APV – Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e. V.

APV NEWS

02 • 2013

Nachrichten und Mitteilungen

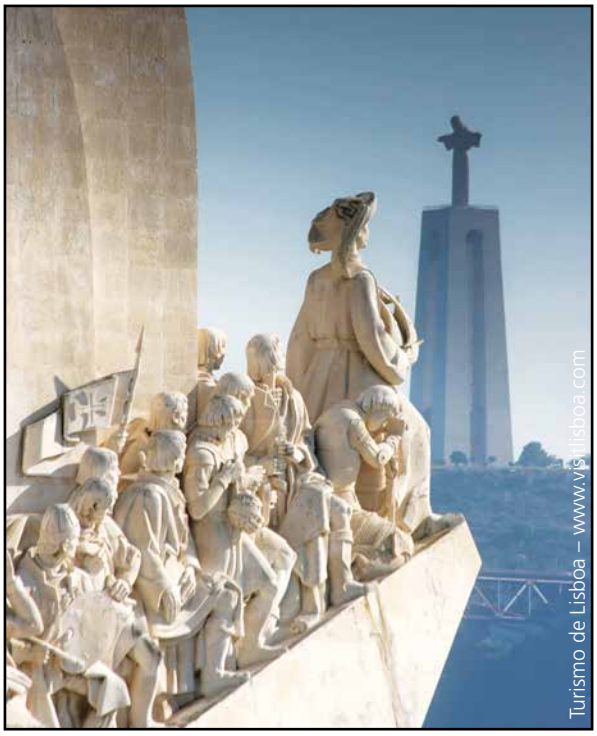
MAKING SCIENCE WORK

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

9th PBP World Meeting in Lisbon, Portugal

Industry and Academia meet up in Lisbon from March 31st to April 03rd, 2014

After such illustrious destinations like Budapest, Paris, Berlin, Florence, Geneva, Barcelona, Malta and Istanbul, the 9th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology will be held in Lisbon, Portugal, in 2014.



New medicinal products and innovative medical devices are urgently needed in our rapidly changing world. The dramatic raise of world's population, ageing of some societies, global economy and the continuous progress towards a better understanding of diseases, targets and new drug substances are extremely demanding. Small molecules, biologicals and non-biological complex drugs require new technologies to be administered to the patient. New and generic products need to be developed considering patients' needs, industrial processes, economics, safety, drug quality and regulatory requirements. We would like to invite you to discuss the risks, opportunities and challenges of the development and production of new medicinal products and medical devices.

Scientific Programme

The meeting provides two parallel sessions on industry-related topics presented by distinguished invited speakers. The international programme committee could win renowned speakers who will talk on the hot topics, such as Dr. Frederic Bourgois from Sanofi will give a talk on Drug Counterfeiting, Professor Alexander Kabanov from University of North Carolina will talk about latest trends in Nanomedicines. To take into account the challenges of Pharmaceutical Engineering, we offer our delegates an additional session discussing the role of pharmaceutical engineering in product development (Jean-Rene Authelin, Sanofi, France) and the demands one is facing by planning and building a new plant for parenterals (Philip Schneider, F.Hoffmann-La Roche, Switzerland) as well as what to do when transferring sciences to biopharmaceutical manufacturing (David Estape, M+W Germany, Germany). This is just to name a few topics the 9th PBP World Meeting is treating. At www.worldmeeting.org you can find the complete and updated scientific programme.

In addition to the sessions by invited speakers, we have two more parallel tracks of oral presentations given by young or established scientists from all over the world. In these contributions selected from many hundreds submitted abstracts by the Programme Committee, most recent scientific findings and experiences will be presented on a broad range of topics related to Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology.
We are looking forward to receiving your short paper. Next Meetings hot topics are

- Advanced Drug Delivery Systems
- Controlled Drug Delivery
- Technical Innovations
- Starting Materials
- Physical Pharmacy
- Preformulation
- Pharmaceutical Manufacturing & Engineering
- Packaging
- Quality Control & PAT
- Quality Assurance
- Stability Testing
- Regulatory Affairs
- Oral Delivery
- Buccal and Nasal Delivery
- Parenteral Delivery
- Pulmonary Delivery
- Transdermal Delivery
- Dermal preparations
- Nanoparticles & Vesicles
- Protein Formulation & Aggregation
- Gene Delivery
- Advances Therapy Medicinal Products
- Pediatric & Geriatric Drug Delivery
- Bioavailability and Absorption Enhancement
- In-Vitro/In-Vivo Correlations
- Cellular Drug Transport
- Green & sustainable Pharma

Exhibition ResearchPharm®

The accompanying exhibition ResearchPharm® is an integral part of this meeting. This constantly growing exhibition is a very good opportunity to showcase your products and services in the field of

- Laboratory Equipment
- Small Scale Equipment
- Analytical Instruments
- API – Active Pharmaceutical Ingredients
- Excipients
- Services for the Pharmaceutical Industry
- CRO – Contract Research Organisations
- Recruiting

Exhibition

ResearchPharm
International Exhibition for R&D

Exhibitors can take advantage of the meeting which provides perfect networking opportunities for delegates. Plenty of young researchers in the field of pharmaceutics will be on site, this is an excellent chance to scout for young professionals. In 2014 the organisers will provide rooms for interviews with potential candidates. The set up of poster panels will be in the exhibition area so that as an exhibitor you can be sure of attracting many visitors. We offer stand space and rental booths starting from 9 square meter, for detailed information please look at **www.researchpharm.org**.

Social Programme

PBP WORLD MEETING

Monday night, 31st March, is reserved for the Welcome Reception, which will be held at the Congress Centre right where the exhibition ResearchPharm® takes place. Enjoy a glass of wine and a bite while networking with old and new friends or strolling around the exhibition area getting to know the latest trends in R&D.

Our Event Dinner evening enjoys great popularity and is well known for its great atmosphere. In Lisbon we have managed to find again an extraordinary location for this event. The Event Dinner takes place on Wednesday, 2nd April, 2014 in "Convento do Beato" an ancient convent built in the 16th century , which is today a Heritage Site of Public Interest. Enjoy the evening under splendid vaulted ceilings and in one of its many cloisters.

Location

Located by the Tagus River near the historic buildings of Belém quarter, the 9th PBP World Meeting will take place at the Congress Centre in Lisbon. Lisbon is an illuminated city. The almost constant presence of sunshine and the River Tagus transform the Portuguese capital into a mirror of a thousand lights. There are so many things to see and do in Lisbon that you will have access to a wide array of different experiences. After a long meeting day you may take a walk through Lisbon – whose history spans back thousands of years – and find streets filled with heritage monuments, and characteristic neighbourhoods where the city first developed and can still be experienced at its most genuine level.

IT

Lokale Gruppen

Neue Treffpunkte und -zeiten der lokalen Gruppen:

17. April 2013	Lokale Gruppe Rheinhessen-Rheingau ab 19.30 Uhr Ort noch nicht bekannt.
25. April 2013	Lokale Gruppe Oberbayern ab 19.30 Uhr Zurück von der TechnoPharm® – Neuigkeiten vom Messebesuch. Stadtschreiberei im Hofer Der Stadtwirt, Burgstr. 5, 80331 München
22. Mai 2013	Lokale Gruppe Rhein-Neckar ab 19.30 Uhr Restaurant Lindbergh, Am City Airport Mannheim, Seckenheimer Landstraße 170, 68163 Mannheim
29. Mai 2013	Lokale Gruppe Hamburg ab 18.30 Uhr Hofbräuhaus Hamburg, Esplanade 6, 20354 Hamburg
03. Juni 2013	Lokale Gruppe Westfalen ab 19.30 Uhr Hövels-Hausbrauerei, Hoher Wall 5-7, 44137 Dortmund

Die lokale Gruppe Westfalen – kollegialer Gedankenaustausch in ungezwungener Atmosphäre
In gemütlicher Runde mit Kollegen fachsimpeln. Darum geht es bei den lokalen Gruppen der APV, die sich mittlerweile an zahlreichen Orten in Deutschland gebildet haben.

Die Lokale Gruppe Westfalen, die sich alle 3 Monate trifft, wurde 2010 als Pilotprojekt gegründet und hat sich mittlerweile fest im Vereinsleben der APV etabliert. Nach dem Ende der Weihnachtsmarkt-Saison war Ende Februar Treffpunkt diesmal wieder die Hövels Hausbrauerei in Dortmund. Neben dem fachlichen Austausch kam dabei wie immer natürlich auch der Spaß nicht zu kurz.

Wie schon oft in der Vergangenheit zeichnete sich auch dieses Treffen durch seinen interdisziplinären Charakter aus. Mit von der Partie waren Kollegen aus Industrie und Hochschule aus den Bereichen Forschung, Entwicklung, Herstellung sowie Qualitätskontrolle und Qualitätssicherung. Mit Rottendorf, NextPharma, Gerresheimer und Wessling waren vom Lohnhersteller über den analytischen Servicedienstleister bis hin zum Packmittellieferanten alle dabei. Die Seite der Hochschule war durch die HHU Düsseldorf, die TU Dortmund und die WWU Münster vertreten. Beste Voraussetzungen also für einen informativen und zugleich unterhaltsamen Abend in netter Gesellschaft.

Beim nächsten Treffen am 03.06.2013 ab 19:30 (Treffpunkt Hövels Hausbrauerei, Hoher Wall 7-11, Dortmund) feiert die lokale Gruppe Westfalen ihr 3-jähriges Bestehen. Die Organisatoren würden sich freuen, dann vielleicht auch noch das eine oder andere neue Gesicht zu diesem Treffen begrüßen zu dürfen.

Bei Interesse erhalten Sie weitere Informationen bei Dr. Kathrin Bartscher **(kathrin.bartscher[at]nextpharma.com)**

Besuch aus Thailand in Regensburg zur 6. Galenus Gastprofessur

Prof. Dr. Kwunchit Ounghbo (rechts)

Prof. Dr. Achim Göpferich

Als Gastgeber der 6. Galenus-Gastprofessur hatte sich Prof. Dr. Achim Göpferich, seit 1997 Leiter des Instituts für Pharmazeutische Technologie der Universität Regensburg, seine thailändische Kollegin Prof. Dr. Kwunchit Ounghbo von der Prinz-von-Songkla-Universität in Hat Yai als Gastprofessorin gewünscht, weil ihn mit ihr bereits eine lange und erfolgreiche wissenschaftliche Zusammenarbeit verbindet. Prof. Oungbho hat die Einladung zur Gastprofessur angenommen und wird vom 15. April bis zum 15. Juni 2013 am Institut für Pharmazeutische Technologie in Regensburg tätig werden. Forschungsschwerpunkte der wissenschaftlichen Arbeit am Institut für Pharmazeutische Technologie in Regensburg sind neben der Erforschung von Biomaterialien das Tissue Engineering sowie die Entwicklung von Drug Delivery Systems.

Prof. Ounghbo wurde nach ihrem Pharmaziestudium in Thailand an der Christian-Albrechts-Universität Kiel im Jahr 1997 promoviert. Sie ist heute als Assistenzprofessorin an der 1967 gegründeten südthailändischen Prinz-von-Songkla-Universität tätig und forscht dort aktuell auf dem Gebiet der „Local Drug Delivery Systems for Bone Tissue Engineering".

In ihrer Zeit als Galenus-Gastprofessorin an der Universität Regensburg wird Prof. Oungbho neben ihrer Lehrtätigkeit in Vorlesungen und Seminaren zusammen mit Prof. Göpferich und seinem Team am gemeinsamen Projekt „Physico-chemical characterisation of SIMVASTATIN-nanoparticles" ihre wissenschaftlichen Erfahrungen einbringen und am 8. Mai 2013 ihren Festvortrag halten.

What's hot in European Journal of Pharmaceutics and Biopharmaceutics?

Stefanie Funke, Ludwig-Maximilians-Universität, D-München

O-linked glucosylation of a therapeutic recombinant humanised monoclonal antibody produced in CHO cells

Megumi Tanaka, Akiko Koga, Atsuto Kobe, Yasuo Sekimori, Yoshinori Aso, Katsuhide Terada
European Journal of Pharmaceutics and Biopharmaceutics Volume 83, Issue 1, January 2013, Pages 123–130

An unpredictable modification of a therapeutic recombinant humanised monoclonal antibody (rh-mAbX) produced using CHO cells was found. LC/MS analysis of rh-mAbX indicated the presence of heterogeneity in the light chain with a corresponding mass shift of 162 Da compared to the theoretical mass. To characterise the heterogeneity, that is, the attached moiety, several analyses were performed. Peptide mapping of rh-mAbX indicated that the attached moiety was located in the amino acid sequence from Leu20 to Lys45, which is a part of the variable region of the light chain. The peptide was efficiently purified in two-steps by RP-HPLC by utilising two different types of RP columns. N-terminal sequencing and LC/MS/MS analysis of the peptide suggested that Ser29 of the light chain was the modification site, and that the attached moiety was a single O-linked hexose. HPAEC–PAD analysis following b-elimination indicated the presence of an O-linked glucose in the modified peptide. Monosaccharide composition analysis after acid hydrolysis supported this result. The content of antibodies containing this species was determined to be approximately 10% by Lys-C peptide mapping detected at 280 nm. Thus, this study demonstrated the formation of a unique O-linked glucosylation posttranslational modification in a recombinant humanised monoclonal antibody produced in CHO cells.

Solid crystal suspensions containing griseofulvin – Preparation and bioavailability testing

Elena Reitz, Chris Vervaet, Reinhard H.H. Neubert, Markus Thommes
European Journal of Pharmaceutics and Biopharmaceutics Volume 83, Issue 1, January 2013, Pages 193–202

The improvement of the bioavailability of poorly soluble drugs has been an important issue in pharmaceutical research for many years. Despite the suggestion of several other technologies in the past, drug particle size reduction is still an appropriate strategy to guarantee high bioavailability of various drugs. A few years ago, the Solid Crystal Suspension (SCS) technology was suggested, in which crystalline drug particles are ground and dispersed in a highly soluble crystalline carrier by a hot melt extrusion process. The current study demonstrates the scale-up of the SCS technology to standard, lab-scale extrusion equipment—a change from previous investigations, which used small batch sizes. A twin-screw extruder was modified to account for the rapid crystallization of the carrier. The screw speed and the barrel temperature were identified as critical process parameters and were varied systematically in several experimental designs. Finally, parameters were identified that produced extrudates with rapid dissolution rates. After extrusion, the extrudates were milled to granules and then tableted. These tablets were investigated with respect to their bioavailability in beagle dogs. It was found that drug particle size reduction in the hot melt extrusion led to 3.5-fold higher bioavailability in these dogs than occurred with the physical mixture of the used substances. The solid crystal suspension formulation had a slightly higher bioavailability than the marked product. In conclusion, the SCS technology was successfully scaled up to lab-scale equipment, and the concept was confirmed by a bioavailability study.

Spatially discrete thermal drawing of biodegradable microneedles for vascular drug delivery

Chang Kuk Choi, Kang Ju Lee, Young Nam Youn, Eui Hwa Jang, Woong Kim, Byung-Kwon Min WonHyoung Ryu
European Journal of Pharmaceutics and Biopharmaceutics Volume 83, Issue 1, January 2013, Pages 224–233

Spatially discrete thermal drawing is introduced as a novel method for the fabrication of biodegradable microneedles with ultra-sharp tip ends. This method provides the enhanced control of microneedle shapes by spatially controlling the temperature of drawn polymer as well as drawing steps and speeds. Particular focus is given on the formation of sharp tip ends of microneedles at the end of thermal drawing. Previous works relied on the fracture of polymer neck by fast drawing that often causes uncontrolled shapes of microneedle tips. Instead, this approach utilizes the surface energy of heated polymer to form ultra-sharp tip ends. We have investigated the effect of such temperature control, drawing speed, and drawing steps in thermal drawing process on the final shape of microneedles using biodegradable polymers. XRD analysis was performed to analyze the effect of thermal cycle on the biodegradable polymer. Load–displacement measurement also showed the dependency of mechanical strengths of microneedles on the microneedle shapes. Ex vivo vascular tissue insertion and drug delivery demonstrated microneedleinsertion to tunica media layer of canine aorta and drug distribution in the tissue layer.

A novel dry powder inhalable formulation incorporating three first-line anti-tubercular antibiotics
John Gar Yan Chan, Hak-Kim Chan, Clive A. Prestidge, John A. Denman, Paul M. Young, Daniela Traini
European Journal of Pharmaceutics and Biopharmaceutics
Volume 83, Issue 1, January 2013, Pages 285–292

Treatment for tuberculosis (TB) using the standard oral antibiotic regimen is effective but inefficient, requiring high drug dosing and lengthy treatment times. Three concurrent first-line antibiotics recommended by the World Health Organization (WHO) guidelines are pyrazinamide, rifampicin and isoniazid. Combining these antibiotics in a novel formulation for dry powder inhalation (DPI) may facilitate rapid and efficient resolution of local and systemic infection. However, spray-dried individually, these antibiotics were found to be physically unstable. A solution of the three antibiotics, at the WHO-recommended ratio, was spray-dried. The collected powder was assessed by a series of in vitro methods to investigate aerosol performance, particle physico-chemical characteristics and dissolution profile. Particles obtained were spherical with a surface composed primarily of rifampicin, as identified by TOF-SIMS. A mass median aerodynamic diameter of 3.5 ± 0.1 μm and fine particle fraction (<5 μm) of 45 ± 3% indicated excellent aerosol performance. The combination powder was differentiated by the presence of rifampicin dehydrate and the delta polymorph of pyrazinamide. Quantitative analysis indicated individual particles contained the three antibiotics at the expected proportions (400:150:75 w/w). This excipient-free triple antibiotic DPI formulation could be used as a significant enhanced treatment for TB.

Impressum:

Redaktion

Prof. Dr. Jörg Breitkreutz (Präsident)
Dr. Martin Bornhöft (Leiter Geschäftsstelle)

Vorstand der APV

Dr. Rainer Alex · Dr. Hermann Allgaier · Prof. Dr. Jörg Breitkreutz · Dr. Hubertus Folttmann · Prof. Dr. Achim Göpferich · Prof. Dr. Heribert Häusler · Dr. Hermann P. Osterwald · Dr. Andreas Rummelt

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e. V. (APV)
Kurfürstenstraße 59
55118 Mainz (Germany)
Telefon +49 6131 9769-0
Telefax +49 6131 9769-69
e-mail: apv@apv-mainz.de
http://www.apv-mainz.de

Verlag

ECV · Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH
Baendelstockweg 20
88326 Aulendorf, Germany

Telefon +49 7525 940-0
Telefax +49 7525 940-180

e-mail: info@ecv.de
http://www.ecv.de

Druck

Holzmann Druck GmbH & Co. KG
Gewerbestr. 2
86825 Bad Wörishofen, Germany

Satz

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e. V. (APV)
Kurfürstenstraße 59
55118 Mainz (Germany)

Kfz-Leasing: Vorteile für APV-Mitglieder

Die APV hat für ihre Mitglieder einen Rahmenvertrag mit einem bekannten Leasing-Unternehmen geschlossen. Als Kooperationspartner der APV bietet das Unternehmen Leasing von Neu- und Gebrauchtfahrzeugen zu Sonderkonditionen. Alle Marken und Modelle sind lieferbar. Leasing ohne Anzahlung ist selbstverständlich auch möglich. Die nachfolgende Tabelle gibt nur wenige aktuelle Beispiele möglicher Modelle und Marken wieder.

Alle Preise in Euro zuzüglich gesetzlicher Mehrwertsteuer. Beschaffung durch die Leasing-Gesellschaft. 36 Monate Laufzeit, 20.000 km pro Jahr, Angebote freibleibend. Der Nachlass auf den Listenpreis ist in die ermäßigte Rate einkalkuliert.

Anfragen bitte an **apv@apv-mainz.de**, das Leasing-Unternehmen wird sich dann mit Ihnen in Verbindung setzen.

Leasing auch für andere Investitionsgüter

Leasing und Finanzierung zu günstigen Konditionen sind auch für andere Investitionsgüter wie Laboreinrichtungen etc. (auch für Ihre eigenen Produkte) über die APV möglich. Sprechen Sie uns an.

Hersteller/Typ	Listenpreis	mtl. Rate
Audi A3 Cabrio Ambition 1.4 TFSI 92kW/125PS inkl. Klimaanlage, Radio/CD MP3, LM-Felgen, Einparkhilfe hinten, Sitzheizung vorn etc.	25.285,00 €	335,00 €
Audi Q3 2.0 TFSI quattro 125kW/170PS inkl. Klimaanlage, Audioanlage, Sitzheizung vorn, Komfortpaket, LM-Räder etc.	27.941,00 €	339,00 €
Audi A5 Coupé 125kW/170PS inkl. Navigationssystem plus, Audioanlage, Klimaautomatik, LM-Felgen, Sitzheizung etc.	32.021,00 €	399,00 €
BMW 118i Cabrio 105kW/143PS 6-Gang inkl. Klima, Einparkhilfe (PDC), Radio/CD, Sitzheizung Fahrer/Beifahrer etc.	28.042,00 €	369,66 €
BMW 520d Touring 135kW/184PS inkl. Automatic, Metallic-Lackierung, Navigation, Klimaautomatik, LM-Felgen, Sitzheizung etc.	42.916,00 €	448,44 €
BMW X5 xDrive30d 180kW/245PS inkl. Metallic, Navi-Professional, Klimaautomatik, Xenon, PDC, Lederpolster, Sitzheizung etc.	56.823,00 €	695,39 €
Jaguar XF 2.2 L Diesel Sportbrake 147kW/200PS inkl. 8-Gang-Automatik, Navi, LM-Felgen, Klimaautomatik, PDC mit Kamera, Sitzheizung etc.	44.588,00 €	479,00 €
MINI One Cabrio "Pepper" 72kW/98PS inkl. Klimaautomatik, Einparkhilfe (PDC), Radio/CD MP3, Ablagenpaket, Lichtpaket etc.	19.202,00 €	245,20 €
Porsche Boxster 195kW/265PS inkl. Navigationssystem, ParkAssistent, Klimaautomatik, Bi-Xenon, Sitzheizung etc.	47.246,00 €	759,00 €
Porsche Cayenne Diesel 180kW/245PS inkl. Automatik, PCM Navigation, Bi-Xenon-Scheinwerfer, Sitzheizung vorne etc.	57.900,00 €	884,00 €
SEAT Leon Style 5-Türer 1.4 TSI 103kW/140PS inkl. Navi, Klimaanlage, LM-Felgen, Einparkhilfe, Voll-LED-Scheinwerfer, Winter-Paket etc.	19.970,00 €	199,00 €
Toyota Auris 5-Türer 1.33 6-Gang Cool 73kW/99PS inkl. Klimaautomatik, Navigation, Multimedia-Audiosystem, 5 Jahre Garantie etc.	15.798,00 €	209,00 €
Toyota Yaris Hybrid "Life" Automatik 74kW/100PS Systemleistung mit Klimaautomatik, Navi, Radio/CD, Bluetooth-Freispr., 5-Jahre Garantie etc.	15.840,00 €	199,00 €
VW Beetle Cabrio "Design" 1,2l TSI 77kW/105PS inkl. Metallic, Klimaanlage, Radio/CD, LM-Felgen, Tempomat, Windschott etc.	20.197,00 €	249,00 €
VW Passat Variant Comfortline BMT 2,0l TDI 103kW/140PS inkl. Metallic, Navi, ParkPilot, Klimaautomatik, Sitzheizung vorne etc.	29.970,00 €	379,00 €