Audrey's Life Science Meeting Picks for July16 2017 – Oct. 2017
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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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HBA San Francisco Bay, Wednesday Evening, July 19, 2017

Topic: "Uncover and Embrace Your Super Powers"
Speaker: Denice Torres, Former chief strategy and business transformation officer, Johnson & Johnson
Date and Time: Wednesday, 19 July, 5:30PM - 8:00PM PST
Agenda
5:30 - 6:30 PM Networking and reception
6:30 - 6:45 PM Welcome remarks by Carol Wells, HBA
6:45 - 7:30 PM Keynote with Denise Torres
7:30 - 8:00 PM Facilitated Q&A
Location: Genentech, 330 DNA Way, Builiding 33,South San Francisco,CA 94080

Special instructions: Please bring a valid government-issued ID card and Genentech employees please bring employee badge. Although last-minute walk in registration is welcome, attendees who are able to register online will have expedited security processing.

Location: Genentech, 330 DNA Way, Builiding 33, South San Francisco, CA 94080 United States

Topic Description
As a senior executive at Johnson & Johnson, Denice Torres (2015 HBA Woman of the Year) led one of the most significant turnarounds in the company's history. As president of McNeil Consumer Healthcare, she led the remediation of quality, manufacturing, customer, brand and cultural issues. Denice also served as chief strategy and business transformation officer for J&J Medical Devices. Prior to J&J, Denice held senior leadership roles at Eli Lilly. She has an MBA from the University of Michigan, a JD from Indiana University and a BS from Ball State. In 2016, Denice was the sole recipient of the J&J HONOR award for her work in diversity and inclusion. She was also named by J&J and Working Mother as Working Mother of the Year.
Join other San Francisco Bay area women in networking and listening to Denice's inspiring advice for finding and leveraging your own super powers.

Learning objectives
1. Recommit to your career goals
2. Learn to embrace uncertainty and the ups and downs of careers
3. Begin to identify and let go of boulders that weigh you down

Registration information
Event is open to: HBA members and nonmembers
Online registration deadline: 17 July 2017
Onsite (walk-in) registration: Is allowed

Cancellations/refunds
Is this event refundable? Yes
If yes, requests must be submitted in writing to events@hbanet.org by 17 July 2017; no refunds are available after this date.

Registration information
The registration button at the bottom of the page will not show if online registration has closed or if the event has reached capacity. If you are a guest and the registration button is not showing, it may be that this is a member-only event. Read more about the benefits of membership or contact us about membership.
The HBA will make reasonable modifications to policies and programs to ensure that people with special needs have an equal opportunity to enjoy all of its programs. Contact us if you require special accommodations for this event.
See details and registration information at
https://my.hbanet.org/MyHBA/EventDetails.aspx?MeetingID=49C2B39D-894C-E711-B5CE-0050569C00A7

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BioScience Forum, Wednesday Evening, July 19, 2017

Topic: "Gaining Momentum in Gene Therapy for Rare Diseases and Ocular Diseases"
Speaker: Amber Salzman, Ph.D., President and Chief Executive Officer, Adverum Biotechnologies
Date and time: Wednesday, July 19th, 2017

6:00 PM - networking
7:00 PM - dinner
8:00 PM - presentation
Location: The Holiday Inn, 275 S Airport Blvd, South San Francisco, CA 94080
Price:
$50 before 9PM, Monday, July 17th
$60 on-site
$40 full-time students pre-registration
$50 full-time students on-site
$3 service fee will be added to the pre-registration price
Details and registration at http://www.biosf.org/

Topic Description
With the discovery of novel adeno-associated virus (AAV) serotypes and the engineering of novel AAV capsids, gene therapy technology has made considerable progress in efficiently targeting certain tissues such as the liver and retina. In addition, gene therapy approaches to treat diseases are particularly attractive when standard of care consists of repeated frequent injections of recombinant proteins to prevent symptoms.

Adverum is developing novel therapies utilizing recent AAV technology for diseases with well established therapeutic pathways. Alpha-1 antitrypsin deficiency (A1AT) and Hereditary angioedema (HAE) are two diseases where patient's hepatocytes do not express inhibitors of two distinct types of proteases which left uncontrolled are responsible for the development of the disease. AAV.rh10 is highly efficient at transferring DNA to hepatocytes with long lasting potential, so a single administration of an AAV vector with the appropriate transgene has the potential to treat the disease in a well tolerated way.

Wet Age related Macular Degeneration (wAMD) is currently treated with monthly or bimonthly intravitreally administered anti-VEGF recombinant proteins. Adverum's proprietary AAV.7m8 vector has been shown in non human primates to transfer DNA to retinal tissue when delivered intravitreally, therefore providing the potential to treat wAMD with a single administration with a long lasting therapeutic effect. Preclinical proof of concept for each of these three diseases has been demonstrated. ADVM-043, ADVM-053, and ADVM-022 are now moving towards the clinic.

Speaker Bio
Amber Salzman, Ph.D. was appointed president and chief executive officer of Adverum in October 2016 after joining the company earlier in the year as president and chief operating officer after the merger of Annapurna Therapeutics with Avalanche Biotechnologies. Dr. Salzman was the president and chief executive officer of Annapurna Therapeutics between 2012 and 2016. Dr. Salzman has served in leadership roles at large pharmaceutical companies, small pharmaceutical companies, and in the rare disease community, including her role as chief executive officer of Cardiokine Inc. prior to its acquisition by Cornerstone Therapeutics, Inc. in 2011. Dr. Salzman had a 25-year career at GlaxoSmtihKline plc, where she served as a member of the R&D executive team, leading drug development projects and clinical trials in more than 30,000 patients worldwide.

Since 2001, Dr. Salzman has served as president of the Stop ALD Foundation, a patient-advocacy group seeking improvements in treatments for patients with adrenoleukodystrophy (ALD), and played a key role in developing a lentiviral gene therapy treatment for this disease.

Dr. Salzman received a B.A. in Computer Science from Temple University and a Ph.D. in Mathematics from Bryn Mawr College.

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WIB-San Francisco, Thursday Evening, July 20, 2017

Event: "East Bay Ice Cream Social and Networking"
Date and Time: July 20, 2017, 5:30 – 8:00 pm
Location:Emery Pharma, 100 Atlantic Ave, #110, Alameda, CA 94501
Details and registration at http://womeninbio.org/eventdetails.aspx?EventId=31656

Event Description
Have a sweet tooth? Loving the warmer weather? Come celebrate summer and network with amazing Women In Bio at our ice cream social, being held at Emery Pharma in Alameda! Loard's ice cream will be on hand to help you build the perfect ice cream sundae.

Registration Deadline
July 19, 2017

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Bio2Device, Tuesday Morning, July 25, 2017

Topic: New Method and Catheter to Treat Patients Experiencing Kidney Failure
Speaker: Ronald C. Allen, PhD, CEO and President, Chrysalis Medical
Date and Time: Tuesday, July 25, 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There is no cost nor registration required for morning meetings.

Event Description
Ron will present and discuss a newly developed method to treat Chronic Kidney Failure developed by Chrysalis Medical.
Chrysalis Medical, Inc. is a developer, manufacturer, and marketer of breakthrough, disruptive medical technologies. In concert with university research facilities, physicians, entrepreneurs, and engineers, Chrysalis reviews and evaluates promising medical technologies for their potential positive impact on current patient treatment modalities. Technologies that are disruptive (offer superior treatment outcomes, eliminate the need for current devices, and/or are significantly cost efficient, are potential Chrysalis projects.

Speaker Bio
Ron has 37 years of management experience in the medical device industry and has held executive management positions with Stryker, Boston Scientific, and Cohort Medical. Ron has extensive experience in the fields of Orthopedics, Cardiology, Neurosurgery, and Vascular Surgery. He is a graduate of the University of California, received his MBA from Golden Gate University, and his doctorate from the American Academy of Neurological and Orthopedic Surgeons.

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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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Bio2Device Group, Tuesday Evening, August 8, 2017

Topic: "Drug Safety and Pharmacovigilance, the Past, Present and Future
Event Date:
Speaker: Anupam Agarwal, MD, MPH, Head of Clinical Safety and Pharmacovigilance, Zogenix, Inc.
Date and Time: Tuesday Evening, August 8, 2017 - 6:00pm
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
This presentation will cover:
-How pharmaceutical companies evaluate the safety of a drug during preclinical and phase I, II and III trials
-How drug safety is evaluated after a drug is marketed (post-marketing phase)
-What methods were utilized in the past?

-What lies in the future; how machine learning and AI will revolutionize this field

Speaker Bio
Anupam Agarwal, MD, MPH is the head of the clinical safety and pharmacovigilance at Zogenix, Inc, Emeryville, CA. Dr. Agrawal is a cardiologist with over two decades of experience in treating patients and clinical research in academia. He holds a medical degree from the GSVM Medical College, Kanpur, India and a Master of Public Health degree from the Harvard School of Public Health. Dr. Agarwal has been working in the pharmaceutical

industry for more than 11 years; in the past he worked at GSK, Pfizer, and Gilead. He is also a board member of San Mateo Health Foundation and Harvard Club of San Francisco.
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WIB-San Francisco, Wednesday Evening, August 9, 2017

Topic: "Exploring Themes in Translational Research: An Essential Element of Therapeutic Development"
The panel includes our moderator, **Maureen Cronin**, Ph.D. (Executive Director of Informatics and Knowledge Utilization at Celgene), and panelists:

- **Oranee Daniels**, M.D. (CMO at Antiva Bioscience)
- **Ellen Filvaroff**, Ph.D. (Senior Director in Translational Development at Celgene)
- **Nancy K. Pryer**, Ph.D. (Vice President of Translational Sciences at BioMarin)
- **Victoria Sung**, Ph.D. (Director of Translational Development at Celgene)

Date and Time: Wednesday, August 9, 2017, 5:00 p.m. – 8:30 p.m. PST
Location: Nektar Therapeutics, 455 Mission Bay Boulevard South, San Francisco, CA 94158
Learn details and register at http://womeninbio.org/eventdetails.aspx?EventId=31688

Topic Description
WIB-San Francisco Bay Area will host a panel discussion at Nektar Therapeutics featuring women at the forefront of translational research. Transferring insights from bench to bedside is a critical component of the biopharmaceutical industry's mission, and this event is focused on demystifying translational research in the context of a lively, interactive discussion. Our expert panelists will shed light on this underexplored process, drawing from their own experiences in therapeutic areas ranging from infectious disease to cancer to rare diseases.

These veteran researchers will share insights and describe the paths that led them to success in translational research. Please join us for what promises to be an exciting evening of discussion and networking!

Registration Deadline
August 7, 2017

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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.