

USP/APV 3DP Virtual Workshop Series

July 13–16, 2020

Please note: times are in Eastern Standard Time (EST)

Webex – details to follow in email

Agenda

DAY ONE – 3DP Now & What’s Next: Monday, July 13, 2020

- 9:00 – 9:10 a.m.** **Welcome/Intro**
Brandon Barrett, *Senior Manager | Digital & Innovation, USP*
- 9:10 – 9:25 a.m.** **Opening remarks/USP overview**
Ron Piervincenzi, *CEO, USP*
- 9:25 – 9:35 a.m.** **D&I overview**
Michael Levy, *SVP | Digital & Innovation, USP*
- 9:35 – 9:45 a.m.** **APV overview**
Jörg Breitzkreutz, *President, APV*
- 9:45 – 10:15 a.m.** **3DP @ point-of-care: where we are and where we’re going**
Alvaro Goyanes, *Co-founder & Development Director, FabRx*
- 10:15 – 10:50 a.m.** **3D printed polypills as a point-of-care option**
Mohamed Alhnan, *Sr. Lecturer Pharmaceutical Medicine, King’s College*
- 10:50 – 11:00 a.m.** **Break**
- 11:00 – 11:15 a.m.** **The “new reality” – the pandemic’s implications on 3DP**
Kimberly Eggers, *VP | Medical and Clinical Affairs, Aprelia*
- 11:15 – 11:55 a.m.** **3DP in the regulatory space**
Akm Khairuzzaman, *Senior Reviewer | ONDP – OPQ/CDER, FDA*
Thomas O’Connor, *Division Director | OTR – OPQ/CDER, FDA*
- 11:55 – 12:00 noon** **Outro**
Brandon Barrett, *Senior Manager | Digital & Innovation, USP*

DAY TWO – Tech Talks: Tuesday, July 14, 2020

- 9:00 – 9:05 a.m.** **Intro**
Brandon Barrett, *Senior Manager | Digital & Innovation, USP*
- 9:05 – 9:30 a.m.** **DFE Pharma**
Korinde van den Heuvel, *Senior Product Developer, DFE Pharma*
- 9:30 – 9:55 a.m.** **Triastek**
Xiaoling Li, *Professor/Associate Dean of Graduate Education and Research, University of the Pacific & Co-founder, Triastek*

9:55 – 10:20 a.m.	Multiply Labs Alice Melocchi, <i>Researcher, University of Milan & Co-founder & CSO, Multiply Labs</i>
10:20 – 10:35 a.m.	Break
10:35 – 11:00 a.m.	Vitae Daniel DeCiccio, <i>Co-founder & CTO, Vitae Industries</i>
11:00 – 11:25 a.m.	FabRx Alvaro Goyanes, <i>Co-founder & Development Director, FabRx</i>
11:25 – 11:55 a.m.	Aprecia Jae Yoo, <i>CTO, Aprecia</i>
11:55 – 12:00 noon	Outro Brandon Barrett, <i>Senior Manager Digital & Innovation, USP</i>

DAY THREE – Quality Considerations: Wednesday, July 15, 2020

9:00 – 9:05 a.m.	Intro Brandon Barrett, <i>Senior Manager Digital & Innovation, USP</i>
9:05 – 9:30 a.m.	FDM in pharmaceuticals and dietary supplements: QA Alice Melocchi, <i>Co-founder & CSO, Multiply Labs</i>
9:30 – 10:00 a.m.	Making the formulations work: practical and novel solutions to formulation screening and development of 3DP medicines Clive Roberts, <i>Professor of Pharmaceutical Nanotech & Head of College of Pharmacy, University of Nottingham & Director, Eminate Limited</i>
10:00 – 10:30 a.m.	Making the formulations work: balancing reactivity, rheology, and resolution in 3DP pharmaceuticals Timothy Long, <i>Faculty at SMS and SEMTE, Arizona State University & Director, BCSM3</i>
10:30 – 10:45 a.m.	Break
10:45 – 11:05 a.m.	Digital printing of drugs: the process flow as an example in social security systems Markus Dachtler, <i>Managing Shareholder, DiHeSys</i> Christian Franken, <i>Managing Shareholder, DiHeSys</i>
11:05 – 11:30 a.m.	Industry perspective on 3DP Markus Weigandt, <i>Executive Director Pharmaceutical Technologies, Merck KGaA</i>
11:30 – 11:55 a.m.	The small distributed model and quality assurance Kimberly Eggers, <i>VP Medical and Clinical Affairs, Aprecia</i>
11:55 a.m – 12:00 noon	Outro Brandon Barrett, <i>Senior Manager Digital & Innovation, USP</i>

DAY FOUR – Current Guidance & Opportunities: Thursday, July 16, 2020

- 9:00 – 9:05 a.m.** **Intro**
Brandon Barrett, *Senior Manager | Digital & Innovation, USP*
- 9:05 – 9:35 a.m.** **Early adopters: the Vitae end-user experience**
Jeanine Sinanan-Singh, *Co-founder & CEO, Vitae Industries*
- 9:35 – 10:00 a.m.** **Early adopters: the PharmaPrinter end-user experience**
Arun Giridhar, *Co-founder, PharmaPrinter & Researcher, Purdue University*
- 10:00 – 10:15 a.m.** **Break**
- 10:15 – 10:45 a.m.** **The pharmacopeial perspective**
Nurisha Rush, *Senior Director | SMPO, USP*
Rick Schnatz, *Senior Manager | HQS, USP*
- 10:45 – 11:35 a.m.** **Moderated session: current guidance and opportunities**
Ivan da Gama Teixeira, *1st VP, Anfarmag*
Don Wetherhold, *SVP | Business Development, Aprecia*
Jeanine Sinanan-Singh, *Co-founder & CEO, Vitae Industries*
Moderator: Brandon Barrett, *Digital & Innovation, USP*
- 11:35 – 11:55 a.m.** **Closing remarks**
Brandon Barrett, *Senior Manager | Digital & Innovation, USP*
Julian Quodbach, *Postdoctoral Researcher, Uppsala University & 3DP SME, APV*
- 11:55 – 12:00 noon** **Thank you**
Brandon Barrett, *Senior Manager | Digital & Innovation, USP*