PharmaED RESOURCES, Inc.

Microneedle & Transdermal Delivery Forum 2025

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

September 9-10, 2025, Racquet Club of Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

Tycho Speaker
AbbVie

Jonathan Chen
Georgia Institute of Technology

Courtney Jarrahian
PATH

Smital Patil
Inventprise

Thanh Nguyen
University of Connecticut

Jessica Chiaruttini
ValSource

Daisuke Ando
NIHS-Japan

Tom Lake
Vaxxas

Dawn Reyna
TSRL, Inc.

Sebastien Henry
Micron Biomedical

Marie Chivers
Facilipharma, Inc.

Muhammet Avcil
Imperial Bioscience

Gyorgy Vas
Intertek

Narasimha Murthy
Topical Products Testing

Sean Grzywaczewski
Applied Vision Technology

Chizimuzo Chibuko
Georgia Institute of Technology

Waleed Faisal
Array Patch, Ltd.

Audra Stinchcomb
University of Maryland

Bai Xu
Nanomed Skincare

With Comprehensive Coverage On:

- **Regulatory Updates on Microbiological Controls for Microneedle Array Patches**
- **Insights From PATH's Human-centered Design Activities to Ensure Microarray Patches Meet Global Health Needs**
- **Scaling Up MAPS for Commercialization**
- **Microneedle Patch to Induce Sweating for the Screening of Cystic Fibrosis**
- **Self-boosting and Stabilized Vaccine Microneedle Technology**
- **Pre-clinical Development and Phase 1 CMC Readiness of a Novel Vaccine-Dissolving Microneedle Patch to Improve Outbreak Response and Vaccine Equity**
- **Securing Market Access for MAPs**
- **Case Study: Payer Value Drivers for DerMap™ in Onychomycosis**
- **Developing High-Precision, Multi-Camera Vision Systems for Automated Inspection of Microneedle Arrays**
- **Case Study: Dissolving Microneedle Technology for Drug and Vaccine Administration**
- **Development of a Self-Administered, Painless Microarray Patch (MAP) Platform for Delivery of Poorly Membrane-Permeable Therapeutics**
- **Combining Microneedles with Biophysical Technologies for Enhanced Dermal Drug Delivery**
- **Use of X-ray Micro-computed Tomography to Assess Skin Penetration Depth of Microneedle Patches**
- **Identifying Critical Quality, Material and Design Attributes for MNs**
- **And More!**

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Tuesday, September 9, 2025

7:30 *Registration Check-in & Breakfast*

8:30 *Chairperson Tycho Speaker's welcome and Opening Remarks*

Conference Keynote

8:35 **Off the MAP: Driving Innovation in New Generations of Transdermal Delivery**

Tycho Speaker, Senior Principal Research Scientist, Combination Product Development & Drug Delivery, AbbVie

While microneedle and transdermal delivery technologies have become a platform for systemic and localized drug administration, much of the progress in this field has occurred within a framework of familiar assumptions about device structure and delivery mechanics. Drawing on insights from David Epstein's Range, this talk explores how true breakthroughs often arise not from specialization alone, but from stepping outside inherited contexts and applying interdisciplinary perspective to difficult, multifaceted problems. In this complex domain, where biological, mechanical, and logistical constraints intersect, meaningful innovation demands more than optimization. It requires reframing the problem itself. As Clayton Christensen observed, industry leaders often dismiss disruptive approaches precisely because they don't yet meet conventional benchmarks—only to find themselves displaced when those approaches redefine the field. This talk will examine how generalist, lateral thinking and cross-domain insight have driven paradigm shifts in microneedle technology, and why companies in this space must learn to recognize, foster, and respond to emerging innovation before it bypasses them entirely.

Technology Spotlight—Enhancing Dermal Drug Delivery

9:15 **Combination of Microneedles with Biophysical Technologies for Dermal Drug Delivery**

S. Narasimha Murthy, CSO, Topical Products Testing, LLC

The combination of microneedle technology with other biophysical technologies offers a promising strategy to enhance transdermal drug delivery. Microneedles create microchannels that bypass the stratum corneum, while biophysical technologies such as iontophoresis, electroporation and magnetophoresis drive drug molecules deeper into the skin. This synergistic approach may enable efficient delivery of APIs, macromolecules and nanoparticles. The fundamental principles and case studies of such combination approaches will be discussed in the presentation.

9:55 *Morning Networking & Coffee Break*

Regulatory Spotlight

10:25 **Current Status: Regulatory Updates on Microbiological Controls for Microneedle Array Patches (MAPs)**

Jessica Chiaruttini, PhD, Microbiology Consultant, ValSource, Inc.

Unlike approved pharmaceutical products, microneedle products target an area of the body that has not been clinically investigated before. The global compendia and published guidance and literature stress the need to develop a product-specific, risk-based approach that places the burden on individual developers to assess, define, and justify their proposed investigational control strategy. The microbiological product quality control strategy for microneedle products currently under clinical trial investigation varies from non-sterile to low-bioburden to sterile. Additionally, variability exists for the control strategy for endotoxins and particulates. Without a clear example of a successful microbial control strategy, there is concern that investigational product specifications may not be accepted in the marketing application, thus significantly impacting product approval timelines. This presentation will summarize the published global regulatory requirements and present the current state of the field. Examples of proactive, risk-based approaches that include development of novel upstream microbial control points will also be discussed to support development of process analytical technology (PAT) design space considerations.

Spotlight on Human-centered Design of MAPS

11:05 **Learnings From PATH's Human-centered Design Activities to Ensure Microarray Patches Meet Global Health Needs**

Courtney Jarrahian, Global Program Leader—Med Devices & Health Technologies, PATH

Microarray patches (MAPs) for drug and vaccine delivery could have a transformative impact on health. PATH aims to improve health in regions and communities experiencing disproportionate burdens of disease and barriers to well-being. To address these challenges, our multidisciplinary team works with global and local stakeholders to develop and scale up responsive, sustainable, human-centered health solutions. For more than a decade, PATH has assessed and MAP technologies that have the potential to improve access to and delivery of a broad range of vaccines and essential medicines in resource-constrained settings. We use human-centered design (HCD) to ensure that innovative medical technologies such as MAPs are appropriate, sustainable, and reflective of local priorities. Our approach includes developing Target Product Profiles informed by user and stakeholder needs; conducting human factors analyses on site in countries; evaluating acceptability and programmatic fit; performing health economic modeling;

ensuring environmental sustainability; assessing thermostability; strategizing regulatory and product development pathways; and conducting clinical trials to advance programmatically-suitable products for delivery of measles-rubella vaccine and other global health priorities.

11:45 **Amcor Presentation**

Speaker TBA.

Abstract Coming Soon

12:05 *Complimentary Lunch Sponsored By*

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Research Spotlight—Novel Applications of MAP Products for Unmet Medical Needs

1:05 **Development of Cost-effective, Scalable and Modular Dissolvable Microneedle Array Patch Technology**

Smital Patil, Scientist I, Viral Vaccines Team, Inventprise, Inc.

Inventprise Inc. is a vaccine development and manufacturing company established in 2013 in Redmond, Washington, USA. Our company mission is to make vaccines efficient, affordable, and globally accessible with primary focus being low- and middle-income countries (LMICs). With our proprietary conjugation technology, we have developed multiple polysaccharide-based vaccines which are currently in clinical trials.

As part of our company's mission to make affordable and accessible vaccines to LMICs, we are developing a Dissolvable Microneedle Array patch as a delivery platform. As proof-of-concept, we are evaluating Measles and Rubella (MR) attenuated viruses as antigens for delivery. Our MR-D-MAP product comprises of quick dissolving polymers that dissolves the needles (>80%) in 2 minutes after application to human ex vivo skin model thereby delivering an equivalent dose to commercial MR vaccine. Our product has demonstrated favorable thermostability results for both viruses at 25°C and 37°C, projecting its elimination from cold chain, improving accessibility to LMICs and reducing cost. Our manufacturing process consists of simple steps making it highly amenable to large-scale manufacturing. We have successfully developed our own silicone mold and continue development of our own applicator, significantly reducing production costs. Our product has demonstrated promising preclinical data when tested in cotton rats. Additionally, we have developed a panel of characterization and quality control tests critical for the comprehensive development of this platform. In this presentation, we will be providing an overview of our technology and our development of MR-D-MAP product.

1:45 **Microneedle Patch to Induce Sweating for the Screening of Cystic Fibrosis**

Jonathan Y. Chen, PhD Candidate, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology and Emory University

Abstract Coming Soon

2:25 *Afternoon Networking Break*

2:55 **Interstitial Fluid Extraction from Skin Using Microneedles**

Chizimuzo S. Chibuko, PhD Candidate, Wallace H. Coulter Department of Biomedical Engineering, Georgia Institute of Technology and Emory University

Microneedles are widely studied and used for drug delivery. This minimally invasive technology creates pathways in the skin, which not only provide pathways for drug delivery into the skin but can enable the extraction of dermal interstitial fluid (ISF) out of the skin. ISF is a fluid that surrounds skin cells, does not clot, shares many biomarkers with blood, and contains unique markers not found in blood. As a result, ISF offers a valuable alternative for biomarker and drug concentration monitoring, particularly for transdermal delivery and topical treatments. Moreover, the field of point-of-care (POC) diagnostics is rapidly developing as more patients seek to self-monitor their health. A major challenge in incorporating ISF into POC diagnostic devices is the low volume of ISF typically extracted. By combining microneedles with suction-driven flow, we have achieved efficient ISF collection, positioning microneedles as a promising tool for clinical diagnostics and drug monitoring in dermal ISF.

3:35 **TBA**

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

Abstract Coming Soon

Critical Issues—Securing Market Access for MAPs

4:15 **Case Study: Payer Value Drivers for DerMap™ in Onychomycosis**

Waleed Faisal, CEO/Founder, Array Patch, Ltd., & Marie Chivers, PhD & MPharm, CEO/Founder, Facilipharma Ltd.

Securing market access for microneedle products will rely on evidence packages that meet payer expectations for pricing and reimbursement. Successful pricing and reimbursement outcomes for new microneedle products will require delivery of an evidence package that is accepted by the decision-makers ("payers") who govern patient access to medicines, globally.

This study explored payer perspectives on DerMap™, a microneedle-based treatment for onychomycosis, through desk-based research and interviews with payers in the US, Germany, France, and Italy.

Key findings showed that comparative clinical efficacy, cost, and self-administration were the most important value drivers. Clinical superiority over standard of care is essential to achieve a price premium, with greater disease burden recognized in high-risk groups, such as people with diabetes.

These insights inform evidence generation strategies to support successful market access for DerMap™ microneedle technology.

5:05 *End of Day One*

Wednesday, September 10, 2025

7:30 *Complimentary Breakfast*

8:30 **From Bench to Body: Translational Hurdles & Breakthroughs in Dissolvable Microneedle Therapeutics**

Dr. Muhammet Avcil, Founder, Imperial Bioscience

Dissolvable microneedle (MN) arrays have advanced from lab curiosity to clinical contender, yet many programs stall in the translational "valley of death." This talk dissects failure points via three 22-subject dermatological trials—hyperpigmentation, cosmetic acne, and wrinkle reduction—that established first-in-human safety and efficacy, plus a medical-grade adapalene MN system now IND-cleared and preparing for Phase 1 acne treatment. We map where projects derail at scale-up, biocompatibility panels, and dermal pharmacokinetics, and show how bespoke in-vitro release and in-vivo dermatokinetic assays de-risk submissions. Finally, we outline how a blended capital stack of targeted venture funding and non-dilutive grants can compress timelines for hardware-plus-formulation platforms. Delegates leave with a practical checklist spanning formulation, regulatory strategy, and financing to carry MN innovations from bench to body.

9:10 **Self-boosting and Stabilized Vaccine Microneedle Technology**

Thanh Duc Nguyen, PhD, Associate Professor of Mechanical Engineering, Department of Biomedical Engineering, Institute of Materials Science, Polymer Program, 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 vaccine antigens repeatedly over a long period, simulating the immunogenic effect of multiple bolus injections in the conventional vaccination process. Our lab also develops this microneedle patch technology for other medicines such as anti-HIV immunogen, antiviral-drugs, antibodies, diabetic drugs and other medicines etc.

9:50 *Morning Networking & Coffee Break*

Spotlight on Vaccine & Therapeutic Product Development—Lessons Learned

10:20 **Development of a Self-Administered, Painless Microarray Patch (MAP) Platform for Delivery of Poorly Membrane-Permeable Therapeutics**

Dawn Reyna, COO, 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, is designed to deliver Zanamivir for the treatment of seasonal influenza and is progressing toward first-in-human studies in Q1 2026.

Building on this foundation, we have established an efficient screening process to identify additional drug candidates, unlocking the broad platform potential of our 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.

We will present data on our latest product candidate, TSR-825, a Trospium Chloride MAP for the treatment of overactive bladder. Additionally, we will outline the key physicochemical, pharmacokinetic and commercial characteristics that make a drug suitable for MAP delivery. Finally, we will discuss our regulatory approach, which leverages the 505(b)(2) pathway to enable accelerated product development and approval.

Our progress supports the continued development of follow-on MAP products, particularly for therapeutics with poor membrane permeability, moving us closer to fully realizing the potential of this versatile delivery platform.

11:00

Pre-clinical Development and Phase 1 CMC Readiness of a Novel Vaccine-Dissolving Microneedle Patch to Improve Outbreak Response and Vaccine Equity

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

The COVID-19 pandemic showed the need for vaccines that can be deployed rapidly in response to outbreaks of new pathogens to reduce morbidity and mortality associated with such outbreaks. Making vaccines available within weeks of the identification of a new threat can be critical to minimizing the impact of future pandemics.

Micron Biomedical (Micron) and CastleVax aim to develop next-generation vaccines combining CastleVax's Newcastle Disease Virus (NDV) vaccine platform and Micron's dissolving microneedle patch (dMP) technology platform to leverage both platform attributes and create vaccines that are thermostable, safe, immunogenic, provide superior protection against breakthrough infection, can be administered by personnel with minimal or no prior training or that can be self-administered, and that can be deployed quickly after the identification of a new pathogenic strain. The resulting vaccine-dMPs are expected to have low COGS with a simple manufacturing process that can be transferred to LMIC countries.

The novel vaccines are based on two innovative technology platforms: 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) CastleVax's rapid-response vaccine platform whose benefits include no pre-existing immunity, flexible genome, bilipid membrane (allowing foreign antigens to be incorporated into the viral particle), and multiple presentations (live attenuated or inactivated, mono-or multivalent). It has been shown in pre-clinical and clinical studies to be safe and immunogenic and CastleVax's COVID-19 vaccine has received Emergency Use Authorization in Mexico and full market approval in Thailand.

In this presentation, we will discuss ongoing development activities and plans for pre-clinical activities including CMC readiness to support future clinical evaluation.

11:40

Clinical and Manufacturing Scale-up Progress Update

Tom Lake, SVP, Strategic Alliances & Commercialization, Vaxxas [Co-authors: Alexandra C. I. Depelsenaire, Vaxxas and The University of Queensland, School of Chemistry & Molecular Biosciences, Faculty of Science; et. al.]

Vaccination using microarray patches (MAPs) has the potential to achieve greater acceptance, ease of application, broader community reach and to be more cost-effective compared to current needle and syringe injection. Drying vaccine on the high-density microarray (HD-MAP) offers improved thermostability, and the intradermal delivery of vaccine into the immune-cell-rich epidermal layers has the potential for dose sparing. We report the Phase 1 clinical study results for the delivery of a quadrivalent influenza vaccine using Vaxxas' high-density MAP (HD-MAP). The multi-centre, randomized, partially-blinded, placebo-controlled study evaluated the safety and tolerability of HD-MAP coated with quadrivalent influenza vaccine (QIV) administered to healthy volunteers 18 to 50 years (n=150). The HD-MAP influenza vaccine was delivered at three targeted dose levels 5, 10, 15 mcg HA per strain and compared against an uncoated HD-MAP group and the registered intramuscular vaccine (Influvac Tetra) at standard 15 mcg HA dose. All HD-MAP doses were delivered using a single application to the upper arm, overlaying the deltoid muscle with 2-minute application time. Participants were assessed up to 60 days post vaccination, with blood samples taken over the course of assessment to evaluate immunogenicity. HD-MAP vaccination was safe and well tolerated; any systemic or local adverse events (AEs) were mild or moderate and local AEs were application-site reactions, usually erythema. HD-MAP vaccination induced HAI and MN antibody titres that were 1.4 to 3 times higher than those seen with IM injection of Influvac Tetra, depending on the strain. The enhanced antibody responses relative to IM injection were observed at all HD-MAP dose-levels, including the lowest (5 µg) dose (Figure 1); there was no dose-response relationship with HD-MAPs. CD4+ T cell and memory B cells were induced by HD-MAP delivery to at least similar levels to those seen with IM injection. A post-hoc analysis indicated that for all strains, timepoints and all dose-levels, HAI GMTs induced by HD-MAP delivery were non-inferior to IM injection. At day 22, HAI titres induced by HD-MAPs were superior to IM for three of the four strains at all dose levels. Ex vivo pig skin application studies using the Phase 1 product show that application times of less 10 seconds deliver an equivalent QIV dose to 2 minutes. This is the first demonstration of delivery of QIV by a MAP in a clinical trial and the first to indicate potential for lower QIV doses. Vaccination using

the HD-MAP was safe and well tolerated and resulted in serological responses that were approximately 50% greater than those following IM injection, even at ~30% of the IM dose. The results support continued development of HD-MAPs for delivery of influenza vaccines.

12:20 *Complimentary Lunch*

1:20 **Use of X-ray Micro-computed Tomography to Assess Skin Penetration Depth of Microneedle Patches Loaded with Contrast Agent**

Daisuke Ando, Division of Drugs, National Institute of Health Sciences, Japan, & Georgia Institute of Technology [Co-authors: Erkan Azizoglu & Mark R. Prausnitz, School of Chemical & Biomolecular Engineering, Georgia Institute of Technology]

Measuring skin penetration depth of microneedles is important to assess microneedle patch (MNP) performance. One of the major challenges in X-ray micro-computed tomography (micro-CT) imaging of MNP penetration into the skin is the poor contrast sensitivity between microneedles and the surrounding skin. Here we present the development of micro-CT methods for quantitative measurement of skin penetration depth using contrast agents to evaluate MNP quality and performance.

Although the needles in MNPs without contrast agent were not visualized in the skin by micro-CT, organic iodine compound (iopamidol)-loaded non-dissolving MNPs were clearly visualized, delineating the needle-skin interface. On the other hand, iopamidol-loaded dissolving MNPs were not visualized in skin, suggesting that once the needles dissolve, the contrast disappears. To overcome this, we fabricated dissolving MNPs containing iron oxide nanoparticles (ferucarbotran) in the tips and iopamidol in the backing. Hence, the deepest insertion points and the interface between the remaining needles and the skin were identified by ferucarbotran and iopamidol, respectively. We applied this method to clarify the differences in MNP performance with different designs (e.g., tip angle, height, number of needles) quantitatively. Micro-CT imaging in conjunction with contrast agents allows evaluation of skin penetration depth of dissolving and non-dissolving MNPs.

1:50 **Extractables & Leachables Testing for MAPs**

Gyorgy Vas, Business Technical Scientific Liaison, Intertek Pharmaceutical Services

Abstract Coming Soon

2:30 *Afternoon Break*

2:45 **Safe and Effective Non-invasive Delivery Systems for Consumer Products--A Case Study**

Bai Xu, Founder/CEO, Nanomed Skincare, Inc.

Despite growing interest in aesthetic dermatology, research focus often prioritizes facial and neck skin over the critical periorbital region. Sun exposure and dynamic muscle activity induce accelerated wrinkle formation around the eyes, frequently preceding visible facial aging. To address this gap, we initiated a targeted product development program for periorbital anti-aging interventions. This report elucidates the program's conceptual framework, navigated regulatory pathways, as well as real-world clinical evidence of safety and efficacy.

Technology Spotlight—Automated Inspections of MAPs

3:25 **Developing High-Precision, Multi-Camera Vision Systems for Automated Inspection of Microneedle Arrays**

Sean Grzywaczewski, President, Applied Vision Technology, Inc.

As microneedle-based drug delivery systems advance from research to commercial-scale manufacturing, ensuring the structural integrity and dimensional accuracy of each microneedle presents a critical quality control challenge.

This presentation explores the development of high-precision, multi-camera vision systems designed for automated inspection throughout the microneedle array fabrication process, including final product quality assessment. Additionally, the presentation addresses the critical inspection of medicinal coating—both its quantity and uniform distribution—which directly impacts product efficacy.

Key topics include sub-millimeter defect detection, inspection of reflective and translucent materials, management of product variability, and strategies to minimize false reject rates.

Real-world challenges such as variations in needle length, angular deviations, physical damage, incomplete tip formation, and surface contamination will be discussed, alongside hardware selection, optical design, and advanced illumination techniques.

Given the diversity of microneedle array types and their complex manufacturing and assembly processes, customized vision solutions are required to address unique inspection challenges.

4:05 *Close of Program*

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