Transdermal and Intradermal Drug Delivery Systems, 2015
Advanced Design, Development, and Delivery of Skin-Mediated Therapies and Vaccines
May 11-12, Racquet Club of Philadelphia, PA

Featured Speakers Include:

- Thean Yeoh
  Pfizer
- Ajay Banga
  Mercer University
- Audra Stinchcomb
  University of Maryland
- Bobby Singh
  Corium

With Comprehensive Coverage On:

- Key Formulation Considerations for Skin-Mediated Therapies and Vaccines
- Latest Advances in Microneedle Patches for Drug Delivery
- Understanding Regulatory Requirements for Product Quality and Performance Testing, Including the New Proposed Changes to USP General Chapter <3>
- Novel TD Patch Designs and Technologies
- Enhancement Techniques for Drug Delivery and Efficacy
- Designing the Future: Dissolvable Polymeric Microneedle Arrays
- Large Molecule Delivery and Expanding the Range of Compounds for Use in TDD & IDD
- Overcoming Obstacles to Iontophoretic Drug Delivery
- Absorption Kinetics of Dermal and Transdermal Absorption of Drugs
- Disposal of Transdermal Patches Containing Abuse Potential Drugs
- Development of a Novel Antimicrobial Nanoemulsion Therapy
- And more!

The growing interest in alternative routes of drug administration has experts predicting that the market for transdermal and intradermal drug delivery systems will exceed $30 billion in 2015. That's why you cannot afford to miss this two-day intensive conference. Pharma Ed brings together leading researchers in the field to share the most recent advances in the design, formulation, and delivery of skin-mediated therapies and vaccines.

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### Monday, May 11, 2015

**Complimentary Breakfast & Chairperson’s Welcome and Opening Remarks**

### Keynote: Re-conceptualizing Transdermal Delivery

**Thean Yeoh, Ph.D., Associate Research Fellow, Pfizer**

The transdermal route of delivery represents an attractive alternative to peroral delivery of medicine. This concept is commonly evaluated for potential product enhancement opportunities of marketed products. Increasingly, transdermal delivery is also being considered during development of NCE to address certain unmet medical needs. This presentation will discuss various aspects to consider when developing a compelling concept for transdermal delivery using case study examples highlighting opportunities in:

- Safety improvement through differentiated PK profiles
- Disease areas attractive for transdermal delivery

### Expanding the Transdermal Universe with Next Generation Technologies

**Bobby Singh, Ph.D., Chief Technical Officer, Corium**

Transdermal drug delivery is a useful and proven alternative route of administration to oral and parenteral modes of administration. It overcomes the pain and fear of needles, bypasses GIT and hepatic first pass effects, enhances bioavailability, and improves safety and efficacy by providing sustained and controlled drug plasma levels. Due to the excellent barrier properties of the stratum corneum layer of the skin, only a handful of drugs have been successfully commercialized using passive transdermal systems. Active transdermal delivery systems can significantly expand the universe of transdermally delivered drugs, including large molecular weight and water soluble drugs. The current active systems employ a number of innovative technologies such as iontophoresis, thermal ablation and microneedles. Corium has developed a polymeric adhesive technology platform, “Corplex”, for the transdermal delivery of difficult to deliver small molecules and a biodegradable microneedle technology platform, “MicroCor”, for the transdermal delivery of large molecules.

This presentation will summarize the transdermal technology landscape and highlight next generation technologies capable of expanding the universe of drugs and biologics which can be delivered transdermally.

**Transdermal Devices and Patches – Enhancement Techniques and Disposal of Residual Drug**

**Ajay Banga, Professor and Department Chair, College of Pharmacy, Mercer University**

Hydrophilic molecules and macromolecules do not normally pass through the skin unless enabling technologies are used. Some of the enabling physical enhancement technologies include iontophoresis, phonophoresis, or the various skin microporation approaches. Recent innovations in these technologies, especially for iontophoresis and microneedle-based devices, will be presented. Application, limitations, challenges, and commercialization of these technologies will be discussed. FDA guidelines now require diligent efforts to be made to minimize residual drug in patches, especially for controlled substances. Development of an activated carbon based disposal system designed specifically to deactivate the remaining drug in used transdermal patches will be discussed. The benefits of this talk include:

- Learn how new technologies are expanding the scope of transdermal delivery to include hydrophilic macromolecules
- Learn the success and failures of iontophoretic delivery systems developed and marketed over the years and the recent excitement and activity centered around microneedle based research
- Learn how unused medications, including controlled substances in patches, can be safely disposed of to prevent abuse and environmental hazards.

**Case Studies – Microneedle-based Drug Delivery Systems for Drugs and Biologics**

**Development and Scale-Up of Microneedle Based Drug Delivery Systems**

**Allan Bohlke, Ph.D., Technical Project Manager, 3M Drug Delivery Systems Division**

As population demographics shift and new medicines become available, patient preference and new technologies remain top of mind for 3M. In recent years, 3M has been working on a patient-friendly and easy to use microneedle delivery platform that expands the range of drug molecules and formulations open to dermal delivery. This microneedle drug delivery technology provides...
Transdermal and Intradermal Drug Delivery Systems, 2015

solid and hollow microneedle options for enabling administration of both small and large molecules, including difficult-to-deliver biologics. These devices are well suited for dermal skin targets or systemic distribution for drugs that enter the lymphatic system. This presentation will cover highlights and recent accomplishments.

11:15 Transdermal Delivery Technologies for Current and Emerging Drugs
Frank Tagliaferri, Ph.D.,
Vice President of R&D, 4P Therapeutics

While it has been more than three decades since the first approval of a transdermally delivered drug (scopolamine/Transderm-Scop®), there has yet to be a significant transdermal product containing a water-soluble drug form marketed in the US. The technology that scopolamine and essentially all currently available transdermal patches on the market utilize relies on the passive diffusion of small lipid-soluble molecules through the skin and eventually into the blood. The limitations imposed by these types of systems have prevented the use of water-soluble or large drug molecules which typically require some type of breach in the lipophilic stratum corneum of skin for effective systemic delivery. In order to expand the field of transdermal delivery to the majority of current drugs as well as emerging drug classes, 4P Therapeutics has been developing several technologies that can disrupt the skin barrier in a simple and painless manner. The transdermal delivery of water-soluble small molecules, peptides, oligosaccharides, as well as small and large proteins using both microporation and microneedle systems will be covered. The criteria for delivery system and formulation selection along with the current status and future prospects for these technologies, especially in light of the expanding biologic drug pipelines, will also be discussed.

11:55 Complimentary Lunch Sponsored By Delta Mod-Tech

1:15 Hydrogel-forming Microneedles for Drug Delivery and Patient Monitoring
Prof R.F. Donnelly & Dr Thakur R.R. Singh,
School of Pharmacy, Queens University Belfast, Medical Biology Centre

Here we describe unique microneedle arrays prepared from crosslinked polymers which contain no drug themselves. Instead, they rapidly take up skin interstitial fluid upon skin insertion to form continuous, unblockable, hydrogel conduits from attached patch-type drug reservoirs to the dermal microcirculation. Importantly, such microneedles, which can be fabricated in a wide range of patch sizes and microneedle geometries, can be easily sterilized, resist hole closure while in place and are removed completely intact from the skin. Delivery of macromolecules is no longer limited to what can be loaded into the microneedles themselves and transdermal drug delivery is now controlled by the crosslink density of the hydrogel system rather than the stratum corneum, while electrically-modulated delivery is also a unique feature. Since we have also shown that these microneedles efficiently imbibe skin interstitial fluid, employing them in blood-free therapeutic drug monitoring is another important potential application. This technology has the potential to greatly increase the range of type of drug deliverable transdermally and enhance therapeutic monitoring, with ensuing benefits for industry, healthcare providers and, ultimately, patients.

1:55 Microneedle Enhanced Transdermal Delivery: Academic Bench to Clinical Trials
Audra L. Stinchcomb, PhD, RPh, University of Maryland School of Pharmacy, Baltimore, MD

Transdermal microneedle (MN) systems have become a very popular means of delivering skin impermeable drugs through the stratum corneum at therapeutic rates. Most of the previous research on microneedle systems has focused on optimization of the microneedle geometry. Our approach to microneedle-assisted delivery research has been in the following areas:

1. Investigation of prodrugs and salt forms with optimal physicochemical properties for drug flux after microneedle treatment
2. Investigation of viscosity and other formulation factors that influence drug flux after microneedle treatment
3. Investigation of micropore lifetime using transepidermal water loss (TEWL), impedance spectroscopy, and pharmacokinetic analysis
4. Investigation of micropore lifetime after treatment with COX inhibitors and fluvastatin
5. Investigation of codrugs with optimal physicochemical properties for drug flux and micropore lifetime after microneedle treatment
The hypotheses for increased micropore lifetime were evaluated in hairless guinea pigs and humans. A human study for evaluation of the pharmacokinetics of naltrexone in combination with MN’s and diclofenac was completed. Finally, a codrug strategy was used to enhance flux and micropore lifetime after MN treatment. NOTE: We would like to acknowledge the National Institutes of Health for providing funding for this project (R01DA013425, R42DA32191 and R21DA31439).

### 2:35 Afternoon Networking Break

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![Harro Höfliger](image)

### 2:55 Microneedles for Allergen Immunotherapy and Cancer Treatment

**Harvinder Gill, Ph.D., Assistant Professor, Texas Tech University**

Microneedles offer a minimally-invasive and painless approach for drug and vaccine delivery. Two different applications of coated microneedles will be discussed:

1. To modulate the immune system for allergy immunotherapy, and
2. To treat surface tumors. Subcutaneous injection of the allergenic material is clinically used to treat some allergies. We show that microneedles coated with an allergen when applied to the skin can provide immunotherapy comparable to the subcutaneous route. As another application of coated microneedles we show that microneedles coated with an anti-cancer drug can be used to distribute the drug to the tumor area, and it can lead to tumor regression.

- Microneedles coated with an allergen provide a unique approach to implement allergen immunotherapy in a painless manner
- Microneedles coated with anti-cancer drug can help distribute the drug in the tumor and can lead to tumor regression

### 3:35 Technology Spotlight - Intradermal Adapters

**Usability Evaluation of Intradermal Adapters (IDA)**

**Glen Zimmermann, Sr. Director, Business Development, West Pharmaceutical Services; and Izzy Tsals, President, SID Technologies**

West Pharmaceutical Services has developed and is marketing an Intradermal Adapter (IDA), an innovative and simple device increasing the success of ID injection while reducing the required nurse training. The ID success when using IDA has been evaluated in three preclinical studies. The evaluation was based on the assessment of bleb formation, an accepted indicator of ID injection success. The presentation will address the IDA effectiveness. The audience will learn:

* The simplicity of the IDA application and use
* IDA similarity to the conventional Mantoux technique
* The improvements in the bleb formation over the conventional Mantoux

### 4:15 USP Requirements for Product Quality and Performance Testing of Transdermal Products

**Michael N. Eakins, Ph.D., Principal Consultant, Eakins & Associates**

The presentation will briefly outline some of the USP chapters that are relevant to transdermal systems and topical dosage forms. The focus will be on new chapters, and chapters under revision that have been published recently in the USP’s Pharmacopeial Forum for comment. For example, new chapters include <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems, <1664> Assessment of Leachables Associated with Pharmaceutical Packaging/Delivery Systems and the proposed revision of chapter <661> Plastic Packaging Systems and their Materials of Construction. In addition the recent proposed changes in <3> Topical and Transdermal Products – Product Quality Tests will be addressed.

### 4:35 Open Forum Discussion – Regulatory Considerations for TDD & IDD Systems

**Moderators:** Ken Miller, ISYN Consulting, Inc., and Michael Eakins, Principal Consultant, Eakins & Associates

**Participants:** The Audience

Regulatory bodies continue to develop procedures and acceptance criteria for critical quality attributes in transdermal, intradermal, and topical drug delivery systems, including uniformity of dosage, uniformity in containers, and drug performance characteristics. Harmonization of criteria across the world’s various regulatory bodies is a central concern as well. This open forum discussion will survey key areas of the regulatory landscape, and provide opportunities to raise questions and gain insights from others in the industry on a range of current issues, including: QbD for TDDS; Cold Flow; Shear Testing; In Vitro Drug Release Testing; Harmonization; Uniformity in Containers; and much else. Bring your questions and share your stories.
5:00  
End of Day One

Tuesday, May 12, 2015

8:15  
Complimentary Breakfast & Chairperson’s Remarks

8:30  
Exploring Novel Patch Designs And Technologies: Skinning The Cat While Not Reinventing The Wheel

Ken Miller, ISYN Consulting Inc.

I don’t know much about cats, but I do know that there are often many solutions to a given problem. This talk is my opportunity to acknowledge and express admiration for my colleagues and their novel approaches to the design, use, manufacturing and packaging challenges of transdermal patches. From maintaining thermodynamic activity to preventing oxidation to managing cold flow to maximizing yield to minimizing irritation to maximizing delivery; we will explore some of the most elegant, novel and downright coolest solutions to problems every patch developer faces at one time or another.

There is another old saying that we should avoid reinventing the wheel. This is a good concept to keep in mind during the development process because sometimes the solution to your problem already exists. In the depths of the development process, it is easy to develop tunnel vision and waste valuable resources trying to overcome a particular challenge on your own. Often, the solution already exists outside our areas of expertise, but we must make the conscious effort to raise our eyes above the trenches and look for it. To illustrate the value of cross- or inter-disciplinary thinking, we’ll explore a few simple examples of how tried and true techniques and technologies outside the world of transdermal patches can be adopted and adapted in our own programs.

9:10  
Spotlight on Iontophoretic Design

9:10  
Solving the Iontophoretic Design Puzzle

Andy Rensink, President/COO, Tapemark

Iontophoretic drug delivery has been around for a long time with limited success. Recent advances in printable/wearable electronics, advanced manufacturing techniques and improvements in Iontophoretic product design have created a renewed interest in the technology, including new products being filed and approved and several new projects being initiated. The promise of controlled drug delivery with cost effective and efficacious designs is now achievable by taking advantage of the many technology improvements made over the past decade. The talk will focus on the key considerations in choosing and developing a successful Iontophoretic drug delivery dosage form.

9:50  
Commercialization Challenges and Strategies for Active Delivery Systems

Lakshmi Raghavan, President & CEO, Solaris Pharma Corporation

Active transdermal delivery systems offer exciting opportunities to deliver drug molecules that are difficult to penetrate the skin barrier via passive delivery mechanisms. Several enhancement technologies have been evaluated by the Industry in the last 20 years by utilizing various forms of energy. Such technologies include iontophoresis, microneedles, thermal and laser ablation and radio frequency. In spite of significant efforts, only two products have got the approval from the FDA until now, namely LidoSite® an iontophoretic patch for local anesthesia and more recently ZECUITY, an iontophoretic patch for migraine.

In spite of these approvals, there remain significant challenges both in the development and commercialization of active delivery systems. These challenges include:

* Complexity of develop drug-device combination technologies
* Cost of development
* Patient safety – skin irritation
* Scale up of delivery systems to commercial quantities
* Regulatory challenges
* Patient compliance

In spite of these challenges, active delivery systems have an important role in the future of drug delivery, especially with more and more large molecules getting into the market. Successful development and commercialization of such systems requires concerted efforts from the Industry both in terms of funding as well as allocating enough resources to address the technical challenges.

10:30  
Mid-Morning Networking Break  
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In Vivo Absorption Rate Constants were from 2- to 20-fold higher following ID administration vs. SC injection. However, in some cases the kinetic absorption process following either ID (Insulin) or SC (Human Growth Hormone and Insulin) administration could not be adequately described by a first-order kinetic process suggesting that inclusion of additional factors and possible specific interactions with tissue may be necessary to more accurately describe the transport process. Comparing across different molecules, there is a general trend of more rapid ID systemic uptake for smaller molecules (absorption half-life values in minutes) compared to large molecules (absorption half-life values in hours).

Takeaway points:

- In vivo absorption rates of macromolecules in human and minipigs were analyzed through simultaneous data fits to PK models and numerical deconvolution.
- In general, in vivo absorption rate constants were from 2- to 20-fold higher following ID administration vs. SC injection for a given peptide or protein.

Mechanism Of A Novel Antimicrobial Nanoemulsion For The Treatment Of Burn Wounds

Susan Ciotti, Director of Formulations, & Stephen Gracon, VP Regulatory and Quality, NanoBio Corporation

Nanoemulsions (NE) are oil-in-water emulsions containing high energy nanometer-sized droplets stabilized by surfactants, and specifically designed for topical treatment of skin infections. Due to their size (0.5µm) and surface active properties they are thought to traverse skin pores and hair follicles, but are excluded from entering the tight junctions of the epithelium. As a result they can be highly bioavailable in the dermal tissues, without causing disruption of the normal epithelial matrix.

A topical therapy that halts burn wound progression while acting as a topical antimicrobial would be a significant breakthrough in the treatment of thermal burn injury. It would lessen the need for skin grafting, speed recovery, result in fewer infectious complications, and improve the outcomes for many burn patients. In a rodent and swine model, we have used a novel anti-microbial nanoemulsion formulation applied topically to treat burn-injured skin. The nanoemulsion reduces bacterial growth in the burn wound exudate to minimal levels and significantly reduces inflammatory cytokines. Reducing excess influx of neutrophils into the burn wound and modulating the pro-inflammatory response, the nanoemulsion formulations attenuate burn wound progression.

The pathways of drug absorption across the stratum corneum are well understood based on long term permeation of therapeutic molecules. The physico-chemical properties of the drug determine the penetration of drugs through the skin. However, a significant amount of actives get absorbed within short duration when the formulation comes in contact with skin, particularly when the formulation has considerable amount of solvent in it. It was found that the penetration of drug into the deeper layers of stratum corneum layer (through a depth of 15-20 micrometer) was dependent predominantly on properties of the formulation/solvent rather than the physicochemical nature of drug. The mechanistic studies have shown functional evidence regarding the existence of convective transport pathways in the skin. The work holds significance in dermal drug delivery and occupational uptake of chemicals on short-term exposure.

Dermal Absorption During Short-term Exposure

Narasimha Murthy, Ph.D., Professor, Ole Miss

The pathways of drug absorption across the stratum corneum are well understood based on long term permeation of therapeutic molecules. The physico-chemical properties of the drug determine the penetration of drugs through the skin. However, a significant amount of actives get absorbed within short duration when the formulation comes in contact with skin, particularly when the formulation has considerable amount of solvent in it. It was found that the penetration of drug into the deeper layers of stratum corneum layer (through a depth of 15-20 micrometer) was dependent predominantly on properties of the formulation/solvent rather than the physicochemical nature of drug. The mechanistic studies have shown functional evidence regarding the existence of convective transport pathways in the skin. The work holds significance in dermal drug delivery and occupational uptake of chemicals on short-term exposure.

Complimentary Lunch
in the early post-injury phase. Also, the nanoemulsion has specific affinity for hair follicles and sebaceous glands via the transfollicular route that may attribute to stem cell renewal.

Topically applied nanoemulsion was effective in preventing the conversion of partial thickness burn wounds to full thickness wounds with a concomitant decrease in inflammation. Nanoemulsion therapy is a potential new breakthrough treatment for preventing burn wound progression.

Penetration and Permeation Enhancers in Dermal Delivery

**Jasmine Musakhanian, Scientific & Marketing Director, Pharmaceutical Division, Gattefossé USA**

The growing interest in transdermal, topical and subcutaneous drug delivery is a reflection of the industry’s quest for alternative routes of administration, much needed for the delivery of new chemical entities and or existing (known) active molecules that stand to benefit from reformulation. Needle free passage of drugs to and across the skin layers however, is a significant challenge. It necessitates inclusion of safe and functional excipients with consideration of the unique role each vehicle may play in the final product. Additionally, the objective of each formulation may be different. The selection of the appropriate vehicle(s) thus may take into consideration the solubilization and suspension of the active in the dose; facilitating passage of the active across the outermost layer and barrier function of the skin, the stratum corneum; and permeation of the active in subsequent layers of the epidermis. By modulating the rate of partitioning and diffusion of the active into the dermis it is therefore possible to create sustained action or to develop formulations whereby the active drug molecule can be absorbed by the systemic circulation.

This presentation covers the current understanding of the mechanisms by which molecules may penetrate or permeate in the skin; the relationship between the chemical structure and functionality of vehicles alone and also in relation to other components of the formulation; considerations in formulating aqueous gels for local delivery and in design of micro (nano) emulsions for transdermal applications.

Takeaway points include:

- **Mechanisms of dermal penetration and permeation enhancement**
- **Excipient selection: chemistry vs functionality in dermal delivery**
- **Modulating drug release: aqueous gels for local or sustained delivery**
- **Utility and design of microemulsions in transdermal applications**

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**A Phase 2 Clinical Study of Transdermal Patch Delivering the PTHrP Analog, Abaloparatide, for Treatment of Postmenopausal Women with Osteoporosis**

**Gary Hattersley, PhD, Chief Scientific Officer, Radius Health**

It is estimated that over 200 million people worldwide have osteoporosis, and osteoporosis causes more than 8.9 million fractures worldwide. The vast majority of osteoporotic fractures occur in elderly women, and incidence increases markedly with age. Most fractures occur at the spine, wrist and hip. Of these, hip fractures carry the highest morbidity and mortality.

Abaloparatide is a synthetic analog of PTHrP that greatly increases bone mass and bone strength with preservation of normal bone quality in animal models of osteoporosis. Daily subcutaneous self-administration of abaloparatide (Abaloparatide-SC) at doses of up to 80 µg daily in postmenopausal women with osteoporosis for up to 48 weeks was associated with increases in spine and femoral neck BMD of up to 12.9 and 4.1% respectively, to 48 weeks was associated with increases in spine and femoral neck BMD of up to 12.9 and 4.1% respectively, with good safety and tolerability. In this study, the percent change from baseline in BMD at the 80 µg dose exceeded those seen with teriparatide 20 µg SC daily, significantly so at the hip (2.6 vs., 0.45, p=0.0056). Many, but not all, patients with osteoporosis can self-administer injections of abaloparatide or teriparatide, but a dosage form that increases BMD and avoids the need for daily injections would clearly be a valuable alternative for some patients.
Using 3M’s Solid Microstructured Transdermal System (sMTS), which consists of an array of 316 microneedles that penetrate the skin through the stratum corneum into the upper dermis, we developed a short-wear-time abaloparatide transdermal (Abaloparatide-TD) patch coated with doses of 50, 100 and 150 µg, and a placebo patch. 199 postmenopausal osteoporotic patients applied a patch containing either one of these three doses or placebo daily to their peri-umbilical region for 5 min once daily for up to 24 weeks. At the end of treatment spine and hip BMD increased dose dependently, with 150 µg increasing these by 2.9% (p<0.001) and 1.5% (p=0.002) relative to placebo, respectively. Therefore, this study provides strong proof of concept that a transdermal patch delivering abaloparatide produces meaningful increases in spine and hip BMD. Abaloparatide-TD was generally well tolerated. With further optimization ongoing to achieve enhanced efficacy, this approach holds substantial promise for a future alternative to existing and investigational injectable treatments for osteoporosis.

4:10 Close of Program
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