APV Focus Group Drug Delivery

Combining Science & Technology to Create Advanced Drug Delivery Systems

INTERNATIONAL ASSOCIATION FOR PHARMACEUTICAL TECHNOLOGY

NEWSLETTER **ISSUE 1/2020 - June**

TABLE OF CONTENTS

DRUG DELIVERY EVENTS

BACK TO TABLE OF CONTENTS

2020 Controlled Release Society Virtual Annual Meeting: 2020 Vision for Global Impact
June 27-July 1, 2020 | Las Vegas, NV, USA — Details

The Promise of 3D Printing in Pharmaceuticals and Dietary Supplements: Quality and Standards Considerations
July 13-16, 2020 | online workshop — Details

12th conference of the European Paediatric Formulation Initiative - EuPFI 2020 | KN 6808
September 09-10, 2020 | virtual conference — Details

Suggest a meeting to be announced!

DRUG DELIVERY PRODUCTS

BACK TO TABLE OF CONTENTS

Provided by Dr. Johannes Bartholomäus

SLENYTO®

In September 2018 RAD Neurim Pharmaceuticals EEC SARL (Paris, France) was granted a paediatric-use marketing authorization (PUMA) throughout the European Union for Slenyto, a prolonged release minitablet containing 1 or 5 mg melatonin for the treatment of insomnia (difficulty sleeping) in children and adolescents (2 to 18 years old) who have autism spectrum disorder (ASD), a range of conditions that affects the patient's social interactions or Smith-Magenis syndrome, a condition that can lead to learning difficulties [1].

Prolonged release tablets with 2 mg melatonin had been already granted marketing authorization in June 2007 and marketed under the trademark Circadin® [2]. However, on the one hand this product is indicated for the treatment of insomnia in patients of 55 years of age and older. On the other hand, the tablets are of about 8 mm in diameter and 3-5 mm thickness. Thus, to allow easy administration to children starting from 2 years, a paediatric formulation of bi-convex minitablets with a diameter of 3 mm was developed on the basis of prolonged release poly(meth)acrylate matrices.

The development started from the composition of Circadin® which consists of ammonio methacrylate copolymer (type B), calcium hydrogen phosphate dihydrate, lactose monohydrate, anhydrous colloidal silica, talc and magnesium stearate [3]. However, to achieve a similar dissolution profile to the 8 mm matrix tablet of Circadin® from a minitablet matrix of 3 mm needs quite a lot of adjustments as one of the typical rules of PR matrix tablets is the smaller the size the faster the release. A nice description of a series of adjustments in the ratio of excipients to arrive at the intended dissolution profile can be found in patent application WO2018/078429 [4]. Finally, the composition of Slentyo® is qualitatively the same as for Circadin® with the exception that only the matrix of the 1 mg tablet uses ammonio methacrylate copolymer (type B) (as does Circadin®), whereas in the 5 mg tablet no talc and type A of the polymer is used which is more permeable. In general, ammonio methac-

rylate copolymers are hydrophobic polymers which are insoluble but exhibit pH-independent swelling in all parts of the GI tract. The manufacturing process for the 1 mg tablets is straightforward involving dry blending, direct compression of cores, colour coating and packaging whereas for the 5 mg tablet a dry slugging and milling step is inserted before compression [3]. The minitablets can be administered like normal tablets but also added to food like yoghurt, orange juice or ice cream to allow for easier swallowing [5]. If the tablets are mixed with food or drink, they should be taken immediately.

The benefits in clinical studies were that Slenyto has been shown to be effective in improving sleeping time in children and adolescents with neurological conditions, including autism spectrum disorder and Smith-Magenis syndrome. In a main study of 125 patients, those given Slenyto over 13 weeks had on average 51 extra minutes of sleep a night compared with 19 extra minutes for those given placebo (a dummy treatment). In addition, children who took Slenyto fell asleep around 38 minutes earlier than normal while those taking placebo fell asleep 13 minutes earlier. All patients had previously tried other measures, such as keeping to a regular sleeping routine, which did not work. The most common side effects with Slenyto (which may affect up to 1 in 10 people) are sleepiness, tiredness, mood swings, headache, irritability, aggression and feeling hungover [1].

In the EPAR, the discussion on chemical, pharmaceutical and biological aspects comes to the following conclusion: This product was developed as a PUMA following an agreed paediatric investigation plan (PIP). The finished product, an age appropriate dosage form, is designed for prolonged delivery of melatonin using a polymeric matrix tablet. The modified release profile maintains melatonin levels during sleep. The dimensions of the bi-convex 3 mm tablets make them easy to swallow [3].

References and Further Information

[1] European Medicines Agency on Slenyto https://www.ema.europa.eu/en/medicines/human/EPAR/slenyto#authorisation-details-section

[2] Fachinformation Circadin® 2 mg Retardtabletten https://www.fachinfo.de/suche/fi/020194

[3] European Public Assessment Report on Slenyto. https://www.ema.europa.eu/en/documents/assessment-report/slenyto-epar-public-assessment-report_en.pdf

[4] Laudon M, Zisapel N Melatonin mini-tablets and method of manufacturing the same, WO2018/078429A1, Applicant Neurim Pharmaceuticals LtD, Tel Aviv (Israel), international filing date Nov 29, 2016.

[5] Slenyto Summary of Product characteristics https://www.ema.europa.eu/en/documents/product-information/slenyto-epar-product-information_en.pdf

DRUG DELIVERY PEOPLE

BACK TO TABLE OF CONTENTS

Provided by Dr. Lea Ann Dailey

For this issue of the Newsletter, we would like to introduce **Wolfgang Frieß** as our featured Drug Delivery Scientist. Prof. Frieß is a pharmacist by training with an undergraduate degree followed by a PhD in Pharmaceutics both from the University of Erlangen, Germany. Following his graduate studies, he spent some time in the United States as a postdoctoral research associate at the University of Illinois in Chicago. Following a brief position as a staff scientist at the Genetics Institute, Wyeth Ayerst (now Pfizer) in the US, he returned to academia in 1997 to complete his habilitation at the University of Erlangen.

In 2001, he accepted a position as Professor of Pharmaceutical Technology and Biopharmacy at the Ludwig Maximillian University in Munich, Germany, where his research interests involve protein formulation, development of drug delivery systems and new biomaterials.

Prof. Frieß has been a pivotal figure in the field of protein formulation development, although his interests are wide ranging and his experience extensive. With over 178 original articles, reviews and book chapters to his name, he also holds numerous patents in the field of drug delivery. He sits on the scientific advisory board of Coriolis PharmaService and is co-editor of the European Journal of Pharmaceutics and Biopharmaceutics. He also holds editorial board membership in several other pharmaceutical journals.

ACADEMIC GROUPS WITH MODELLING AND SIMULATION CAPABILITIES IN PHARMACEUTICS

This newsletter section is intended to give a brief overview of academic groups working on modelling and simulation in pharmaceutics. It is part of an occasional series giving brief details of European research teams exploring different aspects of drug delivery research. It is not intended to be a comprehensive list of those involved in the area. As it is a living document, our readers are most welcome to suggest other research teams they are aware of for inclusion in our next edition. The contact person given is the head of the department or working group.

AUSTRIA

Research Focus	Pharmaceutical Process Modeling
Institution	TU Graz, Institute of Process and Particle Engineering
Address	Institute of Process and Particle Engineering, Inffeldgasse 13/III, 8010 Graz
Contact	Johannes Khinast
eMail	khinast@tugraz.at
Web site	https://www.tugraz.at/en/institutes/ippt/research/pharmaceutical-engineering-and-particle-technology/

FRANCE

Research Focus	Computational Modeling of Tableting Process
Institution	University of Bordeaux, Department of Science and Technology
Address	Campus Carreire - UFR Pharmacie, 146, rue Léo Saignant, 33076 Bordeaux, Cedex
Contact	Pierre Tchoreloff
eMail	pierre.thoreloff@u-bordeaux.fr
Web site	https://www.u-bordeaux.fr/Recherche/Plateformes/Sciences-de-l-ingenierie-et-du-numerique/Plateforme-caracterisation-des-systemes-granulaires

GERMANY

Research Focus	Simulation and Modeling for mulitphase flow
Institution	TU Kaiserslautern, Institute of Particle Process Engineering
Address	Gottlieb-Daimler-Straße, 67663 Kaiserslautern
Contact	Sergiy Antonyuk
eMail	sergiy.antonyuk@mv.uni-kl.de
Web site	https://mvt.mv.uni-kl.de/en/home/

Research Focus	Particle based simulation methods and coupling with continuum approaches (CFD)
Institution	Hamburg University of Technology, Institute of Solids Process Engineering and Particle Technology
Address	Denickestraße 15 (K), 21073 Hamburg
Contact	Stefan Heinrich
eMail	stefan.heinrich@tuhh.de
Web site	https://www.tuhh.de/spe/institute/staff/prof-stefan-heinrich.html

Research Focus	Particle technology and simulation
Institution	Technische Universität Braunschweig, Institute for Particle Technology
Address	Volkmaroder Str. 5, Main Building 007, Braunschweig
Contact	Arno Kwade
eMail	a.kwade@tu-bs.de
Web site	https://www.ipat.tu-bs.de/de/

Research Focus	Pharmaceutical Process Modeling and Simulation
Institution	Heinrich-Heine-Universität Düsseldorf, Institut für Pharmazeutische Technologie und Biopharmazie
Address	Heinrich-Heine-Universität Düsseldorf, Universitätsstr. 1 / Gebäude 26.22, D-40225 Düsseldorf
Contact	Peter Kleinebudde
eMail	kleinebudde@uni-duesseldorf.de
Web site	http://www.pharmazie.hhu.de/institute/ptb/arbeitskreise/prof-dr-p-kleinebudde.html

IRELAND

Research Focus	Process modeling
Institution	University of Limerick, Department of Chemical and Environmental Science
Address	Analog Devices Build, University of Limerick
Contact	Gavin Walker
eMail	gavin.walker@ul.ie
Web site	https://bernalinstitute.com/our_people/gavin-walker/

ITALY

Research Focus	Powder flow characterization and modeling
Institution	Universita Devli Studi Di Salerno, Dipartimento di Ingegneria Industriale/DIIN
Address	Campus di Fisciano, Edificio E, Piano Terzo, stanza 040 (U.FSTEC-06.P03.040)
Contact	Massimo Poletto
eMail	mpoletto@unisa.it
Web site	https://docenti.unisa.it/001715/home

Research Focus	Multiscale modeling of materials and process systems engineering
Institution	Polytechnic University of Turin, Department of Applied Science and Technology
Address	Politecnico di Torino, Corso Duca degli Abruzzi, 24, 10129 Torino
Contact	Antonello A. Barresi
eMail	antonello.barresi@polito.it
Web site	http://www.disat.polito.it/personale/scheda/(nominativo)/antonello.barresi

Research Focus	CFD simualtion of stirred tank chemical and bio-reactors
Institution	Università di Bologna, Department of Industrial Chemistry "Toso Montanari"
Address	Dipartimento di Chimica Industriale "Toso Montanari", Via Terracini 34, Bologna
Contact	Giuseppina Montante
eMail	giuseppina.montante@unibo.it
Web site	https://www.unibo.it/sitoweb/giuseppina.montante/research

NETHERLANDS

Research Focus	Particle simulations by Discrete Element Method
Institution	University of Twente, Faculty of Engineering Technology
Address	Horst Complex (building no. 20), room N248, De Horst 2, 7522LW Enschede
Contact	Stefan Luding
eMail	s.luding@utwente.nl
Web site	https://people.utwente.nl/s.luding

SWITZERLAND

Research Focus	Scale-up and Scale-down of bioprocesses
Institution	Zürcher Hochschule für angewandte Wissenschaften, Fachstelle Bioverfahrens- und Zellkulturtechnik
Address	Grüental, 8820 Wädenswil
Contact	Dieter Eibl
eMail	dieter.eibl@zhaw.ch
Web site	https://www.zhaw.ch/de/lsfm/institute-zentren/icbt/bioverfahrens-und-zellkulturtechnik/

Research Focus	Data- and knowledge-driven tools to accelerate Pharamceutical Developement
Institution	ETH Zürich, Institute of Chemical and Bioengineering
Address	ETH Zürich, Inst. f. Chemie- u. Bioing.wiss., Morbidelli Group, HCI F 129, Vladimir-Prelog-Weg 1-5/10, 8093 Zürich
Contact	Massimo Morbidelli
eMail	massimo.morbidelli@chem.ethz.ch
Web site	https://morbidelli-group.ethz.ch/research/mammalian-cell-bioprocessing.html

UNITED KINGDOM

Research Focus	Particle Technology, Process engineering, complex fluids
Institution	School of Chemical Engineering
Address	The University of Birmingham, Edgbaston, Birmingham, B15 2TT, UK
Contact	Mike Adams
eMail	m.j.adams@bham.ac.uk
Web site	https://www.birmingham.ac.uk/staff/profiles/chemical-engineering/adams-mike.aspx

Research Focus	Modeling of powder processing
Institution	University of Oxford, Department of Engineering Science
Address	Parks Road, Oxford, OX1 3PJ
Contact	Alan Cocks
eMail	alan.cocks@eng.ox.ac.uk
Web site	http://www2.eng.ox.ac.uk/solidmech/people/professor-alan-cocks

Research Focus	Particle technology and simulation
Institution	University of Leeds, Institute of Particle Science and Engineering (ISPE)
Address	Institute of Particle Science and Engineering (IPSE), School of Process Environmental and Materials Engineering, University of Leeds, Clarendon Road, Leeds, LS2 9JT
Contact	Mojtaba Ghadiri
eMail	m.ghadiri@leeds.ac.uk
Web site	http://ghadiri-group.leeds.ac.uk/

Research Focus	Mechanics of granular and porous materials
Institution	University of Leicester, Department of Engineering
Address	The University of Leicester, University Road, Leicester, LE1 7RH
Contact	Csaba Sinka
eMail	ics4@le.ac.uk
Web site	https://www2.le.ac.uk/departments/engineering/people/academic-staff/csaba-sinka

Research Focus	Computational formulation engineering, discrete element modeling
Institution	University of Surrey, Department of Chemical and Process Engineering
Address	University of Surrey, Guildford, Surrey
Contact	Charley Wu
eMail	c.y.wu@surrey.ac.uk
Web site	https://www.surrey.ac.uk/people/charley-wu

FEATURED ARTICLE

BACK TO TABLE OF CONTENTS

The featured article in this Newsletter edition concerns the latest developments in the field of personalized medicine. It is a reprint of an article written in German by Dr. Andreas Ziegler which first appeared in the *Deutsche Apotheker Zeitung* and is re-published here with their permission.

Ziegler, Individualisierte Medizin: Die Zukunft hat bereits begonnen!
Bericht von der 5th APV Winter Conference Innsbruck, in: Deutsche Apotheker Zeitung, 160. Jahrgang, Nr. 7, 13.02.2020, Seite 62-63

https://www.apv-mainz.de/fileadmin/dateiablage/apv-mainz/DAZ_2020_07_APV__4_.pdf

DRUG DELIVERY LITERATURE

BACK TO TABLE OF CONTENTS

Provided by Dr. Carsten Timpe

RECENTLY PUBLISHED LITERATURE REVIEWS IN THE FIELD OF DRUG DELIVERY

Peptide, Protein-based Drug Delivery

A review on parenteral delivery of peptides and proteins
Jain D, Mahammad SS, Singh PP, Kodipyaka R. Drug Dev Ind Pharm. 2019 Sep;45(9):

This review provides an overview of the stability and formulation development for peptides and proteins. The most common route for protein delivery, parenteral, has been focused on parenteral solution and lyophilization as the formulation strategy. Additionally, new drug delivery and half-life extension approaches will further the reach of this unique class of molecules. Efforts are underway to explore the area with new technologies and development.

Peptide-mediated drug delivery across the blood-brain barrier for targeting brain tumors
Jafari B, Pourseif MM, Barar J, Rafi MA, Omidi Y. Expert Opin Drug Deliv. 2019 Jun;16(6):583-605

This review delineates the biological impacts of BBB on brain drug delivery and targeting. The nanoscaled multifunctional shuttles armed with targeting entities (e.g., antibodies and peptides) are discussed. Important insights are given into the combinatorial screening methodologies used for the identification of de novo peptides capable of crossing BBB and targeting the brain.

Dermal and Transdermal Drug Delivery

Transdermal patches: Design and current approaches to painless drug delivery
Al Hanbali OA, Khan HMS, Sarfraz M, Arafat M, Ijaz S, Hameed A. Acta Pharm.
2019 Jun 1;69(2):197-215

This article reviews various transdermal patches available in the market, types, structural components, polymer role, and the required assessment tools. Although transdermal patches have medical applications for smoking cessation, pain relief, osteoporosis, contraception, motion sickness, angina pectoris, and cardiac disorders, advances in formulation development are ongoing to make transdermal patches capable of delivering more challenging drugs.

Topical and Transdermal Drug Delivery: From Simple Potions to Smart Technologies.
Benson HAE, Grice JE, Mohammed Y, Namjoshi S, Roberts MS. Curr Drug
Deliv. 2019;16(5):444-460

This overview on skin delivery considers the evolution of the principles of percutaneous ab-sorption and skin products from ancient times to today. Over the ages, it has been recognised that products may be applied to the skin for either local or systemic effects. As our understanding of the anatomy and physiology of the skin has improved, this has facilitated the development of technologies to effectively and quantitatively deliver solutes across this barrier to specific target sites in the skin and beyond. The review focus on these technologies and their role in skin delivery today and in the future

Limitations and Opportunities in Topical Drug Delivery: Interaction Between Silica Nanoparticles and Skin Barrier
Arriagada F, Morales J.. Curr Pharm Des. 2019;25(4):455-466

This paper reviews significant findings about the interaction between silica-based nanocarriers and the skin. First, this review focuses on the properties and functions of the skin, the skin penetration properties of silica nanoparticles, their synthesis strategies and their toxicity. Finally, advances and evidence on the application of silica nanocarriers in skin drug delivery are provided, in which the use of nanoparticles increases the stability and solubility of the bioactive compound, enhancing its performance, act as penetrator enhancer and improve controlled release. Thus, improving the treatment of some skin disorders

Expanding the applications of microneedles in dermatology
Sabri AH, Ogilvie J, Abdulhamid K, Shpadaruk V, McKenna J, Segal J, Scurr DJ, Marlow M. Eur J Pharm Biopharm. 2019 Jul;140:121-140

This review aims to provide the background on microneedles, the clinical benefits, and challenges of the device along with the potential dermatological conditions that may benefit from the application of such a drug delivery system.

Gene Drug Delivery, Gene Therapy, siRNAs

RNAi therapeutic and its innovative biotechnological evolution.
Weng Y, Xiao H, Zhang J, Liang XJ, Huang Y. Biotechnol Adv. 2019 Sep - Oct;37(5):801-825.

Recently, United States Food and Drug Administration (FDA) and European Commission (EC) approved first RNAi therapeutic all over the world: Alnylam Pharmaceuticals' RNA interference (RNAi) therapeutic, ONPATTRO™ (Patisiran), for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults. This paper introduces the basic information on ONPATTRO and the properties of RNAi and nucleic acid therapeutics, provides an update on the clinical and preclinical development activities, reviews its complicated development history, summarizes the key technologies of RNAi at early stage, and discusses the latest advances in delivery and modification technologies. It provides a comprehensive view and biotechnological insights on RNAi therapy for the broader audiences.

The current state and future directions of RNAi-based therapeutics
Setten RL, Rossi JJ, Han SP. Nat Rev Drug Discov. 2019 Jun;18(6):421-446

In this review, key advances are discussed in the design and development of RNAi drugs leading up to the landmark achievement of ONPATTRO™ approval, the state of the current clinical pipeline and prospects for future advances, including novel RNAi pathway agents utilizing mechanisms beyond post-translational RNAi silencing.

Nanosystem-based Drug Delivery

Nanocrystals: An Overview of Fabrication, Characterization and Therapeutic Applications in Drug Delivery
Pardhi VP, Verma T, Flora SJS, Chandasana H, Shukla R. Curr Pharm Des. 2018;24(43):5129-5146

One of the main advantages of nanocrystals is their wide range of applicability such as oral delivery, ophthalmic delivery, pulmonary delivery, transdermal delivery, intravenous delivery and targeting (brain and tumor targeting). The enhancement in market value of nanocrystals as well as the number of nanocrystal products on the market is gaining attention to be used as an approach in order to gain commercial benefits.

Nanotechnology: Revolutionizing the Science of Drug Delivery
Mishra M, Kumar P, Rajawat JS, Malik R, Sharma G, Modgil A. Curr Pharm Des. 2018;24(43):5086-5107

This review emphasizes on providing a cursory literature of the past events that led to the procession of nanomedicines, various novel drug delivery systems describing their structural features along with the pros and cons associated with them and the nanodrugs that made a move to the clinical practice. It also focuses on the need of the novel drug delivery systems and the challenges faced by the conventional drug delivery systems.

Ocular Drug Delivery

Ocular Drug Delivery: Present Innovations and Future Challenges
Gote V, Sikder S, Sicotte J, Pal D. J Pharmacol Exp Ther. 2019 Sep;370(3):602-624

In this review article, past successes, present inventions, and future challenges in ocular drug-delivery technologies are discussed. This expert opinion also discusses the future challenges for ocular drug-delivery systems and the clinical translatable potential of nanotechnology from benchtop to bedside.

Recent advances in slow and sustained drug release for retina drug delivery
Behar-Cohen F. Expert Opin Drug Deliv. 2019 Jul;16(7):679-686

Striking recent advance has occurred in the field of medical retina, greatly because intraocular drugs have been developed, enhancing their clinical efficacy while avoiding systemic side-effects. However, the burden of repeated intraocular administration limits the optimal efficacy of treatments, prompting the development of new drugs with prolonged half-life or of sustained drug delivery systems. In this review the various drugs and drug delivery systems that have reached the clinical stage are described and those that are in clinical development. Limitations to clinical translation are discussed.

Intranasal Drug Delivery

Intranasal Nanoparticulate Systems as Alternative Route of Drug Delivery
Alshweiat A, Ambrus R, Csoka I. Curr Med Chem. 2019;26(35):6459-6492

The aim of this review is to focus on the topicalities of nanotechnology applications for intranasal delivery of local, systemic, brain, and vaccination purposes during the last decade, referring to the factors affecting delivery, regulatory aspects, and patient expectations. This review further identifies the benefits of applying the Quality by Design approaches (QbD) in product development. Despite the significant research effort in this field, nanoparticle-based products for intranasal delivery are not available. Thus, further efforts are required to promote the introduction of intranasal nanoparticulate products that can meet the requirements of regulatory affairs with high patient acceptance.

Oral Drug Delivery

A Review on Oral Liquid as an Emerging Technology in Controlled Drug Delivery System
Torne SR, Sheela A, Sarada NC.. Curr Pharm Des. 2018;24(13):1349-1356

The Oral Liquid Drug Delivery System (OLDDS) remains the primary choice of dosage form, though challenging, for the pharmaceutical scientists. In the last two decades, Oral Liquid Controlled Release (OLCR) formulation has gained a lot of attention because of its advantages over the conventional dosage forms. This review also emphasizes on the existing techniques and the developments that have been made to improve on its efficacy including various formulation related factors. It also provides valuable insights into the role of polymers in the development of OLCR formulation that can be used in the management of Gastroesophageal Reflux Disease (GERD).

Oral Drug Delivery Technologies-A Decade of Developments.
Kaur G, Arora M, Ravi Kumar MNV. J Pharmacol Exp Ther. 2019 Sep;370(3):529-543

The aim of this review is to take stock of the advances in oral delivery technologies that are applicable for injectable to oral transformation, improve risk-benefit profiles of existing orals, and apply them in the early discovery program to minimize the drug attrition rates.

Orally disintegrating tablets and orally disintegrating mini tablets - novel dosage forms for pediatric use
Comoglu T, Dilek Ozyilmaz E. Pharm Dev Technol. 2019 Sep;24(7):902-914

The objective of this article is to highlight the development of ODTs and mini-ODTs, their significance, ideal characteristics, various techniques, and aspects related to design and formulation, marketed preparations, and future perspectives, especially for the pediatric patients.

Design and application of oral colon administration system
Cheng H, Huang S, Huang G. J Enzyme Inhib Med Chem. 2019 Dec;34(1):1590-1596

This review summarizes oral colon administration systems that have become a new method to treat intestinal diseases. The implementation of colon drug delivery system is restricted by many aspects, including physical and chemical properties, drug delivery mode, gastrointestinal physiological factors, and so on. Delivery methods to overcome these challenges revolve around the mechanisms of drug delivery, including the use of rational dosage forms to avoid the complex pH environment, and the prevention of drug release and absorption in the upper digestive tract.

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

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

Johannes Bartholomäus, PhD
APV Liaison Officer
Pharmakreativ Consulting, Aachen (D)

Martin Bornhöft, PhD
APV Office, Mainz (D)

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

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

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

Bernd Riebesehl, PhD
Novartis Pharma, Basel (CH)

Lea Ann Dailey, PhD
University of Vienna (A)

Bianca Brögmann, PhD
Evonik, Darmstadt (D)

Simon Geißler, PhD
Merck Serono, Darmstadt, (D)

Karsten Cremer, PhD
Pharma Patents, Basel (CH)

Florian Unger, PhD
Bayer, Wuppertal (D)

Peter van Hoogevest, PhD
Lipoid, Ludwigshafen (D)

Simone Wengner, PhD
Catalent, Eberbach (D)
(formerly R.P. Scherer)

Uwe Hanenberg, PhD
Catalent, Schorndorf (D)

Contact us!

EDITORIAL GROUP OF THE NEWSLETTER

Editor: Dr. Louise Rosenmayr-Templeton, Tower Pharma Consulting, Berndorf (A)
Layout: Christoph Blümer, Corden Pharma, Plankstadt (D)