 39655 Eureka Drive, Newark, CA
Cost: The seminar is free, but registration is required for planning purposes
Register at
https://events.r20.constantcontact.com/register/eventReg?oeidk=a07ee7uwrh30e8c9a8e&oseq=&c=&ch=

Seminar Description
AI is moving from consumer applications to the enterprise and is already affecting all parts of operations-from the customer to the product to the enterprise. Stephen Pratt, the CEO of Noodle.ai and former head of Watson for IBM GBS, presents a shareholder value perspective on why enterprise artificial intelligence (eAI) will be the single largest competitive differentiator in business over the next five years-and what you can do to end up on top.

We'll discuss:
- A framework for why AI is key to creating shareholder value
- How to determine where to start and how to progress (with case studies)
- How to manage spread of AI in your enterprise (with lessons from the past)
- How to ensure proper adoption of AI solutions (implementing organizational change)

- A future vision of the algorithmic enterprise

Stephen will draw from his extensive expertise as a cutting-edge technologist, global strategist, innovator, and internationally renowned executive.

Speaker Bio

Stephen is an instigator, agitator, and pioneer in creating world-class technology services organizations. He has spent his career building innovative ways to create value for the world's most important organizations. Prior to Noodle, he was responsible for all Watson implementations worldwide for IBM Global Business Services. He also was the founder and CEO of Infosys Consulting, a Senior Partner at Deloitte Consulting, and a technology and strategy consultant at Booz, Allen & Hamilton. He twice has been selected as one of the top 25 consultants in the world by Consulting Magazine. He has Bachelors and Masters degrees in Electrical Engineering from Northwestern University and The George Washington University focused on Satellite Communications. For fun, Steve plays competitive tennis, races sailboats, and formerly was a crazed rugby player. He enjoys playing acoustic guitar for his children (not ready for prime time).

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Palo Alto AWIS, Thursday, July 6, 2017

Event: Here's the scoop: AWIS Palo Alto Ice Cream Social andSURPAS Happy Hour
Date and Time: Thursday Early Evening, July 6th, 5-7 PM
Location: Dean's Lawn (locatedat the corner of Campus Drive West and Roth Way, next to the James H. Clark Centeron Stanford Campus)
Parking:Please park at Roth Way Garage, at the corner of Campus Drive West and Roth Way. Additional parking availableat Via Ortega Garage, at the corner of Via Ortega and Panama Street.
Free
Register at http://www.brownpapertickets.com/event/3017910

Event Topic

Do you know what the benefits of volunteering are?

1. Learn and develop new skills
2. Be part of our community
3. Get motivated and feel a sense of accomplishments
4. Boost your career by meeting other successful people
5. Find new personal interests and experiences

Join us for an Ice Cream Social and learn about Volunteering with AWIS Palo Alto to support the growth and development of Women in STEM

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Bio2Device Group, Tuesday Evening, July 11, 2017

Topic: "Pharma and Digital Health"
Speaker: Yan Chow, MD. Medical Director for Digital Health in the Medical Sciences Early Development, Amgen

Date and Time: Tuesday, July 11, 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 www.Bio2DeviceGroup.org

Topic Description
In today's turbulent healthcare landscape, every stakeholder from care providers to payers to patients is on new ground. The life sciences industry is an important part of this ecosystem in generating new therapeutic agents for cancer, heart disease, and many other serious conditions. This talk will discuss why business as usual will not be possible for pharma/biotech companies in the future, and the critical role that digital technologies will play. The objective will be to better understand the factors motivating pharma today.

Speaker Bio
Yan Chow, MD, MBA is Medical Director for Digital Health in the Medical Sciences Early Development group at Amgen, the world's largest independent biotechnology company, where he studies the use of wearables, devices, mobile technology, and analytics in clinical trials and programs. Amgen's areas of focus include oncology, cardiovascular disease, inflammation, bone disease, nephrology, and neuroscience.
Before that, he was Chief Innovation Officer at LongView Technology Solutions, a federal health IT services contractor.
Prior to LongView, Dr. Chow was national Medical Director of the Innovation & Advanced Technology Group (IAT) at Kaiser Permanente. IAT assessed over 2,000 emerging health IT technologies, promoted innovation through an employee innovation grant program, and worked with the Garfield Innovation Center, an award-winning care delivery simulation laboratory.
Dr. Chow has founded and advised a number of startups. He has 3 U.S. patents and has been an invited speaker at industry conferences. Dr. Chow earned an A.B. from Harvard University, his M.D. from UC San Diego, and his MBA in 2005 from UC Berkeley.
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East Bay AWIS and GGSC, Wednesday Evening, July 12, 2017

Topic: "How to Accomplish More by Doing Less"
Speaker: Christine Carter, Ph.D. A sociologist and senior fellow at UC Berkeley's Greater Good Science Center,
Date and Time: Wednesday, July 12th 2017, 5:30 p.m. - 8:30 p.m.
Event Schedule:
5:30-7:00pm -- Dinner and networking (meet local AWIS and GGSC members) -- room 2063 VLSB
7:00pm-8:30pm -- Dr. Christine Carter "How to Accomplish More by Doing less" -- lecture hall 2060 VLSB
(dinner and a book included -- talk starts at 7pm)
Location: UC Berkeley, Room 2063, Valley Life Sciences Building, Berkeley, CA 94720
Event price includes dinner and a paperback copy of Christine Carter's book "The Sweet Spot."
Register at http://ebawispresents.brownpapertickets.com/

Pre-purchase your ticket for a discounted rate (students and members for $20, general admission for $25) -- ticket price increases to $35 at the door.

It's summer at the university, so parking is easy! Berkeley city street parking is free after 6pm. This event is easy to get to from Downtown Berkeley BART. For transportation options, see http://pt.berkeley.edu

Event Description A lovely evening that includes a networking dinner, an interactive talk, and a copy of Christine Carter's book, "The Sweet Spot." This event is co-hosted by East Bay AWIS and the UC Berkeley Greater Good Science Center.

The UC Berkeley Greater Good Science Center (GGSC) and the East Bay Chapter of the Association for Women in Science (AWIS) co-host a delightful evening with Christine Carter. Join us for dinner, mingling and an engaging talk. Registration price includes dinner and a paperback copy of "The Sweet Spot."

Learn how to increase your ability to get things done and enjoy the life you've worked so hard to create.

Carter is a sought-after keynote speaker, author and executive coach. Presenting the latest research on productivity and elite performance, Christine Carter, PhD, demonstrates a sweet paradox: by doing less we can actually accomplish more. Using surprising science and lively anecdotal evidence, Carter offers a practical game plan for mitigating stress by working with our brains innate hardwiring to increase happiness, balance, and ultimately, success.

She'll discuss:
-What happens to our brain when we tip into overwhelm
-Why some digital habits make us less productive (even as they make us *feel* like we are working harder)
-Easy-to-implement strategies to harness the power of your unconscious mind

Speaker Bio:
A sociologist and senior fellow at UC Berkeley's Greater Good Science Center, Christine Carter, Ph.D., is the author of "The Sweet Spot: How to Accomplish More by Doing Less" (2015) and "Raising Happiness" (2011). Drawing on the latest scientific research on positivity, productivity, and elite performance, Carter demonstrates a sweet paradox: by doing less we can actually accomplish more.

Dr. Christine Carter writes an award-winning blog, which is frequently syndicated by the Huffington Post, PsychologyToday.com, Medium.com, and several other websites.

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Bio2Device Group, Tuesday Morning, July 18, 2017

Topic: “Cyber-security in Medical Device Industry”
Speaker: Rollie Olson, Systems Engineer, Varian Medical
Date and Time: Tuesday, July 18, 2017, 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There is no charge or registration for morning meetings.

Topic Description
Today's interconnected world has brought numerous advances in health care and with it increased risk. Connected medical devices are susceptible to multiple vulnerabilities from cyber attacks; the most catastrophic of which is death to those who the intended use of the

device is to treat. Pressure is on medical device developers to identify these vulnerabilities and implement safeguards. This presentation will explore some of the vulnerabilities and the challenges faced by medical device developers to eliminate or protect the patients for harm.

Speaker Bio
Rollie Olson is a Systems Engineer with Varian Medical Systems responsible for risk management. He has over 20 years of experience as a systems engineer in both defense and medical systems. He worked on the signal processing of the advanced synthetic aperture radar for the US Air Force SR-71 Blackbird, the intel processing for the U-2 Dragonlady, and the command and control for the digitized battlefield for the US Army M2A3 Bradley Fighting Vehicle, before transitioning to work at Varian on radiotherapy systems to eliminate the fear of cancer.
I am the past President for SFBAC of INCOSE and we have been striving to get more participation in our monthly meetings. With that aim, I would like to know how you learned of our meeting and your input on the experience with the remote connection.

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PBSS, Friday Midday, July 28, 2017

Event PBSS-San Francisco Bay Seminar Luncheon
Topic: "Developing Relevant Human Neural In Vitro Assays for CNS Safety Assessment and Drug Discovery: Challenges and Perspectives"
Date and Time: 7/28/2017, 11:00-13:30
Speakers: Jonathan Davila PhD., CEO / Co-Founder, NeuCyte Inc.
Food: $0
Location: SF Bay Area: Foster City Crowne Plaza
Registration: http://www.pbss.org/aspx/eventInfo.aspx?eID=541
Registration deadline: 7/26/2017 (it will close sooner if the seating cap is reached)
Topic Description
High attrition rates of novel CNS drugs indicate that current preclinical testing is largely insufficient to support development of urgently needed therapies for millions of patients. iPSC technology and rapidly improving methods to generate functional human tissues offer new opportunities to develop novel disease relevant cell-based assays. This approach comes with high expectations but also presents many challenges. NeuCyte develops human neural in vitro platforms uniquely suited for assessing relevant complex electrophysiology readouts allowing for more reliable prediction of drug efficacy, CNS safety, and identification of neurotoxicity. In this presentation, we will provide an overview of critical considerations that need to be taken when developing human iPSC derived neural in vitro assays.

support@PBSS.org
www.PBSS.org
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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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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.