

**Audrey's Life Science Meeting Picks for July 9, 2017 – Oct. 2017  
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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](http://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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**11th Annual AWIS-NCC, Saturday, August 12, 2017**

Event: Potluck Picnic

Date and Time: Saturday, August 12, 2017, noon – 3 pm

Location: Beresford Park (Area #3), 2720 Alameda de las Pulgas, San Mateo

Cost: Free, but please bring a side dish or dessert to share with six to eight people.

Free

Register via Brown Paper Tickets by August 8 at

<http://www.brownpapertickets.com/event/2966926>

#### Event Description

Join us for our summer family picnic! This is a great opportunity to meet members of all the Northern California Chapters (NCC) of AWIS (Palo Alto, San Francisco, East Bay, and Sacramento Valley) in a casual setting. We will be grilling delicious tri tip and will provide drinks and games.

This event is open to all scientists and non-scientists. You do not need to be an AWIS member to attend. Families welcome! Beresford Park has paths for walking, grassy and picnic areas, several playgrounds, skate park, bocce ball courts as well as tennis and basketball courts nearby.

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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, Building 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, Building 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](mailto: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 GlaxoSmithKline 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/asp/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](mailto:support@PBSS.org)  
[www.PBSS.org](http://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 Pharmacochimistry 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 Pharmacocyclics), 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\\_FnZwyd7pQI87Jxs2qahhnJkceE1Kkgy6fxExtreaKo x4rcqv8OpC3JT24izkU2u3oyD7n9ut2Vg06FOSYMUz4xfKCfZky3xUIN6MYktmk07ZSjQtk aZ2vj2Wlxplu6fTZvrHcQ3zKJP\\_bUxMWjGTLJcEK76qxH1vEhHdB7Sr\\_ iyPOS-8Suak-Ub8bNULkb16heaZmjRswHZZ5kSeqNMgr5dmJ&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re\\_w==&ch=U55Vv8DstNx5o7FGRomWV\\_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==](http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1_uEwZB6HmF8Y-GoeWGrHvynXUOlzxCtra1HLXnby75b_FnZwyd7pQI87Jxs2qahhnJkceE1Kkgy6fxExtreaKo x4rcqv8OpC3JT24izkU2u3oyD7n9ut2Vg06FOSYMUz4xfKCfZky3xUIN6MYktmk07ZSjQtk aZ2vj2Wlxplu6fTZvrHcQ3zKJP_bUxMWjGTLJcEK76qxH1vEhHdB7Sr_ iyPOS-8Suak-Ub8bNULkb16heaZmjRswHZZ5kSeqNMgr5dmJ&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re_w==&ch=U55Vv8DstNx5o7FGRomWV_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==)  
[http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1\\_uEwZB6HmF8Y-GoeWGrHvynXUPZldooFkfgQ\\_eQ6kik64Gop6fbw1r5yKjdxJ59BRGI7pPdRjgRd81yJWU4AYdds3ozLR8TS84dM0aWOAZgI1hE\\_1USOZFgJg8pomY0nh0nZq6YthoTWGa5PGaqbH-RHadUy\\_m\\_E1rox&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re\\_w==&ch=U55Vv8DstNx5o7FGRomWV\\_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==](http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1_uEwZB6HmF8Y-GoeWGrHvynXUPZldooFkfgQ_eQ6kik64Gop6fbw1r5yKjdxJ59BRGI7pPdRjgRd81yJWU4AYdds3ozLR8TS84dM0aWOAZgI1hE_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-7lkLTVF3jVmJJarxI5BNBPTWwKfLECT2TnfouEhIUc8YOjx6Ipkp7QsCWPKQGoka9s7Jo0Fbc2blgfvO96TaZKyoYqajQauVk8UL5fRCPSVhgYHrfSx5Fe5WUgBEUZba4c0g=&c=JtsptXrUwFmB37fCrXetXYPhPr7DN7FNady1nHNPV8zYr7xUn7re\\_w==&ch=U55Vv8DstNx5o7FGRomWV\\_HPpAbP8-KV66O2ZcdAWJ-81SBNB0EBjw==](http://r20.rs6.net/tn.jsp?f=001m98NlmtMh6VKoS8LXPqNtVKF3hY1_uEwZB6HmF8Y-GoeWGrHvynXUKsoSrsU0nwnKV8xCh-7lkLTVF3jVmJJarxI5BNBPTWwKfLECT2TnfouEhIUc8YOjx6Ipkp7QsCWPKQGoka9s7Jo0Fbc2blgfvO96TaZKyoYqajQauVk8UL5fRCPSVhgYHrfSx5Fe5WUgBEUZba4c0g=&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/asp/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](mailto:support@PBSS.org)  
[www.PBSS.org](http://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\\_kKNhICbbCnfqMPvnCMxDxk1rOIjtf9IfmMagWmdpvkbdIM-XnTE3uTdHIZi3uuAR91jppKvEnmh3XzmmhIYHlg0TtoT5BRGJDZO-4dbC8kb6iLGvPmpwzttgCxDrACTSf3vN0NsCYI6&c=7IK8faFTT1QFfDnYW1Mb11LS7Gp0-hKzr\\_4fgrwwOiV46KxBRm-4HA==&ch=oY7vJfNs5oKhHHtZVSAzOqpbDDvrpkwodW-igkScTVk8Y4RKQ0x-jw==](http://r20.rs6.net/tn.jsp?f=0014Vr7KTt4HYkT3ScXChii0DLMeywI5tsIFrkMhpfXuJjexrFY8BrCk_kKNhICbbCnfqMPvnCMxDxk1rOIjtf9IfmMagWmdpvkbdIM-XnTE3uTdHIZi3uuAR91jppKvEnmh3XzmmhIYHlg0TtoT5BRGJDZO-4dbC8kb6iLGvPmpwzttgCxDrACTSf3vN0NsCYI6&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.