October 7-8th 2019
Boston, MA
By: Danny McCarthy and Andrew Goldstein
PODD Reporters

Overview
The PODD editorial team is pleased to provide you with a re-cap from the 2019 conference. 2019 was the 9th annual and largest PODD with over 450 attendees, 100 speakers and 500+ partnering meetings. Enjoy the re-cap.

Day One, October 7th, 2019

Chair’s Opening Remarks
Dr Shawn Davis, Senior Director of Drug Delivery at AstraZeneca stepped in nicely to welcome everybody to the 9th Annual Partnership Opportunities in Drug Delivery and introduced the first keynote, Dr Robert Langer. He graciously acknowledged Dr Barbara Lueckel, Global Head of Research Technologies, Roche Pharma Partnering at F. Hoffmann-La Roche, who had a schedule conflict, but had chaired all prior years and remains a lead advisor.

Keynote Fireside Chat: Building a Company Around a Transformative Drug Delivery Invention

Dr Robert Langer, MIT leading the Keynote Fireside Chat: Building a Company Around a Transformative Drug Delivery Invention

Dr Robert Langer, David H. Koch Institute Professor, MIT, was joined onstage by Langer Lab researchers and collaborators Dr Sangeeta Bhatia, MIT, Dr Jeffrey Karp, Harvard Medical School and Brigham and Women’s Hospital, and Dr Giovanni Traverso, Brigham and Women’s Hospital, Harvard Medical School, MIT. The panelists highlighted the characteristics of the Langer Lab that contributed to its overwhelming successes.

Dr Langer and the other panelists agreed that the exploratory atmosphere and interdisciplinary nature of his lab contributed to its innovative
culture. Without a specific timeline or investors who expect a profitable product, students were able to explore their curiosities without fearing failure. The collaborative environment provided students of diverse academic backgrounds the space to approach problems from all different angles. The panelists advised other labs and companies to think of patient needs, utilize interdisciplinary resources and expertise to solve problems, de-risk development early on through meaningful models and rapidly iterate after initiating programs. Over the next 15-20 years, the speakers expect further development of genetic medicines and their delivery mechanisms, tissue-specific delivery and more women in the space.

Industry Keynote: Modality Fluid Development: Tales of Evolving Pipelines and Drug Delivery Solutions

Keynote, Dr Allen Templeton, Merck, explained that Merck’s drug development pipeline has doubled in the last five years and that new modalities of drug delivery are needed for these and future drugs. He gave examples of medications and delivery modalities that Merck viewed as most promising.

Based on 12 weeks of data, a single 62mg implant of Islatravir (MK-8591), an anti-HIV agent, was estimated to deliver concentrations well above pharmacokinetic thresholds at 12 months and possibly beyond. Dr Templeton said Merck was interested in attempting to develop a single implant for both pregnancy and HIV prevention. As a second example, Dr Templeton presented data on Keytruda (pembrolizumab), a PD-1 inhibitor, which, as a first-line treatment with chemotherapy for NSCLC, boosts response to 50% from 30% for standard. Merck is looking for additional agents to improve the efficacy to 70%.

Dr Allen Templeton, Merck

Dr Templeton ended his presentation by challenging the audience to expand patient access through patient monitoring, home delivery and non-provider given therapies, as well as to develop a flexible manufacturing footprint through the development of new strategies, digitizing and a flexible infrastructure.

Future Outlook for Novel Drug Delivery

When asked by moderator Dr Shawn Davis, AstraZeneca, about the value of drug delivery, panelists Andre LaFreniere, Batelle, Dr Maria Teresa Peracchia, Sanofi, Dr Julia Rashba-Step, Phospherex, and Theresa Scheuble, Johnson & Johnson, listed examples such as simplifying the user experience and consolidating regimens, enhancing the properties of existing molecules, enabling future molecules and technologies and understanding the journey of different disease areas to co-develop delivery devices and formulations, all with the aim of improving compliance and patient outcomes. “Patients are people, and what they want to do is go back to being people,” Dr Davis said.
The panelists also highlighted the importance of integrating conversations about drug delivery technologies earlier in the drug development process and utilizing strategic partnerships to de-risk, improve efficacy and overcome business and regulatory challenges.

“Patients are people, and what they want to do is go back to being people.”

- Dr Shawn Davis, AstraZeneca

**Formulation & Device Lifecycle Management for Biotherapeutics – Clinical and Industry Perspectives on Subcutaneous Delivery**

Moderated by Dr Beate Bittner, Roche, panelists Dr Mary Nauffal, Brigham and Women’s Hospital, Dr Manuel Sanchez-Felix, Novartis Institutes of BioMedical Research, Dr Anand Subramony, AstraZeneca, and Dr David Ting, MGH Cancer Center and Harvard Medical School, discussed the benefits of subcutaneous formulation products.

Subcutaneous products come in fixed packages, have faster administration times and can be taken outside of the hospital setting. With improved patient monitoring, subcutaneous delivery can enable house care and patient personal care, to increase compliance, outcomes, quality of life and cost-effectiveness.

Dr Sanchez-Felix highlighted areas of risk and opportunity for subcutaneous delivery including high dose, high volume; bioavailability; immunogenicity; patient preference between IV and subQ; clinical trial strategy; pair preference; and patient experience.

**Drug Delivery Pipeline and Technologies, A Year in Review**

Kurt Sedo, PharmaCircle, rapidly reviewed the drug delivery pipeline and technologies as an industry, as well as trends within injectables, oral, inhalation, ophthalmic, nasal, topical, transdermal and brain areas.

While oral products have remained the most marketed products, injectables have overtaken them in the pipeline while. In 2018, nine out of the ten highest selling products were injectables.

While small molecules haven’t gone away, there has been a large uptick in diversified biologics in the pipeline. There has also been an increase in the development of drug delivery products in the cancer area. Cell-based products have outpaced nucleic acids in the pipeline. Additionally, companies are incorporating multiple device strategies into first approvals. When categorized by region, 74% of venture capital funding is in the United States. When categorized by drug delivery type, injectables receive 45% of funding while oral receives 29% of funding.
Company Spotlights Part I

Dr Sujit Basu, Takeda, Dr Nima Akhavein, GSK, and Dr Mandana Borna, Biogen, each presented their companies’ work, partnership philosophy, current needs, and scouting interests, as related to drug delivery and enabling technologies.

Delivering Flexible Dosage Forms for Innovative Modalities and an Evolving Development Plan

After lunch, Dr Advait Badkar, Pfizer, profiled the BioTherapeutics division of Pfizer. Half of Pfizer’s portfolio is biologics. Dr Badkar explained that Pfizer’s approach to drug products is platform-based, utilizing automation and templates. This allows them to leverage experiences across projects, do things more quickly, develop deep knowledge, reduce labor costs and speed up drug development processes.

These platforms reduced labor costs by 50% for the IND for the last 12 mAb molecules the company has developed, and accelerated development, sometimes allowing for a jump from phase I to phase III trials. Dr Badkar also spoke about the uses of platforms and challenges facing AAV gene therapy and nanoparticles, such as immune interactions, manual processes within manufacturing, dosage and administration, scalability, translation between species, in-vitro in-vivo correlation and bioanalytical characterization. Dr Badkar concluded by advising the audience to incorporate development experts and drug experts to standardize the approach of drug delivery and development.

Drug Delivery Technology Presentations, Six Tracks

The event then split into three track options with 45 presenting companies. Track 1A was “Injectable Formulation Technologies,” and after the break, 1B was “Pre-Filled Syringes, Auto-injectors and Pen Injectors.” Track 2A and 2B were “Non-injectable Technologies,” and “Novel Injectable and Non-Injectable Formulation Technologies,” respectively. Track 3A was “Connected Delivery Devices, Wearables & Other Novel Delivery Devices, Part 1,” followed by 3B “Connected Delivery Devices, Wearables & Other Novel Delivery Devices, Part 2,” after the break.

This concluded the end of Day One of PODD, and was followed by a networking reception and partnership meetings.
Day Two, October 8th, 2019

Gene Therapy Keynote: Turning Genes into Medicines: Gene Therapy for Genetic Disease

Dr Katherine High, Spark Therapeutics, opened the day as the Gene Therapy Keynote. Dr High reviewed the current state of gene therapies, and talked about developing gene therapies for previously untreatable diseases and for diseases with already existing therapeutics. She pointed to the increasing number of IND submissions as a positive inflection point for the world of gene therapies. “It’s a rapidly growing field,” said Dr High.

Dr Katherine High, Spark Therapeutics

Dr High highlighted the work she and her team had done for inherited retinal diseases with the novel treatment Luxturna, the first treatment for an inherited disease to be approved by the FDA. The challenge in treating previously untreatable diseases, High said, was in creating novel endpoints; Luxturna’s endpoint was a series of mobility exercises that tested the patient’s vision in increasingly dark circumstances.

Dr High also worked in the Hemophilia B space, using gene therapy to enhance existing treatments. The end result was a single, durable infusion using FIX-Padua, a naturally occurring mutation with an extremely high clotting factor.

Zeitgeist Presentation: The Immune Targeting Nanomedicine Approach

For the Zeitgeist Presentation, Dr Anand Subramony, AstraZeneca, addressed the therapeutic benefits of nanoparticles, such as the Cornell dot: more effective targeting of tumors rather than tumor tissue and the possibility for increasing the abscopal effect.

Dr Anand Subramony, AstraZeneca

Dr Subramony’s team at AstraZeneca demonstrated that nanoparticles avoid getting trapped in the liver and can be renally excreted. They found through animal studies that more than 15% of these micro antibody-drug conjugates, when modified with short fragments of antibodies, ended up in the tumor. Nanoparticles were also able to capture antigens released from dying tumor cells and alert them to antigen presenting cells to increase the abscopal effect in distant tumors.

Dr Subramony emphasized that immune-targeting nanoparticles are an emerging tool of immuno-oncology that have changed the paradigm from tissue targeting to in-tumor localization.
Company Spotlights Part II
After Dr Subramony’s talk, Dr Simon Geißler of Merck KGaA and Dr Kristian Kolind of Novo Nordisk took to the stage to discuss their respective companies’ work, current needs and scouting interests.

Dr Simon Geißler, Merck KGaA

Case Study: Forming and Managing a Drug Delivery Alliance
Jennifer Guzman, Halozyme Therapeutics, moderated a conversation between Michael Cucuolo and Brian Davideit, both of BMS, and Halozyme’s Tom Witt and Dr Renee P Tannenbaum about their ongoing collaboration for drug deliveries.

Halozyme and BMS had been in contact over the years but finally joined in business when a Halozyme technology fit the need for a BMS product: an enzyme that breaks down the hyaluronan in the subcutaneous space to administer large volumes of therapeutics as a single injection. The partnership wasn’t without its learning curves, such as the challenge of the 300-person Halozyme communicating with Bristol-Myers Squibb with employee numbers in the 20,000s. But by honing their communication efforts, enhancing transparency and building on their early trust, the two companies were able to come together.

MedTech Fireside Chat: The Journey of an Emerging Medical Device Company: From a Blank Piece of Paper Toward Commercialization
To trace the pathway of a young drug delivery technology company, Mathias Romacker, Pfizer, spoke with John A Merhige of Credence MedSystems, Inc. Credence’s technology are a series of syringes that innovate without changing the fundamental experience.

“If we’re not getting your honest feedback, it’s a faulty signal in our decision-making process.”

-John Merhige, Credence MedSystems

Credence saw a niche in the market and, from the start, worked with people within the supply chain to maintain trusted processes and preferred partners. For fundraising, Mr Merhige and his team utilized their existing network of investors, with whom they had proven their potential. He also advised highlighting marketable, milestone events to investors. When it came to enhancing conversations with big pharma, Mr Merhige asked for honesty, saying, “If we’re not getting your honest feedback, it’s a faulty signal in our decision-making process.”
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DDS Technology Soapbox

The soapbox section thanks to the support from Pfizer, featured young start-ups, entrepreneurs, inventors, licensing officers and university researchers pitching their cutting-edge innovations; it was moderated by Dr Patrick Lim Soo of Pfizer.

- “COMMAND Nanotech: one-step nanomedicine manufacturing,” from Dr Justin YW Tian of Queen’s University Belfast
- “Painting the Brain and Spinal Cord Using Drug-eluting Magnetic Alginate Capsules,” from Dr Lamar Mair of Neuroparticle Corporation
- “Curadigm Platform: Shifting the Therapeutic Paradigm to Elevate Treatment Outcomes for Every Patient,” from Dr Matthieu Germain of Curadigm
- “Delivering Biologics Orally,” from Dr Tyler Brown of i2O Therapeutics
- “Transdermal Drug Delivery and Novel API to Solve US Opioid Crisis,” by Dr Sam Dylan Moré of DendroPharm
- “Continuous Processing Technology for Liposomal Drug Products,” from Dr Antonio Costa of DIANT Pharma
- “Sustained Delivery of Anti-VEGF Protein Therapeutics for the Treatment of wAMD,” by Dr Yu Yu of Pleryon Therapeutics
- “Comparison of Intrathecal Bolus Delivery to EnClear Therapies System Delivery in Porcine Model,” from Laura Paulsen of EnClear Therapies

Pfizer’s, Dr Patrick Lim Soo (left) with the 2019 DDS Technology Soapbox Presenters

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After lunch, the conference then divided into two breakout choices, **Devices** and **Formulations**:

**Breakout 1: “Devices”**

Device Platforms – The Good, the Bad and the Ugly

This panel was moderated by Mathias Romacker, Pfizer, and Dr Chris Coletta, Alcyone Sciences, and included panelists Dr Tommaso Borghi, Flex, Stephen Fournier, Alnylam, Lidia Massimi, Eli Lilly, and Ian Thompson, Ypsomed.

The panelists felt that drug delivery platforms must fundamentally fit the product they’re attempting to deliver: taking into account user experience, formulation and quantity. “The last thing you want to tell the C-Suite is that the device delayed the drug,” said Mr Romacker. Some platforms can be used across multiple therapeutics with alterations made for look and feel.

However, the panel agreed that relying on a platform, or hesitancy to go off-platform, could put you behind the trend, or, worse, behind production. Continuing to iterate, with your own platforms and the industry at large, is necessary as the market moves towards trends such as disposable injectors or patches.

**Breakout 2: “Formulations”**

Smart Drug Design and Development – from Candidate to Phase I

This panel addressed the early development of drug molecules, was moderated by Dr Cornell Stamoran, Catalent Applied Drug Delivery Institute, and included panelists Dr Rebecca Carrier, Northeastern University, Dr Keith Horspool, Boehringer-Ingelheim Pharmaceuticals, James Spavins, Spavins Consulting LLC/ formerly Pfizer, and

Transforming the Injection Experience Through a Patient-Centric Approach

This panel was moderated by Sudeshna Dutta Ray, Amgen, and included panelists Dr Bryce Rutter, Metaphase Design Group, Lilly Stairs, Savvy Cooperative, Alex Therrien, Sunrise Labs, and Dr Rémy Vomscheid, Ipsen.

“Everyone talks about the dignity of dying, I’d like to talk about the dignity of living.”

- Dr Bryce Rutter, Metaphase Design Group

Involving the patient voice for feedback in autoinjector design becomes increasingly more important as the market moves more and more into self-administration. The panel addressed the work they had done, as patient advocates, designers and providers, to improve not only the patient’s experience with autoinjectors but also the complementary instructions for use.

The end goal, as Dr Rutter puts it, is preserving the dignity of patients. “Everyone talks about the dignity of dying,” he said. “I’d like to talk about the dignity of living.”

*Images of Sudeshna Dutta Ray, Amgen leading the panel on Transforming the Injection Experience Through a Patient-Centric Approach*
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Dr Katarina Vulic and Dr Sudhakar Garad, both of Novartis Institutes for BioMedical Research.

Dr Horspool stressed the importance of getting the basics of form, formation and formulation settled. Dr Vulic spoke about the importance of understanding the mitigating or enhancing factors surrounding the pharmacokinetic profile in early models to address down the line. Previously a formulation scientist at Pfizer, Dr Carrier advised to study the body’s processes individually to understand how a drug will be impacted.

For Dr Garad, it was all about bringing the development and research teams together from the beginning to discuss what each side needs from the molecule. Mr Spavins recommended maintaining data integrity and communication across teams and timelines. “The last thing you want to know is somebody did an API study, an excipient study, a dissolution study,” he said, “and it didn’t make it into the mainstream conversation.”

**The Therapeutic & Delivery Potential of Biologically-Derived Delivery Systems**

This panel focused on the benefits and disadvantages of relying on the body’s own mechanics, such as bacteria or viruses, for drug delivery. It was moderated by Dr Robert Saklatvala, Merck, and included panelists Dr Daniel G Anderson, MIT, Dr Amy S Espeseth, Merck, Dr Rishab Shyam, PureTech Health, Dr Marija Tadin-Strapps, SQZ Biotechnologies, and Dr Nele Van Dessel, Ernest Pharmaceuticals.

“[Bacteria are] basically like these robots that you can program to go where you want them to go,” said Dr Van Dessel. Similarly viruses, Dr Espeseth said, are designed to enter specific cell types. Disguising a drug as a fat using an exosome, Dr Shyam found, makes the body traffick it differently. Synthetically reproducing biological delivery systems allows for definition at a molecular level, said Dr Anderson.

There are difficulties in mutations, stability and access, but utilizing biologically derived systems opens up new delivery methods.

Attendees came back together for a plenary afternoon on **Connected Health & Drug Delivery**

Kevin Deane, Phillips-Medisize leading the panel Defining the Value Proposition and Supporting Business Models for Scaled Connected Health Drug Delivery Products

Defining the Value Proposition and Supporting Business Models for Scaled Connected Health Drug Delivery Products

Connected health systems have hit the market, but there haven’t been any moved to scale. Kevin Deane, Phillips-Medisize, Dhairya Mehta, Takeda, Paul Upham, Roche/Genentech, Amir Zur, Teva Pharmaceuticals, and Paul Schultz, BrightInsight, discussed the benefits and barriers for connected health.
One impediment to wide-scale implementation is defining ROI and profit. Shifting the perspective on what counts as ROI, and utilizing the data gathered from connected health devices, could shift the perspective on what is seen as profitable. Suppliers can’t wait the same amount of time as pharma to see a return on investment.

Another hurdle is setting the definition of scaling out. A company like Takeda deals in rare diseases, scaling might mean reaching 6,000 out of 10,000 patients across dozens of countries: their definition of scaling out will differ from another company’s. Despite barriers, connected health provides a faster timeline and increased impact for patients.

Kovalchick compared the human body to a car: a car receives regular maintenance checks, but the human body gets a slew of vaccines early on and doesn’t come back until something is wrong.

“We put all this emphasis on hospital care, instead of keeping people from being in the hospital.”

- Dr Chris Kovalchick, Eli Lilly

To promote wellness by utilizing contextualized composite data, Dr Kovalchick pointed to two companies that used wearables to drastically improve their consumer experiences: Disney’s MagicBand helped executives and planners design the park to fit the consumers’ needs; WHOOP’s wearable adapted to its user and provided custom strain, sleep and recovery metrics.

The top seven chronic conditions managed in the U.S. rack up an annual bill of over $1.2 trillion. Only 3% of healthcare costs go to disease prevention rather than disease management. “We put all this emphasis on hospital care,” Dr Kovalchick said, “instead of keeping people from being in the hospital.”

Achieving the Ultimate Outcome for Patients – Utilizing Digital Health Data to Improve Disease Management, Prevention and Overall Wellness

Dr Chris Kovalchick, Eli Lilly, closed out the conference by advocating for a shift from managing health to emphasizing wellness using digital health data.

The focus in the industry is disease management, but focusing on increasing patient wellness is more cost-effective in the short and long term. Dr
This marked the conclusion of the 9th Annual Partnership Opportunities in Drug Delivery conference. We would like to thank the sponsors, speakers, and exhibitors for the largest and most interactive PODD yet!

The next drug delivery event is Drug Delivery West (DDW), scheduled for May 11-12, 2020 in San Francisco. DDW addresses scientific and business solutions for the best routes of delivery across different therapeutic areas with an emphasis on emerging technologies and to prepare for the future of R&D and clinical care. The 10th annual PODD conference is on October 8-9, 2020 at the Renaissance Boston Waterfront Hotel in Boston.

For information visit www.theconferenceforum.org

A special thank you to ONdrugDelivery and Drug Development & Delivery for going above and beyond as media partners.
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