

Goodbye to old Paradigms – Transfer & Scale Up Approaches for the 21st Century

13 - 14 October 2020
Brussels, Belgium



Organised in cooperation



Objectives

To present future perspectives on scale up and tech transfer, including PAT and control strategy, Quality-by Design (QbD), applying predictive process modelling for enhanced process understanding and continuous improvement, future virtual trends and regulatory aspects.

Target audience

People working in formulation & process development, pharmaceutical engineering, scale-up & tech transfer, commercial manufacturing, academia and authorities. Attendees will learn on current challenges during scale up and tech transfer of oral solid dosage forms, they will learn predictive modelling approaches on different technology platforms, future trends and regulatory aspects.

Committee

Joint workshop between APV and APS:

- Stuart Charlton, Bristol-Myers Squibb, UK
- Michael Leane, Bristol-Myers Squibb, UK
- Katharina Paulsen, Abbvie, Germany
- Kendal Pitt, GlaxoSmithKline, UK
- Geert Verreck, Janssen R&D, Belgium
- Iris Ziegler, Corden Pharma, Germany

Moderators



Kendal Pitt, GlaxoSmithKline, UK

Kendal Pitt is a Senior Technical Director and a Senior Fellow in Pharma Supply Chain Technical based at Ware, UK. He is a Fellow of the Royal Pharmaceutical Society (FRPharmS) and an Eminent Fellow of the Academy of Pharmaceutical Sciences and has worked in the Pharmaceutical Industry for over 30 years in both R&D and Production.

He has headed groups in both the United States and Great Britain and led project teams responsible for the successful filing and launch of tablets, capsules and freeze-dried dosage forms.



Geert Verreck, Janssen R&D, Belgium

Dr. Geert Verreck is a Scientific Director and Fellow in Drug Product Development at Janssen R&D in Beerse, Belgium. His expertise is in the area of oral solid development, from preformulation to early and late development as well as transfer to commercial manufacturing. Dr. Verreck specifically has expertise in enabling technology platforms such as hot melt extrusion, spray drying, bead coating, supercritical fluid technology and nanotechnology (particle size reduction via milling and electrostatic spinning). He started working for J&J in 1995 after graduating as a chemical engineer. In 2005 he received his Ph.D. in Pharmaceutical Sciences at the Catholic University of Leuven, Belgium.

He has published 38 peer reviewed journal articles as author or co-author and holds 8 patents in the area of solid dispersions. Dr. Verreck also presented approximately 90 meeting abstracts and delivered approximately 50 oral presentations. He is also the recipient or co-recipient of various recognitions including the ISASF (International Society for the Advancement of Supercritical Fluids) PhD thesis award (2005), the J&J Philip B. Hofmann Award (2006), the J&J Business Excellence Award (2008), the J&J Standards of Leadership Award (2009).

organised in cooperation



Programme

Tuesday, 13 October 2020, 09:00 - 18:30 h

Welcome of participants, Introduction
Kendal Pitt and Geert Verreck

The old paradigms of scale up and late stage development
- and why they have failed us so many times?
Kendal Pitt, GlaxoSmithKline, UK

QbD as a roadmap for a successful tech transfer and scale
up for launch
Oscar Kalb, Hofmann-La Roche, Switzerland

PAT AND CONTROL STRATEGY

Modern PAT applications - powerful tools for real time
monitoring of CQAs and beyond
Thomas de Beer, University Ghent, Belgium

PAT case studies

PAT for development and commercial: Good, Bad and
Ugly
Sander van den Ban, Reckitt Benckiser, UK

PAT for tech transfer to full containment site
Iris Ziegler, Cordem Pharma, Germany

PAT for real time release
Jacqueline Maximilien – Janssen R&D, Belgium

Raman PAT for Film Coating
Markus Wirges, Bayer, Germany (tbc)

Plenary discussion with Mentimeter questions and
challenges

MODELLING AND PREDICTION OF PROPERTIES AND PROCESSES FOR SOLID DOSAGE FORMS

Morphology modification on drug substance to ensure
successful late stage development
Alain Colas, Janssen R&D, Belgium

Use of continuous API crystallization to aid transfer from
development manufacturing
Brian Keegan, APC, Ireland

Including flow enhancers, prediction of crystallisation
behaviour
Dierk Wieckhusen, Novartis, Switzerland (tbc)

No longer a fiction but reality today: virtual reality tools as
enablers for better machine and process understanding. Live
demonstration by Fette Compacting.

Networking dinner and event

Programme

Wednesday, 14 October 2020, 09:00 - 17:00 h

MODELLING AND PREDICTION OF PROPERTIES AND PROCESSES FOR SOLID DOSAGE FORMS - CONTINUED

Process Modelling – Case Studies

Why do we do modelling?
Elisabeth Schaefer, Janssen R&D, Belgium

Predictive modelling for continuous DC
Kai Lee, Pfizer, Germany

Process modelling and high shear granulation
Emmanuela Gavi, F. Hoffmann-La Roche, Switzerland

Process modelling and fluid bed granulation
Elisabeth Schaefer, Janssen R&D, Belgium

Use of GPROMS modelling in roller compaction
Gavin Reynolds, AstraZeneca, UK

Compaction Simulation to predict large scale tableting
Johnny Bertels, Janssen R&D, Belgium

Process Modelling and Film Coating
Jörg Crönlein, Colorcon, UK

Data and multivariate data analysis (MVA) as efficient
tools for process optimization and scale-up
Michael Leane, Bristol-Myers Squibb, UK

FUTURE TRENDS AND REGULATORY ASPECTS

Continuous manufacturing and scale up
Bernd Van Snick – Janssen R&D, Belgium

What do regulators expect as successful scale-up in
submissions for solid oral dosage forms?
Andreas Grummel, BfArM, German (tbc)

Plenary discussion with Mentimeter questions and
challenges

Closure and adjourn participants
Kendal Pitt and Geert Verreck

programme subjected to be changed

Location

Renaissance Brussels Hotel
Rue du Parnasse 19
1050 Bruxelles
Belgium
phone 0032 2 505 29 29

Registration fee

Industry	1490 EUR
Authority/University	745 EUR
Students	178 EUR

(free of VAT according to § 4,22 UStG)

Coffee breaks, luncheons, dinner and electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Registration

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

You will receive a confirmation of your registration with the invoice.

I herewith repealable authorise the organizers to use my e-mail address to send me relevant material including current programme information. My acceptance can be cancelled at any time in writing.

Hotelreservation

Renaissance Brussels Hotel
Rue du Parnasse 19
1050 Bruxelles
Belgium
phone 0032 2 505 29 29

Single room from 165 €/night incl. breakfast. Participants should make their own hotel reservation referring to the APV seminar.

Conference rates valid until 13 August 2020.

Date

Course No. 6821
from 13 October 2020 09:00 h
to 14 October 2020 17:00 h

Goodbye to old Paradigms – Transfer & Scale Up Approaches, 13-14 October 2020, Brussels, Belgium, Course no.: 6821

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

By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

All other information can be found in our privacy policy (www.apv-mainz.de/en/imprint/data-protection-statement/).

Title, first name, last name *

Company name *

Street/no. or P.O. box *

Location

Zip-code and city *

Phone

E-mail-address participant *

Order no. and/or billing address

Pay via invoice

pay via credit card (Visa, MasterCard, Amex)

(You will receive further payment information with the invoice)

Date *

Signature *

* Mandatory

Arbeitsgemeinschaft für Pharmazeutische
Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

www.apv-mainz.de/en

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