



3DP Speaker Biographies (listed alphabetically by last name) July 13-16, 2020



Mohamed. Alhnan (MAA)
Senior Lecturer in Pharmaceutical Medicine
King's College London (KCL)

Mohamed. Alhnan (MAA), is a Senior Lecturer in Pharmaceutical Medicine at King's College London (KCL). His research is focused on applying the latest advances in material science and electronics in the pharmaceutical field. His fundamental research has led to several world firsts; first example of using pharmaceutical grade polymers in FDM 3D printing (WO2017072536A1), first 3D printed tablets to meet the US and British Pharmacopoeias (BP) for delayed release products (Okwuosa et al., 2016, Pharm Res, 34(2):427-437), and first examples of 3D printing of liquid-filled capsules (WO2018020237A1). He introduced and patented the innovative concept of tablets of complex architecture as a solution for fast disintegration and dissolution (WO2017072536A1). MAA invented a novel approach for manufacturing via extrusion under low temperature (WO2016038356A1). He provided an innovative approach for natural pharmaceutical coating systems for pharmaceutical and nutraceutical products (WO2017187194A1). MAA has published 39 peer-reviewed articles (16 articles on manufacturing solid dosage form using innovative technologies), >60 conference abstracts, and 5 patent applications (Scopus *h*-index 20).

Presentation: Day 1 - 3D printed polypills as a point-of-care option



Brandon Barrett
Senior Manager, Digital and Innovation
United States Pharmacopeia (USP)

Brandon Barrett serves as a Senior Manager for USP's Digital and Innovation division. He leads an agile team of innovators to bring innovative ideas and prototypes to life, focusing on the incubation of emerging technologies, informatics, and digitalization. Prior to joining USP in 2019, he joined Eli Lilly as a fellow. He then served as Innovation Lead for their

Clinical Innovation Lab, earning a Lilly Top Innovator award in 2017. Brandon earned a Bachelor's Degree in Biology from the University of South Carolina, and his PharmD and Masters in Clinical Research from the Medical University of South Carolina.

Moderator: Days 1-4



Jörg Breitzkreutz

President
APV

Jörg Breitzkreutz studied Pharmacy from 1987 to 1991 at the Westphalian Wilhelms-University of Münster, Germany. He finished his PhD in 1996 at the Institute for Pharmaceutical Technology and Biopharmaceutics in Münster under supervision of Prof. Rüdiger Gröning. From 1996 to 1997 he joined Thiemann Arzneimittel GmbH in Waltrop, Germany, as the head of Product Coordination. In 1997 he went back to the university in Münster to work on his habilitation thesis (2004) on pediatric drug formulations. In 2004 he became professor for pharmaceutical technology at the Institute of Pharmaceutics and Biopharmaceutics at the Heinrich-Heine-University in Düsseldorf, Germany, and today is the director of this institute. Joerg Breitzkreutz serves as external expert for various regulatory bodies and companies. He is presently heading the Paediatric Formulation group at the European Directorate for the Quality of Medicines and Healthcare (EDQM). Since 2010 he is president of the non-for-profit International Association of Pharmaceutical Technology (APV). His research focuses on pediatric and geriatric drug formulations, drug printing technologies, orphan drugs, process analytical technologies, green and sustainable medicinal products.

Presentation: Day 1 - APV overview



Dr. Markus Dachtler, MBA. PMP

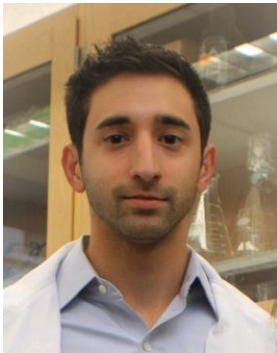
Managing Shareholder
DiHeSys Digital Health Systems GmbH

Dr. Markus Dachtler studied chemistry in Tübingen, Germany and economics in Neu-Ulm, Germany. In 2000 he finished his Ph.D. thesis in analytical chemistry in Tübingen dealing with direct LC-NMR-MS coupling analysis of biomaterials. From 2000-2004 Dr. Markus Dachtler was employed as scientist at Unilever R&D, Vlaardingen, the Netherlands. From 2004-2015 he joined ratiopharm (since 2010 within Teva group), Ulm, Germany and worked in different departments (Stability control, R&D Project Management, General Management).

In June 2015 Dr. Markus Dachtler acquired Gen-Plus GmbH & Co KG in Munich, Germany. Gen-Plus is a small CRDO and offers as state-of-the-art Pharmaceutical R&D and Technology Center formulation development for solid & semi-solid dosage forms and oral films (ODF) / transdermal patches (TTS) on a contract service level. The GMP facility (1000 sqm) allows IMP production as well as handling of high potents and narcotics. Novel technologies include 2D/3D Drug Printing and e-Health applications. Dr Dachtler is also co-founder of the company DiHeSys – Digital Health Systems. The company is a healthcare provider for personalized medication.

Dr. Dachtler gives regular lectures in the field of generics development and pharma business. He has authored more than 20 publications in international journals and also holds 1 patent. In his scientific career he got several innovation awards and the Richard R. Ernst Prize in 1998.

Presentation: Day 3 - Digital printing of drugs: the process flow as an example in social security systems



Daniel DeCiccio
Co-Founder & CTO
Vitae Industries

Daniel DeCiccio has served as Chief Technology Officer at Vitae Industries since its founding in 2015. He is the chief designer of Vitae's first-to-market compounding automation platform. Daniel is a serial entrepreneur and engineer with dual degrees in biomedical engineering and chemical physics from Brown University. His work in engineering began at Brown where he developed novel carbon-dioxide capture and conversion technologies. After his time at Brown, Daniel co-founded Research Instruments Corporation which developed and commercialized the world's brightest tabletop x-ray source. The x-ray sources are currently in use in laboratory settings where they help image molecular motion.

Presentation: Day 2 – Vitae



Kimberly Eggers, PharmD
VP, Medical and Clinical Affairs
Aprecia Pharmaceuticals

Dr. Kimberly (Kim) Eggers serves as Aprecia's Vice President of Medical & Clinical Affairs, where she oversees the company's clinical research and safety, data management/biostatistics, pharmacovigilance, medical information, and new product research departments.

Dr. Eggers holds a Doctor of Pharmacy degree from the University of Georgia. Prior to joining Aprecia in 2019, she served 13 years in several leadership positions at Publix Super Markets, Inc.

Presentation: Day 1 - The "new reality" – the pandemic's implications on 3DP

Presentation: Day 3 - The small distributed model and quality assurance



Christian Franken
Managing Shareholder
DiHeSys Digital Health Systems GmbH

Christian Franken, geboren 1969, ist approbierter Apotheker mit Weiterbildungen zum Fachapotheker für klinische Pharmazie und Arzneimittelinformation. Er wurde in der Pharmakologie des pharmazeutischen Institutes der Rheinischen Friedrich-Wilhelms-Universität Bonn promoviert und hat erfolgreich den IWW Studiengang BWL/VWL an der Fernuniversität Hagen absolviert. Von 199 bis 2007 war er als Klinikapotheker tätig, in den Jahren 2003 bis 2007 leitete er die Krankenhausapotheke des Universitätsklinikums Düsseldorf. Von 2007 bis 2020 war er Chefapotheker und seit 2013 Vorstand bei DocMorris, Heerlen, Niederlande. Zusätzlich ist er Professor für Klinische Pharmazie am Department für Klinische Pharmakologie und Systematische



Medizin an der Universität Maastricht, außerdem hat er verschiedene Lehraufträge in Public Health und Gesundheitsökonomie an den Universitäten in Jena und Basel inne. Seit Juni 2020 ist er Geschäftsführer der DiHeSys Digital Health Systems, deren Gesellschafter er bereits ist. Christian Franken hat mehrere Peer-Review-Publikationen und Bücher veröffentlicht. Er ist Mitglied der Deutschen Pharmazeutischen Gesellschaft, der Gesellschaft für Arzneimittelforschung und Pharmakoepidemiologie sowie Mitglied der Liga für Patientensicherheit.

Christian Franken, born in 1969, is a licensed pharmacist with further training as a specialist pharmacist for clinical pharmacy and drug information. He received his doctorate in pharmacology from the Pharmaceutical Institute of the Rheinische Friedrich-Wilhelms-University of Bonn and successfully completed the IWW course of studies in business administration at the University of Hagen. From 1999 to 2007 he worked as a hospital pharmacist, and from 2003 to 2007 he was head of the hospital pharmacy of the University Hospital Düsseldorf. From 2007 to 2020 he was Chief Pharmacist and since 2013 he was a member of the board of DocMorris, Heerlen, Netherlands. In addition, he is Professor of Clinical Pharmacy at the Department of Clinical Pharmacology and Systematic Medicine at the University of Maastricht. He also holds various lectureships in public health and health economics at the universities of Jena and Basel. Since June 2020, he has been managing director of DiHeSys Digital Health Systems, of which he is already a shareholder.

Christian Franken has published several peer-reviewed publications and books. He is a member of the German Pharmaceutical Society, the Society for Drug Research and Pharmacoepidemiology and a member of the League for Patient Safety.

Presentation: Day 3 - Digital printing of drugs: the process flow as an example in social security systems



Arun Giridhar

Research Scientist, Purdue University
Co-founder, PharmaPrinter (Pinpoint Pharma), a printed medicine company

Arun Giridhar works with personalized medicine technologies. Arun brought inkjet printing from R&D to a fully functioning commercial compounding pharmacy that printed medicine on demand. Currently he is looking for new ways to continue improving healthcare. He is also experienced with process automation and advanced process control and integration, pioneering it in an advanced manufacturing testbed, and is using this background to progress Pharma 4.0. Arun is a Chemical Engineer by

education.

Presentation: Day 4 - Early adopters: the Pharmaprint end-user experience



Alvaro Goyanes

Co-founder and Development Director
FabRx

Alvaro is co-founder and Development Director at FabRx, the first company focused on developing 3D printing technology for fabrication of personalised medicines and medical devices. He is honorary lecturer at University College London - School of Pharmacy (UK) and also part-time lecturer at the Faculty of Pharmacy - University of Santiago de Compostela (Spain). Alvaro is one of the first researchers to evaluate the opportunities of 3D printing using new 3D



printing technologies to manufacture oral dosage forms and medical devices. Alvaro has published more than 48 articles. He has been distinguished as Highly Cited Researcher 2019 from Web of Science and is a recognized world expert in 3D printing of medicines with more than 100 communications to international conferences. He holds a PhD in Pharmaceutics from University of Santiago de Compostela (Spain) and he worked for 3 years as a Registered Pharmacist, thus has first-hand knowledge of the needs in terms of medicines in the community pharmacy.

Presentation: Day 1 - 3DP @ point-of-care: where we are and where we're going

Presentation: Day 2 – FabRx



Akm Khairuzzaman, B. Pharm., MS., Ph.D.

Senior Reviewer

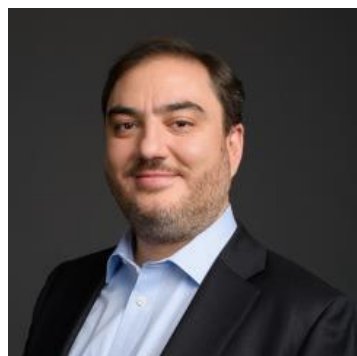
Office of New Drug Product, Office of Pharmaceutical Quality, CDER
Food and Drug Administration

Dr. Khairuzzaman is a Senior Reviewer at FDA's Office of Pharmaceutical Quality in CDER. His scientific review work at the FDA focuses on the chemistry, manufacturing, and controls of investigational new drug applications (IND) and new drug applications (NDA). Prior to joining the FDA in 2008, he worked as a formulation scientist and research investigator in pharmaceutical industry. Dr. Khairuzzaman has published several papers and one book chapter on 3D printing and presented on this subject matter at many national

and international science meetings.

Dr. Khairuzzaman earned a B.S. in pharmacy. His Master's degree in industrial pharmacy, and Ph.D. in pharmaceuticals are from the Arnold and Marie Schwartz College of Pharmacy, Long Island University, New York.

Presentation: Day 1 - 3DP in the regulatory space



Michael Levy, M.Sc., M.B.A.

Senior Vice President, Digital and Innovation
United States Pharmacopeia (USP)

Michael Levy is Senior Vice President, Digital and Innovation. In this role, Mr. Levy oversees several forward-looking pillars of activity, including Research and Innovation, Digital & Informatics, and the Pharmaceutical Supply Chain Center.

Research & Innovation identifies, assesses, and as appropriate, incubates emerging technologies that may impact the industries USP works in, the way USP standards are used, or the way those standards are produced.

Digital & Informatics focuses on digitizing USP's standards to better integrate them into digital environments, fostering standards for digital solutions, and enhancing USP's digital delivery of content. The Pharmaceutical Supply Chain Center leverages a unique, integrated data set and analytics to explore complex medicine supply chains, identify potential vulnerabilities, and recommend risk mitigating interventions.



Mr. Levy's diverse background includes shaping public policy through advocacy, counseling biopharmaceutical and healthcare regulatory executives and staff as a management consultant, and providing deep scientific and technical expertise to academic and industry researchers. Prior to his current role, Mr. Levy was the creator and first Head of USP's Quality Institute. Previously, he served as Deputy Vice President, Science & Regulatory Advocacy, at the Pharmaceutical Research and Manufacturers of America (PhRMA), where he shaped the drug development and regulatory review processes—with an emphasis on using non-traditional data and advanced analytics to inform clinical trial design and regulatory decision making. Mr. Levy also served as an Associate Principal at McKinsey & Company, where he supported biopharmaceutical companies and regulators on a broad set of topics in Research and Development and technology enablement. Earlier in his career, Mr. Levy was part of the team that sequenced Human Chromosome XIV as part of the Human Genome Project, and he was the lead bioinformatician in a bioinformatics start-up.

Mr. Levy earned his Masters of Business Administration Degree from Cornell University's Johnson Graduate School of Management, and his Master of Science and Bachelor of Science degrees from Concordia University in Montreal, Canada.

Presentation: Day 1 - D&I overview



Xiaoling Li, Ph.D.

Professor of Pharmaceutics and Associate Dean of Graduate Education and Research
Thomas J. Long School of Pharmacy and Health Sciences at the University of the Pacific
Co-founder, Triastek

Xiaoling Li, Ph.D. is a Professor of Pharmaceutics and Associate Dean of Graduate Education and Research in Thomas J. Long School of Pharmacy and Health Sciences at the University of the Pacific. Dr. Li is a Fellow of American Association of Pharmaceutical Scientists and a Fellow of American Institute for Medical and Biological Engineering. He received BS in Pharmacy and MS in Nuclear Pharmacy from Shanghai Medical University in 1982 and 1985, respectively. Under the guidance of Dr. Sung Wan Kim, Dr. Li obtained his Ph.D. in Pharmaceutics from the University of Utah in 1991. Prior to his academic career, he was a postdoctoral research fellow at Ciba-Geigy Corp (now Novartis). Dr. Li's research interest areas include oral mucosal drug delivery, novel polymers for pharmaceutical and medical application, targeting drug delivery, antibody mimics, drug transport across biological membranes, and application of physicochemical concepts to novel dosage form design. His research projects are funded by both NIH and pharmaceutical industry. He holds 10 patents with 41 patent applications pending and has published 97 papers/book chapters, over 170 abstracts/presentations, and two books entitled "Design of Controlled Release Drug Delivery Systems" and "Oral Bioavailability". Dr. Li received CRS Outstanding Paper Award for the *Journal of Controlled Release* in 1992. He is a Thomas J. Long Fellow, recognized as a Distinguished Faculty Research Lecturer (2003), received Distinguished Faculty Award (2012) and Eberhardt Teacher/Scholar Award (2019) at the University of the Pacific. Dr. Li is the recipient of AAPS Outstanding Educator Award in 2015. He is a member of the Association of American Pharmaceutical Scientists, Controlled Release Society, and a convention member of USP. Dr. Li has mentored and trained 26 Ph.D., 3 MS, 16 post doctoral research fellows, and 18 visiting scientists. He co-founded two companies, Formurex, Inc., a formulation development company in 2006 and Triastek, a 3D printing pharmaceutical company in 2015. Dr. Li works closely with the pharmaceutical industry and provides consultation for product development to various pharmaceutical companies.

Presentation: Day 2 - Triastek



Tim Long, Ph.D
Professor of Chemistry
Virginia Tech

Tim received his Ph.D. in Chemistry from Virginia Tech under the direction of Prof. James McGrath, and he subsequently joined both Eastman Kodak and Eastman Chemical companies for eight years upon graduation. He joined the faculty in the Department of Chemistry at Virginia Tech, where he also served as the Director of the Macromolecules Innovation Institute until 2019. In 2020, Prof. Long accepted an interdisciplinary faculty position across the School of Molecular Sciences (SMS) and the School for

Engineering Matter, Transport, and Energy (SEMTE) at Arizona State University (ASU) where he will launch and lead the Biodesign Center for Sustainable Macromolecular Materials and Manufacturing (BCSM3). In addition to over 400 peer-reviewed publications, his research awards include the 2020 Virginia Outstanding Faculty Award, 2015 Virginia Scientist of the Year, 2010 Virginia Tech Alumni Research Award, ACS PMSE Collaborative Research Award, PSTC Carl Dahlquist Award, 2019 ACS Rubber Division Thermoplastic Elastomer Award, and the ACS POLY Mark Scholar Award. He has served as the Chair of the ACS Division of Polymer Chemistry, Chair of the Gordon Research Conference in Polymers, 2012 Chair of the IUPAC World Polymer Congress, and he currently serves as the Past-President of the Adhesion Society. He is a member of advisory boards for leading journals, and he was recently appointed as Editor-in-Chief of Wiley *Polymer International*.

His research interests span structure-property-processing relationships for polymers with a focus on multiphase systems including ion-containing and hydrogen bonding containing block copolymers, biomaterials and hydrogels, sustainable polymers and processes, renewable feed stocks, and green chemistry. New monomer syntheses and polymerization processes have led to novel families of thermoplastic elastomers including controlled radical polymerization, living anionic polymerization, and the formation of segmented step-growth polymerization processes with a focus on polyurethanes, polyimides, polysulfones, polyketones, and polyesters. His most recent research efforts address the need for tailored advanced macromolecules for advanced manufacturing (3D printing), including vat photopolymerization, direct ink write, binder jetting, powder bed fusion, and melt extrusion. This research has led to new families of engineering polymers, photo-reactive polymers, tissue scaffolds, and enzyme delivery systems. He has published in the area of drug/gene delivery and most recently focused on hydrogels for brachytherapy in oncology. This interdisciplinary research program has garnered over \$50M in research funding from federal (NSF, NIH, DOE, PRF, and DOD) agencies and diverse international corporate sponsors.

Presentation: Day 3 - Making the formulations work: balancing reactivity, rheology, and resolution in 3DP pharmaceuticals



Alice Melocchi
Co-founder & CSO
Multiply Labs

After graduating cum laude in Pharmacy, Alice Melocchi spent 9 months at Massachusetts Institute of Technology as a visiting student, working within the Novartis-MIT Center for Continuous Manufacturing. In 2015, she earned her Ph.D. from Università degli Studi di Milano and currently she is a researcher at the Department of Pharmaceutical Sciences of the same University. Her research activity concerns the exploitation of hot processing techniques as advantageous alternatives for the production of already existing dosage forms or for the manufacturing of innovative drug delivery systems. More recently, her work has also been focused on the use of 3D printing, and in particular on fused deposition modeling technique. In 2016 Alice co-founded the startup Mutiply Labs in which she holds the position of CSO besides her academic roles. The company was selected for taking part in the 2016 summer batch of Y Combinator and aims at the fabrication of personalized drug products thanks to the use of robotics. In December 2018, Alice was also nominated among the Inspiring 50 Italy, the most inspiring Italian women in technology.

Presentation: Day 2 - Multiply Labs

Presentation: Day 3 - FDM in pharmaceuticals and dietary supplements: QA



Thomas O'Connor, Ph.D.
Director Division of Product Quality Research
Office of Testing Research, Office of Pharmaceutical Quality
CDER
Food and Drug Administration

Dr. O'Connor is the director of the Division of Product Quality Research in the Office of Testing and Research in the Office of Pharmaceutical Quality and is a member of CDER's Emerging Technology Team. His responsibilities include managing regulatory science projects to support the implementation of emerging technologies in pharmaceutical manufacturing such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Tom is a co-author of several papers and book chapters on continuous manufacturing and emerging pharmaceutical technology. He has participated in the review of several regulatory applications utilizing continuous manufacturing. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA.

Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Dr. O'Connor earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

Presentation: Day 1 - 3DP in the regulatory space



Ronald T. Piervincenzi, Ph.D.
Chief Executive Officer
United States Pharmacopeia (USP)

Ronald T. Piervincenzi, Ph.D., has served as Chief Executive Officer of the United States Pharmacopeia since February 2014. Dr. Piervincenzi provides strategic leadership to USP's global staff of over 1,200 across 10 global sites. His transformative vision has launched key USP initiatives in bringing quality across the healthcare spectrum, upholding USP's reputation as a quality leader since its founding in 1820. Under his leadership, USP has modernized its operations and launched innovative new science, including in the areas of digital medicine, cutting-edge manufacturing technologies and advanced biologics. USP is better connecting to its stakeholders and customers through new initiatives including the Hyderabad Training Institute in India, the Quality Institute, and USP's new Impurities for Development program. Dr. Piervincenzi served as Chair of the Council of Experts, USP's scientific standards-setting body of 24 Expert Committees and over 750 standards-setting experts until June 2015.

Dr. Piervincenzi brings more than 20 years of industry experience across pharmaceutical sciences, research and business strategy. Before joining USP, Dr. Piervincenzi was Vice President of Development Sciences with Biogen and was a partner and leader in McKinsey & Company's global pharmaceutical and medical products practice for over 12 years. Dr. Piervincenzi earned his M.S. and Ph.D. from Duke University in Biomedical Engineering, with research focused on protein engineering. He is the proud co-founder and chairman of the board for the Newark Mentoring Movement.

Presentation: Day 1 - Opening remarks/USP overview



Clive Roberts
Head of the School of Pharmacy
University of Nottingham

I received my PhD in 1991 from the Department of Physics, Imperial College, London in nanotechnology. Following a post-doc at Nottingham I became a Lecturer in Biophysics in the School of Pharmacy, UoN, and in 2001 as Reader in Biomedical Nanotechnology. In January 2005 I was promoted to a Chair of Pharmaceutical Nanotechnology.

Clive is Head of the School of Pharmacy, University of Nottingham (2013-) and a member of the UK Pharmacy Schools Council (PhSC) Executive. During his time as Head of School, Nottingham has risen to 7th in the QS World Rankings for Pharmacy & Pharmacology and has significantly expanded its research and teaching offer, including an International Pharmacy degree with China and a four-year Pharmaceutical Sciences degree with a year in Industry. The School also has a joint 2+2 MPharm degree with its sister School on the Nottingham Malaysia campus and was the first to offer a 5-year MPharm degree with integrated pre-registration (from 2012).

In his research Clive founded the successful [Nottingham Nano and Microtechnology Centre](#). Nanotechnology has also served as a great platform to support public engagement including leading several major public exhibitions and roadshows directly engaging over 30,000 members of the public. More recently his research has included 3D printing of medicines, with substantial multi-million pound support from EPSRC, AstraZeneca and GSK. Some of the first tablets produced from this work were

exhibited in the London Science Museum and Manchester Industrial Science Museum. With his collaborators Clive has demonstrated a number of examples of 3D printing of oral dosage forms with a range of printer types, including extrusion and hot-melt/solvent ink jet printing. Clive received the UK Academy of Pharmaceutical Sciences Medal Award in 2019. Clive was also a co-founder and Technical Development Director of a successful pharmaceutical research spin-out, Molecular Profiles Ltd a recipient of two Queens Award for Enterprise. Molecular Profiles Ltd became part of Juniper Pharma Inc based in Nottingham and the US and was purchased by Catalent Inc in 2019.

Presentation: Day 3 - Making the formulations work: practical and novel solutions to formulation screening and development of 3DP medicines



Nurisha Rush, M.B.A.

Senior Director, Strategic Marketing and Program Operations for Healthcare, Quality and Safety and USP Verification
United States Pharmacopeia (USP)

Professional Experience

- Leads integration of USP's activities and overall strategy for Healthcare, Quality and Safety including compounded drug preparations
 - Served in a variety of scientific leadership roles and has more than 20 years of experience at USP, McCormick and Company, Campbells Soup Company, and Morton Salt Inc.
- Expertise globally across the healthcare and consumer landscape with strategy and planning, breakthrough innovation, operational excellence, and growth

Presentation: Day 4 - The pharmacopeial perspective



Rick G. Schnatz, Pharm.D.

Senior Manager, Healthcare Quality and Safety
Healthcare Quality Standards Division
United States Pharmacopeia (USP)

Rick G. Schnatz, Pharm.D. is the Senior Manager for the the United States Pharmacopeia's (USP) Healthcare Quality and Safety Group. In this position he is responsible for managing and coordinating the volunteer efforts of three Expert Committees: 1) Compounding Expert Committee, 2) Healthcare Quality and Safety Expert Committee and 3) Nomenclature and Labeling Expert Committee. During his tenure at USP, he has been responsible for the clinical enhancements to the MEDMARX Medication Error and Adverse Drug Reaction program and the MEDMARX training contract for the Department of Defense,

including both CONUS and OCONUS.

He has over 44 years of pharmacy experience in patient safety, including serving as an adjunct faculty member to the Medical University of South Carolina's College of Pharmacy and the Department of Family Medicine at the Regional Medical Center in South Carolina. He received his BS degree in biology from Furman University and his Doctor of Pharmacy degree (Pharm.D.) from the Medical University of South Carolina in Charleston (MUSC).



After graduation he established the first medical practice in the country to pair a board-certified Family Physician with a clinically trained family medicine Doctor of Pharmacy providing collaborative medical and pharmaceutical patient care management. In 1981 he founded Kinetic Consultants® offering pharmacokinetic consultation services to healthcare practitioners in various settings. Prior to joining USP he spent 19 years with National Data Corporation where he was responsible for the clinical development of the Managed Care Inpatient and Outpatient Pharmacy Systems.

Since beginning his professional career, he has multiple publications, both articles and chapters, and has given scores of lectures to numerous professional groups including medical and house staffs, universities and national pharmacy meetings as well as international presentations. He authored the chapter entitled *Modern-Day Drug Discovery and Development* in the current version of Remington: The Science and Practice of Pharmacy.

He is a member of the American Pharmacy Association, the American Society of Health-System Pharmacists, and the Alliance for Pharmacy Compounding (formerly IACP). He serves on the Board of Directors for the *International Society of Pharmaceutical Compounding* headquartered in Spain.

Presentation: Day 4 - The pharmacopeial perspective



Jeanine Sinanan-Singh
Co-Founder & CEO
Vitae Industries

Jeanine Sinanan-Singh co-founded Vitae Industries in 2015 to develop 3D printing technology that enables widespread production and accessibility of personalized medications. Prior to joining Vitae full-time as its chief executive officer, she was a Program Manager at Microsoft where she managed engineers to complete cloud buildouts, develop big data tools and release developer APIs. She holds a BA from Harvard University in Computer Science.

Presentation: Day 4 - Early adopters: the Vitae end-user experience

Panel: Day 4 - Moderated session: current guidance and opportunities



Ivan da Gama Teixeira
1st VP
Anfarmag

Graduated in Pharmacy and Biochemistry from the College of Pharmaceutical Sciences of the University of São Paulo.
Served as Pharmaceutical Officer of the Brazilian Air Force from 1985 to 1991
Specialist in Homeopathy by Paulista Association of Homeopathy

Acted as:

- Treasurer, 1st Secretary, Vice President and President at the Brazilian Association of Homeopathic Pharmacists - ABFH, having also exercised the functions of co-responsible for institutional relations, member of the scientific committee, review of the Manual of Technical Standards and representation of the entity before the Agency National Health Surveillance Agency - ANVISA in the review of RDC 33/2000;



- Member of Anfarmag in the Commission of the Equivalence Manual of the entity since its first edition and coordinator of the last two editions, 5th and 6th.
- Rapporteur of the methodology development project for calculating the average weight for the magistral sector that gave rise to the method of the National Formulation of Brazilian Pharmacopoeia.
- Member of the Technical Board of this same entity from 2005 to 2015;
- Invited professor at Escola Paulista de Homeopatia to teach Pharmaceutical Care to pharmacists and Prescription Good Practices in Homeopathy to doctors.
- Director of Anfarmag Nacional, holding the following positions: 1st Vice-President (2013-2015 management), 2nd Vice-President (2011-2013 management), Secretary-General (2009-2011 management), and Technical Director.
- Currently performs the following functions:
 - Anfarmag representative in the Brazilian Pharmacopoeia National Form
 - AD HOC Technical Advisor to Anfarmag's Board of Directors
 - Director and owner partner of Botica Belluz - Homeopathy and Allopathic Manipulation Pharmacy

Panel: Day 4 - Moderated session: current guidance and opportunities



Korinde van den Heuvel

Senior Product Developer
DFE pharma

Korinde van den Heuvel is senior product developer at DFE pharma since April 2014. In this role she contributed on multiple OSD projects but currently mainly focusing on 3D printing of pharmaceutical tablets. Prior to working at DFE pharma she worked for 10 years at Synthon in formulation development developing various generic plus OSD forms such as ODT, IR and MR tablets and capsules. Korinde holds a master degree of Organic chemistry from the Radboud University in Nijmegen, The Netherlands.

Presentation: Day 2 - DFE Pharma



Dr. Markus Weigandt

Executive Director
Pharmaceutical Technologies
Merck Healthcare KGaA
Darmstadt, Germany

Dr. Weigandt is a pharmacist by training and since 2015 Head of Pharmaceutical Technologies at Merck Healthcare. He is heading a team of ~100 pharmaceutical experts working at the Merck R&D hubs Darmstadt and Boston. Main tasks are pharmaceutical development, characterization, formulation, process development and GMP manufacturing of all projects in the Merck R&D pipeline. This comprises all project phases (from Discovery to Life Cycle Management) and dosage forms (esp. parenteral and solid dosage forms).



After a PhD at University of Heidelberg, he started his career 2001 at Cytonet, a biotech spinoff from Roche, working on development and manufacturing of adult stem cells. He joined Merck in 2003 as Qualified Person for development projects and since then held several positions at Merck.

Presentation: Day 3 - Industry perspective on 3DP



Don Wetherhold
SVP, Business Development
Aprecia Pharmaceuticals

Mr. Don Wetherhold serves as a Senior Executive Advisor to the Chairman and executive team at Aprecia as well as Senior Vice President and Head of Business Development. Mr. Wetherhold previously served as the company's Chief Executive Officer (2013 – 2017) prior to which he served as Senior Vice President, long-term care at Omnicare, Inc. Mr. Wetherhold was Aprecia's Corporate Commercialization Officer previous to his time at

Omnicare.

Mr. Wetherhold's career spans 30 years of experience in the healthcare industry, including key leadership roles and management positions at Omnicare, Prasco Laboratories, Hampton Lane, Cardinal Health, Snyder Healthcare Sales and Solvay Pharmaceuticals.

Panel: Day 4 - Moderated session: current guidance and opportunities



Jae Yoo, Ph.D. MBA
Chief Technology Officer
Aprecia Pharmaceuticals

Dr. Jae Yoo serves as Chief Technology Officer for Aprecia Pharmaceuticals since August 2018. His 3DP journey started at MIT in the early 1990's where he developed and used an inkjet printing based 3DP process to fabricate advanced ceramic materials with compositional gradient. He explored and demonstrated a wide range of pharmaceutical and biomedical applications of 3DP while working for Therics, Inc., a VC backed company that licensed the

technology from MIT.

In 2003, he co-founded Aprecia Pharmaceuticals and headed its research and engineering efforts to develop a high-speed, additive manufacturing process suitable for cGMP operation. His work set the foundation for first ever FDA approval of a 3D printed pharmaceutical product, SPRITAM®, manufactured and marketed by Aprecia. He was part of GlaxoSmithKline (2014-2018) and explored automation for R&D productivity gain and evaluated platform capabilities for Advanced Manufacturing Technology initiative. He is a co-inventor of many US and international patents on additive manufacturing of pharmaceutical products and medical devices. Prior to his graduate work at MIT, he studied Metallurgical Engineering and Materials Science at Carnegie Mellon University. He holds MBA from Wharton School at University of Pennsylvania.

Presentation: Day 2 - Aprecia