CONFERENCES REVIEW

Here, Napoleon Monroe, Managing Director, New Directions Technology Consulting, summarises the intensifying coverage of connectivity as a key theme at two recent drug delivery conferences he attended, Partnerships in Drug Delivery and PDA's Universe of Prefilled Syringes and Injection Devices.

The drug delivery Autumn conference season began at the Seventh Annual Partnerships in Drug Delivery Conference (PODD), which took place on October 19-20th, 2017 in Boston, MA, US. As a hub for medical innovation and connected drug delivery device development, Boston is a great, convenient venue for tapping into emerging connected technologies. Most of the PODD sessions featured discussions of connectivity. Also, many of the exhibitors introduced new refinements and extensions of their connected product platforms.

In her opening "Year in Review" talk, PODD Chair, Barbara Lueckel, PhD, Global Business Development Director, Roche, briefed on US FDA clearances of connected health solutions. Actual clearances show the reality and importance of connectivity for drug delivery systems and related diagnostics, and Dr Lueckel covered:

- the FDA clearance of Adherium's SmartTouch monitoring device for AstraZeneca's Symbicort inhaler (510(k))
- the FDA clearance of Bayer's appconnected Betaseron (interferon beta-1b) injector for multiple sclerosis, BETACONNECT (developed by Medicom Innovation Partner)
- Glucose monitoring systems: clearance of several connected systems, including Ascensia's CONTOUR NEXT ONE, Smart Meter's iGlucose and Abbott's new FreeStyle Libre
- Otsuka Pharmaceutical and Proteus Digital Health's resubmission of the FDA application for sensor-embedded formulation of Otsuka's antipsychotic pill, Abilify (aripiprazole). This product was subsequently cleared in November 2017.

Other connectivity highlights of the conference included a panel dedicated to connected delivery devices chaired by Kevin Deane, Executive Vice-President, "The question of who advocates with regulators and legislators for connected drug delivery devices was raised in the final conference Q&A."

Medicom, and a very interactive panel chaired by Paul Jansen, Board Member, Haselmeier, on platforms.

Kurt Sedo's (Vice-President, PharmaCircle) slides "Injectables are Taking Over the Pipeline" and "Innovator Drug Approvals Since 2012" highlighted what we all know about the growing importance of injectables and other combination products. Kurt advised that one can search the PharmaCircle database to find which products are connected.

Jeffrey Karp, PhD, Associate Professor of Medicine / Director of the Laboratory for Accelerated Medical Innovation Harvard Medical School / Brigham and Women's Hospital, discussed personalised medicine targeting and led me, a layman, non-scientist, to a far better beginning understanding of the related complexities. Lars Rebien Sørensen, Former President and Chief Executive, Novo Nordisk, gave a "Fireside Chat" that showed why he is so widely respected a leader.

Connectivity will undoubtedly feature strongly again at the 2018 Eighth Annual PODD, which will take place again in Boston, at the Westin Copley Place Hotel, on October 17-18, 2018. The conference staff at PODD were super, by the way!

The conference season continued in Vienna, Austria, with the PDA's 14th Universe of Prefilled Syringes and Injection Devices Conference. PDA Universe, too, was largely about connectivity. A Pre-



Mr Napoleon Monroe Managing Director T: +1 718 427 3038 E: nap.monroe@ newdirectionsconsulting.net

New Directions Technology Consulting, LLC 1442 Drake Ln Lancaster PA 17601 United States

www.mmedhealth.com

Conference Workshop focusing wholly on "Connected Health & Drug Delivery" was very well attended.

During the workshop, Markus Bauss, Managing Director of SHL Connect, covered his research on market trends and introduced two fascinating patient centric diabetes presentations. The first was by a very informed type 1 diabetes patient. The second by another type 1 patient, the founder of mySugr. He discussed their creative approach – business-to-consumer for product development, followed by business-to-business with insurers and pharma being target partners to bring product sales. mySugr claims 1.1 million registered users and growth of 1,000 users per day. Bauss cited the importance of pens, auto-injectors and infusions and industry plans to invest in connecting these devices.

In their pre-conference presentation, West Pharmaceutical Services included a quote from Prescriptions for a Healthy America in their presentation: "Medications cost the healthcare system approximately \$325 billion annually, and research indicates that suboptimal medication use—including taking too much or not taking enough—leads to avoidable annual healthcare costs totaling \$300 billion. People who don't take their medicines are more likely to end up back in the hospital or in the emergency room than those who do." One audience member (me) noted that Prescriptions for a Healthy America is part of the Horizon Group. Horizon also advocates for interoperability.

A recurrent theme of both the pre-conference and main conference presentations was the benefits of connected devices. The regulatory status of several connected devices was discussed. The exhibition was far larger than prior years and many exhibitors featured connected products this year.

The emphasis on adding connectivity to devices is being driven by the need to improve patient outcomes and add value to delivery devices. One noted gap in the US healthcare system was the lack of interoperability of information systems across the stakeholder communities.

A number of presenters shared their experiences. Sub themes included: the need for collaborations; the concept of device platforms; potential pitfalls; human factors; and other regulatory issues.

In the final presentation, "The Future of Parenteral Drug Delivery in a Connected Health Ecosystem", Divakar Ramakrishnan, PhD, Executive Director of Manufacturing Science and Technology at Eli Lilly, provided predictions. His top three predictions were:

- 1) Auto injectors and pens will remain key for parenteral delivery
- 2) On-body devices will gain share
- 3) Connectivity will become standard.

The question of who advocates with regulators and legislators for connected drug delivery devices was raised in the final conference Q&A. PDA advised that it would consider how this might best be addressed. The PDA organisers and staff again did a masterful job in 2017.

In 2018, PDA Universe of Prefilled Syringes and Injection Devices will return to the US, taking place on October 8-9th, 2018, at Loews Royal Pacific in Orlando, FL, US.

The current conference season continues at Drug Delivery Partnerships (DDP), which also takes place in Florida, on January 22-24th, 2018. My presentation at DDP is entitled: "Breaking News", and will be one of several covering the emergence of connectivity in drug delivery. We look forward to learning from our colleagues there.



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FEATURED SPEAKERS

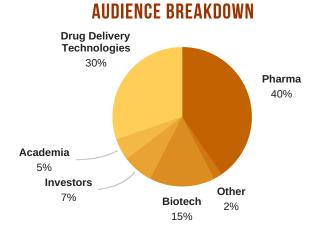




Barbara Lueckel, PhD Roche



Bioinspirationalist Keynote Jeffrey Karp, PhD Harvard Medical School / Brigham and Women's Hospital



HIGHLIGHTS

- 400+ partnering meetings held during PODD 2017
- 100+ speakers
- 50+ exhibiting companies
- 40+ partnering tables
- 5+ hours of built-in networking
- 15 countries represented
 - 3 drug delivery tracks, covering:
 - Injectable Technologies
 - Non-Injectable Technologies
 - Device Technologies

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