



APV FOCUS GROUP DRUG DELIVERY

COMBINING SCIENCE & TECHNOLOGY TO CREATE ADVANCED DRUG DELIVERY SYSTEMS

INTERNATIONAL ASSOCIATION FOR PHARMACEUTICAL TECHNOLOGY

NEWSLETTER

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DRUG DELIVERY EVENTS

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Drug Delivery to the Lungs - DDL25

December 10-12 2014, Edinburgh, Scotland, UK

[Details](#)

1st European Conference on Pharmaceutics: Drug Delivery

- ◇ April 13-14, 2015, Reims, FR

[Details](#)

The 42st Annual Meeting & Exposition of the Controlled Release Society

July 26-29, 2015, Edinburgh, Scotland, UK

[Details](#)

[Suggest a meeting to be announced!](#)

APV EVENT SUMMARIES

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Provided by Dr. Michael Horstmann

SKIN FORUM - 14TH ANNUAL MEETING, PRAGUE, CZECH REPUBLIC (4TH TO 5TH SEP 2014)

For the second time in the last three years the Skin Forum held its Annual Meeting in conjunction with the APV. This time the meeting took place in Prague at the IMG Conference Centre with the APV Headquarters in the form of Dr. Bornhöft and Ms. Schmidt leading the meeting organizational efforts. About 200 skin scientists attended the meeting and gave it, with their discussions in the lectures and at the posters, a lively and stimulating atmosphere. The location of historic and beautiful Prague only added to the enjoyment of the meeting.

As in the past the APV-associated organizers (S. Wiedersberg, Reinhard Neubert and myself were in the group), selected predominantly industry speakers, transdermal and transungueal researchers while the Skin Forum representatives stayed with the core part of their mission and invited excellent speakers mainly from academia. The meeting started early on Thursday with Gopinathan K. Menon's (Ashland Specialty Ingredients) talk on "Surmounting the Stratum Corneum barrier: some insights from morphology" which brought us immediately into the heart of skin science.

The transdermal session started in the afternoon and was entitled "Transdermal Drug Delivery - the Industrial Perspective". The first lecture "Prediction of transdermal drug flux: Theory versus reality" was given by Sandra Wiedersberg (LTS Lohmann). Presentations from Michael Horstmann, Armin Breitenbach (Tesa Labtec) and Terri Sebree (US Pharmaceutical Consultant), who spoke about a newly registered iontophoretic sumatriptan device, followed. All groups of presentations were interspersed with Young Researcher sessions, where researchers from universities went into more

detailed presentations of their research. In the topic-wise more mixed sessions on Friday, Dr. Kosciessa (Photonamic) reported from an industrial view-point on the success of Alacare (a transdermal formulation of 5-aminolevulinic acid for photodynamic applications), while in the session dedicated to drug delivery to the nail, Gareth Winckle (Galderma) presented the R&D background of nail lacquer and Reinhard Neubert (Martin Luther University) spoke on nail delivery using different formulations and different model systems. After Prof Neubert's talk there was an open final discussion session with poster awards and this brought the meeting to a climax with the right mixture of science and development as it has been traditionally associated with Skin Forum meetings.

DRUG DELIVERY PRODUCTS

Provided by Dr. Louise Rosenmayr-Templeton

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MOVENTIG®/MOVENTIK® TABLETS (AstraZeneca)

In Sep 2014 the FDA approved AstraZeneca's naloxegol, a pegylated derivative of the mu-opioid receptor antagonist naloxone, [1] while the Committee for Medicinal Products for Human Use (CHMP) of the EMA issued a positive opinion on the product [2]. The product will be sold in Europe under the tradename Moventig, while in the US its tradename will be Moventik. The tablets contain 14.2 mg and 28.5 mg of naloxegol oxalate, equivalent to 12.5 and 25 mg naloxegol respectively in a film-coated immediate release formulation. If it receives marketing authorization from the European Commission (anticipated within the next 2 months), Moventig will be licensed for the treatment of opioid-induced constipation (OIC) in adult patients who have not responded adequately to laxatives. The approved indication for Moventik is more restricted in that it is intended for patients with OIC receiving opioids for non-cancer pain. The dose is 25 mg daily, reduced to 12.5 mg if the higher dose is not tolerated, on an empty stomach as food increases the rate and extent of absorption.

Pegylation of naloxone makes it highly water-soluble and poorly permeable, thus, restricting its action mainly to the GI tract. It is also a substrate for P-glycoprotein and, hence, naloxegol that is absorbed is likely to be pumped out of the brain before it can interfere with centrally-acting opioids. It therefore is able to reduce the constipating effects of opioids without interfering with their central action.

Approval was based on the results of the KODIAC clinical programme which comprised four clinical studies: KODIAC-4, -5, -7 and -8. KODIAC-4 and -5 were identical in design, placebo controlled, double-blind, 12 week studies assessing safety and efficacy, while KODIAC-7 was a 12 week safety extension to KODIAC-4, and KODIAC-8 was a 52 week long-term safety study. The three most common side-effects observed were abdominal pain, diarrhea and nausea. Symptoms that might indicate possible opioid withdrawal were seen in 3 % of patients on the 25 mg dose and 1% of the 12.5 mg cohort in the two placebo controlled studies. AstraZeneca licensed the product in 2009 from Nektar Therapeutics and it was developed using Nektar's oral small molecule polymer conjugate technology.

SPIRIVA® RESPIMAT® INHALATION SPRAY (Boehringer Ingelheim)

The FDA also in September approved the once-daily anticholinergic, tiotropium, in the Spiriva Respimat inhaler for the long-term treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD) and to prevent exacerbations of COPD [4]. The dose is 2 actuations of 2.5 mcg tiotropium (equivalent to 3.124 mcg of the bromide salt) once daily. Approval was based on the positive outcome of 7 clinical trials in which 8,700 patients were treated with the product [5]. The product consists of 4 g of sterile aqueous solution of drug filled into a plastic container which is crimped into an aluminium cylinder (Spiriva Respimat cartridge) plus the hand-held Respimat inhaler. The inhaler device uses mechanical energy to generate a slow-moving aerosol spray of medication and this means that delivery is not dependent on the patient's inhalation rate. The product is designed to deliver 28 actuations or 60 actuations (14 and 30 days treatment respectively) after priming prior to the first use. According to a company press release the existing tiotropium dry powder inhaler, Spiriva® HandiHaler® will remain on the market so that patients have a choice. Boehringer Ingelheim plans to launch Spiriva Respimat on the US market in January 2015.

On 30.9.2014 in a related announcement Boehringer made public plans to expand Respimat production at its Boehringer Ingelheim microParts GmbH site at Dortmund, Germany [6]. The more than €100 million investment will increase annual production to 44 million units and create around 100 new jobs.

[1] Entry for Movantik on Drugs@FDA
http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo (accessed on 30.9.2014).

[2] Summary of Opinion for Moventig
http://www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002810/WC500173691.pdf (accessed on 30.9.2014).

- [3] MOVENTIG® (naloxegol) receives positive CHMP opinion in the EU for the treatment of adults with opioid-induced constipation. <http://www.astrazeneca.com/Media/Press-releases/Article/20142609--moventig-naloxegol-receives-positive-CHMP-opinion-in-the-EU-for-the-treatment-of-adults-with-opioid-induced-constipation>. (accessed on 30.9.2014).
- [4] Entry for Spiriva Respimat on Drugs@FDA http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#labelinfo (accessed on 30.9.2014).
- [5] Boehringer Ingelheim Announces FDA Approval of Spiriva® Respimat® (tiotropium bromide) Inhalation Spray for the Maintenance Treatment of COPD. http://us.boehringer-ingelheim.com/news_events/press_releases/press_release_archive/2014/09-25-14-boehringer-ingelheim-announces-fda-approval-spiriva-respimat-tiotropium-bromide-inhalation-spray-maintenance-treatment-copd.html. (accessed on 30.9.2014).
- [6] Boehringer Ingelheim invests €100 million: Expanded Respimat® production in Dortmund. http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2014/30_september_2014respimat.html (accessed on 30.9.2014)

DRUG DELIVERY COMPANIES

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Provided by Kaspar van den Dries, PhD, Patheon, Contact: Kaspar.vdDries@Patheon.com

NANOMI (Oldenzaal, The Netherlands)

Fact sheet:

Founded:	2004
Location:	Oldenzaal, The Netherlands
Ownership:	Subsidiary of Lupin Limited
Employees:	25
Key technology:	Nanomi is a drug delivery company specialized in the formulation, development and manufacturing of sustained release products based on particles, especially injectables with superior injectability. The company's proprietary Monosphere Technology, that brings the precision of semiconductor technology to the pharmaceutical field, provides unprecedented predictability, uniformity and scalability of the microsphere manufacturing process from lab to fab.
Products:	Complex injectables based on particles (sustained release, especially injectables with controlled release profiles and superior injectability). Fields of application range from CNS, oncology, ophthalmology and cardiovascular, among others.
Development status:	From preclinical to GMP manufacturing
Partnerships:	Pharmaceutical Product Development with pharmaceutical and biotech companies. Nanomi does not provide fee-for-service based services but is involved in all stages of product development. Nanomi has served more than 70 customers worldwide and has a proven track record of product development programs for top pharmaceutical companies.
Website:	http://www.nanomi.com
Contact:	Miriam Gironès (Director Business Development) Zutphenstraat 51, 7575 EJ Oldenzaal, The Netherlands Phone: +31 (0) 54 15 39 918 e-mail: bd@nanomi.com

MOEIN MOGHIMI is based at the University of Copenhagen (Denmark) where he serves as the Professor of Nanomedicine at the Department of Pharmacy, as Professor of Pharmaceutical Nanotechnology at the NanoScience Centre, and as Director of the Centre for Pharmaceutical Nanotechnology and Nanotoxicology. He is also a full member and professor at the Department of Translational Imaging, Houston Methodist Research Institute (Weill Cornell Medical College), Houston Methodist Hospital Systems, Houston, Texas (USA), adjunct professor at the Department of Pharmaceutical Sciences, Skaggs School of Pharmacy and Pharmaceutical Sciences, University of Colorado-Denver Medical Center, USA, and the elected Fellow of the Institute of Nanotechnology (FIoN), UK. Earlier, he was also the Honorary Professor of Nanomedicine at the Multidisciplinary Research Center, Shantou University (China).



Education and Previous Career

Moein earned his degree from the University of Manchester (UK), where he read biochemistry, and obtained his PhD in biochemistry (liposome immunobiology) in 1989 from Charing Cross Hospital Medical School, Imperial College, University of London. Afterwards, he completed a four-year post-doctoral training programme in Advanced Drug Delivery Research at the School of Pharmaceutical Sciences (University of Nottingham, UK) under the guidance of Prof. S.S. Davis. He then became University Research Fellow in Advanced Drug Delivery Systems at the Department of Pharmaceutical Sciences, University of Nottingham (UK). Immediately prior to joining Copenhagen he was Senior Lecturer in Biopharmacy and Molecular Pharmaceutics at the School of Pharmacy, University of Brighton (UK).

Research Interests and Achievements

Moein's research activities are focused on pharmaceutical nanoscience, and fundamental nanomedicine/nanosafety. He has pioneered research in design and surface engineering of nanoparticles and functional nanosystems for parenteral site-specific targeting/drug delivery and imaging modalities (splenotropic entities, lymphotropic agents, 'phagocyte-resistant' nanoparticles, cerebral endothelial cell specific nanoplatfoms and anti-cancer nanomedicine) as well as the molecular basis of nanomaterial/polymer immune toxicity and cytotoxicity. Since 2009, Moein has been the recipient of many research awards securing over €10 million in competitive research funds in nanomedicine research as the principal investigator and partnering two large-scale competitive European Commission FP-7 programmes in translational nanomedicine/drug delivery, addressing Alzheimer's disease and atherosclerosis with secured budgets of €14 million and €8.5 million, respectively.

Moein has over 170 peer-reviewed publications/patents to his credit with over 9800 citations. He has edited many Theme Issues of Advanced Drug Delivery Reviews (Elsevier), Maturitas (Elsevier), Journal of Biomedical Nanotechnology (American Scientific Publishers) and Current Drug Delivery (Bentham), and currently acts as Associate Editor of Nanomedicine: Nanotechnology, Biology and Medicine (Elsevier) and the Journal of Biomedical Nanotechnology. Furthermore, Moein is a member of the editorial/advisory board of more than 20 peer-reviewed scientific international journals, including Advanced Drug Delivery Reviews, Nanomedicine-UK (Future Medicine), Journal of Liposome Research (Informa Healthcare), Drug Delivery (Informa Healthcare) and Molecular and Cellular Therapies (BioMed Central). He is currently completing two books in nanomedicine pharmacokinetics and nanomedicine innovation/business.

FEATURED ARTICLE

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The impact of personalized medicine, patient-centric drug products and the aging of society – Challenges and opportunities for drug delivery

By Sven Stegemann, Graz University of Technology, Institute of Process and Particle Engineering, Graz, Austria.

Introduction and Background to Personalized Medicine

Personalized medicine has been defined as "Providing the right treatment to the right patient, at the right dose at the right time." (European Union) and the modern day era of personalized medicine has its roots in discoveries made in the middle and late 20th century. In 1944 DNA was first identified as the material controlling biological inheritance [1]. Ten years later Watson & Crick discovered and published the helix structure of DNA which can be considered the first step towards the development of genomics and genomic research [2]. Fifty years later the human genome was sequenced by two independent research groups: the publically funded International Human Genomic Sequencing Consortium which published the draft sequence of the human genome in 2001 [3] and finalized the Human Genome Project in 2004 [4] and Craig Venter's Celera Genomics. Just 4 years later, in 2008, the first 1000 human genomes were

sequenced, providing an understanding of the diversity of the genome between humans [5]. In addition to these major breakthroughs, the genetic and pharmacogenomics research of the past decades has led to a greater fundamental understanding of disease mechanisms, biomarkers, drug transporters and systems biology that has changed drug discovery and development significantly [6] and resulted in the introduction of personalized medicine. Some specific examples of the impact that genomic research has already made on drug development and therapy are given below:

- The R&D based pharmaceutical industry is constantly making incremental progress in therapies for complex diseases, whose underlying disease mechanism is known to be the result of a specific genetic mutation within a patient population. Imatinib (Gleevec®) was one of the first drugs introduced for a patient population with a specific genetic mutation. Imatinib is a Bcr-abl tyrosine kinase inhibitor effective in Philadelphia chromosome positive patients with chronic myeloid leukemia.
- In 2007 the FDA approved a genetic test for the metabolic enzymes, CYP2C9 and VKORC1, to be used when prescribing warfarin (Coumadin®) to patients. This was followed by a warfarin dosing calculator, which was launched in 2009, in order to support physicians in defining the right dose for the patients (www.warfarindosing.org). As a consequence, warfarin, which was available until then only as 1 and 5 mg tablets, became available in 9 different dose strengths ranging from 1 to 10 mg.
- Pharmacogenomics are also used in identifying patients with a severe adverse drug reaction to Abacavir due to a genetic predisposition. Abacavir is a reverse transcriptase inhibitor used in the treatment of HIV-1 infection. Abacavir leads to a serious and sometime fatal hypersensitivity reaction in patients with the HLA-B*5701 allele and a genomic test is mandatory before starting treatment.
- The introduction of new diagnostic tools based on genomic research is slowly shifting medicine from a reactive discipline to a preventive one and from prescription standard based approach to a patient stratified therapeutic one. There is clear evidence that women carrying certain BRCA1 and BRCA2 gene variations have a 4-8 times higher risk of developing breast cancer and must therefore be monitored closely throughout their lifetime. When it comes to the treatment of breast cancer, two complex diagnostic tests are already available to assist physicians to decide on the most appropriate treatment. Oncotype DX® can identify women who will most likely respond to chemotherapy and MammaPrint® determines the risk of recurrence of cancer in early breast cancer patients following surgery.
- On-going research will further increase the availability of early diagnostic tools especially for those diseases which are known or suspected to start long before the first clinical symptoms become evident. For example, today there is a good understanding that Alzheimer's disease progresses silently over many years before the first symptoms occur. This is supposed to be one reason for the poor therapeutic outcomes of the pharmacological interventions developed and evaluated to date. Recently there has been significant advances in identifying early biomarkers for Alzheimer's disease [7]. Such early biomarkers will have a tremendous impact on Alzheimer's drug research and the development of preventive medicines that provide effective treatment against the progression of plaque formation in the brain. Moreover, such biomarkers could potentially allow monitoring of disease progression in clinical trials as well as the response to therapy in patients.

The impact of Personalized Medicine on Drug Therapy

Despite the examples of personalized medicines and therapy given in the previous section, the field is still in its infancy. The changes that accompany the use of genetic information and additional biomarkers in drug discovery, development as well as in diagnosis and drug therapy can be considered to be a disruptive innovation. This means that it is likely to alter significantly the approach that the pharmaceutical industry takes to developing new medicines and how physicians make decisions to prescribe them. The various challenges that will come along with further progress and implementation of precision medicine have recently been addressed by Mirnezami and co-workers [8]. Taking for granted that personalized medicines lead to enhanced therapeutic outcomes and quality of life for patients, the main areas that need to be addressed are as follows:

- Regulatory issues regarding the development of personalized medicines
- The impact on the clinical trial framework
- The potential reclassification of diseases based on increased genetic information,
- The handling and interpretation of the multiparametric data
- The implementation of personalized medicines into clinical practice including the education and training of healthcare professionals
- The impact of the patient-clinician interaction and ethics
- And last but not least the delivery of precision medicines to patients and their financing by public healthcare systems or private insurance.

However, these questions are likely to be answered rather quickly in the coming years given the healthcare industry's ability to deal with the scientific dynamic and the exponential advances in life sciences that have occurred over the last 50 or more years.

The current expectations of personalized medicine are mainly based on a purely clinical perspective of being able to stratify the drug therapy for an individual patient. Primarily the present focus of personalized medicine is on improving the efficacy of a drug therapy and avoiding potential adverse drug reactions by selecting the right drug(s), the right dosing regimen and time for the individual patient. Even though such efficacy goals may be achieved; the question is if effectiveness will be improved to the same extent or if the gap between efficacy and effectiveness will remain a major concern. It is well understood that improved health outcomes and effectiveness can only be achieved in collaboration with the patient and by respecting patient needs beyond purely clinical considerations. To achieve this goal the development of personalized medicine products has to be based on patient-centric drug product design to facilitate adherence and reduce the risk for potential unintentional medication errors.

The challenge of combining personalized medicines with patient-centric drug product design is further increased by the aging population and the significant rise in the number of older patients with high (85 – 94 years) and very high age (≥ 95 years). As chronic diseases continue to occur around the same time in life as in previous generations, future very elderly patient groups will be characterized by multimorbidity and polypharmacy. The personalization of medicine in these multimorbid patients will no longer be focused on managing the individual diseases but instead will set therapeutic priorities by focusing on the patients' goal to maximize the health and quality of life [9]. The focus on the patients' goals and quality of life will include a critical selection of appropriate drug products and their ease of use and administration by the concerned patient. As older patients have age and disease-related physiological and functional impairments [10], the personalization of medicine will increase the variety of different drug combinations and dose strengths used in daily practice. Age and disease related functional impairments will affect drug product use and administration by the patients or care giver. The appropriateness of a drug product will therefore become an important criteria in selecting a particular medicine in order to prevent inappropriate medication altering [11] and medication errors. The reason why specifically medication errors will get more attention in the future is the fact that they recently became a reportable product safety issue in the EMA pharmacovigilance guidelines [12, 13]. Moreover, the appropriateness of drug products for older adults will be addressed in an up-coming reflection paper regarding drug product quality aspects [14].

Implications for Drug Product Development and Manufacturing

As a result of the ongoing personalization of medicine, the aging population and the need for patient-centric drug product design triggered by regulatory initiatives to prevent medication errors and increase effectiveness [15], pharmaceutical product development and manufacturing will have to make adjustments to their existing paradigms. The following main points should be considered in this respect:

- **Number of dose strengths/dose strength flexibility**
For certain types of drug (e.g. narrow therapeutic window, high (pre)systemic metabolism) personalization of therapy is expected to lead to the prescribing of patient-specific dose strengths that are normally not covered sufficiently by the typical dosage forms developed today. However, precise dosing without the need to modify the dosage form (e.g. tablet splitting) is required for patient populations with disabilities as they might not be able to perform the modification. Moreover, it is important to consider that medication errors occur much more frequently when the drug product needs to be modified to achieve the patient-specific dose.
- **Dosage forms and delivery systems alternatives**
Single unit, solid oral dosage forms are traditionally developed as the first choice for a new product. Several issues have been reported with alterations to solid oral dosage forms due to swallowing issues which are a common comorbidity of certain diseases like dementia, Alzheimer's Disease, Parkinson's Disease, cancer and also cardiovascular disease and diabetes [16]. Alternative dosage forms should be considered based on a thorough understanding of the target patient population in order to overcome such and other predictable issues. For example, sprinkle formulations filled into easy-to-open capsules are often used to provide an alternative way of delivering the drug.
- **Drug product complexity/simplicity**
Patients are lay persons who do not have knowledge on medicines. Even though drug products may look very similar to each other, they are products with very specific characteristics and administration requirements. It is well known that health literacy is very limited even in high income countries [17] and that an average patient is not necessarily able to use the product as intended, especially patients with polypharmacy. Sophisticated drug delivery systems requiring special administration procedures or use of special packaging should be considered very carefully and avoided as much as possible to reduce complexity.

- **Patient-product interface (micro- and macroergonomics)**
Drug products are used by patients within their environment (e.g. home or work). Patients interact with the product by trying to understand the task and task execution to achieve the goal of drug therapy. The potential task performance depends on the age and disease-related impairments of the patients when in their home/work settings. When designing a product, the patient-product interface needs to be predicted in the target patient population and taken into account in the product design. For example peel-off blisters are likely to be perceived as push-through blisters which are a common form of packaging and familiar to patients. Alternatively they can be pushed through unintentionally by patients through simple force of habit.
- **Fixed dose combinations**
For the majority of chronic diseases, there are a few drug classes that are used in combination. It can be expected that the personalization of medicine will provide further evidence for disease clusters [18]. Therefore the combination of drugs from different classes will continue to be the standard in future drug therapy. Combination products are known to reduce the complexity of the therapeutic schedule and improve adherence and finally effectiveness.
- **Drug-device combinations**
Medical devices play an important role in the administration of drugs via the parenteral and pulmonary drug delivery route. To provide precise doses or combination of drugs, medical devices might be considered in the future drug development, as they offer some unique opportunities like the combination of delivery with adherence monitoring systems. Recent advances in medical devices for personalized medicines have been reviewed by Wening and Breitzkreutz and could serve as a starting point [19].
- **Manufacturing flexibility, proximity of manufacturing**
The provision of personalized, patient centric drug products to patients will require manufacturing platforms with high flexibility in dose strength variation as well as in final dosage form options. For example, multiparticulates are known for their flexibility in terms of targeting release from immediate to modified release, as well as for their suitability to be administered in form of sprinkles to patients with swallowing issues. Delivering personalized medicines can also lead to the miniaturization and localization of pharmaceutical manufacturing close to the patients. Manufacturing for critical patients might then take place in dedicated manufacturing units or hospital pharmacies based on pre-manufactured bulk products provided by the pharmaceutical industry. Possible examples of this could be multiparticulates or mini-tablets which are filled with the patient-specific dose e.g. on small capsule filling machines.

It should be noted that the above points are not considered an exhaustive list and only represent a limited and brief overview of the implications of personalized medicine for drug product development and manufacturing for the purpose of this short review article.

Conclusion

Advances in personalized medicines will have a significant impact on healthcare provision in general. For the pharmaceutical industry, personalized medicines offer new opportunities in drug discovery, clinical trials, development and marketing. Pharmaceutical development will play an important role in translating improved efficacy resulting from pharmacogenomics and precision medicines into improved effectiveness by patient-centric drug product design. The disruptive nature of the personalization and patient centricity in drug product development will face resistance at various levels of pharmaceutical organizations and those companies which are able to resolve this resistance quickly will benefit most from the opportunities derived from the fast growing progress in personalized medicine and patient-centric drug product design and manufacturing. Personalized medicines, as well as patient-centric drug product design, are evolving quickly and will soon provide the evidence to healthcare providers that they improve the success rate of drug therapy, the efficacy as well as effectiveness and safety.

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DRUG DELIVERY LITERATURE

Provided by Dr. Carsten Timpe

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RECENTLY PUBLISHED LITERATURE REVIEWS IN THE FIELD OF DRUG DELIVERY

Combination of microRNA therapeutics with small-molecule anticancer drugs: Mechanism of action and co-delivery nanocarriers

Dai X, Tan C.. *Adv Drug Deliv Rev*. 2014 Oct 2. pii: S0169-409X(14)00208-7.

Recent advances in controlled pulmonary drug delivery.

Liang Z, Ni R, Zhou J, Mao S. *Drug Discov Today*. 2014 Oct 2. pii: S1359-6446(14)00386-9.

siRNA nanotherapeutics: a Trojan horse approach against HIV

Mishra V, Kesharwani P, Jain NK.. *Drug Discov Today*. 2014 Oct 2. pii: S1359-6446(14)00385-7.

Liposomes as carriers of hydrophilic small molecule drugs: Strategies to enhance encapsulation and delivery

Eloy JO, Claro de Souza M, Petrilli R, Barcellos JP, Lee RJ, Marchetti JM.. *Colloids Surf B Biointerfaces*. 2014 Sep 22. pii:S0927-7765(14)00500-1.

Targeting myeloid cells using nanoparticles to improve cancer immunotherapy

Amoozgar Z, Goldberg MS. *Adv Drug Deliv Rev*. 2014 Oct 2. pii:S0169-409X(14)00205-1.

Hybrid poly(lactic-co-glycolic acid) nanoparticles: design and delivery prospectives

Pandita D, Kumar S, Lather V . *Drug Discov Today*. 2014 Sep 30. pii: S1359-6446(14)00384-5.

Biomaterial-based delivery for skeletal muscle repair

Cezar CA, Mooney DJ. *Adv Drug Deliv Rev*. 2014 Sep 28. pii: S0169-409X(14)00206-3.

Advances in oral controlled drug delivery: the role of drug-polymer and interpolymer non-covalent interactions

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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 pharmaceuticals.

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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.

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