

# Microneedle & Intradermal Delivery Forum 2023

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

September 18-19, 2023 Philadelphia PA

*Featuring Lessons Learned and Case Studies from Industry Experts:*



**Magdalena Kurzyp**  
Photosynthetic



**Ryan Donnelly**  
Queens College Belfast



**Alina Su**  
NovaXS



**Sebastian Scherr**  
LTS Lohmann AG



**Scott Lovald**  
Exponent



**Jessica Chiaruttini**  
ValSource



**Tim Peterson**  
Kindeva Drug Delivery



**Tom Lake**  
Vaxxas



**Roger Narayan**  
UNC/NCSU



**Waleed Faisal**  
University College Cork



**Elke Lipka**  
TSRL, Inc.



**Tanima Sinha**  
USDHHS/BARDA



**Hyungil Jung**  
Juvic/Yonsei Univ.



**Narasimha Murthy**  
Topical Products Testing



**Donna Bibber**  
Isometric Micro Molding



**Sebastien Henry**  
Micron Biomedical



**Sion Coulman**  
Cardiff University



**Michael Schrader**  
Vaxess Technologies



**Michael Eakins**  
Eakins & Assoc.

## With Comprehensive Coverage On:

- Glass Microneedles: A New Horizon for Intradermal Drug Delivery
- Latest Advances in Dissolvable Microneedle Technology for Drugs & Biologics
- Clinical Trial Updates—Lessons Learned and Paths Forward
- Needle-Free Injector as Cost-effective, Smart Drug Delivery Platform
- Microbiological Control for Active Transdermal Products: A Former Regulator's Perspective
- Microneedle Delivery Systems for Neurological Diseases
- Analysis of Skin Deformation and Puncture for Full Microneedle Arrays
- Microneedles for Diagnostic Assessment for Cystic Fibrosis during Sweat Testing
- Novel 3D Printing Techniques for Serial Production of Microneedle Patches
- Polymer Coated Polymeric (PCP) Microneedles for Controlled Delivery of Drugs
- Scaling It Up—Key Manufacturing Experiences and Challenges for MN arrays
- Key Regulatory Considerations for Microneedle Systems
- Identifying Critical Quality, Material and Design Attributes for MNs
- Key Formulation Considerations for Skin-Mediated Therapies and Vaccines
- And More!

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# MICRONEEDLE & INTRADERMAL DELIVERY FORUM 2023

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## Monday, September 18, 2023

7:00 *Registration Check-in and Complimentary Breakfast*

8:00 *Chairperson Michael Eakins' Welcome and Opening Remarks*



### Meeting Regulatory Challenges to MAP Products

8:05 **Microbiological Control for Active Transdermal Products: A Former Regulator's Perspective**



**Jessica Chiaruttini, PhD, Microbiology Consultant, ValSource, Inc. (Co-author Christine Craig, PhD, ValSource, Inc.)**

Microneedle and novel transdermal products have the potential to revolutionize the pharmaceutical marketplace and make a dramatic impact on global public health. Currently, there is minimal global guidance on microbiological requirements for these innovative drug products. Historically, the US Food and Drug Administration (FDA) has allowed clinical trials to proceed with both sterile and nonsterile novel transdermal products. While the FDA has expressed support for novel transdermal product development, in the absence of clear guidance from the agency it can be difficult for firms to navigate product development and establish appropriate controls for each stage of clinical trials. This lack of clear expectations leads to inconsistencies across the industry and slowed development of microneedle products. Essential product attributes and patient characteristics impacting sterility or low-bioburden approaches will be discussed along with case studies to highlight the scientific rationale required to support proposed microbiological controls and assure patient safety. Additionally, the most effective modes of regulatory communication will be presented to obtain product-specific information to help efficiently navigate the regulatory process in the US and globally. Finally, the presentation will propose potential industry driven paths to elicit official regulatory recommendations for microbiological product quality of microneedle products.

8:45 **Collaborative Development of the Regulatory Science for MAP Products: Test Methods and Guidance**



**Sion Coulman, Senior Lecturer, Cardiff University, & Co-Chair, Microneedle Array Patch (MAP) Regulatory Working Group**

As part of PATH's Microneedle Array Patch (MAP) Centre of Excellence, PATH and Cardiff University have partnered to co-chair a Regulatory Working Group (MAP-RWG), that aims to help guide and define the reg-

ulatory science for MAPs, in consultation with the MAP community and key stakeholders. Consultation activities with the MAP community have identified several workstreams related to the development of guidance and test methods for this emerging dosage form. This talk will provide (i) a general overview of progress against these workstreams and (ii) detail on the development of a test to exemplify MAP puncture performance, which has been identified as a critical quality attribute (CQA) of the dosage form that cannot currently be tested by simply adopting internationally recognised validated tests methods (e.g. in international Pharmacopoeia) for analogous products. We will describe how we have identified, developed and validated (using in vivo human data) a synthetic skin surrogate that has comparable compression properties to human skin, for use in a simple in vitro puncture performance test for finished MAP products.

9:25

### Manufacturing Microneedle Products for Regulatory Approval



**Tim Peterson, Director of Product and Process Development, Kindeva Drug Delivery**

Microneedle products have progressed to the pre-clinical and early human clinical stage by many developers, but few have made it to Phase 3 clinical studies or beyond. Kindeva Drug Delivery, with an extensive track record of partnering with pharma companies to develop and scale up drug delivery systems, submitting data packages, and most importantly, manufacturing marketed combination drug delivery products, provides recommendations for development of manufacturing, specifications, methods, and stability programs based on experience with its solid intradermal drug delivery platform. Manufacturing process scale-up with intention of regulatory submission follows a strategic path. It is critical to capture data, decisions, and key learnings into documentation which can be used in support of a design history file and future submission content. Documents should be raised at the time of data generation and cover topics such as, but not limited to, product development decisions, process development milestones, and device development choices. Likewise, methods and specifications mature during development. Data destined for regulatory submissions should be collected consistently over time. If a method changes, comparison data sets utilizing the two methods and the same set of samples should be generated in support of the change. When a testing site is added, documented training and passing method crossover results are documented. Site-to-site and/or analyst-to-analyst differences should be investigated and resolved. Specification setting is also an evolutionary process, with specifications growing more detailed and narrower as the development proceeds. On one hand, drug product manufacture becomes more reproducible with larger batches and automation. This is balanced by an increase in testing variability as additional instrument models, analysts, and sites are added. Production of stability data is often on the critical path and timeline. Working backwards, for example, data to support a

two-year shelf-life for raw materials and components for the drug product dictates that suppliers, materials, stability chambers and documentation systems must all be in place more than two years ahead of submission. The same is true for devices (including device design) and device component handling. For the device and drug portions, it is advantageous to make large batches early on, for entry into controlled chambers where they can age and be tested strategically. As microneedle delivery system technologies mature, manufacturing, specifications & methods, and stability will all play a significant role for the successful commercialization of this promising dosage form.

10:05 *Morning Networking & Coffee Break*

10:35 **How Can We De-Risk the MAP Technology to Make it Attractive for Pharmaceutical Companies?**



**Sebastian Scherr, Head of Process Development--MAP CDMO, LTS Lohmann Therapie-Systeme Ag**

Micro Array Patches (MAPs) are a drug delivery technology which has been known for at least two decades. Despite the advantages offered by the technology, there is no commercial product available on the market yet. A recently performed gap analysis by LTS revealed three major hurdles hindering access of the technology to the market:

- Lack of pre-clinical and clinical data, demonstrating the suitability of the MAP technology in general to address a clear unmet medical need.
- Lack of industrial experience and capabilities, showing that the technology can be manufactured in a GMP-compliant manner and is ready for commercialization.
- Unknowns in the regulatory pathway to commercialization and requirements of the regulatory authorities to be fulfilled.

We believe, those three points are the main obstacle because the pharmaceutical industry is still considering the MAP technology as explorative and not ready to enter the market. As presented at the Microneedle & Transdermal Drug Delivery Forum in 2022, LTS has tackled the lack of clinical data with our successful Hepatitis B vaccine study. In this year's presentation, we will focus on the remaining two points, GMP-compliant manufacturing, and regulatory considerations, which are essential to bring the MAP technology to the market. Some of the points LTS considers important for a commercialization of the MAP technology are:

- Consideration of GMP requirements, already at an early stage of development.
- Selection of regulatory compliant raw materials, excipients, and single-use-systems.

- "Speak the language of Pharma Industry" and manage their expectations in respect to quality.
- Scalability of the process.
- Transfer capability of the manufacturing process into an aseptic environment.
- Identify your critical quality attributes (CQA) and critical process parameters (CPP)
- Involvement of regulatory authorities at an early stage.

## Conference Keynote—The Promise of MNs for Various Neurological Diseases

11:15 **Microneedle Delivery Systems for Neurological Diseases**



**Ryan F. Donnelly, Chair, Pharmaceutical Technology, Queen's University Belfast**

Neurological diseases are notoriously difficult to manage. For example, in Parkinson's disease, gastrointestinal motility is often unpredictable, which means absorption of oral medication can be variable. In schizophrenia, patients are often not compliant with oral medication and long-acting injections are painful and require healthcare visits. Patients with Alzheimer's disease often forget to take their medication. Transdermal delivery would avoid inconsistent absorption in Parkinson's disease, avoid needles in schizophrenia and potentially enhance compliance in Alzheimer's disease. However, most drugs used to treat these conditions cannot be effectively delivered across intact skin. In this presentation, delivery of drugs for treatment of Parkinson's disease, schizophrenia and Alzheimer's disease using novel polymeric microneedle systems will be described. Formulation strategies, in vitro and in vivo evaluation will be discussed, with a focus on scaled-up manufacture and translation to the clinic.

12:00 *Complimentary Lunch, sponsored by*



1:10 **Advancements in Micro Molded Needles**



**Donna Bibber, CEO, Isometric Micro Molding, Inc.**

Microneedles have been in existence for decades. The use of microneedles as a transdermal drug delivery method has increased post-Covid due to its immediate and future use in self-administering vaccines and other shipment-ready medications. Polymer-based microneedles can be globally distributed and safely disposed of as opposed to stainless steel needles where melting foundries and safe disposal practices are required. Some time-lapse degradable polymer microneedles can be easily and safely disposed of, leading to a

global sustainability advantage as opposed to stainless steel microneedles where melting foundries and rigid disposal containers are required.

Micro injection molding methods result in single micron tip radius needles as well as specialized transdermal surfaces and continue to evolve and play a key role in scaling high volume, wearable and transdermal drug delivery devices. Advances in micro injection molding provide a scalable option for creating needle geometry, near metal sharpness, lumen sizes, and thin wall thicknesses. This presentation will discuss the benefits of micro injection molding for microneedles including:

- Sizes and features of micro molded needles
- Materials used in micro molding needles including thermoplastics, bioresorbables and silicone
- Density – micro needle spacing and aspect ratio
- Micro injection molded silicone needle arrays as used as disposable needle molds in inverse geometry

## Technology Spotlight—A Smart Device for Intradermal Delivery

1:40

### Needle-free Injector as Cost-effective, Smart Drug Delivery Platform



**Alina Su, Founder & CEO, NovaXS Biotech**

NovaXS is building an affordable needle-free drug delivery platform with patient-centric focus to improve efficacy and adherence, all at a cost lower than traditional parenteral delivery options. The platform includes a patient engagement app and physician on-line portal which provide a closed-loop patient-provider platform enabling improved medication adherence. This presentation will focus on the key benefits of the NovaXS platform, including:

- Improved efficacy: faster absorption time, lower dosage
- Superior safety: fewer injection-site adverse events, fewer administration errors
- Improved patient satisfaction
- Improved medication adherence
- Substantial cost savings (when compared to traditional delivery modes)

2:20

### Polymer-coated Polymeric (PCP) Microneedles for Controlled Delivery of Drugs



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

The dissolvable polymeric microneedles are micron size polymeric needles intended to dissolve in the tissue. The microneedles would disintegrate and immediately release the drug, polymer and other excipients used to construct the microneedles. The mate-

rials as well as the drug when dumped into the tissue could potentially cause skin irritation and sensitization particularly when applied to ocular or mucosal tissues. Therefore, to overcome the consequences of deposition of polymer and dumping of API in the tissue, the dissolvable microneedles were coated with polymers that are insoluble in skin interstitial fluid and forms a thin semi-permeable coating around the microneedles. The PCP microneedles were explored as a potential approach to deliver drugs into the back of the eye, mucosa and skin.

3:00

*Afternoon Networking & Coffee Break*

## Technology Spotlight—3D Applications for MN Manufacture & Parameter Specification

3:30

### A Novel Rapid Micro-3D Printing Technique for Serial Production of Microneedle Patches



**Magdalena Kurzyp, CBO, Photosynthetic**

During the past decade we have witnessed development of a number of materials and methods for fabrication of microneedle patches. Many of these methods face a common challenge: the need to achieve extremely small feature size, complex geometry, and cost-effectiveness all at the same time. We would like to present a novel method of rapid polymer-based 3D printing at the microscale. Our fabrication method enables cost-effective production of highly complex polymer-based needles in situations where the state-of-the-art mass-production methods are constrained in terms of the complexity and the resolution of the fabricated structures.

4:10

### Finite Element Analysis of Skin Deformation and Puncture for Full Microneedle Arrays



**Scott Lovald, PhD, MBA, Senior Manager Engineer, Exponent**

The mechanics of microneedle insertion have thus far been studied in a limited manner. Previous work has focused on buckling and failure of microneedle devices, while providing little insight into skin deformation, puncture, and the final positioning of needle tips under full microneedle arrays. The current study aims to develop a numerical approach capable of evaluating deformation and puncture conditions for full microneedle array designs. The analysis included a series of finite element submodels used to calibrate the microneedle-epidermal interface for failure properties using traction-separation laws. The single needle model is validated using experimental data and imaging, including results from a customized nanoindentation procedure to measure loads and displacements during microneedle insertion. Upon validation, full microneedle arrays are implemented in a 3D-finite element model and a design framework is developed, allowing evaluation of different design variables (i.e. needle shape, material, spacing) with respect to outputs relevant to successful microneedle perfor-

mance. Results from the model include skin deformation, force to puncture, penetration depth, and the punctured state at each microneedle tip. In addition to microneedle parameters, patient parameters such as subcutaneous tissue thickness are included to evaluate the sensitivity of different microneedle designs to expected patient and anatomical region variability.

4:50 **Happy Hour Mixer**

Join your colleagues in the hotel lounge for informal networking. A complimentary beverage & appetizers are provided.

**Tuesday, September 19, 2023**

7:00 **Complimentary Breakfast**

**Critical Issues—MAPs & Global Public Health Needs**

8:15 **From Crises to Innovation: Applications of Microarray Systems for Preparedness and Response**



**Tanima Sinha, Lead Interdisciplinary Scientist, US Department of Health & Human Services/ BARDA**

Within the U.S. government, U.S. Department of Health and Human Services, the Administration for Strategic Preparedness and Response (ASPR), and the Biomedical Advanced Research and Development Authority (BARDA) within ASPR were stood up to prepare for and respond to natural and manmade disasters. ASPR/BARDA invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermeasures (MCMs) – vaccines, therapeutics, diagnostic tools, and devices needed to respond to public health medical emergencies such as chemical, biological, radiological, and nuclear incidents; pandemic influenza; and emerging infectious diseases.

The BARDA Strategic Plan is built on four goals to fortify and strengthen national health security:

1. Enhancing PREPAREDNESS by investing in development of a robust pipeline of innovative MCMs
2. Embracing our role as an agile RESPONSE organization
3. Expanding and sustaining public-private PARTNERSHIPS
4. Continuing to invest in the organization's WORKFORCE

In implementing this plan, BARDA is investing in innovative technologies, such as microneedle arrays and microarray patches, to enhance the nation's capabilities to respond in a public health emergency by providing alternative routes of administration for vaccines and therapeutics and to expand access to lifesaving MCMs.

**Spotlight on Product Development—Lessons Learned from Preclinical Through Phase 1-2**

8:55

**A Five-Day Treatment Course of Zanamivir with a Single, Self-administered, Painless Microarray Patch (MAP): Maximizing Patient Reach and Compliance During Epidemic and Pandemic Flu Outbreaks**

**Elke Lipka, CEO, TSRL, Inc**



Yearly influenza epidemics strike millions of people, causing up to 500,000 deaths, with significant mortality in the young and the elderly populations. When a new pathogenic influenza strain enters the population, a pandemic could kill tens of millions of people. As a result of the ineffectiveness of the current vaccines, pharmacotherapy remains critically important. Currently, the use of small drug molecules to treat seasonal influenza is partly effective, with some strains exhibiting resistance to the neuraminidase inhibitor oseltamivir (Tamiflu®), and even the newly approved baloxavir marboxil (Xofluza®). However, while zanamivir (Relenza®) remains highly active against oseltamivir-resistant influenza strains, its therapeutic impact is severely limited by its route of administration, via oral inhalation, which renders it unsuitable for patients with a compromised respiratory system. Therefore, development of a novel delivery alternative for zanamivir is poised to address a significant unmet medical need. Transdermal delivery of zanamivir could allow large numbers of patients to be reached during an influenza outbreak. While zanamivir itself cannot cross the human skin barrier, MicroArray Patch (MAP)—enhanced transdermal delivery is an elegant, efficient, and painless method for increasing the skin permeation of the drug. Our novel drug-device combination product, TSR-066, consists of a swellable microneedle array, which has been shown in rats and minipigs to continuously deliver zanamivir from a specially formulated reservoir over 5 days. We have obtained agreement with the FDA on the preclinical studies needed to open the IND, as well as on the Phase I clinical development plans and the overall 505(b)2 regulatory strategy.

9:35

**Safety, Immunogenicity, and Acceptability of a Measles-Rubella Vaccine Delivered to Adults and Children by Dissolving Microneedle Technology**



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

Micron Biomedical, a leader in the field of microneedle technology, is a clinical-stage biopharmaceutical company developing drugs and vaccines that are formulated into a proprietary dissolving microneedle technology that simplifies and improves the way actives are delivered, stored, and distributed. With three clinical trials completed, one underway, and several in planning stages, Micron's technology is on a rapid path to commercialization.

In this presentation, we will review the results of the first-ever microneedle trial in children. In this Phase 1/2 trial, Micron's dissolving microneedle technology was used to successfully deliver a measles-rubella vaccine to adults, toddlers, and infants. Safety, immunogenicity, and acceptability results from the trial will be discussed.

10:15

*Morning Networking & Coffee Break*

10:45

**Vaccine Microarray Patch Self-administration: An Innovative Approach to Improve Pandemic and Routine Vaccination Rates**



**Tom Lake, Senior Vice President Vaccine Alliances, Vaxxas**

Vaxxas has the potential to impact the global vaccination market by replacing outdated needle technology with a vaccine microarray patch (HD-MAP) that delivers vaccinations more efficiently and effectively with reduced patient anxiety. Vaxxas HD-MAP can potentially improve the distribution of many vaccines on a global level, reaching those that typically don't receive vaccines due to cold chain issues. Clinical trials are showing effectiveness in dose sparing, which may increase the distribution of an in-demand vaccine into a population faster, potentially sparing lives.

11:25

**Phase I Clinical Results from MIMIX-Flu, a Patch-Based Influenza Vaccine Intended for Home Administration**



**Michael Schrader, Co-founder & CEO, Vaxess Technologies**

Vaxess is a venture-backed, clinical-stage company bringing healthcare out of the clinic with the MIMIX Smart Release patch platform. The MIMIX platform, developed at MIT, uses breakthrough immune-activating biology to enable best-in-class vaccines and immunotherapies in a shelf-stable, self-applied format. The company's lead program, a seasonal influenza vaccine, just read out strong Phase I interim results. The company will share an update on these results as well as future pipeline activities underway.

12:05

*Complimentary Lunch*

**Manufacturing Spotlight—Scale Up & Product Development**

1:15

**Glass Microneedles: A New Horizon for Intradermal Drug Delivery—A Case Study Using a Quality by Design Approach**



**Dr. Waleed Faisal, Project Manager, School of Pharmacy, University College Cork**

The ability of microneedles to deliver medications intradermally safely and effectively is likely to appeal to patients and clinicians. However, issues with low drug loading, sterility, scale-up, and biocompatibility of excipients have hampered their introduction to the marketplace as an alternative delivery system. In this regard, we identified an opportunity to develop an effective, polymer-free glass microneedle for intradermal treatment, ArrayPatch. ArrayPatch is a propriety wearable device with platform potential consisting of an array of sharp, but painless, dissolvable microneedles manufactured with 100% drug. Using a Quality by Design (QbD) approach to pharmaceutical product development, a quality target product profile (QTPP) and the critical quality attributes (COA) of ITZ-ArrayPatch are identified.



1:55

**The Latch Applicator: A Novel Applicator by Thumb Force for Efficient Dissolving Microneedle-Based Vaccination**



**Hyungil Jung, CSO and Founder, JUVIC Inc./ Professor, Yonsei University**

Dissolving microneedles (DMNs), while offering great promise in vaccine delivery due to their relative painless administration combined with safety from lack of medical waste, have undergone hindered development due to incomplete insertion leading to drug loss and insufficient administration. As a result, various DMN application methods to increase the insertion rate, such as weights, springs, and electromagnetic devices, have been studied. However, these applicators have complex structures that counteract the convenience of DMN and are often accompanied by high production costs. Hence, this presentation proposes a latch applicator, developed by JUVIC Inc., that consists of only simple plastic latches and operates via thumb force, eliminating the need of an additional supplementary device. Protrusion-shaped latches and impact distances have been optimized to accumulate thumb force energy of 25 N through elastic deformation and to supply impact velocity of 5.9 m s<sup>-1</sup> to fully insert the vaccine-loaded tip of the DMN into the skin. In an ovalbumin (OVA) immunization test, DMN with the latch applicator showed higher IgG antibody production rate (3.066 ± 0.329 µg/mL) as opposed to that of intramuscular (IM) injection (1.826 ± 0.293 µg/mL) despite OVA-IM being formulated with an alum adjuvant, indicating the promising nature of transdermal vaccination. Based on these results, JUVIC Inc. aims to further apply the latch applicator for various DMN-based vaccinations and offer a groundbreaking alternative of vaccine administration to conventional syringes.

2:35

*Afternoon Break*

2:50

**Additive Manufacturing of Microneedles for Sensing and Drug Delivery**



**Roger J. Narayan, Professor, UNC/NCSU Joint Department of Biomedical Engineering**

In this talk, I will describe my group's use of several laser-based additive manufacturing techniques to process microneedles for biosensing and drug delivery. For example, an additive manufacturing approach known as two photon polymerization has been used to polymerize photosensitive resins and obtain structures with small scale features. Polymerization of structures with microscale and nanoscale features using the two photon polymerization approach is possible since the two photon absorption process exhibits a nonlinear relationship with the incident light intensity. We have used two photon polymerization used to create several types of microneedles for transdermal delivery of drugs or transdermal sampling of body fluids. Application-specific testing of the additive manufacturing-produced materials and microneedles will be described.

3:30

*End of Program*





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