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DRUG DELIVERY EVENTS

Meeting: Drug Carriers In Medicine & Biology
Big Sky, MT (USA), August 20th – 25th 2006
Details...

Meeting: E-MRS 2006 Fall Meeting
Warsaw (PL), September 4th – 8th 2006
Details...

Meeting: Drug Delivery Global Summit
Central London (UK), September 20th – 21st 2006
Details...

APV Seminar: Granulation
Ljubljana (SI), September 21st - 22nd 2006
Details...

Meeting: PolypHarma - Polymers in Pharmacy
Halle (D), September 24th – 26th 2006
Details...

APV Seminar: Biopharmaceutical Manufacturing Excellence: APIs derived from Microorganisms
Vienna (A), October 10th - 11th 2006
Details...

Meeting: 2006 AAPS Annual Meeting and Exposition
San Antonio, TX (USA), October 29th - November 2nd 2006
Details...

Suggest a meeting to be announced!

DRUG DELIVERY PRODUCTS

Exubera® (Pfizer / Nektar). Pfizer received marketing authorization in Jan. 2006 from both the FDA and the EMEA for inhalable human rDNA derived insulin for treatment of adults with type 1 and type 2 diabetes. Phase III clinical trials showed that Exubera® is as effective as injections in controlling blood sugar. It works by reaching the deep lung, where the absorption of inhaled insulin is greatest. Exubera® sets a precedent for systemic therapy delivered by inhalation, and it is also the first non-invasive insulin therapy ever approved. Exubera® was developed by Nektar Therapeutics, of San Carlos, California, in partnership with Pfizer. Pfizer acquired the sole marketing rights from the French pharmaceutical company Sanofi-Aventis SA in a transaction reported to be valued at approximately 1.0€ billion, net of German taxes. Nektar receives a 15% royalty on Exubera® sales from Pfizer.

The dry powder form of insulin is delivered using an inhaler designed specifically by Nektar for the delivery of the powdered insulin. The first insulin product not to require refrigeration during storage, Exubera® contains ~60% insulin. The chemical and physical stability of the formulation is high, because the insulin is stabilized in an amorphous glass of mannitol, glycine and sodium citrate. The dry powder is manufactured using a three-story tall spray dryer. In order to be able to reach the deep lung, the individual particles are between 1 and 5 µm in diameter. Details...

Vivitrol™ (Cephalon / Alkermes). Vivitrol™ was approved for marketing in the United States in Apr. 2006 by the FDA for the treatment of alcohol dependence. Vivitrol™ is a one-month controlled release intramuscular injection formulation of naltrexone. The formulation is based on Alkermes’ proprietary MEDISORB® technology. 380 mg naltrexone is incorporated in a 75:25 polylactide-co-glycolide matrix, with a drug load of 25.2% by weight. The particles are packaged in a dry state, and before use are suspended with an accompanying diluent, containing polymer, wetting agent and osmotic pressure adjustment. Interestingly, burst peaks are observed in the pharmacokinetic profile, with both and initial burst 2 hours after injection and another 2-3 days later. Alkermes has already developed an oral controlled release form of naltrexone.

Details...
Vivitrol™ works by binding to opioid receptors in the brain. Although the mechanism responsible for the reduction in alcohol consumption observed with Vivitrol™ treatment is not entirely understood, preclinical data suggests that occupation of the opioid receptors results in the blockade of the neurotransmitters in the brain that are believed to be involved with alcohol dependence. This blockade may result in the reduction in alcohol consumption observed in patients treated with Vivitrol. A 50-mg tablet formulation of naltrexone HCl (ReVia®, made by DuPont Pharmaceuticals) was approved previously by the FDA for once-daily administration in the treatment of alcohol dependence and for the blockade of the effects of exogenously administered opioids.

**OctoPlus (NL-Leiden)** is a product-oriented drug delivery company. OctoPlus has several products in clinical development, based on its novel drug delivery systems for parenteral controlled release. OctoPlus is also an internationally established provider of pharmaceutical development services and cGMP manufacturing for pharmaceutical and biotechnology companies.

OctoPlus' key proprietary technologies are biodegradable polymer-based drug delivery platforms for controlled parenteral release of proteins and small molecules over a period of several weeks up to months. With these drug delivery platforms, OctoPlus aims to develop products that are more patient-friendly and that are potentially safer and more efficacious. A particular area of attention is the development of controlled release formulations of proteins and vaccines.

**Fact sheet**

- **Founded:** 1995
- **Location:** Leiden, The Netherlands
- **Employees:** 135
- **Ownership:** Privately funded - most recent funding round: Jan 2005 / Euro 18.3 mio
- **Key technologies:** OctoPlus is active in the area of parenteral controlled release technology where it has three different, polymer-based technology platforms available:
  - **OctoDEX™** is a delivery system for the controlled release of therapeutic proteins and particulate systems. It is based on cross linked dextran microspheres, which are prepared in an all-water environment without the use of organic solvents.
  - **PolyActive™** represents a series of poly(ether ester) multiblock copolymers, based on poly(ethylene glycol) and poly(butylene terephthalate). By varying the amount and length of each of the two building blocks, a diverse family of customized polymers can be created. Due to the presence of hydrophilic poly(ethylene glycol) segments, PolyActive exhibits a hydrogel character. Unlike PLGA, degradation products of PolyActive do not create an acid environment. Using PolyActive allows the development of burst-free drug delivery systems, and its hydrophilic nature conserves the stability of labile biopharmaceuticals, such as proteins. PolyActive is a regulatory approved polymer for development of devices both in the US as well as in Europe.
  - **SynBiosys™**: The SynBiosys polymer platform comprises poly(ether ester) multi-block copolymers composed of various pre-polymeric building blocks of different combinations of DL-lactide, glycolide, e-caprolactone and polyethylene glycol. By varying the molecular composition, molecular weight (Mw 1200 – 6000) and ratio of the pre-polymer blocks, different characteristics can be induced in the polymers, which enables the creation of a drug delivery system with various physico-chemical properties.

**Clinical stage product pipeline:**

- **OctoDEX-hGH**: controlled release formulation of recombinant human growth hormone for release over 1 week or more. *Proof of principle study completed in humans*

**Website:** [http://www.octoplus.nl](http://www.octoplus.nl)

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"ORALLY DISINTEGRATING DOSAGE FORM" (definition provided by Karsten Cremer)

Solid single-unit dosage form that rapidly disintegrates in the mouth without chewing.

Write a comment on this definition

Often less accurately referred to as fast-dissolve or fast-melt tablets, these dosage forms are designed for oral administration involving intraoral disintegration. Typically, their disintegration takes place within less than about half a minute. They can be taken without liquid. The short disintegration time does not necessarily imply rapid drug dissolution or even a fast onset of action. Most orally disintegrating dosage forms are manufactured by compression (tablets) or freeze drying (lyophilisates).

German: "In der Mundhöhle zerfallende Darreichungsformen"
French: Provide a translation
Spanish: Provide a translation

"IMMEDIATE RELEASE SOLID ORAL DOSAGE FORM" (definition provided by Karsten Cremer)

Solid dosage form for peroral administration that is not formulated to provide modified release.

Write a comment on this definition

Immediate release ("IR") solid oral dosage forms are designed to be swallowed with liquid. They usually disintegrate in gastric fluid within a few minutes. The actual drug release is rarely "immediate". According to a standard requirement, at least 85 % of the drug substance should be released after 15 minutes. In practice, the release profile depends on various factors including the formulation and the solubility of the drug substance. Most IR solid oral dosage forms are designed as tablets, hard capsules, or soft capsules.

German: "Schnellfreisetzende feste orale Darreichungsformen"
French: Provide a translation
Spanish: Provide a translation

DRUG DELIVERY PEOPLE

Professor Nicholas A. Peppas is the Fletcher S. Pratt Chair in Engineering with appointments in the Departments of Chemical Engineering, Biomedical Engineering and Pharmaceutics of the University of Texas at Austin.

Peppas was educated in chemical engineering at the National Technical University of Athens, Greece (Dipl.Eng., 1971) and at the Massachusetts Institute of Technology (Sc.D., 1973) and did postdoctoral work at the Arteriosclerosis Center of MIT. He joined Purdue University as an Assistant Professor of Chemical Engineering in 1976, and was promoted to Associate Professor in 1978 and Professor in 1982. From 1993 to 2002 he was the Showalter Distinguished Professor of Chemical and Biomedical Engineering at Purdue University in recognition of his research contributions to the fields of biomaterials, drug delivery, pharmaceutical technology, and biomedical engineering. For these contributions, he received honorary doctorates from the University of Ghent, Belgium and the University of Parma, Italy, both in 1999, and from the University of Athens, Greece in 2000. In addition to his main academic appointment, Professor Peppas has been active in international collaboration with major research centers around the world. Peppas’ administrative experience and contributions have been numerous and far-reaching. At UT Austin he serves as the Associate Chair of the Department of Biomedical Engineering and as Director of the Laboratory for Biomaterials, Drug Delivery, Bionanotechnology, and Molecular Recognition. Since 2003 he has also been the co-Director of the NSF Program on Cellular and Molecular Imaging for Diagnostics and Therapeutics.

Peppas is internationally known for his work on the preparation, characterization and evaluation of the behavior of compatible, cross linked polymers known as hydrogels, which have been used as biocompatible materials and in controlled release devices, especially in controlled delivery of drugs, peptides and proteins, development of novel biomaterials, biomedical transport phenomena, and biointerfacial problems. Peppas’ polymer research has examined fundamental aspects of the thermodynamics of polymer networks in contact with penetrants, the conformational changes of networks under load or in the presence of a diluent, the anomalous transport of penetrants in glassy polymers, and the kinetics of fast UV-polymerization reactions. In the field of controlled release, his group has provided the fundamental basis for a rational development of such systems. In addition, his work has led to a series of novel controlled release systems known as swelling controlled release systems, a series of pH-sensitive devices for drug delivery and a wide range of bio- and mucoadhesive systems. Other biomedical work of his group has dealt with understanding of transport of biological compounds in tissues, analysis of polymer/tissue interactions, and understanding of the behavior of biomembranes. More recently, his group has announced new inventions of oral insulin delivery systems and new biomaterials. More recently, his group has announced new inventions of oral insulin delivery systems and new biomaterials.
Peppas is the author of 920 publications, 250 abstracts and 20 US and international patents. He is the coauthor or coeditor of 29 books and volumes. He is one of the most cited scientists with more than 16,000 citations. From 1998 to 2003 he was the editor of Advances in Chemical Engineering. From 1982 to 2001 he was the editor of the premier journal in his field, Biomaterials. From 1985 to 1990 he was also the editor of the Elsevier Chemical Engineering Book Series. He sits on the editorial boards of numerous other journals, including the Journal of Controlled Release, Journal of Applied Polymer Science, Advanced Drug Delivery Reviews, Journal of Biomedical Materials Research, Journal of Biomaterials Science, Biomedical Materials, Tissue Engineering, S.T.P. Pharma Sciences, and the European Journal of Pharmaceutics and Biopharmaceutics (where he served as US Editor from 1992 to 1995).

He has been active in various societies. Since 1975 he has been active in the Society for Biomaterials and served as its President (2003-04). He was president of the Controlled Release Society its President in 1987-88. In addition he has been very active in the American Institute of Chemical Engineers, where he was a Director (1999-2002), the 1988-90 Chairman of its 1500-member Materials Division and a Director of the Food, Pharmaceuticals and Bioengineering Division. He is also a member of the American Physical Society, American Chemical Society, New York Academy of Sciences, Materials Research Society, American Association of Pharmaceutical Scientists, Biomedical Engineering Society, Tissue Engineering Society, North American Membrane Society, American Society for Engineering Education, American Association for the Advancement of Sciences, Sigma Xi, and Phi Kappa Phi.

He has been recognized by numerous awards including the 2002 Eurand Award for Outstanding Contributions in Oral Drug Delivery of the Controlled Release Society, the 2002 recognition as a Pioneer in Biomedical Engineering from the IEEE Engineering in Medicine and Biology Society, 2000 APV Best Paper Award, the 2000 APV Best thesis in the Pharmaceutical Sciences Award, 1999 Research Achievement Award in Pharmaceutical Technology of AAPS, the 1995 APV-International Pharmaceutical Technology Medal, the 1994 Pharmaceutical and Bioengineering Award of AIChE, the 1992 Clemson Award for Basic Research of the Society for Biomaterials, the 1992 George Westinghouse Award of ASEE, the 1991 Founders Award for Outstanding Research from the Controlled Release Society. Peppas has been elected a Founding Fellow of the American Institute of Medical and Biological Engineering (1993), a Fellow of the American Association of the Advancement of Science (2000), a Fellow of the American Physical Society (1997), a Fellow of the American Institute of Chemical Engineers (1997), a Fellow of the Society for Biomaterials (1994), a Fellow of the American Association of Pharmaceutical Scientists (1993) and an Honorary Member of the Italian Society of Medicine and Natural Sciences (1996). In 1991 he was named a Polymer Pioneer by Polymer News. In 2002 he was named a Pioneer in Biomedical Engineering by the IEEE Engineering in Medicine and Biology Society.

Nicholas Peppas has supervised the theses of 62 Ph.D. students, including 27 current professors in other Universities, and another 35 students and 24 postdoctoral fellows and visiting scientists. His former students include many industrial leaders in chemical, pharmaceutical or medical companies.

FEATURED ARTICLE

A BRIEF OVERVIEW OF PARENTERAL DEPOT FORMULATIONS

by Dr. Karsten Cremer, Pharma Concepts GmbH, Unterer Rheinweg 50 CH-4057 Basel

INTRODUCTION

Primarily due to the steadily increasing number of biotechnology-derived drugs, parenteral depot formulations and their drug delivery technologies have received much attention in recent years. For many compounds which cannot be administered via the oral route, injectable or implantable depot formulations are presently the only viable option for reducing the frequency of administration, thereby increasing patient convenience and potentially improving compliance.

Depot formulations have been developed for a broad range of applications, providing therapeutic effectiveness over periods ranging from one day to several years. A significant patient benefit, which should be the driving force for initiating the development of any depot formulation, not only requires that the dosing frequency can be substantially reduced in comparison with the corresponding standard formulation, but also that dosage form-related risks, such as dose dumping or poor carrier tolerability, are largely avoided.

TECHNOLOGIES FOR DEPOT FORMULATIONS

Already several decades ago, injectable drug products based on depot formulations were available. These early formulations were mostly drug suspensions or oily solutions, with a typical duration of action of 1 to 12 weeks. With the advent of the first implants based on biodegradable polymers in the 1980's, a new era in drug delivery began. These implants paved the way for a second generation of dosage form designs for parenteral controlled release which were also suitable for the incorporation of peptides and proteins, including biodegradable microparticles and non-degradable implants. The most recent development in this field has been the introduction of injectable gels which now compete with the established microparticle- and implant-based technologies.

Suspensions for injection. Aqueous suspensions of poorly soluble drug substances have been developed for applications such as depot contraceptives (e.g. Lunelle®, Depo-Clinovir®) and glucocorticoid therapy (e.g. Celestan® Depot). The duration of action is up to about 3 months (e.g. Depo-Clinovir®), depending on the physical properties of the active ingredient. Injectable suspensions do not provide real control over the release of the drug; the release profile simply reflects the dissolution kinetics of the drug substance particles. Therefore, the active compound must be comparatively non-toxic and even large plasma level fluctuations should be uncritical. Among the advantages of injectable suspensions are their high drug load capacity and the relatively low degree of complexity in their formulation and manufacturing technology.
Sterile oily carriers such as castor oil or semi synthetic triglycerides have been used as vehicles for injectable depot formulations if no poorly soluble and stable form of the active ingredient was available. The depot effect is based on the rather long local retention of the carrier at the subcutaneous or intramuscular injection site and on the diffusion of the drug substance from the oil phase into the interstitial fluid. Oily formulations with effectiveness up to 4 weeks have been developed. Product applications include antipsychotics (e.g. Decentan® Depot, Fluanxol® Depot), hormonal disorders (e.g. Androcur® Depot), and various other uses of synthetic hormones or hormone antagonists (e.g. Gynodian® Depot, Depotstat®). Poor control over the release profiles and plasma levels make this formulation approach unsuitable for drug candidates with a narrow therapeutic index. On the other hand, the technical development and large-scale manufacture of drug products formulated as oily solutions is relatively uncomplicated.

**Polymeric implants.** The incorporation of a drug substance in a polymeric matrix allows substantial control over the release profile, using diffusion and (if the polymer is biodegradable) polymer erosion as release mechanisms. Implants have proved versatile and suitable for the delivery of a variety of active compounds including peptide drugs (e.g. Zoladex®, Profact® Depot). Depending on the choice of the polymer, drug release times of up to several years can be achieved (e.g. Norplant®, Implanon®). However, such long durations usually require the use of non-degradable polymers such as polydimethylsiloxane or poly(ethylene-co-vinyl acetate), which necessitates the microsurgical removal of the implant after the designated period of use. In contrast, biodegradable polymers such as poly(lactide-co-glycolide) and poly(ε-caprolactone) are fully absorbed and do not need to be removed. The subcutaneous insertion of implants, which are often cylindrically shaped, requires needles with relatively large diameters, and sometimes even minor incisions (e.g. for Norplant®), in which case a pain-free procedure is ensured by the pre-administration of a local anesthetic. Drug delivery companies offering know-how in the development of implants include Durect (Durin® technology), Debio (Mimplant® technology), and Valera (Hydron technology).

**Osmotic micro pumps.** These drug delivery systems can probably control the rate of drug release more precisely than any other depot formulation technology. Typically, implantable osmotic micropumps have a non-degradable (e.g. metal) casing which houses a drug reservoir. Through osmosis, water from the body is slowly drawn through a semi permeable membrane into the pump. The increasing internal pressure is used to steadily push the drug substance through an orifice, either directly or via a movable piston. A commercially available version of this type of delivery system is available from Durect (Duros® technology).

**Microparticles.** Microparticles based on biodegradable polymers are usually administered subcutaneously or intramuscularly as aqueous suspensions, using needles in the range of 20 to 24 Gauge which cause relatively little pain, so that no local anesthetic is needed. Therefore, microparticles are usually considered as particularly patient-friendly depot formulations. Depending on their specific morphology, microparticles are sometimes also referred to as microcapsules (having a distinct core and a shell) or microspheres (being substantially spherical). In practice, the differences between these particles in shape and internal structure are rather small. The particle diameter is typically between 10 and 150 µm, resulting in a large total surface area which makes release control somewhat more difficult than in the case of polymeric implants. Consequently, the maximum duration of drug release is in the region of several months rather than years, and the release profiles typically involve some degree of “burst effect”, which means that a portion of the incorporated drug dose is rapidly released during the initial phase of drug release. On the other hand, novel polymeric carriers and improved manufacturing process designs have recently become available which could overcome some of these drawbacks. Drug products incorporating microparticles are available with various active compounds, most of which are peptides or proteins, such as leuprolide (Lupron® Depot), somatropin (Nutropin® Depot), triptorelin (Trelstar® Depot), and octreotide (Sandostatin® LAR). Examples of small molecules that have been incorporated into microparticles include risperidone (Risperdal® Consta) and naltrexone (Vivitrol®). Drug delivery companies with competence in microparticle technologies are e.g. Alkermes (ProLease® and Medisorb® technologies), Debio, SkyePharma (Biosphere® technology), Baxter (ProMaxx® technology), Oakwood Labs (Chronoject® technology), and OctoPlus (OctoDex® and PolyActive® technologies).

**Injectable gels.** More recently, depot formulations in the form of injectable gels have been developed. These gels, which may be understood as semisolid implants, are either injected as such or in the form of a viscous liquid which solidifies after injection at the site of administration ("in-situ gelling systems"). The solidification may be caused by an incorporated polymer which is desolvated either by the migration of a biocompatible solvent or through the thermal, ionic, or pH-conditions in the tissue. Ideally, the gels are as convenient as simple aqueous solutions, easily and painlessly injectable with a small needle, while providing nearly the same release control as solid implants. In practice, their performance is more comparable to that of microparticles, perhaps with slight advantages in terms of injectability, but with a pronounced
risk of burst release. The only injectable gels for systemic use that have become commercially available so far are a series of 1-, 3-, 4-, and 6-month depot formulations of leuprolide (Eligard®). Platform technologies for the formulation of such gels have been developed by several drug delivery companies such as by QLT (formerly Atrix Laboratories; Atrigel® technology), MacroMed (ReGel® technology), Alza (Alzamer® technology), Direx (Saber® technology), and DelSite Biotechnologies (GelSite® technology).

**Other options.** Liposomes and other lipid-based colloidal systems are most often used to achieve other pharmacokinetic effects than controlled release. Nevertheless, they may be suitable for designing s.c. or i.m. depot formulations with a comparatively short duration of action of up to about 2 to 4 weeks at the most (Lentaron® Depot, DepoCyt®). Pegylation, i.e. the conjugation of active compounds with polyethylene glycol, has been used successfully with several therapeutic proteins whose conjugated forms exhibit substantially prolonged circulation times and require less frequent injection (e.g. Neulasta®, Pegasys®, PegIntron®, Somavert®). However, it is debatable whether pegylation is a drug delivery technology, strictly speaking, as it does not relate to the formulation of a given compound; instead, it creates novel, chemically and biologically distinct compounds.

**CONCLUSION**

A drug substance which cannot be administered orally may make a good candidate for an injectable depot formulation which is more convenient to patients than frequent injections. Various types of dosage form designs are available, ranging from conventional drug suspensions to modern in-situ gelling drug delivery systems. Obviously, no single delivery technology will match the requirements of every product concept. However, a careful assessment of the pharmaceutical profile of the active compound, a clear definition of the target product characteristics, and a thorough evaluation of the capabilities and development status of the available delivery technologies will help to identify attractive product opportunities.

**FURTHER READING**


**IMAGES**


**DRUG DELIVERY LITERATURE**
Regimen and device compliance: key factors in determining therapeutic outcomes.

Recent advances in aerosol therapy for children with asthma.

Systemic delivery of drugs to humans via inhalation.

Advances in aerosols: adult respiratory disease.

Liquid atomizing: nebulizing and other methods of producing aerosols.

Boron containing macromolecules and nanovehicles as delivery agents for neutron capture therapy.

Ocular drug delivery.

Drug delivery from ocular implants.

Gastroretentive drug delivery systems.

Multi-functional polymeric nanoparticles for tumour-targeted drug delivery.

Transactivating transcriptional activator-mediated drug delivery.

Targeted magnetic resonance imaging contrast agents.

Single molecule fluorescence control for nanotechnology.

Antibody conjugates and therapeutic strategies.

Follicular targeting--a promising tool in selective dermatotherapy.

Designing dendrimers for biological applications.

Peptide-enhanced cellular internalization of proteins in neuroscience.

Supramolecular structures from dendrons and dendrimers.

Recent progress in ocular drug delivery for posterior segment disease: emphasis on transscleral iontophoresis.

Dendrimers in biomedical applications - reflections on the field.

Micro- and nanoparticulates.

Topical and systemic drug delivery to the posterior segments.

Ocular delivery using poly(ortho esters).

Block copolymer micelles: preparation, characterization and application in drug delivery.

Nanotechnology for drug and gene therapy: the importance of understanding molecular mechanisms of delivery.
Intraocular sustained drug delivery using implantable polymeric devices.

Transfollicular drug delivery - is it a reality?

Microfabricated drug delivery devices.

Applications of carbon nanotubes in drug delivery.

Molecularly imprinted drug delivery systems.

New delivery approaches for pediatric brain tumors.

The potential advantages of nanoparticle drug delivery systems in chemotherapy of tuberculosis.

Therapeutic potential of nanoparticulate systems for macrophage targeting.
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.

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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