Microneedle & Transdermal Delivery Forum 2026

Advanced Design, Development and Delivery of Skin-Mediated Therapies and Vaccines

August 27-28, 2026, Providence Marriott Downtown

Featuring Lessons Learned & Case Studies from Industry Experts:

Tycho Speaker
AbbVie

Mark Prausnitz
Georgia Institute of Technology

Nahid Kamal
FDA

Ryan Donnelly
Queen's University

Alex Josowitz
Regeneron

James Birchall
Cardiff University

Thanh Nguyen
University of Connecticut

Harsha Jain
University of Iowa

Elke Lipka
TSRL, Inc.

Sebastien Henry
Micron Biomedical

Waleed Faisal
ArrayPatch, Ltd.

Jessica Mistilis
PATH

Muhammet Avcil
Imperial Bioscience

Akiko Pawlak
Nihon Bioresearch, Inc.

Huanhuan Li
Queen's University

Tim Peterson
Kindeva

Audra Stinchcomb
University of Maryland

Jim Scull
BA Sciences

Shogo Horiuchi
Kyowa Kirin Co., Ltd

And Comprehensive Coverage On:

- **Biodegradable Polymer STAR Particles for Enhanced Drug Delivery to the Skin**
- **Engineering Skin Mechanics into Microneedle Array Performance**
- **Influence of Microneedle Design Parameters on Transdermal Delivery of Naproxen Sodium**
- **Delivery of High Concentration Monoclonal Antibodies with a Needle Free Injector**
- **Microneedle Delivery: Platform Progress and Pathways to Commercialization**
- **Holding the Barrier Open: Dissolving Microneedles for Dual Antiproliferative and Antiplatelet Delivery**
- **Development of New Hydrogel-forming Microneedles for High-dose Drug Delivery**
- **Enabling the Next Generation of Peptide Therapies**
- **Advancing Long-acting LNG MAPs: Early Regulatory Insights to Guide Development**
- **Dose Verification as a Regulatory Endpoint: Lessons from Microneedle Clinical Trials and a Novel Solution**
- **Accelerating Transdermal and Microneedle Drug Development: Leveraging Göttingen Minipig Models for Regulatory Success**
- **Evaluation of Skin Insertion Performance of Dissolving Microneedle Patches Using a Research Applicator**
- **Regulatory Update: A Multi-Modal Testing Framework for Critical Quality Attribute Characterization of Dissolving Microneedles**
- **Optimization of Trospium Chloride Delivery via Hydrogel Microprojection Array Patches: Impact of Device Architecture and Reservoir Design**
- **Identifying Critical Quality, Material and Design Attributes for MNs**
- **And more!**

With Representation From:

Micron Biomedical · ArrayPatch · abbvie · FDA · REGENERON · Kindeva · PATH · nbr · CARDIFF UNIVERSITY · Georgia Tech · Queen's University Belfast · SCIENCES · TSRL inc · University of Maryland · University of Connecticut · KYOWA KIRIN · The University of Iowa

Contact: Kim Hubbard
khubbard@pharmaedresources.com or call (217) 721-5774

MICRONEEDLE & TRANSDERMAL DELIVERY 2026 IS SPONSORED BY:

Silver Sponsors

Media Partners

Thursday, August 27, 2026

7:45 *Registration Check-in & Complimentary Breakfast*

8:40 *Chairperson Tycho Speaker's Welcome and Opening Remarks*

Conference Keynote

8:45

Biodegradable Polymer STAR Particles for Enhanced Drug Delivery to the Skin

Mark Prausnitz, Regents' Professor & Chair in Chemical & Biomolecular Engineering, Georgia Institute of Technology

We developed STAR particles with microscopic needles that can be rubbed on the skin to increase skin permeability by creating microscopic punctures across the stratum corneum. In a first human clinical trial using STAR particles, we demonstrated increased drug delivery and local anesthesia by the addition of STAR particles to a commercial lidocaine/epinephrine/tetracaine formulation (L.E.T. gel) applied to the skin of healthy adult subjects. To address potential environmental and safety concerns of STAR particles made of non-biodegradable materials, like ceramic and metal, we fabricated biodegradable polymer STAR particles that are water-soluble, enzyme-degradable, or hydrolyzable, using femtosecond laser micromachining. Polymer STAR particles were able to puncture skin and enhance delivery of three model drugs – tacrolimus, methotrexate, and copper tripeptide-1 – by up to 37-fold. These studies advance STAR particles into clinical-stage study and expand STAR particle formulations to include biodegradable polymers.

Engineering Spotlight—Enhancing Dermal Drug Delivery

9:30

Engineering Skin Mechanics into Microneedle Array Performance

Tycho Speaker PhD, President and CEO, Capsulent, & Senior Principal Research Scientist, AbbVie.

Microneedle array patch (MAP) engineering is conventionally framed in terms of parameters intrinsic to the device, such as needle geometry, tip sharpness, material properties, and actuation force. What is less often made explicit is that penetration depth, dose uniformity, and payload utilization are not properties of the array alone, but of the coupled system formed by the array and the skin at the moment of actuation. Local tissue deformation dynamics are as important as any needle parameter.

The central delivery failure mode, tenting, occurs when the skin deforms inward under the advancing array before needle tips achieve penetration, resulting in shallow, non-uniform insertion and poor payload utilization. High-velocity applicators are the most common approach to overcoming these dynamics, but are not always successful, and introduce their own costs, including human factors costs.

This presentation explores approaches to integrate skin dynamics more directly into the design of alternative MAP and related drug delivery devices, and articulates several generalizable design principles. Specific examples of some of these will be presented in the context of the UniDose/UniVax post-driven microneedle platform, in which an adhesive elastomeric tray stabilizes the skin at the penetration surface prior to and during needle actuation.

Comparative penetration data will be presented in the context of three concurrent mechanisms: frictional constraint of lateral skin displacement, local tissue engagement during penetration, and mechanical isolation of individual penetration sites. Together these mechanisms collectively suppress tenting through passive biomechanical design rather than increased actuation velocity. More broadly, this work proposes treating tissue mechanics as a primary design input: a parameter to be leveraged from the outset rather than a challenge addressed after the device architecture is already fixed.

10:10 *Morning Networking & Coffee Break*

The Regulatory Landscape

10:40

A Multi-Modal Testing Framework for Critical Quality Attribute Characterization of Dissolving Microneedles

Nahid Kamal, PhD, Research Pharmacologist, OPQ/CDER/FDA

The absence of standardized characterization methods remains a critical barrier to dissolving microneedle (DMN) product development and regulatory assessment. Using polyvinyl alcohol-based DMNs containing metoprolol succinate as a model system, we developed and validated a comprehensive multi-modal testing framework encompassing three characterization domains: AI-assisted X-ray microscopy for spatially resolved drug distribution mapping, standardized mechanical testing protocols for fracture force and skin insertion assessment, and dissolution/permeation studies conducted using dermatomed human cadaver skin under physiologically relevant conditions.

Our data revealed consistent, quantifiable formulation trade-offs: higher polymer concentrations significantly enhanced mechanical integrity but correspondingly reduced drug release rates. Notably, manufacturing-induced heterogeneity in spatial drug distribution correlated directly with permeation behavior identifying a previously underappreciated determinant of in vitro biopharmaceutical performance. Collectively, these findings demonstrate that no single testing modality sufficiently characterizes DMN performance; rather, integrated mechanical, imaging, and biopharmaceutical assessment

is essential to capture the full formulation performance profile.

Although developed and validated within a single polymer-drug system, the framework and its underlying decision logic are designed to be adaptable across diverse DMN formulations, providing a structured, evidence-based foundation for regulatory-grade standardized testing protocols to advance microneedle-based product development.

11:20 **Development of Long-acting Microneedle Array Patches (MAPs) to Address Unmet Needs**

James Birchall, Professor & Deputy Head, School of Pharmacy, Cardiff University

Cardiff University have led a number of projects funded by the Gates Foundation, to develop a long-acting MAP suitable for addressing family planning needs in low-and middle-income countries (LMICs). The aim in this context is to deliver biodegradable microneedles containing levonorgestrel (LNG) hormonal contraceptive using a simple, discreet, cost-effective and self-administrable applicator device. Preclinical studies have demonstrated complete and reliable delivery of the microneedles with an LNG release profile relatively comparable to a commercial reference product, with no local or systemic tolerability issues. We are now positioning these projects for clinical readiness and commercial feasibility. We are also considering other applications for the long-acting MAP platform.

Cardiff University also co-chairs the Microneedle Array Patch Regulatory Working Group (MAP-RWG) and is a member of the VaxHub network; an update on the regulatory science relating to drug and vaccine MAP products will be provided.

12:00 **Accelerating Transdermal and Microneedle Drug Development: Leveraging Göttingen Minipig Models for Regulatory Success**

Akiko Pawlak, PhD, Assistant General Manager, Preclinical Study Design, Nihon Bioresearch Inc.

In transdermal drug development, particularly for innovative platforms like microneedle patches, selecting a translatably relevant animal model is paramount. Pigs are widely recognized for their structural and permeability similarities to human skin. Among them, Göttingen minipigs offer distinct practical advantages, such as manageable body weight and slower growth rates, which optimize study design and significantly reduce the required amount of test compounds—a critical factor in early-stage safety and efficacy evaluations.

Nihon Bioresearch Inc. (NBR), a premier Japan-based nonclinical contract research organization (CRO), is a recognized leader in minipig studies. Fully compliant with GLP regulations for pharmaceuticals and medical devices, and accredited by AAALAC International, NBR provides comprehensive safety (toxicology) and pharmacology evaluations utilizing Ellegaard Göttingen minipigs.

With a robust track record in microneedle patch evaluation, NBR specialized protocols assess systemic pharmacokinetics (PK), site-specific tissue concentration, systemic toxicity, and local skin irritation. Our extensive expertise ensures the generation of reliable, regulatory-ready data tailored to support successful submissions to global authorities, including the FDA.

In this presentation, we will showcase NBR's technical expertise and provide practical insights into optimizing nonclinical study designs for transdermal systems using minipig models. Furthermore, we will highlight how a strategic partnership with NBR can streamline your development pipeline and accelerate your path to global regulatory approval.

12:20 *Complimentary Lunch, Sponsored by*

1:20 **Advancing Long-acting LNG MAPs: Early Regulatory Insights to Guide Development**

Jessica Mistilis, Group Leader, Medical Devices & Health Technologies, PATH

Novel contraceptive technologies are needed to expand the availability, accessibility, and acceptability of long-acting contraception globally. Microneedle array patches (MAPs) have the potential to address this need, and several developers are advancing long-acting levonorgestrel-containing MAPs. However, regulatory guidance applicable to this novel delivery system is limited, and no vaccine- or drug-containing MAPs have been approved to date. To support timely and streamlined development approaches in the absence of regulatory precedent, PATH sought product-agnostic, nonbinding regulatory scientific advice from agencies recognized as operating at an advanced level of regulatory performance: the European Medicines Agency (EMA), the UK Medicines and Healthcare products Regulatory Agency (MHRA), and the US Food and Drug Administration (FDA). The requests for scientific advice focused on specific chemistry, manufacturing, and controls (CMC) aspects as well as nonclinical and clinical considerations for first-in-human clinical trials. This presentation summarizes the advice received from regulatory experts within the EMA, MHRA, and FDA and contextualizes the implications for advancing the development of early-stage, long-acting MAP products.

2:00 **Dose Verification as a Regulatory Endpoint: Lessons from Microneedle Clinical Trials and a Novel Solution**

Huanhuan Li, PhD, Research Fellow in Pharmaceutical Technology, School of Pharmacy, Queen's University Belfast

This talk addresses why recent microneedle vaccines (influenza, measles, rubella) have not advanced to late-stage development despite technical feasibility: potentially the absence of a field-measurable dose verification endpoint. Key takeaways include:

- Explaining the regulatory barrier that has blocked existing MN programs from FDA approval
- How a built-in color-change mechanism solves this problem
- Implications for regulatory strategy in novel delivery devices
- Lessons for other emerging delivery technologies facing similar approval challenges

2:40 *Afternoon Networking Break*

Research Spotlight—Exploring High Volume MAP Technologies

3:10 **Development of New Hydrogel-forming Microneedles for High-dose Drug Delivery**

Ryan F. Donnelly, Professor & Chair, School of Pharmacy, Queen's University Belfast

Unique microneedle arrays prepared from crosslinked polymers, which contain no drug themselves, are described. 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. This technology has the potential to overcome the limitations of conventional microneedle designs and greatly increase the range of the type of drug that is deliverable transdermally, with ensuing benefits for industry, healthcare providers and, ultimately, patients.

In this presentation, hydrogel-forming microneedles prepared from pharmaceutical grade low molecular weight and biodegradable materials that can be translated to the clinic will be described. In addition, the utility of these hydrogel-forming microneedles for high dose drug delivery, for up to 5 days from a single patch application will be discussed, with applications in infectious diseases, schizophrenia, and cardiovascular disease all discussed in depth.

3:50 **Delivery of High Concentration Monoclonal Antibodies with a Needle Free Injector**

Alex Josowitz, Principal Scientist, Drug Product Development and Technology, Regeneron Pharmaceuticals

Regeneron Pharmaceuticals Inc. has collaborated with Portal Instruments to evaluate its novel needle-free injector that can deliver 2.0 mL of high viscosity mAb formulation into the SC space. Drug product compatibility with the device components and ejection performance were assessed. Critical product quality attributes of mAb drug product were acceptable when ejected from the needle-free device and comparable to a traditional 27G needle-syringe system (N&S). Furthermore, the device functionality and delivery capability were evaluated with an ex vivo pig skin model, demonstrating accurate delivery into the SC tissue layer. The device performance was further studied using an in vivo Yorkshire pig model to understand the pharmacokinetic profile of a mAb delivered from the NFI in comparison to a 27-gauge N&S, and data demonstrated comparable PK profiles. Ultimately, the NFI represents an advancement in the ability to deliver high concentration mAb formulations to the SC space with design features focused on patient compliance and ease of use.

Critical Issues—Evaluating Insertion Performance

4:30 **Evaluation of Skin Insertion Performance of Dissolving Microneedle Patches Using a Research Applicator**

Shogo Horiuchi, Research Scientist, Formulation Development Group, Bio Process Research and Development Laboratories, Manufacturing Division, Kyowa Kirin Co., Ltd.

Dissolving microneedle array patches (dMAP) have attracted increasing attention as minimally invasive and userfriendly drug delivery technologies. Insertion performance of dMAP is strongly influenced by insertion parameters, including pressing force and insertion velocity, making manual insertion unsuitable for achieving the uniform skin penetration required for pharmaceutical applications. Therefore, this study aimed to systematically evaluate the impact of insertion parameters on the insertion performance.

dMAP with varying mechanical strengths of needles were prepared and evaluated using a research applicator that allows independent control of pressing force and insertion velocity. In Step 1, insertion testing was conducted using a multilayer plastic film model as a surrogate for human skin, and the velocity insertion enabled more uniform insertion than pressing force. In Step 2, insertion

performance was further evaluated using an ex vivo animal skin model, and insertion depth and uniformity were qualitatively assessed by X ray CT. The analysis enabled visualization and evaluation of insertion state and depth. From the results, insertion performance is highly dependent on insertion parameters, with insertion velocity being a critical factor for reproducible insertion.

In conclusion, the insertion performance of dMAP varies depending on insertion parameters, and insertion velocity is a key determinant of reproducibility. The insights gained in this study are expected to contribute to the optimization of applicator design and practical pharmaceutical applications.

5:00 *Happy Hour Mixer*

Join your colleagues at the poolside bar for a relaxing hour of informal networking. Complimentary appetizers provided.

Friday, August 28, 2026

7:30 *Complimentary Breakfast*

Research Spotlight

8:30

Influence of Microneedle Design Parameters on Transdermal Delivery of Naproxen Sodium

Harsha Jain, Postdoctoral Researcher, College of Pharmacy, University of Iowa (Co-author: Nicole Brogden, Ting-Fong and Nei-Jia Chin Professor in Pharmaceutics, Associate Dean of Faculty, University of Iowa)

This study investigates the influence of microneedle (MN) design parameters on the transdermal delivery of naproxen sodium (NAP) as a potential alternative to conventional migraine therapies. Oral and injectable treatments are often limited by poor patient tolerance, particularly in migraine patients experiencing nausea or vomiting. To address this, dissolving microneedles (dMNs) were developed as a minimally invasive, patient-friendly delivery approach.

dMNs of two lengths (600 and 800 µm) were fabricated using 45% w/w polyvinyl pyrrolidone and 1% w/w NAP. Mechanical strength testing confirmed adequate integrity, with less than 20% height reduction under applied force. In vitro release and permeation studies using Franz diffusion cells and flow-through systems demonstrated rapid drug release and significantly enhanced skin permeation compared to intact skin. Drug detection occurred within 5 minutes following dMN application, indicating accelerated delivery.

Both MN length and array number significantly influenced drug permeation. Increasing needle length from 600 to 800 µm and using two arrays instead of one resulted in higher NAP delivery. Additionally, applying a drug-loaded gel overlay further enhanced permeation. Overall, this work highlights the critical role of MN design parameters in optimizing transdermal drug delivery, supporting dMNs as a promising, fast-acting platform for migraine management.

9:10

Single-administration Multi-dosed, Long-acting Drug and Vaccine Microneedle Technology

Thanh Nguyen, Associate Professor, Mechanical and Biomedical Engineering, University of Connecticut

The ability to transform medical polymers, commonly used for resorbable surgical sutures, into desired 3D forms/shapes/structures at nano and micro scales with "smart" functions, while sustaining the materials' excellent biocompatibility and biodegradability, provides significant applications in different biomedical fields, ranging from tissue engineering and controlled drug/vaccine-delivery to medical implanted devices. Here, I will present our recent research works to develop novel vaccine delivery systems which are made by a newly developed 3D additive manufacturing process. This vaccine system in the form of a skin patch relies on tiny microneedles which can be painlessly administered onto the skin at a single-time, fully embedded into the skin (i.e., no patch left after the application) and pre-programmed to deliver stabilized vaccines and drugs repeatedly over a long period, simulating the therapeutic and immunogenic effect of multiple bolus injections in the conventional administration. Our lab also develops this microneedle patch technology for other medicines such as anti-HIV immunogen, antiviral-drugs, antibodies, diabetic drugs, pain medicines and other medicines etc.

9:50 *Morning Coffee & Networking Break*

Spotlight on Vaccine & Therapeutic Product Development—Lessons Learned

10:20

Enabling the Next Generation of Peptide Therapies

Waleed Faisal, CEO, ArrayPatch, Ltd

Abstract Coming Soon

11:00

Clinical Development of a Novel Rotavirus Vaccine-dissolving Microneedle Patch

Sebastien Henry, EVP, Head of Technical Operations, Micron Biomedical, Inc.

Rotavirus is an important cause of gastroenteritis worldwide. Although live-attenuated vaccines for rotavirus are available for infants, the immunogenicity and vaccine effectiveness in low- and middle-income countries, where morbidity is highest, is suboptimal. Developing rotavirus vaccination strategies with improved immunogenicity could be advantageous in resource-limited settings

Micron Biomedical (Micron) and the US Centers for Disease Control and Prevention (CDC) aim to develop a novel rotavirus vaccine combining CDC's inactivated rotavirus vaccine (IRV) and Micron's dissolving microneedle patch (dMP) to leverage both technology attributes and create a dMP-based IRV (IRV-dMP) that is safe, immunogenic, with enhanced thermostability, and that can be administered with minimal or no prior training.

The novel vaccine is based on two innovative technologies: 1) Micron's dMP technology, designed to deliver vaccines to the skin in a simple and painless manner, which is compatible with a wide range of vaccines and has been evaluated in several clinical trials, including a Phase 1/2 clinical trial of a measles-rubella vaccine in toddlers and infants; 2) CDC's proprietary IRV technology (new human strains and a novel method for rotavirus inactivation).

In this presentation, we will discuss the ongoing development of IRV-dMP including preliminary data from a first-in-human Phase 1 clinical trial.

11:40

Is That a Leachable? The Importance of Extraction Solvent Interactions

Jim Scull, Chief Scientific Officer, E&L and Chemistry, BA Sciences

This case study compilation will explore the generation of compounds that may form as a result of reactions of extractables from transdermal patches with components of the extraction solvent system. The process of determining the true source of those compounds and if they should be designated as leachables will be discussed.

12:00 *Complimentary Lunch, Sponsored by*

SCIENCES
unbreakable bonds. unbeatable science.

1:00

Optimization of Trospium Chloride Delivery via Hydrogel Microprojection Array Patches: Impact of Device Architecture and Reservoir Design

Elke Lipka, President & CEO, TSRL, Inc.

We are advancing the development of a self-administered, painless drug delivery platform based on hydrogel-forming microneedle arrays (MAs). Our lead product, TSR-066, delivers Zanamivir for the treatment of seasonal influenza over five days and is progressing toward first-in-human studies in Q3 2026. Building on this foundation, we have established an efficient screening process to identify additional drug candidates, unlocking the broad platform potential of the drug-free MAs. Our development efforts include formulation screening to demonstrate in vitro permeation through the hydrogel matrix, comprehensive skin irritation assessments, and in vivo delivery validation using rat and mini-pig models.

Our next pipeline candidate is a MA patch (MAP) formulation of Trospium Chloride (TC), TSR-825, a clinically effective therapy for overactive bladder (OAB), yet its commercial utility is constrained by inconsistent oral bioavailability and dose-limiting peak-related adverse events. By systematically evaluating MAP architecture and reservoir configurations, our work generated a robust dataset linking device design, drug release kinetics, and systemic exposure. Importantly, scaffold-based reservoir systems achieved consistent sustained plasma concentrations over the anticipated 7-day period in rats, while minimizing peak exposure.

Data for this product candidate presented here demonstrates the translational and commercial opportunity of hydrogel-forming MAPs, supporting the development of patient-friendly formulations with improved tolerability and compliance potential.

Critical Issues—Scaling Up MAP Platforms for Commercial Success

1:40

Microneedle Delivery: Platform Progress and Pathways to Commercialization

Tim Peterson, Scientific Director, Dermal Drug Delivery, Kindeva

Kindeva's solid coated microneedle delivery platform has been developed to enable efficient, reliable intradermal delivery across a range of therapeutic modalities. Recent results generated with both small- and large-molecule therapeutics, as well as vaccine candidates, highlight the platform's versatility and performance. Key considerations for manufacturing scale-up are addressed, drawing on Kindeva's experience advancing microneedle technologies from early development toward commercial readiness. This experience in solid coated microneedle scale-up provides a foundation for supporting external partners, with capabilities that can be translated to other microneedle technologies within a CDMO framework to accelerate pathways to commercialization.

Research Spotlight—Expanding the Duration of Antiplatelet Delivery

2:20 **Holding the Barrier Open: Dissolving Microneedles for Dual Antiproliferative and Antiplatelet Delivery**

Audra Stinchcomb, Professor, School of Pharmacy, University of Maryland, Baltimore

Dissolving microneedles (DMNs) are desirable dosage forms for painless sustained release drug delivery. Three days is a typical maximum duration of delivery through microneedle created pores in the skin. Our goal is to deliver anti-clotting therapeutics for seven days. DMNs for this purpose will be discussed.

3:00 **TBA**

Muhammet Avcil, PhD, Founder, Imperial Bioscience

Abstract Coming Soon

3:40 *Close of Program*

Poster Sessions

Triple-layered Core-shell Microneedle Patch for Sustained Analgesic Delivery and Chondroprotection in Osteoarthritis

Hoang-Phuc Pham, PhD Student, Institute of Materials Science—Polymer Program, University of Connecticut

Osteoarthritis (OA) is a prevalent chronic condition characterized by persistent pain, necessitating sustained therapeutic interventions to manage symptoms effectively. In this study, we introduce a novel core-shell microneedle system for sustained release, termed Microneedle-based Integrated Release with Advanced Composite Layered Efficacy (MIRACLE). The design is a triple-layered microneedle (MN) patch engineered for the prolonged management of OA-associated pain. The patch consists of a 15 x 15 array within a 1 cm2 area, featuring a specialized three-level architecture. One core-layer of the MIRACLE is designed to provide sustained controlled release of multiple pain drugs. One sub-shell layer is designed to prevent premature burst release (over-dosing) of the encapsulated payloads and an outermost layer is designed to ensure sufficient mechanical strength for skin penetration regardless of the core-layer drug formulation which is often tuned to obtain different sustained release profiles. Within an hour of application, an integrated effervescent layer (between the needle tips and backing layer) is rapidly dissolved and facilitates implantation of the MNs into the skin. Subsequently, the system provides a controlled, co-delivery of Bupivacaine (BUP) and Meloxicam (MEL), which act synergistically to provide sustained anesthetic and anti-inflammatory effects for up to 10 days (for comparison, the only commercial long-acting ZynrelefTM formulation for post-operational pain only has up to 3-day acting period) in OA rat models. Besides the analgesic efficacy, the MIRACLE system demonstrated a significant capacity to mitigate articular cartilage degradation. This multi-layered MNs platform could represent an excellent strategy for not only the treatment of chronic osteoarthritis pain but also the management of other types of neuromusculoskeletal pains, offering a significant and broad impact on modern medicine.

Precision Gene Editing for Dominant Keratin Mutations: Overcoming Delivery Barriers Using Dissolving Microneedles

Manuel Klumpp, PhD Student, Department of Dermatology, Venereology and Allergology, Medical University of Innsbruck, Austria (Co-authors: Carina Kuipers, Medical University of Innsbruck, Austria, et. al.)

Epidermal differentiation disorders (EDDs) encompass a diverse group of inherited skin diseases. Many of these are caused by autosomal dominant mutations in keratin (KRT) genes, where the mutant protein exerts a dominant-negative effect on the wild-type KRT. This disrupts the KRT cytoskeleton by destabilizing intermediate filaments within keratinocytes, leading to compromised skin integrity. Such molecular defects underlie severe conditions including epidermolytic ichthyosis, pachyonychia congenita, and palmoplantar keratoderma, all characterized by skin fragility, hyperkeratosis, painful fissures, and chronic wounds. Due to their monogenic origin, keratinopathies are excellent candidates for precise, targeted genetic correction therapies. Our research specifically addresses the recurrent p.N161S mutation in KRT9. Leveraging advanced gene editing tools, we aim to achieve accurate correction at the DNA level using lipid nanoparticles (LNPs) as delivery vehicles. In addition to in vitro experiments with patient-derived primary keratinocytes, we are focused on optimizing effective in vivo delivery. Our findings reveal that LNP injections often localize deep within the dermis, bypassing the epidermis where target cells reside. Traditional skin pretreatment techniques, such as microneedling and laser poration on human skin explants, have proven insufficient, as LNPs become trapped in the stratum corneum or within microchannels. To overcome these challenges, we are developing a novel delivery system that integrates LNP-encapsulated gene-editing components with dissolvable microneedle patches. We propose that this minimally invasive method enables localized, direct delivery to the basal epidermal layer, targeting keratinocyte stem cells responsible for skin renewal and long-lasting therapeutic outcomes. This innovative delivery platform holds significant potential for durable, mutation-specific correction of dominant keratinopathies. By establishing an efficient, patient-friendly gene editing approach, our work aims to revolutionize treatment options for KRT-related skin disorders and pave the way for broader applications of gene therapy in dermatology.

PharmaED RESOURCES, Inc.

PharmaEd Resources, Inc. • 2810 Robeson Park Drive • Champaign, IL 61822

About Your Conference Destination

The Providence Marriott Downtown is located in the heart of Capital Hill offering 351 luxurious guestrooms, five suites, complimentary WIFI, an exclusive Concierge Lounge, new lobby and over 11,000 square feet of newly renovated function space and dedicated catering services. Our recreational amenities include connecting indoor/outdoor pools, heated whirlpool spa and Club Pace Fitness Center as well as AQUA; Providence's only poolside lounge. The Bluefin Grille is our award-winning restaurant offering breakfast, lunch and dinner featuring innovative seafood specialties and popular American fare. Complimentary parking and shuttle service throughout the city.

Registration Information

Register for the conference using one of three options:
Online: www.pharmaedresources.com **Phone:** (217) 721-5774
Mail: 2810 Robeson Park Drive, Champaign, IL 61822

Please Complete the Following

FIRST NAME: _____

LAST NAME: _____

TITLE: _____

COMPANY: _____

ADDRESS: _____

ADDRESS: _____

CITY: _____ STATE: _____

ZIP: _____ COUNTRY CODE: _____

OFFICE PHONE: _____

MOBILE PHONE: _____

FAX: _____

E-MAIL: _____

VENUE INFORMATION:

Dates:	August 27–28, 2026
Venue:	Providence Marriott Downtown
Venue Address:	1 Orms St. Providence, RI 02904
Venue Phone:	(401) 272-2400

Please register me for:

Microneedle & Transdermal Delivery Forum 2026

Standard Registration	**$1,595**
Early Bird Registration (by July 15th)	**$1,395**
Call for government, academic, or non-profit rate	

PAYMENT METHOD

CREDIT CARD REGISTRATION:

c CREDIT CARD c VISA c MASTERCARD c AMEX

NAME: _____

CARD #: _____

EXPIRATION: ____ / ____

SIGNATURE: _____

BILLING ADDRESS: _____

CHECK REGISTRATION:

To pay by check, please provide a purchase order below. Please note that all payments must be received five (5) days prior to the conference to ensure space. Attendees will not be admitted to the conference without full payment.

PURCHASE ORDER #:

PLEASE NOTE:

PharmaEd Resources does not offer refunds. However, if you cannot attend after registering, we are happy to apply your registration fee to another PharmaEd Resources event, or transfer your registration to a colleague. Notice of cancellation must be received at least 5 days prior to the event.