

PODD

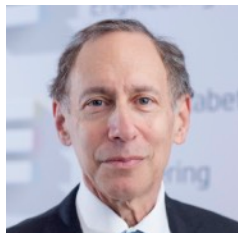
8TH ANNUAL

PARTNERSHIP OPPORTUNITIES IN DRUG DELIVERY

OCTOBER 17-18, 2018

WESTIN COPLEY PLACE, BOSTON, MA

2018 Featured Keynotes



Robert Langer, PhD

David H. Koch Institute Professor
MIT



Amy Schulman

Co-founder and CEO, **Lyndra**
and Partner, **Polaris**



Jeffrey Karp, PhD

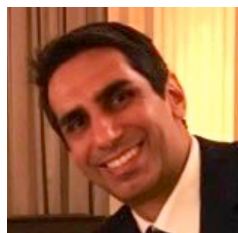
Professor of Medicine
Harvard Medical School



Justin Wright, PhD

Global Head of Innovation
Novartis

2018 Track Chairs



Nima Akhavein, PhD

Associate Fellow and
Scientific Leader
GSK



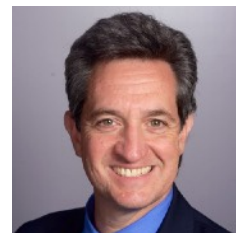
Ulrich Brüggemann

Head Academics and Innovation,
Global Medical Devices Development
Sanofi US



Mathias Romacker

Senior Director, Device Strategy
Pfizer



Michael Cucolo

Director of Business Development
BMS

2018 Chair



Dr Barbara Lueckel

Global Business Development Director, Roche Partnering Innovation
Roche

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DAY ONE -WEDNESDAY, OCTOBER 17, 2018**8:00 am****Registration & Breakfast, Exhibits Open****8:30 am****A Year in Review and PODD Welcome****Barbara Lueckel, PhD***Global Business Development Director, Roche Partnering Innovation, Roche***9:00 am****Keynote Fireside Chat**

Dr Robert Langer and Amy Schulman, two dynamic entrepreneurs in biotech, will be joined together in a fireside chat to discuss:

- ♦ Working together to accelerate new innovations in drug delivery: Lyndra, Suono Bio and SQZ Biotech
- ♦ The “Lyndra” story and how the ultra-long-acting oral technology has the potential to significantly improve patient outcomes
- ♦ How to successfully move a technology out of the lab and into the market
- ♦ Raising funds and structuring deals for startup companies

Robert Langer, PhD*David H. Koch Institute Professor, MIT and***Amy Schulman, JD***Co-Founder and CEO, Lyndra and Partner, Polaris Partners***9:45 am****Stories from Bioinspiration to Innovation**

When developing technologies to solve medical problems, often one encounters significant hurdles, that at times seem insurmountable. Overcoming these hurdles requires new ways of thinking. One approach is to turn to nature for inspiration. Millions and millions of years of research and development at our fingertips, and all we need to do is look outside to the amazing creatures that inhabit our planet. This talk will explore medical technologies being developed that harness lessons from nature for inspiration. Some of the technologies that will be described are rapidly advancing to the clinic and some are already on the market helping patients.

Jeffrey Karp, PhD*Professor of Medicine, Harvard Medical School and Director of the Laboratory for Accelerated Medical Innovation, Brigham and Women's Hospital***10:15 am****Networking Break & Partnering Meetings, Exhibits Open****11:00 am****Pharma's Perspective on Partnering to Advance Drug Delivery Innovation in the R&D Pipeline**

This panel will include business development and technology assessment professionals actively involved in the scouting and evaluating of novel delivery technologies for such areas as oncology, ophthalmology, diabetes, and CNS. The audience will hear pharma's general perspective on

partnering, and will also gain insight into key strategic considerations in evaluating external drug delivery technologies vs. building internal capabilities.

Moderator:**Ronald L. Smith, PhD***Scientific AVP, Pharmaceutical Sciences, Merck Research Laboratories***Panelists:****James Cunningham, PhD***Executive Director, Drug Delivery, Allergan***Dan Groszmann, PhD***Principal Engineer, Device Technologies Innovation Center, Amgen***Barbara Lueckel, PhD***Global Business Development Director, Roche Partnering Innovation, Roche***Imran Nasrullah, MS, JD***Director, Strategic Partnering, BD&L, Boehringer Ingelheim Pharmaceuticals***Terry Reed***Director, Business Development, AstraZeneca***11:45 am****High Volume Subcutaneous Drug Delivery: Challenges, Opportunities, and What the Future Holds**

Over the past few years, there has been a dramatic increase in the number of therapeutic proteins delivered through intravenous infusion and subcutaneous delivery. Conversion of high volume intravenous infusion products to subcutaneous injection as well as optimization of subcutaneously delivered products can reduce treatment burden for patients, save provider time, and potentially reduce health care costs.

Leading biopharmaceutical thought leaders will outline the challenges, opportunities, and emerging trends associated with high volume subcutaneous delivery. The panel participants will discuss the technical considerations, development approaches, and commercial implications.

Moderator:**Cindy Atwell***Senior Director, Business Development and Strategy, Halozyme***Panelists:****Nancy Barbour, PhD***VP, Drug Product Science & Technology, BMS***Chris Coletta, PhD***Drug Delivery Technology Expert, Coactuate***Beate Bittner, PhD***Portfolio Strategy Director, Roche***Robert Epstein, MD***CEO, Epstein Health***Peter Quinn***Platform Leader – Wearable Injection Systems, BD Medical – Pharmaceutical Systems***12:45 pm****Lunch & Partnering Meetings**

2:00 pm

Drug Delivery – Innovative Clinical Stage Pipeline

PharmaCircle will present a brief overview of drug delivery pipeline and then highlight and examine innovative and potentially impactful drug delivery based clinical stage pipeline with both formulation and device based technologies.

Kurt R. Sedo

VP Operations, PharmaCircle

2:15 pm - 6:15 pm

Drug Delivery Technology Presentations in 3 Tracks, 6 sessions

Attendees can choose between the following sessions: Drug Delivery Devices, Injectable Technologies and Non-Injectable Technologies (oral, transdermal, transmucosal and ophthalmic). In these tracks, a wide range of delivery technologies will be presented such as wearable patch pumps, subcutaneous formulation enhancing technologies, sustained release delivery systems, nanoparticle technologies, novel auto-injector devices, “connected” drug delivery systems (digital devices), bioavailability enhancing technologies, long-acting ocular implants, microneedle patches, and orally-disintegrating dosage forms.

Track 1A: Injectable Formulation & Device Technologies Companies will present technologies to improve the formulation and delivery of injectable drugs. Examples of technologies presented: sustained release microspheres, nanoparticles, enabling formulation system for high volume drugs, pre-filled syringes, and multi-vial/multi-syringe systems.	Track 2A: Non-Injectable Technologies: Oral Companies will present controlled release, modified-release, colon-targeted, and orally-disintegrating delivery systems, as well as bioavailability & solubility enhancing technologies.	Track 3A: Device Technologies Companies will present a wide range of novel delivery devices such as needle-free delivery devices, auto injectors, patch pumps/wearable delivery systems, and similar devices. This session also includes “connected” devices and digital health technologies.
Chair: Michael Cucolo , <i>Director of Business Development, BMS</i>	Chair: Manuel Sanchez-Felix, PhD , <i>Senior Fellow, Novel Delivery Technologies / Chemical and Pharmaceutical Profiling, Novartis Institute for BioMedical Research</i>	Chair: Ulrich Bruggemann , <i>Head Academics and Innovation, Global Medical Devices Development, Sanofi</i>
Enable Injections	leon-nanodrugs GmbH	BD Medical
Innocore Pharmaceuticals	Adare Pharmaceuticals	Bespak
Halozyne Therapeutics, Inc	Harro Hofliker	Credence MedSystems
Evonik Corporation	Recro Gainesville	Cambridge Design Partnership
Datwyler	BDD Pharma	BIOCORP
Cureport	Lyndra	Sensile Medical
InnoMedica	Matinas BioPharma	Phillips-Medisize
Adocia	Ileo Science	Portal Instruments
Track 1B: Injectable Formulation & Device Technologies Companies will present technologies to improve the formulation and delivery of injectable drugs. Examples of technologies presented: sustained release microspheres, nanoparticles, enabling formulation system for high volume drugs, pre-filled syringes, and multi-vial/multi-syringe systems.	Track 2B: Non-Injectable Technologies: Oral, Mucosal, Transdermal, Ophthalmic and Pulmonary Companies will present a wide range of technologies for oral, mucosal, buccal, ophthalmic, transdermal, vaginal, and pulmonary delivery. Examples of technologies presented: polymeric delivery systems, dermal nanoparticle systems, and next-generation inhalers.	Track 3B: Device Technologies Companies will present a wide range of novel delivery devices such as needle-free delivery devices, auto injectors, patch pumps/wearable delivery systems, and similar devices. This session also includes “connected” devices and digital health technologies.
Chair: Nima Akhavein, PhD , <i>Associate Fellow and Scientific Leader, GSK</i>	Chair: Ann L. Daugherty, PhD , <i>Senior Manager, Drug Delivery, Genentech</i>	Chair: Mathias Romacker , <i>Senior Director, Device Strategy, Pfizer</i>
Serina Therapeutics	Pharmaero	Vernay
DelSiTech	Excure	Common Sensing
Gerresheimer Regensburg GmbH	Qpharma	Altaviz
		Cureport
		Sorrel Medical
		Ypsomed
		Battelle
		Ichor Medical

DAY TWO -THURSDAY, OCTOBER 18, 2018**8:00 am****Breakfast in Exhibit Hall and Partnering Meetings****8:30 am****Chair's Welcome****Barbara Lueckel, PhD***Global Business Development Director, Roche Partnering Innovation, Roche***8:40 am****Industry Keynote: Harnessing the Digital Exhaust: Incorporating Wellness into the Pharma Model and How Drug Delivery will be a Key Enabler**

The pharmaceutical sector remains one of the largest components of the US and global economy with sales exceeding \$450B domestically and \$900B worldwide. Historically the industry has relied on the 'blockbuster' model for drug entry, where drugs with >\$1B+ annual sales allow investments to be made in early stage projects and smaller markets. However, the industry is undergoing a pivotal transformation as traditional drugs are supplanted by next generation product systems where, in some cases, the drug is only a component of the overall product offering. This situation has created a compelling entry point for non-traditional competitors and start-ups to access this market and potentially re-define the value model associated with drug pricing.

And while, for more than a decade, the pharmaceutical industry has been caught up discussing its role in "beyond the pill" solutions, it will now need to realize a rapid evolution of its current business model in order to remain competitive. The opportunity to reimagine this and move from a reactive to prevention model, and in many cases a fully "closed loop" solution, has finally arrived. At the core of such an evolved model will certainly be a dynamic patient interface which leads to extraordinary patient engagement. And with the delivery system being one of the most intimate parts of this interface, there is no question they will serve as a key enabler going forward. As evidenced by a number of franchises over the past 20 years, a great delivery system can be a true differentiator or can it be a debilitating handicap.

A review of the current and future state along with perspective and case studies will be provided in order to help shed light on the areas of needed focus and corresponding opportunity.

Justin M. Wright, PhD*Global Head of Innovation, Novartis***9:10 am****The Pediatric Patient Perspective featuring Catalent**
Speakers TBA**9:30 am****Digital Health: Paradox or Paragon?**

In today's digital world, we are seeing self-driving cars taking the first leap, while Amazon's Alexa, Google Assistant and

Apple's Siri are becoming commonplace in our households. We are also experiencing increased adoption of digital or "smart" technology to improve healthcare. On one side, we view the "smart" ecosystem and connected medical devices as a way to improve patient adherence and help healthcare providers make evidence-based personalized care decisions; but on the other hand there is the debate about the value, return on investment, etc. for digital health.

This panel discussion not only touches on the strategic topic of digital health but also dives deeper into more pragmatic approaches to execution, value propositions, etc. Our panel consists of bio-pharma executives and strategic partners who are not only KOLs but also possess a successful track record of implementing digital health solutions in the field. The panel will also help to shed light on current digital health strategies currently employed while providing "food for thought" for organizations interested in adopting new digital technology but still looking for the right value proposition.

Moderator:

Dhairya Mehta*Director, eHealth & Connectivity, Medical Device & Combination Products, Shire*

Panelists:

Rhett Guy Alden, PhD*Sr Advisor/Chief Digital Architect for Connected Care, Eli Lilly***Supriya Lagu, PhD***Director, Digital Health Technology, Biogen***Kal Patel, MD***SVP of Digital Health, Flex***Paul Upham***Senior Principal, Smart Device Technology Center, Roche/Genentech***Neil Williams***Director Front-End Innovation, Head of Connected Health, Medicom Innovation Partner Ltd, a Phillips-Medisize Company***10:15 am****Networking Break in Exhibit Hall and Partnering Meetings****11:00 am****Maximizing the Value of Collaboration for Novel Device Design**

Partnering is a vital aspect of medical device development; it provides necessary resources and expertise for development, and brings in new viewpoints and experiences, which truly drive product innovation. This type of collaboration, however, also adds a layer of complexity to a development project that must be carefully managed to successfully reach the end goal. In this session, the speakers will present challenges, best practices and lessons learned for partnering, using case studies for illustration. The speakers will highlight ways they maximized the value of collaboration from the outset, including: how they identified and moved forward with the "right" partner; built a productive multi-partner team; productively managed communications and expectations

throughout the development cycle; measured performance; and made critical decisions to reach a successful outcome.

Doug Boyd, PE, PMP

Manager, Medical Devices and Health Analytics, **Battelle**

Gary Henniger

Senior Director Global Device R&D Operations, **Teva**

11:30 am

8th Annual Company Spotlights

In this session, we highlight four companies to discuss their partnering philosophy, current needs and scouting interests, as related to drug delivery.

Advait Badkar, PhD

Senior Director, Novel Delivery Technologies, **BioTherapeutics, Pfizer**

Grégoire Schwach, PhD

Head of Drug Delivery, **F. Hoffmann-La Roche Ltd**

Srini Sridharan, PhD

Head, Materials Science & Engineering, **Bristol-Myers Squibb**

Simon Todd

Science and Innovation Lead, **AstraZeneca**

12:30 pm

Luncheon Roundtables & Partnering Meetings

The PODD Luncheon Roundtables are open to all delegates and feature a dedicated moderator for each topic. Participating in a Roundtable session is an excellent way to engage in in-depth discussions and meet colleagues with similar interests. Be sure to pick up your Grab-and-Go lunch and join the conversation.

On Market/ Post Market Surveillance for Sustaining Combination Products

Led by:

Maggie Reiff, Device Engineer, **Pfizer**

Long-acting Ocular Drug Delivery Technologies: Challenges and Opportunities

Led by:

Viral Kansara, PhD, Head of Pharmacology and Drug Discovery Lab, Global Project Team Leader, **Ophthalmology, Novartis**

1:30 pm

DDS Technology Soapbox @PODD sponsored by



This session features five minute talks on cutting-edge technologies, inventions and ideas. The PODD Soapbox section is open to start-up entrepreneurs, inventors, licensing officers and university researchers.

Moderator:

Patrick Lim Soo, PhD

Senior Principal Scientist, Novel Delivery Technologies, **Pfizer**

Presenting Companies:

Cam Med LLC

Cinti Medical

Consegna Pharma

Wyss Institute

Better Sense

Massachusetts General Hospital

SiNon Therapeutics

2:10 pm

Disruptive New Models for Advancing Drug Delivery Innovations

This panel will discuss the 2028 model of commercialization – new game-changing models of commercialization that accelerate the development and commercialization of early stage drug delivery technologies.

Moderator:

Rosemarie Truman

Founder and CEO, **The Center for Advancing Innovation**

Panelists:

Bharatt Chowrira, JD, PhD

President and Chief of Business and Strategy, **PureTech Health**

Kristen C. Kosofsky

Senior Managing Director, Life Sciences, **Hercules Capital**

Scott E. Weiner, MBA

Partner, **Pappas Capital**

2:40 pm

Delivering mRNA Drugs and Vaccines: Progress and Future Outlook

mRNA vaccines represent a promising alternative to conventional vaccine approaches for infectious diseases as well as oncology indications, including an emerging application for personalized cancer vaccines. As a technology, mRNA has the potential to enable more rapid design and optimization of antigens, improve quality of immune response due to in situ antigen production, permit expression of multiple antigens, and support more rapid and versatile development and manufacturing platforms. This panel will discuss current state of mRNA vaccines research and opportunities related to:

- ♦ mRNA design optimization for improved stability and antigen translation
- ♦ next-generation delivery approaches for mRNA vaccines
- ♦ mRNA drug substance and drug product CMC
- ♦ safety and regulatory considerations

Moderator:

Marian Gindy, PhD

Executive Director, Discovery Pharmaceutical Sciences, **Merck**

Panelists:

Örn Almarsson, PhD

Head of Formulations, **Moderna Therapeutics**

Danilo Casimiro, PhD

VP & Head, External R&D and Vaccine Platforms, **Sanofi**

Sybil Williams, PhD

Senior Principal Scientist, Personalized Cancer Vaccines Biology Lead, **Merck**

3:20 pm**Innovations and Advances in Protein and Peptide Drug Delivery**

This panel will discuss the latest strategies for improving peptide properties, including stability and half-life, along with covering novel routes of administration. Panelists will also review progress and challenges related to non-invasive delivery, including oral administration.

Moderator:

Joël Richard, PhD

SVP, Peptides, Ipsen

Panelists:

Mark Currie, PhD

SVP, Chief Scientific Officer, and President of R&D, Ironwood Pharmaceuticals

Mohamed E. H. ElSayed, PhD

Sr. Research Advisor, BioTDR Formulation/Delivery, Eli Lilly and Company

Adam Mezo, PhD

Sr. Director, Head of Molecular Design, Ferring Research Institute, Inc

Douglas P Nesta, PhD

Director, Biopharmaceutical Product Sciences, GSK

4:00 pm**The Role of Digital Biomarkers in the Future of Drug Delivery**

Christopher Kovalchick, PhD

Chief Engineer, Drug Delivery & Devices R&D Innovation, Eli Lilly and Company

4:20 pm**Networking & Partnering Meetings, Conference Concludes**