# 3D Printing in Pharma – 4 years after the first FDA approval: where are we now?



23 to 24 May 2019 Antwerp, Belgium

Course no. 6781



### **Hot Topics**

### Target group

This course is organized for scientists and decision makers from industry and academia who are interested in the possibilities and techniques of 3D printing in a pharmaceutical context. 4 years after the first FDA approval of a 3D printed drug, recent scientific advances and developments will be covered and discussed. Furthermore, the course covers topics regarding excipient selection, a first-in-human study, the application of printing technolgies in a hospital setting and regulatory aspects.



### A seminar organised by the APV focus group Solid dosage forms

### **Objectives**

3D printing holds the promise of tailor made, highly individual dosage forms, implants and even tissues and organs. Within the last years, printing techniques that were deemed non-applicable were demonstrated to be viable options for pharmaceutical 3D printing and the investigation of quality standards is shifting into focus. Yet, only a limited number of 3D printed products and only one 3D printed medicine are commercially available.

### Goals of the seminar

In this seminar, leading minds from academia and industry discuss the current state and potential future developments for pharmaceutical 3D printing. Sessions cover the manufacturing of solid dosage forms, the selection of suitable excipients, technical considerations for printers and material considerations for bioprinting. Recent achievements but also limitations of printed drug delivery systems are presented and discussed. The seminar ends with a session by speakers about the application of printing technologies in a hospital setting and regulatory aspects of dosage form printing.

#### Peter Hölig, PhD

Peter Hölig, PhD has more than 10 years of experience in the pharmaceutical and chemical industry. At Evonik Nutrition & Care GmbH he is currently responsible for identifying and leading pharmaceutical and medical strategic innovation



pharmaceutical and medical strategic innovation activities and projects within the Business Line Health Care.

In his previous role at Abbott/AbbVie he was responsible for the formulation and process development - from bench-top up to commercial scale - of commercialized oral and parenteral solid dosage forms including the manufacturing of clinical trial supplies. He is a pharmacist by training (University of Heidelberg) and received his PhD from the University of Marburg in 2005 (Supervisors: Prof. T. Kissel and Prof. A. Fahr, Thesis: "Generation and Characterization of Immunoliposomes", conducted at vectrontherapeutics AG). Peter Hölig is the author and co-author of several research papers, patents and conference abstracts.

#### Julian Quodbach, PhD

Julian Quodbach is a pharmacist by training and started his PhD in 2011 at the Institute of Pharmaceutics and Biopharmaceutics at the University of Düsseldorf under the supervision of



Prof. Peter Kleinebudde. He received his PhD in 2014 and began his work as postdoc in the group of Prof. Jörg Breitkreutz. He is supervising several PhD and master students who work on the progression of pharmaceutical 3D printing as well as the use of PAT in granulation processes. In January 2019, he joined the Drug Delivery Group at Uppsala University for a one year postdoc period.

### **Course leaders**



#### Lieven Baert, PhD

Lieven Baert, Ph.D., M.B.A. Managing Director JALIMA PHARMA. Lieven has studied at the University of Ghent (Belgium) where he has obtained the degrees of Pharmacist, Industrial

Pharmacist, Ph.D. in Pharmaceutical Technology and Master in Business and Administration. After a post doc at Merck Canada, Lieven has worked at Janssen Pharmaceutica for more than 10 years, where he held different positions, such as Manager Clinical Supplies, CM&C leader and Director Formulation group. Thereafter Lieven joined the sister company Tibotec where he became Senior Research Fellow / Vice President Early Development and Innovation. In 2007, Lieven was awarded the Johnson & Johnsons Philip B. Hoffman award for Scientists for his innovation work on novel dosage forms for anti-viral drugs. Lieven is inventor on 22 patents and is Flanders District of Creativity Fellow. Lieven started his own company "Jalima Pharma" in 2010.

#### Anne Seidlitz

Anne Seidlitz obtained her license as a pharmacist in 2003. She worked as a team member and later on team leader in the galenics department of the Arzneimittel Werke Altona AG in Hamburg. She



returned to Greifswald University and received a Doctor of Natural Sciences in Pharmaceutical Technology in 2009. Since then, she has been working as a postdoctoral fellow in the Biopharmaceutics and Pharmaceutical Technology department of the University of Greifswald. In 2015 she was granted the degree of a habilitated Doctor in the Natural Sciences. Her main research area are dosage form development with a focus on 3d-printed formulations and also parenteral dosage forms including injections and implants with special emphasis on (bio-)relevant dissolution testing.

### Programme

Thursday, 23 May 2019, 12:30 - 18:00 h

Welcome and Introduction

#### Session 1: Solid dosage form manufacturing

# Powder bed printing – Using solid binders to simplify formulation development

Julian Quodbach, Institute of Pharmaceutics and Biopharmaceutics, Heinrich Heine University Düsseldorf, Germany

#### Computer simulation of drug release from multicompartment 3D printed dosage forms

Frantisek Stepanek, Faculty of Chemical Engineering , University of Prague, Czech Republic

# Printing of temperature-sensitive drugs via fused deposition modeling, a case example

Anne Seidlitz, Department of Biopharmaceutics and Pharmaceutical Technology, University of Greifswald, Germany

### On Demand manufacturing of oral dosage forms: A focus on multi-material and FDM 3D printing

Mohamed A Alhnan, School of Cancer & Pharmaceutical Sciences, King's College London, United Kingdom

## Developing materials for inkjet 3D printed drug delivery and biomedical devices

Yinfeng He, Centre for Additive Manufacturing, University of Nottingham, United Kingdom

Design and development of a 3D printed capsular delivery platform for nutraceutical/ pharmaceutical applications Alice Melocchi, Co-Founder & Chief Scientific Officer, Multiply Labs, United States; post-doctoral fellow, University of Milan, Italy

#### Networking dinner

Evening round table discussion after dinner

### Programme

Friday, 24 May 2019, 09:00 - 16:30 h

#### Session 2: Excipients

# Excipient selection for fused deposition modeling (FDM) – fundamental material characteristics and functional properties

Christian Mühlenfeld, Technical Leader Pharmaceuticals Europe, Ashland Industries Deutschland GmbH, Germany

#### Key polymer attributes for 3D printing processes

Andrea Engel, Head of Drug Delivery, Business Line Health Care, Evonik Nutrition & Care GmbH, Germany

# AM goes Pharma – considerations for pharmaceutical processing and excipients

Simon Geissler, Director Drug Delivery and Innovation, Merck KGaA, Germany

# Session 3: Alternative applications and technologies in healthcare

## Improving Technology – Engineering aspects of high quality 3D Printers

Tilmann Spitz, Institute of Product Development and Engineering Design, University of Applied Sciences Cologne, Germany

### Selective Laser Sintering (SLS) and Stereolithography (SLA) for pharmaceutical applications Alvaro Goyanes, Director of Development, FabRx Ltd, United

Kingdom

#### **Drug eluting medical devices prepared by 3D-Printing** Jean-Christophe Leroux, Institute of Pharmaceutical Sciences, ETH Zürich, Switzerland

# Chemically modified gelatins and other biopolymers for liquid handling and bioprinting

Achim Weber, Group Manager Particle-based Systems and Formulations, Fraunhofer-Institut für Grenzflächen- und Bioverfahrenstechnik IGB, Germany

# Session 4: From lab to patients – Regulatory and practical Considerations

2D and 3D Printing – an option for hospital pharmacies? Stefanie Sauer, University Clinic Heidelberg, Germany

## The regulatory perspective: benefits and limits of 3D printed drugs

William Shang, Director Regulatory Affairs Central Europe, Johnson and Johnson, Germany

# Pharmaceutical applications of 3D printing: challenges and opportunities

Jae D. Yoo, Senior Vice President & Chief Technology Officer, Aprecia Pharmaceuticals LLC, United States

Wrap up and course closing

### Registration by fax +49 6131 97 69 69 or by email apv@apv-mainz.de



Location		Registration fee		Registration	Hotelreservation
Ramada Plaza Antwerp Desguinlei 94 2018 Antwerp Belgium phone 0032 3 244 82 61 fax 0032 3 216 47 12 events@ramadanlaza-antwerp.com		Industry Authority/University Students* (free of VAT according UStG)	1490 EUR 745 EUR 178 EUR to § 4,22	APV-Geschäftsstelle Kurfürstenstraße 59 55118 Mainz/Germany Phone: 0049 6131 97 69 0 Fax: 0049 6131 97 69 69 E-mail: apv@apv-mainz.de Web: www.apv-mainz.de	Ramada Plaza Antwerp Desguinlei 94 2018 Antwerp Belgium phone 0032 3 244 82 61 fax 0032 3 216 47 12
Date		Coffee breaks, luncheon, dinner and electronic proceedings included. * Limited places for full time students		You will receive a confirmation of your registration with the invoice.	Participants should make their own hotel reservation referring to the APV seminar. Deadline for special conference rate:
Course no.: 6781 from 23 May 2019 to 24 May 2019	12:30 h 16 <sup>:</sup> 30 h	available; written evidence must be submitted.			24 April 2019. Special rate: Single room incl. breakfast from 115,00 € per night excl. city tax.
to 21111a) 2015					Mainz, November 2018

Title, first name, last name \*

### 3D Printing in Pharma, 23 - 24 May 2019, Antwerp, Course no. 6781

#### Registration

As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

#### Registration confirmation

After your registration was successfully processed, you will receive a confirmation.

#### Before the event

A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

#### After the event

You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

#### Follow-up

After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

# Declaration of consent in respect of data protection

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