

Audrey's Life Science Meeting Picks for Oct. 23, 2016 – Dec. 2016
Complimentary Service of AudreysNetwork.com
Oct. 23, 2016

Bio2Device Group, Tuesday Morning, Oct. 25, 2016

Topic: "Medical Device Business Development: Partnering with Larger Companies - Benefits, Challenges, and Strategies."

Speaker: Karun Shimoga, PhD, MBA, Business Development Executive

Date and Time: Tuesday, Oct. 25, 2016, 8:30 am

Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale

There is no fee nor registration required for morning meetings.

Event Description

Partnering with larger companies is often the quickest way for startups and small companies to realize their full market potential. However, creating a partnership with the right company, which is also a dominant player in the specific market, is a daunting task due to a number of challenges involved and lack of a guarantee of eventual success.

Despite these challenges numerous small companies have successfully partnered with larger ones to achieve their goals. Analyses of such examples show that a set of key parameters are essential for successful partnerships with larger players.

In this presentation, my goal is to explore these key parameters and answer the following questions using medtech case studies:

- What are the internal motivations of small companies to partner with large ones?
- What are the challenges of doing so and what are the mitigations?
- What are the key factors for partnership success with larger companies?
- How do you create a partnership strategy specific to your needs?

Event Speaker Bio:

Speaker Bio

Karun Shimoga, PhD, MBA, is a Business Development (BD) professional in the medtech industry with 10+ years of experience in the Valley. His current passion is to help companies achieve growth, nationally or globally, by creating and implementing inorganic BD strategies such as alliances, JVs, collaborations, acquisitions, distribution and IP licensing with strategically chosen partner companies. In the past, he has worked at Applied Imaging (now part of Molecular Devices), Accuray (CyberKnife-fame), RoboDoc (now part of Think Surgical), GMV (Spain), Symbionix (now part of 3D Systems) and Fuse Medical. In his spare times, he enjoys writing blogs about business development strategies for the medtech industry.

CSLA, Tuesday, Oct. 25, 2016

Event: Evening With Thought Leaders

Date and Time: Tuesday, Oct. 25, 2016, 6:00 pm

Location: Sheraton Palo Alto 625 El Camino Real Palo Alto, CA 94301

Panel Discussions

Location: Sheraton Palo Alto, 625 El Camino Real, Palo Alto, CA 94301

Questions? Please contact registration@califesciences.org.

Event Description

CLSA members have come to rely on this program as a way to stay current on trends in the biomedical industry and get fresh insights from key opinion leaders on policy, economics, business and society. Past speakers have included Former Secretary of State and Distinguished Fellow at the Hoover Institution, Stanford University, George P. Schultz, the Dean of Scripps School of Medicine and author of The Creative Destruction of Medicine, Dr. Eric Topol, and the Distinguished Professor, from the UC San Diego Stem Cell program, Dr. Larry Goldstein.

HBA, Tuesday Evening, Oct. 25, 2016

Event: "Chocolate, Wine and Networking!"

Date and Time: Tuesday, October 25, 2016, 5:00 p.m. – 8:00 p.m. PST

5:00 p.m. – 6:00 p.m. Check-in and light snacks

6:00 p.m. – 6:45 p.m. Chocolate tasting and wine pairing

6:45 p.m. – 8:00 p.m. Networking

Location: Foley & Lardner LLP, 975 Page Mill Road, Palo Alto, CA 94304-1013

Registration Deadline

October 24, 2016

Walk-Ins Accepted?

Walk-ins are not accepted – be sure to register early!

Pricing Information

Members: \$35

Non-Members: \$55

Registration Deadline

October 24, 2016

Special Pricing for Guests

When registering, members are also allowed 1 guest at member pricing

Parking Information

Free parking is available.

Details and registration at <http://www.womeninbio.org/eventdetails.aspx?EventId=30066>

Description

Our Fall networking event is even sweeter this year! We are bringing back The Chocolate Garage to delight us with their delicious artisan chocolate bars while we socialize with each other. This event will provide an opportunity to reconnect with colleagues, bring a friend who has expressed interest in joining, or check out WIB for the first time.

Light snacks will be provided.

Learn more and register for this event.

HBA Webinar, Wednesday Evening, Oct. 26, 2016

Topic: "Advanced Practice Social Media"

Featured Speakers:

Lea Carey

Global market strategy lead, Symplur

Julie Kelly

Vice president, business development, Ashfield, par of UDG Healthcare plc

Kelley Connors

President, KC Health, and global chair, HBA Digital Innovators

Jessica Pfenning

Enterprise digital leader, AstraZeneca, global chair, Digital Innovators, HBA

In this hour, attendees will get a deeper understanding of the implications of their social media profile, habits and behaviors, and how those concepts can affect and improve both career and business opportunities. Also discussed will be selected HBA profiles from members who are experts in leveraging their digital persona, and we'll try to answer an increasingly modern day, technological issue: How do you meet peers and increase your professional network online knowing that you may never meet them in person?

Date and Time: Wednesday, Oct. 26, 2016, 8:00 – 9:00 pm ET; 5:00 – 6:00 pm PT

8:00 – 8:03 PM ET Introduction

8:03 – 8:43 PM ET Presentation

8:43 – 8:58 PM ET Q&A

8:58 – 9:00 PM ET Close

Fees: Registration information

Event is open to: HBA members and nonmembers

Online registration available until one hour before the live broadcast begins.

Member rate:\$25; Nonmember rate:\$35

Register at <https://my.hbanet.org/MyHBA/EventDetails.aspx?MeetingID=956055F2-D875-E6...>

Webinar description

Advanced Practice Social Media, presented by the HBA Digital Innovators affinity group, will offer more insights and information for the sophisticated social media user.

In this hour, attendees will get a deeper understanding of the implications of their social media profile, habits and behaviors, and how those concepts can affect and improve both career and business opportunities. Also discussed will be selected HBA profiles from members who are experts in leveraging their digital persona, and we'll try to answer an increasingly modern day, technological issue: How do you meet peers and increase your professional network online knowing that you may never meet them in person?

Lea Carey, global market strategy lead, Symplur and HBA global board member, will lead this highly engaging and informative session that is meant to serve as first part of a two-part webinar series. Lea will be joined by Julie Kelly, global chair, HBA Digital Innovators, and Kelley Connors, president, KC Health, and global chair, HBA Digital Innovators, and Jessica Pfenning, enterprise digital leader, global commercial, AstraZeneca, and global chair, HBA Digital Innovators. The first, beginner to intermediate level webinar, How To Leverage Social Media to Ignite Your Personal and Professional Success, will take place on Wednesday, October 5 from 8:00 to 9:00 PM ET.

Learning objectives

1. Build upon current levels of social media presence.
 2. Assess business opportunity implications of social media profile, habits and behaviors
- *****

Palo Alto AWIS, Wednesday Evening, Oct. 26, 2016

Topic: "Nonprofit Organizations"

Speaker: Amy Peabody, Executive Director of the Los Altos Educational Foundation

Date and Time: Wednesday, October 26th, 7:00 -9:00 pm

7:00-7:30: Networking dinner

7:30-7:45: Announcements

7:45-9:00: Workshop

Stanford Fire Truck House

Palo Alto

7- 9 PM

Location: Stanford Fire Truck House, 433 Santa Teresa Street, Stanford, Palo Alto, CA 94304

Fees:

Palo Alto AWIS Members: FREE

Pre-registered Non-Members: \$15

Fee at Door: \$25

Register at <http://www.brownpapertickets.com/event/2698228>

Topic Description

Switching careers can be daunting especially when you don't know how your skills fit. Are you looking to transition into the non-profit sector? Learn more about getting involved in philanthropy and serving our community?

AWIS Palo Alto has invited Amy Peabody, Executive Director of the Los Altos Educational Foundation, to highlight how a range of diverse skills and expertise can benefit the non-profit world and talk about the challenges and rewards of a career in the non-profit industry.

Speaker Bio

Amy Peabody is the Executive Director of the Los Altos Educational Foundation with a strong commitment to building long-term relationships with people who have a passion for empowering public education. After spending years with The Gap's International Division in Hong Kong and San Francisco in Training & Development, she moved into the non-profit sector as a professional fundraiser focusing on Individual Giving.

JLABS, Thursday Afternoon, Oct. 27, 2016

Topic: "Accelerating Drug Discovery: Business Models for the Computational Pharmaceutical Company"

Speakers:

Steve Quake | Co-Founder, Agenovenir read bio»

Matt Ocko | Co-Managing Partner & Co-Founder, DCVC read bio»

Max Hodak | CEO & Co-Founder, Transcriptic read bio»

Anthony Rowe | Director & Business Technology Leader for Immunology Therapeutic Area, Janssen Human Microbiome Institute, Janssen Immunoscience & Janssen Prevention Centre

Date and Time: Thursday, October 27, 2016 from 3:00 PM to 6:30 PM (PDT)

Agenda:

3:00pm | Registration Opens and Networking

3:30pm | Introductions

3:35pm | Panel

5:00pm | Networking Reception

6:30pm | Program Close

Fees:

\$25 | General Public

\$35 | Onsite

Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Register at <http://www.eventbrite.com/e/accelerating-drug-discovery-business-models-for-the-computational-pharmaceutical-company-tickets-25860813389?aff=weekly>

Event Details

What does it take to become a successful entrepreneur in the drug development space? The landscape of life science startups is no longer composed solely of companies with small molecule or biologic assets, but also includes machine learning technologies, platforms, and software tools to accelerate the R&D process.

The current era of bioinformatics presents opportunities and challenges to both Big Pharma and entrepreneurs alike. Johnson & Johnson Innovation, JLABS in cooperation with Data Collective (DCVC), has assembled a distinguished panel of experts to address how computational prowess can advance pharmaceutical development and shorten time to market as well as the breadth of obstacles faced by modern bioinformatics.

Topics include:

What methods of partnering with Big Pharma have been most successful?

Which models (SaaS, milestone payments, royalties, etc.) work for which situations?

How are Software tools, bioinformatics, and data analyses increasing ROI for pharma R&D?

What is 'machine learning' and how can it be used to accelerate drug discovery?

Our panel discussions are candid, interactive and informal. We hope you walk away with insights and knowledge that can help advance your work or overcome roadblocks. A networking session will take place after the panel.

About Data Collective:

Data Collective is the first venture capital fund to invest exclusively in entrepreneurs building companies in the areas of Big Data and deep compute. Big Data companies capture, store, secure, transmit, transform, and analyze data for economic advantage, either with huge volumes (terabytes to exabytes), at tremendous speed (microseconds to seconds), or both.

According to a report by CB Insights, Data Collective was the most active investor in artificial intelligence startups in 2015.

Data Collective draws on a fund of just under \$1 billion and invests early in a startup's development, focusing on Series Seed, Series A, and some select growth-stage companies. The firm has a unique model composed of 50+ Equity Partners with diverse experience ranging from academics at Stanford University to technical experts at Google and Twitter. These leaders help diligence deals and provide technical and industry vertical expertise. Additionally, a small set of Operating Partners with entrepreneurial experience also work with the portfolio at a deeper level to guide them toward success. With these resources at their disposal, Data Collective companies successfully raise subsequent rounds of capital from Silicon Valley firms ~95% of the time.

Healthcare, the life sciences, and the pharmaceutical industry are natural fits for Big Data technologies, which offer the potential for accelerated drug development, early diagnosis of disease, identification of gaps in care, and other advancements to optimize the patient experience and produce much more targeted, safe, and effective medicines. As such, healthcare has been a specific area of focus for the firm, with roughly 25-30% of the portfolio developing solutions in multiple areas of the healthcare ecosystem.

Data Collective has offices in San Francisco and Palo Alto, California. The firm's two founding and co-Managing Partners, Zachary Bogue and Matt Ocko, are deeply technical and are seasoned entrepreneurs, inventors, and venture capitalists.

Speaker Bios

Steve Quake | Co-Founder, Agenovenir

Stephen Quake studied physics (BS 1991) and mathematics (MS 1991) at Stanford University, after which he earned a doctorate in theoretical physics from Oxford University (1994) as a Marshall Scholar. He then returned to Stanford University, where he spent two years as a postdoc in Steven Chu's group. Quake joined the faculty of the California Institute of Technology in 1996, where he rose through the ranks and was ultimately appointed the Thomas and Doris Everhart Professor of Applied Physics and Physics. At Caltech, Quake received "Career" and "First" awards from the National Science Foundation

and National Institutes of Health and was named a Packard Fellow. These awards supported a research program that began with single molecule biophysics and soon expanded to include the inventions of single molecule sequencing and microfluidic large scale integration, and their applications to biology and human health. He moved back to Stanford University in 2005 to help launch a new department in Bioengineering, where he is now the Lee Otterson Professor and an Investigator of the Howard Hughes Medical Institute. Quake's contributions to the development of new biotechnology at the interface between physics and biology have been widely recognized. Honors include the Human Frontiers of Science Nakasone Prize, the MIT-Lemelson Prize, the Raymond and Beverly Sackler International Prize in Biophysics, the American Society for Microbiology Promega Biotechnology Research Award, the Royal Society of Chemistry Publishing Pioneer of Miniaturization Award, and the NIH Director's Pioneer Award. He is an elected fellow of the American Academy of Arts and Sciences, the National Academy of Inventors, the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, the American Institute for Medical and Biological Engineering and of the American Physical Society.

^ Back to speakers' list ^

Matt Ocko | Co-Managing Partner & Co-Founder, Data Collective Venture Capital (DCVC)

Matt Ocko, co-Managing Partner and co-founder of Data Collective (DCVC), has three decades of experience as a technology entrepreneur and VC, in the US and globally. In addition to large IPO outcomes, many of Matt's prior investments were acquired to become core capabilities of companies like Illumina, Cisco, Google, IBM, Amazon, and Akamai. He was also an early investor in Facebook (FB), Uber, AngelList, and Zynga (ZNGA). Matt's current investments in next generation bioinformatics, genomics, synthetic biology, and robotics and AI to accelerate discoveries in these fields include Transcriptic, Atomwise, Nervana, Zymergen, Vicarious, 3Scan, Diassess, D-Wave, Rigetti Quantum Computing, Scaled Inference, Ginkgo Bioworks, and several other large-scale but stealth companies. Matt holds a degree in Physics from Yale University, and he is an inventor on over 40 granted or in-process patents in areas ranging from computer systems virtualization to fraud detection. He has been active on a pro-bono basis in helping develop China's venture capital and technology regulatory framework for two decades.

Connect with Matt: [Connect on LinkedIn](#)

Max Hodak | CEO & Co-Founder, Transcriptic

Transcriptic is a robotic cloud laboratory for biology. We design, build, own and operate an automated molecular and cell biology infrastructure from our facility in Menlo Park, CA that scientists access remotely via a web browser over the internet. Our customers range from academic labs at Stanford, Harvard, UCSF, UCSD and more, to startups, to large biopharma. Our mission is to enable anyone to start and run a biotech company from a coffee shop with only a laptop, and enable individual scientists to achieve scale never before possible. Max studied biomedical engineering at Duke and worked in a lab studying multiunit electrophysiology in rhesus monkeys to build brain-machine interfaces. He started a company called MyFit to help match students and colleges (which resulted in a two year detour from college through Silicon Valley) that was sold to Naviance. At Transcriptic he is working on building better tools for scientists.

Anthony Rowe, Ph.D. | Director & Business Technology Leader for Immunology Therapeutic Area, Janssen Human Microbiome Institute, Janssen Immunoscience & Janssen Prevention Centre

Dr Anthony Rowe is currently a Business Technology Leader at Janssen Research and Development where he is responsible for defining the digital strategy for the Janssen's Immunology Therapeutic Area, ImmunoScience Centre of Excellence, Disease Prevention

Centre and Human Microbiome Institute. He is passionate about Digital Health and Precision Medicine and its use in developing patient centric healthcare solutions. Prior to joining Janssen he was a Director of Product Management & Founding Member of InforSense Ltd an innovative big data analytics company that provided Pharmaceutical, Financial Services and Telecommunication customers access to machine learning and high performance computing technology. During his tenure at Inforsense he had roles leading Engineering, Marketing, Technical Sales as well as Product Management and was involved in both fund raising, growing the company from 7 to 150 people and a successful exit of the company. Dr Rowe holds a PhD in Computer Science and an MSc in Artificial Intelligence from Imperial College London and a BEng in Computer Systems Engineering from the University of Warwick.

PBSS, Friday, Oct. 28, 2016

Event: Minisymposium: Immuno-Oncology Biomarkers: Fundamentals, Technologies, and Applications in the Development of Cancer Therapeutics

Speakers: Scott Patterson PhD (Gilead), Terri McClanahan PhD (Merck), Rod Prell PhD (Genentech), Michael Angelo MD PhD (Stanford), Luciana Molinero PhD (Genentech), Take Ogawa (Second Genome) , Adil Daud MD (UCSF), Jeff Wallin PhD (Genentech), Jakob Dupont MD (Onco

Date and Time: Friday, October 28, 2016, 8:45-17:30

Agenda:

1. Biomarkers in cancer drug development - Scott Patterson, PhD
2. Maximizing the Benefit of Anti-PD1 Therapy - Terri McClanahan, PhD
3. Safety biomarker in pre-clinical models - Rod Prell, PhD
4. Analysis of the tumor microenvironment using high dimensional IHC and multiplexed ion beam imaging - Michael Angelo, PhD
5. Biomarker for breast cancer immunotherapy - Luciana Molinero, PhD
6. Microbiome for oncology drug discovery and development - Take Ogawa, PhD
7. Biomarker strategy for combination immunotherapy - Jeff Wallin, PhD
8. Novel T cell biomarkers for response to PD1 and PD1/CTLA4 immunotherapy - Adil Daud, MD
9. Biomarkers for novel Immune Checkpoint inhibitors - Jakob Dupont, MD

Registration fee (US\$): Minisymposium fee: \$195; For others, details available upon online login.

Location: Crowne Plaza, Foster City, CA

Registration: <http://www.PBSS.org>

Registration deadline: 10/26/2016 (it will close sooner if the seating cap is reached)

.....
Bio2Device Group, Tuesday Morning, Nov. 1, 2016

Topic: "Artificial Intelligence and Robotics for Chronic Disease Management"

Speaker: Cory Kidd, Founder and CEO, Catalia Health

Date and Time: Tuesday, Nov. 1, 2016, 8:30 am

Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale

There is no fee nor registration required for morning meeting.

Topic Description

Cory will speak about how and why Catalia Health's combination of hardware plus software creates effective patient engagement. The talk will include the background research, a

demonstration of the current technology, and an overview of the business and types of institutional healthcare customers that Catalia Health works with.

Speaker Bio

Dr. Cory Kidd is the founder and CEO of Catalia Health, a patient care management company. The company develops a hardware and software platform that uses a combination of psychology and artificial intelligence to engage patients through interactive conversations. These conversations happen through mobile, web, and interactive robotic interfaces; together these interfaces create a relationship that can reach patients at any time they need support. The data reported back through the system gives Catalia Health's customers valuable information to understand the daily activities and needs of their patients.

Dr. Kidd is a serial entrepreneur who has been working in healthcare technology for nearly two decades. He received his M.S. and Ph.D. at the MIT Media Lab in human-robot interaction and his B.S. in Computer Science at the Georgia Institute of Technology.

JLABS, Tuesday, Nov. 1, 2016

Topic: "Why Ya Buggin' Out? Regulatory Hurdles and Other Obstacles on the Path to Microbiome Market?"

Speakers:

Vern Norviel | Partner, Wilson Sonsini Goodrich & Rosati *read bio»*

KT Moortgat | CEO, Osel *read bio»*

Emma Taylor | Co-Founder & CEO, Naked Biome *read bio»*

[Moderator] Stephanie Robertson, PhD. | New Ventures, Johnson & Johnson (J&J) Innovation, California *read bio»*

Date and Time: Tuesday, Nov. 1, 2016

Agenda:

3:00 PM | Registration Opens and Networking

3:30 PM | Introductions

3:35 PM | Panel Presentation

5:00 PM | Networking Reception

6:00 PM | Program Close

Fees:

\$25 | General Public

\$35 | Onsite

Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Register at <https://www.eventbrite.com/e/why-ya-buggin-out-regulatory-hurdles-and-other-obstacles-on-the-path-to-microbiome-market-tickets-27716170813?aff=weekly>

Topic Description

Along with the enormous promise there's lot of uncharted territory in the world of Microbiome. Separating what we believe we know and what we truly know about the microbiome is essential to directing research and commercialization efforts. From scoping microbiome-based modalities and sourcing new platforms, to identifying regulatory strategies and insights there are a number of steps to development and commercialization from both the industry and startup point of view.

To explore the latest on this topic from the bench through clinical solutions Johnson

and Johnson Innovation gathered a panel of trailblazers for a look at case studies and historical learnings to help better understand if this is truly the golden age of microorganisms.

Topics covered:

- What are the regulatory hurdles? Will the European laws affect the US market?
- What are the concerns of the FDA and how are they viewing?
- What are the clinical hurdles to be overcome?.
- What is the consumer path for microbiome based solutions?
- How will products be marketing in terms of different regulations?
- What are the thoughts on the intellectual property challenges?
- How have startups thought about the regulatory approach and the IP concerns?

Speakers' Biographies:

Vern Norviel | Partner, Wilson Sonsini Goodrich & Rosati

Vern Norviel is a partner at Wilson Sonsini Goodrich & Rosati, where he leads the patents and innovation counseling practice. Vern has three decades of experience in formulating successful strategies for life science companies and the development of their IP programs. He represents a wide variety of companies, as well as venture capital firms, in areas such as therapeutics, diagnostics, nanotechnology, genomics, proteomics, and personalized medicine. In fact, Vern's interest in the field of personalized medicine prompted him to become the first attorney to have had his or her entire genome sequenced and made available in a public database. Before joining the firm in 2003, Vern was the general counsel and corporate secretary of Perlegen Sciences, Inc., a start-up biotechnology company that scans the entire human genome for important therapeutic and diagnostic products. Previously, as senior vice president and general counsel, he was an early employee of Affymetrix, the biotechnology company that pioneered and developed DNA chip technology. He also had been a partner at Townsend and Townsend and Crew in Palo Alto. During his career, Vern has authored or prosecuted more than 20 patents that have been litigated in the United States and abroad, and has overseen intellectual property lawsuits throughout the world. Vern currently serves as a member of Wilson Sonsini Goodrich & Rosati's Executive Committee and on the board of the WSGR Foundation. In addition, he is a lecturer in biotechnology law at UC Berkeley School of Law.

KT Moortgat, Ph.D. | Chief Executive Officer, Osel

KT Moortgat enables the successful translation of life science technologies to companies and products, through startup incubation, investment decision making, and corporate development. She is currently CEO of microbiome therapeutics company Osel Inc. Prior, she provided executive-level advisory services to companies focused on precision medicine, and microbiome and oncology therapeutics. Dr. Moortgat was a partner at the venture capital firm Mohr Davidow Ventures (MDV) for six years. Before this, she founded and directed of the hub of entrepreneurship at the University of California San Francisco and the QB3 Institute, which established a core of resources and services for healthcare entrepreneurs. Dr. Moortgat earned a Ph.D. at the University of California San Diego, and a BA from UC Berkeley. She is on the board of VentureWell. re capital and technology regulatory framework for two

decades.

Stephanie Robertson, PhD. | New Ventures, Johnson & Johnson (J&J) Innovation, California

Stephanie is part of the New Ventures Team at J&J Innovation. As part of her role at J&J Innovation, she works closely with the Janssen Human Microbiome Institute and with J&J Consumer Emerging Sciences to create collaborations with academic experts and biotech companies with a goal of accelerating the translation of microbiome research into breakthrough solutions that promote health. Previously Stephanie was at the University of California, San Francisco UCSF where she helped to establish and grow translational efforts on campus including her role as Program Director for the Sandler Center for Drug Discovery, and for the Grand Multiple Myeloma Translational Initiative. She later took on the role of Director, Strategic Alliances where she led business development and alliance management activities for the campus. Prior to joining UCSF, Stephanie worked for over a decade at Exelixis, Inc, where she held diverse leadership roles including leading a computational biology team and acting as scientific project leader for numerous drug discovery programs in cancer, cardiovascular disease and metabolism as well as managing early oncology clinical programs and alliances for several programmatic collaborations with large pharma. Stephanie earned an undergraduate degree in chemistry (Honors) at the University of Michigan, Ann Arbor, and a Ph.D. in chemistry at the University of California, Berkeley.

Emma Taylor, MD | Co-Founder & Chief Executive Officer, Naked Biome

Emma Taylor, MD is the CEO and founder of Naked Biome, a microbiome-based therapeutics company. She is a UCLA-trained and board-certified Dermatologist and Dermatopathologist, and was a former assistant professor at UCLA before she transitioned to full-time CEO at Naked Biome. Emma has published in notable journals including Nature, Journal of the American Academy of Dermatology, and Dermatology and Therapy. As CEO, she has successfully secured seed funding to take the company through Phase 1 clinical trials.

**

ACRP, Tuesday MidDay, Nov. 1, 2016

Topic: "Webinar: Diverse Women in Clinical Trials Webinar Series – Part I: Planning for Diversity"

Date and Time: Tuesday, Nov. 1, 12:00 – 1:00 pm

Fee: Member: \$25 | Non-Member: \$75

See details and register at <https://www.acrpnnet.org/event/diversity-clinical-trials-webinar-series-part-planning-diversity/>

Webinar Registration Deadline: October 31, 2016

Webinar Description

The Association of Clinical Research Professionals in conjunction with the FDA Office of Women's Health will be hosting a new webinar series on Diverse Women in Clinical Trials

This eLearning series will provide in-depth training on the recruitment and retention of diverse women including women of all ages, races, and ethnicities, as well as women with disabilities and chronic health conditions. This webinar series will provide clinical research professionals with methods and tools to assist them as they plan for successful outreach to

diverse patient populations. Learn practical strategies for overcoming the barriers that can derail provider-based and community-based recruitment of diverse women and for sustaining connections with participants throughout the course of research.

Boost recruitment and retention by learning new approaches for creating research environments that foster effective communication and outreach to diverse patient populations. Hear from FDA Commissioner Robert M. Califf, M.D. and learn about the FDA's Diverse Women in Clinical Trials Initiative.

Upon completion of this Webinar, attendees should be able to:

- Explain the scientific importance of including diverse women in clinical trials
- Describe barriers to participation in clinical trials that are relevant to diverse women
- Describe strategies for engaging diverse women in clinical trials
- List resources for increasing the inclusion of diverse women in clinical trials

ASQ Course, Friday Morning, Nov. 4, 2016

Event: "B113 - Preparing & Submitting 510K's & PMA's"

Instructor: Patrick Lee

Date and Time: Friday, Nov. 4, 2016, 8:00 am – 12:00 pm

Location: International Technological University 2711 North First Street San Jose, CA 95134

Instructor is Patrick Lee

Registration at [Registration at https://goo.gl/MXoXNh](https://goo.gl/MXoXNh)

Overview

- US Regulation history and overview
- Medical Device Users Fee and Modernization Act (MDUFMA)
- Medical Device Classification
- Key terms and elements
- FDA regulatory pathways
- When 510(k) is required
- Types of 510(k)s
- Planning and executing a 510(k)
- The FDA 510(k) review process
- When to submit a 510(k) for a changed device
- When a PMA is required
- Types of PMAs
- Planning and executing a PMA
- Points to consider
- The FDA PMA review process
- PMA Supplements
- Other worldwide regulatory bodies and authority
- Regulatory compliance issues overview

Benefits

This course covers materials that are essential to those individuals who are interested in medical device submissions to the FDA and presents an overview of regulatory pathways for medical devices in the U.S. with a focus on the FDA 510(k) process including IDE, PMA, HDE, de novo 510(k), combination products, and CE Marks.

Soly Paterson ASQ CMQ/OE

Course Coordinator

ASQ Silicon Valley - Section 0613

course-coordinator@asq-silicon-valley.org | 408.410.3934

Bio2Device Group, Tuesday Evening, Nov. 8, 2016

Topic: "SF Bay Area Biomedical Industry Emergence: Sectors, Talent, and Resources"

Speaker: Gregory Theyel, Director, Biomedical Manufacturing Network

Date and Time: Tuesday, Nov. 8, 2016, 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

The biomedical industry is growing and evolving in the SF Bay Area because new sectors are developing, talent is driving innovation, and the region is providing needed resources. This presentation will offer insight on how the biomedical industry is growing, the role talent is playing in this growth, and the integration of industries and resources that are unique to the SF Bay Area. Inventors, firms, investors, job-seekers, and policymakers will benefit from this insight on the emergence of the SF Bay Area biomedical industry.

Speaker Bio

Gregory Theyel is the Director of the Biomedical Manufacturing Network, which assists biomedical companies with the commercialization of technology and governments with the growth of new industries and economic development.

PBSS Workshop, Thursday, Nov. 10, 2016

Topic: "Statistics and Biostatistics for Non-Statisticians: Fundamentals and Applications in Research and Drug Development"

Speakers: Saling Huang and Zhen Zhang (Abbott Vascular)

Organizers: Peter Staehr (Abbott Vascular) and Snow Ge (Nektar Therapeutics)

Date and Time: 11/10/2016, 12:45-17:15

Agenda:

12:45pm - 12:50pm PBSS Welcome

12:50pm - 1:50pm 1. Statistical principals for Non-Statisticians: the basics you need to understand (Zhen Zhang, PhD, Abbott Vascular)

1:50pm - 2:00pm Major Sponsor Presentation, TBD

2:00pm - 2:15pm Break

2:15pm - 3:15pm 2. From Study Objectives to Statistical Design and Analyses (Saling Huang, PhD)

3:15pm - 4:00pm 3. Statistical considerations during a development program change from early to late stage (preclinical, early [Phase 1 and 2a], mid-stage [Phase 2b] and late Clinical Development [Phase 3] - Exploratory, Confirmatory and Adaptive Designs (Saling Huang, PhD)

4:00pm - 4:15 pm Break

4:15pm - 5:00pm 4. Some other important analyses which you find in Scientific-Medical Journals (Univariate and multivariate analysis, Hazard and Odds ratios, Time-to-Event analyses/Kaplan-Meier curves, Meta-analysis) (Zhen Zhang, PhD, Abbott Vascular)

5:00pm - 5:15pm Panel Discussion

Registration fee (USD): Academic: \$75; Regular: \$125; For unemployed & students: \$25;
For major-sponsor rep (incl lunch): \$0; For vendor-show reps: \$25;
Location: SF Bay Area: Foster City Crowne Plaza
Registration: <http://www.PBSS.org>
Registration deadline: 11/8/2016 (it will close sooner if the seating cap is reached)
About the Topic

Workshop outline:

This workshop is designed for scientists in the life science or medical device industry who are non-statisticians but need to deal with statistical problems as part of their research work.

The workshop begins by introducing statistical principals and basics that scientists need to know when conducting their research projects (e.g. types of data, confidence intervals, hypothesis, type 1 & 2 error, power and sample size). The second talk it covers more details about statistical design and analyses such as primary & secondary endpoints, randomization and stratification, pre-specified vs. post-hoc analyses, superiority & non-Inferiority designs, missing data handling, and population subgroup analyses. The third talk will describe how statistical considerations change during development program from a preclinical, early phase [Phase 1 and 2a], to mid-stage [Phase 2b] and finally late Clinical Development [Phase 3] and will also discuss exploratory, confirmatory and adaptive designs. The workshop will close with coverage of analyses that can be frequently found in scientific-medical journals such as univariate and multivariate analysis, hazard and odds ratios, time-to-event analyses/Kaplan-Meier curves, and meta-analyses.

JLABS, Monday, Nov. 14, 2016

Topic: " Making the Connections: A Roadmap for Success at the J.P. Morgan Healthcare Conference"

Speakers:

Shelley Chu | Partner, Abingworth *read bio»*

William J. Newell | CEO, Sutro Biopharma *read bio»*

Lesley Stolz, Ph.D. | Head, JLABS, CA *read bio»*

Date and Time: Monday, Nov. 14, 2016

Agenda:

12:15 PM | Registration, Lunch and Networking

1:00 PM | Panel and Q&A

2:00 PM | Program Close

Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Fees:

\$15 | General Public

\$30 | Onsite

Details and registration at <https://www.eventbrite.com/e/making-the-connections-a-roadmap-for-success-at-the-jp-morgan-healthcare-conference-tickets-28534864548?aff=weekly>

Navigating the sea of life science executives and investors at large healthcare conferences can be an intimidating experience. As one of the largest annual conferences of the life science industry, the J.P. Morgan Healthcare Conference, requires strategic planning for those attending. Our panel represents a cross section of expertise from pharma, venture and business in order to provide a comprehensive

perspective of key players at the event. Please join Lesley Stolz, William Newell and Shelley Chu in an informative and interactive session on how to plan for and succeed at the J.P. Morgan conference.

Topics covered:

- Deciding who to meet with at J.P. Morgan
- How to make the initial connections
- How to schedule your meetings
- How to navigate and network at the even

Speakers Bios

Shelley Chu | Partner, Abingworth

Shelley joined Abingworth in 2015 and invests across a broad range of therapeutic areas and stages of development, from start-ups to late-stage. She has over 15 years of operating and investment experience in the biopharmaceutical industry, including most recently Gilead where she led R&D Strategy and Business Development in Oncology, Immunotherapy and Hepatitis B. Previously Shelley invested and co-founded biotechnology companies at Frazier Healthcare Ventures. Earlier in her career she was an investment professional at Flagship Ventures and a management consultant to healthcare and biotech companies at McKinsey. Shelley holds an MD and PhD in Biochemistry and Biophysics from UCSF, and received her BA in Molecular Biology from Princeton University. She is a first author of publications in Science and other prominent journals and a Co-Chair of the Princeton Alumni School Committee.

William J. Newell | CEO, Sutro Biopharma

Mr. Newell has over 24 years of senior management experience in the biotechnology industry. He joined Sutro Biopharma as CEO in January 2009. Previously, he served as the President of Aerovance, Inc., a venture-backed company developing clinical assets for respiratory diseases. Mr. Newell also was Chief Business Officer and Senior Vice President at publicly-traded QLT, Inc. and served in several senior management positions at public-traded Axys Pharmaceuticals, Inc. For the 16 years prior to joining Axys, Mr. Newell practiced corporate law in the San Francisco Bay Area. He is presently a member of the Board at Symic Bio. Mr. Newell is also a Board member on BIO's Emerging Companies Section and a member of the Board and of the Executive Committee of the California Life Sciences Association.

Lesley Stolz | Head of JLABS, CA, Johnson & Johnson Innovation, JLABS

Dr. Stolz has 20 years of business and corporate development experience working for companies that have been both technology platform and therapeutics focused. After two years negotiating partnering deals for Johnson & Johnson Innovation at the California Innovation Center, Lesley joined the JLABS team as Head of JLABS, CA, to participate in the mission of helping to catalyze new companies in the healthcare ecosystem. Prior to joining Johnson & Johnson Innovation, she held executive positions with BioTime, Inc., Sutro Biopharma, Inc., and Sunesis Pharmaceuticals where she was responsible for corporate strategy, fundraising and all aspects of partnering. Earlier in her career, she served as Senior Director, Business Development for Aerovance, Inc. and for GPC Biotech AG in Munich, Germany from 2002 to 2006. She also served in senior management positions at Cell Genesys, Discovery Partners International and Axys Pharmaceuticals. Dr. Stolz received her Ph.D. in chemistry, and conducted postdoctoral research at Harvard Medical School's Department of Biochemistry and Molecular Pharmacology.

JLABS, Tuesday Mid Day, Nov. 15, 2016

Topic: "Out of the Lab and into the Newsroom"

Speakers:

Carin Canale-Theakston | President and Founder, Canale Communications [read bio»](#)

Victoria Colliver | Health Reporter, San Francisco Chronicle [read bio»](#)

Michael Fitzhugh | Staff Writer, BioWorld Today [read bio»](#)

Ron Leuty | Biotech Reporter, San Francisco Business Times [read bio»](#)

Susan Schaeffer | Editor, BioCentury [read bio»](#)

Date and Time: Tuesday, November 15, 2016 from 11:30 AM to 2:30 PM (PST)

Agenda:

11:30 AM | Registration Opens, Lunch, and Networking

12:00 PM | Panel Discussion

1:00 PM | Hands-on Working session

1:45 PM | Story Pitching

2:30 PM | Program Close

Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Fees:

\$35 | General Public

\$20 | Student/Academic

\$45 | At the door

Topic Description

Anxious at the thought of interacting with the media? Our all-star lineup of reporters is back, bringing you tips straight from the source on the right way to get your story out there.

You've got your cutting-edge technology, you've raised money, and your company is making some great headway on the R&D front. You're ready to bring your company out of stealth mode and into the limelight, but you don't know how. In this three-part workshop event, we'll explore how to take your story out of the laboratory and into the headlines:

First, a panel of industry reporters will provide insight into how they like to be pitched, what makes something "newsworthy" and what they are looking for to include in coverage.

Second, in a working session, seasoned communications professionals will help you craft your story using a framework that works well for telling life science stories that resonate with multiple audiences.

Finally you'll have a chance to pitch the reporters in attendance who will each select one company that will be the subject of a one-on-one background interview at a later date.

Key topics will include:

What makes a story "newsworthy"?

What's the best way to pitch a reporter?

How do you translate complex science into a story others can understand?

Tips for your interview

The workshop will be led by life science communication expert, Carin Canale-Theakston, president and founder of Canale Communications.

Speaker Bios

Carin Canale-Theakston | President and Founder, Canale Communications

Carin Canale-Theakston is the president and founder of Canale Communications Inc. In her role as president, Carin works closely with client teams, having provided senior level strategy to more than 125 life science companies of all shapes and sizes ranging from pre-series A financing to billion dollar public companies such as Amgen and Johnson & Johnson. Through her career in life science communications, she has advised a diverse range of companies including biotechnology, biopharmaceutical, medical device, diagnostics, research organizations and providers of enabling technologies.

In addition to client services, Carin is actively involved in the life science community. She is currently the vice chairwoman of the board of directors for BIOCOM, Southern California's life science trade association, and a member of the board of directors for the San Diego Venture Group. She is also a trustee of the Mission Hills Town Council and a member of the board for A Note to My Kid, a non-profit organization for gay and lesbian youth. A sought-after speaker, Carin frequently leads presentations and trainings on various communication topics for these organizations and others such as PRSA, the Biotechnology Industry Organization and California Healthcare Institute. Prior to founding Canale Communications, Carin was president of the life sciences division of international public relations firm Porter Novelli, managing teams in San Diego, Los Angeles, Boston and New York. Carin joined Porter Novelli when the firm acquired boutique life sciences communication firm, Atkins + Associates, in which Carin was partner and managing director. Carin also held various positions for several agencies including Townsend Inc., Littlefield Communication and Burson-Marsteller. Before becoming engrossed in the agency world, Carin served as community relations director for a non-profit organization (Domestic Violence Intervention Services), where she generated global awareness, managed a national speaking circuit and supported the company's fundraising efforts. Carin holds a bachelor of arts from the University of Tulsa with a major in communications and a minor in marketing.

Victoria Colliver | Health Reporter, San Francisco Chronicle
Bio coming soon!

Michael Fitzhugh | Staff Writer, BioWorld Today

Michael Fitzhugh joined the BioWorld team as a staff writer in 2014. He has contributed to and edited several in-depth annual reports about health care's ever changing landscape as an editor in Burrill & Co.'s San Francisco-based media group while reporting about biopharma's unfolding story. Prior to that, he covered biotechnology and high tech companies for American City Business Journals. He received his MJ from the University of California at Berkeley's Graduate School of Journalism and holds a BA from the University of Michigan. When unplugged from reporting, he enjoys spending time with his young children and playing fiddle in Berkeley, Calif.

Ron Leuty | Biotech Reporter, San Francisco Business Times

Ron Leuty has been a reporter or editor for more than 25 years, including editor of two startup business journals and business editor of the Prague Post in the Czech Republic. He has covered biotech for the San Francisco Business Times for eight years. He also has covered banking, manufacturing, law and sports business.

Susan Schaeffer | Editor, BioCentury

Susan serves as Editor of BioCentury. She has been reporting and commenting on the biopharmaceutical industry for 11 years, covering drug discovery and development, corporate strategy and finance, and regulation and policy as it affects multiple stakeholders in the biomedical ecosystem. Her work has been cited in regulatory

filings and has recently influenced biopharma executives to pursue legislative changes necessary to enable greater experimentation with pricing models designed to make innovation more affordable to healthcare systems.

She was previously Senior Editor in charge of Product Discovery & Development coverage from 2010 through 2012. She was Managing Editor of BioCentury and BioCentury Extra from 2004 through 2010. She joined BioCentury in 2003 after 10 years as an editor in the consumer packaged goods sector, including work with international strategy consultants Kurt Salmon Associates.

Golden Gate Polymer Forum, Wednesday Evening, Nov. 16, 2016

Event: GGPF Dinner Lecture "A Framework for Integrated Product Design and Control in 21st Century Manufacturing Processes: Application to Polymer Nanocomposites"

Speaker: Prof. Babatunde Ogunnaike, Professor of Chemical Engineering and Dean of the College of Engineering University of Delaware

Date and Time: Wednesday, Nov. 16, 2016, 6:00 PM social hour; 7:00 PM dinner and 8:00 PM presentation

Location is Michael's at Shoreline, 2960 N Shoreline Blvd., Mountain View

Cost:

Employed/postdocs: \$30 early registration, \$35 regular registration

Unemployed/retired/students: \$15 early registration, \$20 regular registration

Free if you attend just the lectures at 8:00 PM (but please let us know for headcount)

After deadline: Registration not guaranteed, so contact us; Late fee applies if space available -- \$40 regular/employed, \$25 unemployed/student/retired

Deadlines for registration:

End of discounted advance registration Tuesday, Nov. 8, 11:59 PM

End of regular (full-price) registration Tuesday, Nov. 15, 5:00 PM

Register at www.GGPF.org <<http://www.GGPF.org>> (PayPal is enabled if desired)

Topic Description

Systemic changes in the chemical industry have created a need for the rapid development of new products that meet customer needs as precisely as possible. The traditional chemical engineering focus on process design, while important, must now incorporate "product design". Even so, to translate the result of "product design" into reality, the product must still be manufactured-and in such a way that the resulting product will meet the customer requirements in end-use. Product design must therefore be integrated directly with high level product characteristic control for successful "product engineering". Currently, there are no systematic control paradigms for ensuring that end-use attributes are controlled to specification during the manufacturing process (and not merely "tested" afterwards to ascertain their status). In this presentation, we discuss our efforts to establish a systematic paradigm for product characteristic control and its integration with product design-providing novel solutions to the problems associated with delivering to customers, products that are manufactured precisely to design specifications, and directly incorporating into the control scheme, customer feedback on actual end-use performance.

Because of their current and future importance and because of how they perfectly exemplify product design and the accompanying property control challenges, the work was carried out specifically for polymer nanocomposites, although the end result should be applicable in general to other product classes. The novel modeling and control techniques developed and validated experimentally in a continuing collaboration with DuPont will be discussed. The specific question to be answered in the presentation may be stated as follows:

In manufacturing products (such as polymer nanocomposites) designed for specific end-use applications, what strategy is required for effective control of product properties and

assuring acceptable end-use performance?

Speaker Bio

Babatunde A. Ogunnaike is the William L. Friend Chaired Professor of chemical engineering and Dean of the College of Engineering at the University of Delaware. He received his B.Sc. in Chemical Engineering from the University of Lagos, Nigeria and both his M.S. degree in Statistics and Ph.D. degree in Chemical Engineering from the University of Wisconsin-Madison. He is the author or co-author of four books including a widely used textbook, Process Dynamics, Modeling and Control, and Random Phenomena: Fundamentals of Probability and Statistics for Engineers. His awards include the American Institute of Chemical Engineers 1998 CAST Computing Practice Award, the 2007 ISA Eckman Award, and the 2008 AACC Control Engineering Practice award. He was named a fellow of the American Institute of Chemical Engineers in 2009 and a fellow of the American Association for the Advancement of Science in 2015, and he was elected to fellowship of the Nigerian Academy of Engineering and to the US National Academy of Engineering, both in 2012.

WIB- San Francisco, Tuesday Evening, Dec. 6, 2016

Event: "Holiday Party at Devil's Canyon"

Date and Time: Tuesday December 6, 2016, 6:00 p.m. – 9:00 p.m. PST

Location: Devil's Canyon Brewing Company, 935 Washington Street, San Carlos, CA 94070

Registration Deadline

December 5, 2016

Walk-Ins Accepted?

Walk-ins are not accepted – be sure to register early!

Pricing Information

Members: \$10

Non-Members: \$25

Registration Deadline

December 5, 2016

Register at <http://www.womeninbio.org/eventdetails.aspx?EventId=30029>

Parking Information

There is a parking lot located next to Devil's Canyon and plenty of street parking is available.

Public Transit Information

Devil's Canyon Brewing Company is located between the San Carlos and Redwood City Caltrain stations.

Event Description

Come join WIB-San Francisco Bay Area chapter members at [Devil's Canyon Brewing Company](#) on December 6th to celebrate another phenomenally successful year. None of this would have been possible without the tireless support of our amazing volunteers. Let us say, "Thank You," to them and wish WIB continued success!

To take advantage of a free subscription to WIB-Smartbrief, a weekly newsletter that will keep you updated about women making a difference in biotech and life sciences, please [sign up here](#).
