APV FOCUS GROUP DRUG DELIVERY

COMBINING SCIENCE & TECHNOLOGY TO CREATE ADVANCED DRUG DELIVERY SYSTEMS

INTERNATIONAL ASSOCIATION FOR PHARMACEUTICAL TECHNOLOGY

NEWSLETTER ISSUE 2/2015

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DRUG DELIVERY EVENTS

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7th conference of the European Paediatric Formulation Initiative (KN 6606)
16.-17. Sept. 2015, Antwerp, Belgium — Details

Drug Delivery: Bridging the Gap Between Basic Science & Unmet Medical Needs
28. Sept. - 01. Oct. 2015, Tucson, Arizona, US — Details

DDL26 - drug delivery to the lungs 26
09.-11. Dec. 2015, Edinburgh, Scotland, UK — Details

Suggest a meeting to be announced!

APV COURSE SUMMARY

Provided by Prof. Dr. Johannes Bartholomäus

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1ST EUROPEAN CONFERENCE ON PHARMACEUTICS – DRUG DELIVERY

April 13 – 14, 2015 in Reims, France

This April the 1st European Conference on Pharmaceutics took place in Reims, France. This is the first of a new series of scientific pharmaceutical meetings jointly organized by the APV, APGI and A.D.R.I.T.E.L.F. It is planned to hold these meetings every second year between the World Meetings on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology. In Reims more than 600 scientists from university, industry and regulatory authorities met to discuss the hot topics in drug delivery, which was the focus of this first conference. Two plenary lectures, two parallel streams of oral presentations, two days of poster sessions and a two-day industry exhibition, together with lively discussions and the numerous opportunities for networking, made this first European Conference on Pharmaceutics a success. Each day started with a plenary lecture from a world-renowned speaker.

On the first day Patrick Couvreur talked about "Drug Targeting – Where are we?"; and on the second day Hartmut Derendorf presented on "Advances in Pulmonary Drug Delivery." One of the parallel streams of oral presentations consisted of a series of invited talks on Transdermal Drug Delivery, Oral Drug Delivery and Smart Drug Delivery Systems & Peptide and Protein Delivery (3 presentations per topic). The second stream consisted of scientific short presentations (6 per session) selected from submitted abstracts on Oral Controlled Drug Delivery, Nanoparticles and Vesicles, Advanced Drug Delivery and Development & Manufacture of Solid Dosage Forms.

A total of 193 posters were presented on the first day, and 182 on the second day. The posters covered many facets of drug delivery in the two lively full-day poster sessions. About 30 exhibitors offering formulation services, analytical tools, excipients or equipment provided an insight into their drug delivery expertise. The intermingling of posters, exhibitors

and catering including a champagne reception – virtually a must in the capital of Champagne – allowed for a lot of scientific exchange and networking during these two intensive days and has already raised interest in the 2nd European Conference on Pharmaceutics in 2017.

DRUG DELIVERY PRODUCTS

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Provided by Dr. Louise Rosenmayr-Templeton

APTENSIO® XR

Aptensio® XR, an extended release formulation of methylphenidate hydrochloride, was approved by the FDA on 17 April 2015 [1]. The product is the latest addition to the specialty pharma company, Rhodes Pharma's, (RI, USA) portfolio [2, 3]. The product is indicated for the once-daily treatment of attention-deficit/hyperactivity disorder, a condition which affects over 6 million children in the US alone. It is available in 7 different strengths (10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg methylphenidate hydrochloride) to facilitate dose titration. Treatment of patients 6 years and above is initiated at a dose of 10 mg once daily with or without food in the morning. This dose may be increased weekly in increments of 10 mg per day up to 60 mg per day. Higher doses are not recommended.

The drug is formulated as an extended release capsule containing sugar spheres coated with multi-layers of polymers for once-daily administration. Approximately 40% of the drug is included in the intermediate release layer and 60% in the controlled release layer. Excipients in the formulation include hypromelloses, polyethylene glycol, ammonio methacrylate copolymer, type B; methacrylic acid copolymer, type C; triethyl citrate, talc, colloidal silicon dioxide (added if necessary), titanium oxide, and gelatin. Aptensio® XR can be either swallowed whole, or the capsule opened and the contents sprinkled onto apple sauce. The product is designed to release around 40% of the methylphenidate immediately to achieve an onset of action around 1 hour after administration. The release of the remaining 60% occurs later to enable therapy to be maintained over a 12-hour period. A pharmacokinetic study in adults showed that Aptensio® XR is 102% bioavailable compared to immediate release methylphenidate HCl administered three times daily.

Approval of Aptensio® XR was based on data from two Phase III, randomized, double-blind, placebo-controlled studies conducted in children and adolescents with ADHD. The first study conducted in children from 6 to 12 years, showed that administration of Aptensio® XR resulted in a statistically significant improvement in the total scores on the Swanson, Kotkin, Agler, M-Flynn, Pelham (SKAMP) Scale, from hour one to hour 12 when compared with placebo. This teacher-scored scale assesses behaviours critical to success in school within a class-room setting; the lower the score the better the behaviour.

In the second Phase III study, which included children and adolescents aged 6 to 17 years, Aptensio® XR consistently demonstrated efficacy across the seven different doses, as measured by the Attention-Deficit/Hyperactivity Disorder Rating Scale-IV (ADHD-RS-IV). This rating scale is clinician scored and is a commonly used measure of the severity of ADHD symptoms. The patient-reported adverse events in both studies experienced by ≥2% of patients were commonly-known effects of methylphenidate including headache, insomnia, upper abdominal pain, decreased appetite, nausea, vomiting and dizziness.

The product will be launched on the US market in summer 2015.

TUZISTRA® XR

In the same month the FDA also approved Tuzistra® XR [4]. This is an extended release suspension of codeine polisitirex and chlorpheniramine polistirex for oral administration. It is indicated in adults 18 years of age and older for the relief of cough and symptoms associated with upper respiratory allergies or a common cold The dose of 10 ml can be taken with or without food every 12 hours. Each 5 ml contains 14.7 mg codeine (equivalent to 20 mg codeine phosphate) and 2.8 mg of the anti-histamine, chlorpheniramine (equivalent to 4 mg chlorpheniramine maleate). The two actives substances are bound to sulfonated styrene- divinylbenzene copolymer (polistirex).

The product was developed as a result of a collaboration between the British firm, Vernalis plc and US-based Tris Pharma Inc and employs Tris Pharma's LiquiXR™ technology to extend the release of the two active substances. This technology consists of particles around 100 microns in size in which the drug is complexed to the sulfonated styrene-divinylbenzene copolymer. The drug-co-polymer complex is then coated.

Vernalis entered into a development and licensing deal with Tris Pharma, Inc, in February 2012, and obtained exclusive rights to Tris' extended release technology for use in the US prescription cough cold market [5]. Under the terms of the licensing deal up to 6 products would be developed and in addition to an upfront payment of $5 million, Vernalis undertook to pay Tris up to $13 million for each new product plus royalties on sales once commercialized.

Tuzistra® XR is the first product from Vernalis' development and licensing deal with Tris to be approved by FDA. Vernalis and Tris hope the product will capture a significant share of the US prescription cough and cold market which is said to be worth in excess of $3 billion. At present immediate release codeine-containing cough and cold products account for 38% of this market [6].

References and Further Information

[1] Entry for Aptensio® XR on Drugs@FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo. (Accessed on 14.6.2015).

[2] Rhodes Pharmaceuticals Announces Launch of New, Once-Daily Treatment for ADHD http://www.rhodespharma.com/news/#2014. Accessed on 14.6.2015.

[3] Website of Rhodes Pharma http://www.rhodespharma.com/ (Accessed on 14.6.2015)

[4] Entry for Tuzistra® XR on Drugs@FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails (Accessed on 14.6.2015)

[5] Vernalis and Tris Pharma announce collaboration to develop and commercialize novel products for the US prescription cough/cold market., http://www.vernalis.com/media-centre/latest-releases/2012-releases/626-vernalis-and-tris-pharma-announce-collaboration, (Accessed on 14.6.2015)

[6] Vernalis and Tris Pharma receive FDA approval of NDA for Tuzistra™ XR (codeine polistirex and chlorpheniramine polistirex), http://www.vernalis.com/media-centre/latest-releases/703-vernalis-and-tris-pharma-receive-fda-approval-of-nda-for-tuzistra-xr-codeine-polistirex-and-chlorpheniramine-polistirex (Accessed on 14.6.2015)

DRUG DELIVERY COMPANIES

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Provided by Dr. Kaspar van den Dries

SIGMOID PHARMA LIMITED (DUBLIN, IRELAND)

Sigmoid Pharma Limited is a specialty pharma company headquartered in Dublin, Ireland. Sigmoid's goal is to identify and create meaningful new therapies for unmet clinical needs in gastrointestinal and immunological diseases and disorders. Sigmoid achieves its goal by applying its proprietary SmPill® oral drug delivery technology and pharmacological expertise to approved drugs or new chemical or biological entities.

The process to produce a SmPill®-formulated product involves processing the active pharmaceutical ingredient to:

- Solubilise as an emulsion, microemulsion or suspension
- Formulate into solid mini-spheres
- Apply an outer controlled release coating

The result is an encapsulated drug in "pre-solubilised" form, which when administered orally provides for predetermined immediate or sustained release of the active drug to specific locations and at specific rates along the gastrointestinal tract. In essence, pre-solubilisation of the drug enhances the predictability of its systemic pharmacokinetic profile, while simultaneously enhancing permeability and drug stability

Traditional drug delivery technologies tend to address single formulation issues, such as enhanced solubility, permeability, stability or controlled release. However, many drugs will benefit from addressing a number of formulation issues simultaneously. SmPill® is a convergent system that combines into one technology otherwise disparate formulation approaches in an integrated manner. Sigmoid's SmPill® offers a unique, patent-protected platform.

Fact sheet:

Founded:	2003
Location:	Dublin, Ireland
Ownership:	Privately financed
Employees:	20
Key technology:	SmPill® and LEDDS®
Products:	Its lead product, CyCol®, is based on cyclosporine, and is being developed for the treatment of Ulcerative colitis. It is advancing to phase 3. Sigmoid has successfully formulated molecules such as COXII inhibitors, steroids, farnesyl X receptor agonists, hydroxylase inhibitors and others
Development status:	Cyclosporine for treatment Ulcerative colitis is advancing to phase 3. Other indications being explored are for Crohn's disease and Graft versus Host Disease treatment & prevention, which are in phase 1
Partnerships:	Sigmoid is highly collaborative in its approach to research and innovation, and has created a network of alliances with leading academic and medical centres of excellence as well as international pharmaceutical and biotechnology companies.
Website:	http://www.sigmoidpharma.com/

Contact:	Sigmoid Pharma Limited The Invent Centre Dublin City University Dublin 9, Ireland.

DRUG DELIVERY PEOPLE

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Provided by Dr. Lea Ann Dailey

PETER VAN HOOGEVEST is currently the Managing Director of the Phospholipid Research Centre and Head of Scientific Department/Development at Lipoid GmbH located in Ludwigshafen, Germany. In his role as Director of the Phospholipid Research Center, he has been pivotal in expanding collaborations between industrial and academic scientists to increase general knowledge on the properties and use of phospholipids in the pharmaceutical industry. In addition to his interest in basic and applied phospholipid research, Peter has a broad background in industrial formulation science. From 2000-2012, he was the Managing Director and COO of Phares Drug Delivery AG, where he was involved in the development of innovative lipid-based and state of the art parenteral drug delivery systems for biotechnological and synthetic medicinal compounds. He also worked for Ciba-Geigy and Novartis before joining Phares.

Peter is a trained pharmacist with a PhD in membrane biochemistry from Utrecht University in the Netherlands. He continues to play an active role in pharmaceutics education and research as an Adjunct Professor (Privat Dozent) in Pharmaceutical Technology at Basel University. Additionally, he has been an active member of the APV Drug Delivery Focus Group.

DRUG DELIVERY GROUPS

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PROTEIN DRUG DELIVERY AND FORMULATION UNIVERSITIES 2015

Provided by Prof. Dr. Wolfgang Frieß and Corinna Dürr, Ludwig Maximilian University of Munich (DE)

Basel, Switzerland

Institute	University of Basel
Group	Department of Pharmaceutical Sciences; Pharmaceutical Technology
Key Contact	Prof. Jörg Huwyler
Website	https://pharma.unibas.ch/research-groups/details/home/group/pharmaceuticaltechnology/
E-Mail	joerg.huwyler@unibas.ch
Research Areas	• Liquid dosage forms for proteins

Bonn, Germany

Institute	University of Bonn
Group	Faculty of Mathematics and Natural Sciences; Pharmaceutical Technology and Pharmacy
Key Contact	Prof. Alf Lamprecht
Website	http://www.pharmtech.uni-bonn.de/forschung/arbeitskreis-lamprecht
E-Mail	alf.lamprecht@uni-bonn.de
Research Areas	• Systems for drug delivery of proteins at adsorptive barriers

Bradford, United Kingdom

Institute	University of Bradford
Group	Faculty of Life Sciences; Pharmaceutical Engineering, Biophysical Pharmaceutics
Key Contact	Prof. Robert Forbes
Website	http://www.bradford.ac.uk/life-sciences/pharmacy/our-staff/robert-forbes.php
E-Mail	R.T.Forbes@bradford.ac.uk
Research Areas	• Formulation and delivery of proteins

Copenhagen, Denmark

Institute	University of Copenhagen
Group	Department of Pharmacy; Pharmaceutical Technology and Engineering
Key Contact	Assoc. Prof. Stefania G. Baldursdottir
Website	http://pharmacy.ku.dk/research/section-of-pharmaceutical-technology/pharm_tech_engin/
E-Mail	stefania.baldursdottir@sund.ku.dk
Research Areas	• Freeze-dried biopharmaceutical formulations • Use of polymeric pharmaceutical excipients in the formulation and processing of proteins

Copenhagen, Denmark

Institute	University of Copenhagen
Group	Department of Pharmacy; Biologics
Key Contact	Assoc. Prof. Hanne Mørck Nielsen / Marco van de Weert
Website	http://pharmacy.ku.dk/research/biologics/
E-Mail	hanne.morck@sund.ku.dk / marco.vandeweert@sund.ku.dk
Research Areas	• Formulation design and delivery assessment of peptide and protein therapeutics • Protein structure analysis • Protein physical stability/ fibrillation

Dublin, Ireland

Institute	University College Dublin
Group	School of Veterinary Medicine; Drug Delivery
Key Contact	Prof. David Brayden
Website	http://www.ucd.ie/vetmed/staff/veterinarysciences/davidbrayden/
E-Mail	David.brayden@ucd.ie
Research Areas	• Polymeric peptide conjugates for long-acting injectables • Improving peptide delivery across intestinal epithelia

Erlangen, Germany

Institute	Friedrich-Alexander University of Erlangen
Group	Department of Chemistry and Pharmacy; Pharmaceutical Technology
Key Contact	Prof. Geoffrey Lee
Website	http://www.pharmtech.uni-erlangen.de/index.html
E-Mail	geoff.lee@fau.de
Research Areas	• Spray drying of proteins • Freeze drying of proteins/ cryopelletization

Geneva, Switzerland

Institute	University of Geneva
Group	School of Pharmacy; Biopharmaceutials
Key Contact	Prof. Gerrit Borchard
Website	http://www.unige.ch/sciences/pharm/fagal/page-perso/borchard_EN.php?id=68
E-Mail	Gerrit.Borchard@unige.ch
Research Areas	• Non covalent PEGylation of proteins

Gent, Belgium

Institute	Gent University
Group	Faculty of Pharmaceutical Sciences; Department of Pharmaceutical Analysis
Key Contact	Prof. Thomas De Beer
Website	http://www.ugent.be/fw/en/research/pharmaceutical-analysis/pat
E-Mail	Thomas.DeBeer@UGent.be
Research Areas	• Process Analytical Technology (PAT systems) in freeze-drying of proteins

Groningen, Netherlands

Institute	University of Groningen
Group	Faculty of Mathematics and Natural Sciences; Pharmaceutical Technology and Biopharmacy
Key Contact	Prof. H.W. Frijlink
Website	http://www.rug.nl/staff/h.w.frijlink/
E-Mail	h.w.frijlink@rug.nl
Research Areas	• Stabilization of proteins and vaccines • Inhalation of vaccines

Helsinki, Finnland

Institute	University of Helsinki
Group	Faculty of Pharmacy; Pharmaceutical Chemistry and Technology
Key Contact	Prof. Anne Juppo
Website	http://www.helsinki.fi/pharmacy/chemtech/en/Research/fip.html
E-Mail	anne.juppo@helsinki.fi
Research Areas	• Stabilization of protein pharmaceuticals and protein oral vaccine adjuvants

Leiden, Netherlands

Institute	Leiden University
Group	Faculty of Science; Leiden Academic Centre for Drug Research, Drug Delivery Technology
Key Contact	Prof. Wim Jiskoot
Website	http://drugdeliverytechnology.leidenuniv.nl/people/jiskoot
E-Mail	w.jiskoot@lacdr.leidenuniv.nl
Research Areas	• Formulation and unwanted immunogenicity of therapeutic proteins

Munich, Germany

Institute	Ludwig-Maximilians-Universität München
Group	Department of Pharmacy; Pharmaceutical Technology and Biopharmaceutics
Key Contact	Prof. Wolfgang Frieß
Website	http://www.cup.uni-muenchen.de/pb/aks/friess/
E-Mail	wolfgang.friess@lrz.uni-muenchen.de
Research Areas	• Local protein delivery • Protein freeze-drying and spray-drying • High concentration systems, protein analytics, protein aggregations and protein-material interactions

Munich, Germany

Institute	Ludwig-Maximilians-Universität München
Group	Department of Pharmacy; Pharmaceutical Technology and Biopharmaceutics
Key Contact	Prof. Gerhard Winter
Website	http://www.cup.uni-muenchen.de/pb/aks/winter/
E-Mail	gerhard.winter@cup.uni-muenchen.de
Research Areas	• Formulation and delivery of peptide and protein drugs including depot systems • Protein stability • Protein drying technologies

Padova, Italy

Institute	University of Padova
Group	Department of Pharmaceutical and Pharmacological Sciences; Pharmaceutical Technology
Key Contact	Prof. Paolo Caliceti
Website	http://en.didattica.unipd.it/offerta/docente/FCC15E90D3F0134C4C25E8053AEE3AAE
E-Mail	paolo.caliceti@unipd.it
Research Areas	• Protein polymer conjugates

Regensburg, Germany

Institute	University Regensburg
Group	Faculty of Chemistry and Pharmacy, Department of Pharmaceutical Technology
Key Contact	Prof. Achim Göpferich
Website	http://www.uni-regensburg.de/chemie-pharmazie/pharmazeutische-technologie/index.html
E-Mail	Sekretariat.Pharmtech@chemie.uni-regensburg.de
Research Areas	• Development of protein drug delivery systems

Sheffield, United Kingdom

Institute	The University of Sheffield
Group	Department of Chemical and Biological Engineering; Life Science Interface and Biological Engineering
Key Contact	Dr. Robert Falconer
Website	https://www.sheffield.ac.uk/cbe/staff/staffprofiles/rfalconer
E-Mail	r.j.falconer@sheffield.ac.uk
Research Areas	• Protein stability and formulation • Interaction between proteins, water and small molecules

Utrecht, Netherlands

Institute	Utrecht University
Group	Department of Pharmaceutical Sciences; Pharmaceutics
Key Contact	Dr. Cornelus F. van Nostrum
Website	http://www.uu.nl/en/research/pharmaceutics/research/rene-van-nostrum
E-Mail	C.F.vanNostrum@uu.nl
Research Areas	• Nanogels and polyester nanoparticles for protein delivery

Würzburg, Germany

Institute	Julius Maximilian University of Würzburg
Group	Faculty of Chemistry and Pharmacy; Pharmaceutics and Biopharmacy
Key Contact	Prof. Lorenz Meinel
Website	http://www.pharmaceutics.uni-wuerzburg.de/
E-Mail	l.meinel@pharmazie.uni-wuerzburg.de
Research Areas	• Protein drug delivery for regenerative medicine

DRUG DELIVERY LITERATURE

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Provided by Dr. Carsten Timpe

RECENTLY PUBLISHED LITERATURE REVIEWS IN THE FIELD OF DRUG DELIVERY

Nanomedicine approaches for corneal diseases.
Chaurasia SS, Lim RR, Lakshminarayanan R, Mohan RR. J Funct Biomater. 2015 Apr 30;6(2):277-98

Advances in drug delivery to the posterior segment
Pearce W, Hsu J, Yeh S..Curr Opin Ophthalmol. 2015 May;26(3):233-9

Approaches to develop PLGA based in situ gelling system with low initial burst
Ahmed T.. Pak J Pharm Sci. 2015 Mar;28(2):657-65

Low PS. Principles in the design of ligand-targeted cancer therapeutics and imaging agents
Srinivasarao M, Galliford CV,. Nat Rev Drug Discov. 2015 Mar;14(3):203-19

Nanocarriers: a versatile approach for mucosal vaccine delivery
Mody N, Sharma R, Agrawal U, Vyas SP.. Ther Deliv. 2015 Feb;6(2):231-45

Formulation design for topical drug and nanoparticle treatment of skin disease
Raphael AP, Garrastazu G, Sonvico F, Prow TW.. Ther Deliv. 2015 Feb;6(2):197-216

Nanotherapeutic strategies for the treatment of Alzheimer's disease
Gu X, Chen H, Gao X.. Ther Deliv. 2015 Feb;6(2):177-95

Challenges in the delivery of peptide drugs: an industry perspective
Lewis AL, Richard J.. Ther Deliv. 2015 Feb;6(2):149-63

Targeted delivery of protein and gene medicines through the blood-brain barrier
Pardridge WM.. Clin Pharmacol Ther. 2015 Apr;97(4):347-61

A holistic approach to targeting disease with polymeric nanoparticles
Cheng CJ, Tietjen GT, Saucier-Sawyer JK, Saltzman WM.. Nat Rev Drug Discov. 2015 Apr;14(4):239-47

PLGA: a unique polymer for drug delivery
Kapoor DN, Bhatia A, Kaur R, Sharma R, Kaur G, Dhawan S.. Ther Deliv. 2015 Jan;6(1):41-58

Advances in ophthalmic drug delivery
Morrison PW, Khutoryanskiy VV.. Ther.Deliv. 2014 Dec;5(12):1297-315

Opportunities in respiratory drug delivery
Pritchard JN, Giles RD.. Ther. Deliv. 2014 Dec;5(12):1261-73

Peptide-mediated delivery: an overview of pathways for efficient internalization
Pae J, Pooga M.. Ther Deliv. 2014 Nov;5(11):1203-22

Prodrug-based nanoparticulate drug delivery strategies for cancer therapy.
Luo C, Sun J, Sun B, He Z. Trends Pharmacol Sci. 2014 Nov;35(11):556-66

ABOUT THE FOCUS GROUP

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The APV Drug Delivery Focus Group (APV DD) is a section of the APV (Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V. / International Association for Pharmaceutical Technology), a major European society for those sharing a professional interest in pharmaceutical sciences. The Focus Group was established in 2003 in response to the increasing importance of drug delivery within modern pharmaceutics.

Read more. ***Contact us.***

COMBINING SCIENCE AND TECHNOLOGY TO CREATE ADVANCED DRUG DELIVERY SYSTEMS

OUR MISSION STATEMENT:

Modern drug delivery research and development is a truly multidisciplinary approach and must combine all relevant scientific, technical, medical and regulatory aspects required for the design, preparation, testing, manufacturing and registration of drug delivery systems and their components. It is the mission of the APV Drug Delivery Working Group to foster and promote all aspects of research and development required to transform drug molecules into safe, applicable and acceptable drug delivery systems, which provide therapeutic benefit, convenience to the patient and improve patient compliance.

Our mission includes in particular the following tasks:

- Thoroughly understanding the physical-chemical and biopharmaceutical properties of the drug substance to be delivered and the components of the drug delivery system
- Understanding the biological barriers and the interactions of the drug molecule and its delivery system with the biological environment and the biological target including PK/PD and PK/safety relationships
- Research on excipients, materials and technologies required for the design, preparation and manufacturing of drug delivery systems for a selected route of administration
- Development and understanding of methods for in vitro and in vivo evaluation of drug delivery systems and their components
- Knowledge of regulatory requirements for clinical testing, manufacturing and registration of drug delivery systems

All disciplines relevant to the above mentioned areas of drug delivery R&D are invited to contribute to the APV Drug Delivery Group:

Pharmaceutics, Biopharmaceutics, Analytics, Biology, Physical Chemistry, Biochemistry, Physics, Engineering Sciences, Nano Technology, Material Sciences, Polymer Science, Toxicology, Drug Safety, Clinical Research, Drug Regulatory Affairs, etc.

MEMBERS OF THE APV DRUG DELIVERY FOCUS GROUP

Johannes Bartholomäus, PhD
Focus Group Chairman
Pharmakreativ Consulting, Aachen (DE)

Georg Böck, PhD
Deputy Focus Group Chairman
Boehringer Ingelheim Pharma, Biberach (DE)

Rainer Alex, PhD
APV Liaison Officer
F. Hoffmann-La Roche, Basel (CH)

Martin Bornhöft, PhD
APV Office, Mainz (DE)

Karsten Cremer, PhD
Pharma Concepts, Basel (CH)

Louise Rosenmayr-Templeton, PhD
Tower Pharma Consulting, Vienna (A)

Bernd Riebesehl, PhD
Novartis Pharma, Basel (CH)

Oskar M. Kalb, PhD
F. Hoffmann-La Roche, Basel (CH)

Carsten Timpe, PhD
F. Hoffmann-La Roche, Basel (CH)

Kaspar van den Dries, PhD
Patheon, Tilburg (NL)

Lea Ann Dailey, PhD
Kings College, London (UK)

Michael Horstmann, PhD
Transdermal Pharma, Hamburg (DE)

Gerben Moolhuizen, MBA
OctoPlus, Leiden (NL)

Simone Wengner, PhD
Catalent Pharma Solutions, Eberbach (DE)
(formerly R.P.Scherer)

Sven Stegemann, PhD
Capsugel, Bornem (B) /
Graz University of Technology (A)

Contact us!

EDITORIAL GROUP OF THE NEWSLETTER

Editor: Dr. Louise Rosenmayr-Templeton, Tower Pharma Consulting, Vienna (A)
Layout: Christoph Blümer, Catalent Pharma Solutions, Schorndorf (DE)