PharmaED RESOURCES, Inc.

Microneedle & Intradermal Delivery Forum 2024

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

September 17-18, 2024 Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

Tycho Speaker
AbbVie

Gülçin Arslan Azizoğlu
Georgia Institute of Technology

Ryan Donnelly
Queens University Belfast

Alan Stevens
AbbVie

James Birchall
Cardiff University

Jessica Chiaruttini
ValSource

Tim Peterson
Kindeva Drug Delivery

Tom Lake
Vaxxas

Elke Lipka
TSRL, Inc.

Sebastien Henry
Micron Biomedical

Nicky Bertollo
Pharma Latch

Narasimha Murthy
Topical Products Testing

Vijay Kudchadkar
Isometric Micro Molding

Jorge Capurro
Archimedic

Gyorgy Vas
Intertek

Michael Eakins
Eakins & Assoc.

Waleed Faisal
Array Patch, Ltd.

And Comprehensive Coverage On:

- Development of a User-informed, Long-acting Contraceptive Microneedle Product for Low Resource Settings
- Microneedle Array Patch Regulatory Working Group (MAP-RWG) Update
- Moving MAPS to Commercialization—Addressing the Challenges of Manufacturing
- Navigating Regulatory Expectations and Best Practices for Communications with Global Regulators During Product Development
- Case Study: Dissolving Microneedle Technology for Drug and Vaccine Administration
- Case Study Revolutionizing Delivery of Poorly Membrane-Permeable Therapeutics
- Development of a Microneedle Patch for Long-Acting Contraception
- Microbiological Control for Active Transdermal Products: A Former Regulator's Perspective
- Microneedle Delivery Systems for Neurological Diseases
- Pushing the Envelope: Driving Meaningful Innovation in LMIC Vaccine Delivery
- Microneedle Systems for Management of Infectious Diseases
- A Skin Patch for Improved Thermostability and Accessibility of mRNA Vaccines for All
- Ultra-Precision Tooling and Molding for Polymer Microneedles
- Novel Design Approaches in Microneedle-Mediated Drug Delivery
- Scaling It Up—Key Manufacturing Experiences and Challenges for MN arrays
- Identifying Critical Quality, Material and Design Attributes for MNs
- And More!

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Tuesday, September 17, 2024

7:30 *Registration Check-in & Complimentary Breakfast*

8:30 *Chairperson Michael Eakins' Welcome and Opening Remarks*

The Regulatory Landscape for Microneedle Arrays

8:35 **Navigating Regulatory Expectations and Best Practices for Communications with Global Regulators During MN Product Development**

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

Sterile and nonsterile pharmaceutical products are routinely manufactured using a limited number of manufacturing processes. These processes are well-established and the installation, qualification, and validation of the equipment is published by industry organizations, standards associations, and regulatory guidance documents. However, in many cases the development of microneedle-based products requires deviation from these established practices as the scale and design of the final product requires different equipment and controls. The successful commercialization of a product requires scientific rigor, careful regulatory planning, collaboration, clear communication, and flexibility to bring novel products to market in a timely (or sometimes not so timely) manner. While the scientific basis of published information may be transferrable to microneedle products, there is little public information available to guide the development of alternate approaches. All global regulatory agencies allow deviations from traditional practices with adequate supporting data and scientific or risk-based justification. Navigating the regulatory process and preparation of supporting documents can be challenging. This presentation will cover an ex-regulator's experience with successful, and unsuccessful, approaches to support novel product/process development as it relates to the establishment of novel processes and controls for pharmaceutical products. Several case studies will be presented to demonstrate how unique products and processes were assessed for quality and patient safety to allow for innovative approaches for ensuring critical quality attributes are achieved. This presentation will also provide tips and best practices for how to successfully communicate with regulatory bodies prior to commercial filing of microneedle product applications.

9:15 **Essential Drug Delivery Outputs for Transdermal Drug Delivery Devices**

Alan Stevens, Regulatory Global Head of Complex Devices and Drug Delivery Systems, AbbVie

Abstract Coming Soon

9:55 *Morning Networking & Coffee Break*

Conference Keynote—The Promise of MNs for Various Infectious Diseases

10:25 **Microneedle Systems for Management of Infectious Diseases**

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

Since the first patent for microneedles, or micro array patches (MAPs), was filed in the 1970s, research on utilizing MAPs as a drug delivery system has progressed significantly, evidenced by the transition from the simple 'poke and patch' of solid MAPs to the development of bio responsive systems such as hydrogel-forming and dissolving MAPs. In addition to the extensive research on MAPs for improving transdermal drug delivery, there is a growing interest in using these devices to manage infectious diseases. This is due to the minimally invasive nature of this drug delivery platform which enable patients to self-administer therapeutics without the aid of healthcare professionals. This presentation will provide a critical analysis on the potential utility of MAPs in managing infectious diseases which are still endemic at a global scale. The range of diseases covered in this review include tuberculosis, skin infections, malaria, meticillin-resistant Staphylococcus aureus infections. These diseases exert a considerable socioeconomic burden on a global scale, with their impact magnified in low- and middle-income countries (LMICs). Due to the painless and minimally invasive nature of MAPs application, this technology also provides an efficient solution not only for the delivery of therapeutics but also for the administration of vaccine and prophylactic agents that could be used in preventing the spread and outbreak of emerging infections.

11:10 **Identification of Two Key Biological Quality Attributes of Microneedle Patches**

Waleed Faisal, Founder/CEO, Array Patch, Ltd.

Abstract: Microneedles (MN) incorporate numerous variables compared to traditional dosage forms, necessitating the application of Quality by Design (QbD) principles as outlined in ICH Q8(R2). Implementing these guidelines enables drug developers to identify the QTPP and CQAs of MNs. This study focuses on two key biological quality attributes: quantifying the delivered dose through in vivo pharmacokinetic profiling of MN patches versus standards and testing topical efficacy in vivo in humans.

Current literature predominantly features microneedle formulation studies that either do not assess in vivo bioavailability, relying solely on in vitro data, or use rat models, which are poor predictors of human intradermal bioavailability. Alternatively, pigs offer a suitable model due to anatomical and physiological similarities to hu-

man skin. Our team developed a unique jugular vein cannulation procedure via the ear vein in pigs to study the in vivo pharmacokinetics of microneedles.

While human in vivo testing is the gold standard for assessing topical efficacy, it is often impractical for novel formulations. Thus, we seek experimental models that closely mimic human skin. Our team evaluates in vitro 3D full-thickness skin equivalents (ftSE) as an ethical, innovative alternative to animal models. These models allow for both destructive and non-destructive endpoints post-patch application, including morphology and tissue viability, macroscopic imaging, cellular glucose consumption and lactate production (indicative of metabolism), and intracellular lactate dehydrogenase (LDH) to assess cell membrane integrity and viability.

11:50 *Complimentary Lunch*

Technology Spotlight—Scaling It Up for Commercial Success

1:00 **Moving MAPS to Commercialization—Addressing the Challenges of Manufacturing**

Tim Peterson, Associate Director, Product and Process Development, Kindeva Drug Delivery

The technological promise and the potential of microneedle array patches (MAPs) to provide improved therapies and vaccination are well established. However, the pathway from the laboratory and preclinical feasibility to regulatory approval is daunting for an emerging dosage form like MAPs. In addition to all the effort required to demonstrate safety and efficacy, there remain the challenges of process development, scale-up, and validation of processes capable of supporting commercialization of these highly specialized products.

Many MAP innovators invest heavily (in time and money) to develop the necessary product attributes but defer developing the associated processes (particularly at scale). Some may not have the in-house expertise, nor the business strategy, to perform all the needed scale-up and manufacturing activities.

In that case, what are the important selection criteria for identifying the right contract development and manufacturing organization (CDMO)? What are the critical capabilities to look for when it comes to the scale-up and manufacture of a microneedle array patch product? At what stage of development should the search for a CDMO take place and when should collaboration begin? These questions and other considerations related to tech transfer and scale up at a CDMO will be discussed.

1:40 **Novel Design Approaches in Microneedle-Mediated Drug Delivery**

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

Microneedles have evolved in terms of their design over the last two decades to be able to perform lots of different applications. The dissolving microneedles are made of soluble polymers and are intended for rapid delivery. The dissolving microneedles are modified using materials with special attributes to render them useful for sustained release, sampling of biomarkers, and use as sensors. The microneedles are combined with physical forces such as magnetism and electric field to enable the delivery of drugs and macromolecules to target sites at therapeutically relevant rates and extent. Various novel microneedle design approaches and corresponding novel applications will be discussed in this presentation.

2:20 *Afternoon Networking Break*

2:50 **Enabling a New Era of Intradermal Delivery**

Nicky Bertollo, CTO & Co-founder, Pharma Latch

Pharma Latch is developing a series of HCP and self-administration intradermal delivery devices based on the Latch platform of opposing angled hypodermic needles. Traditional intradermal delivery methods fail to overcome the biomechanical properties of the skin which are inherently resistant to needle puncture. As a result, issues such as poor/inconsistent needle-insertion efficiency, inconsistent dose-delivery, and administration difficulty are common. The Latch platform manipulates the biomechanical properties of the skin, enabling:

- consistent needle penetration depths that are a function of the device, not the user
- complete dose delivery
- very low injection pressures, reducing spray-back and leakage
- high volume/viscosity capabilities
- improved injection distribution

Under manufacture in the USA as a medical device on a FDA 510K pathway, the Pharma Latch Hollow is available now for preclinical work and clinical trials early next year. This talk will provide an overview of product development efforts, supply chain and manufacturing, as well as supporting scientific data.

Critical Issues—Spotlight on Contraceptives for Low Resource Populations

3:30 **Development of a Microneedle Patch for Long-Acting Contraception**

Gülçin Arslan Azizoğlu, PhD, Research Scientist II and Associate Director of the Laboratory of Drug Delivery, Georgia Institute of Technology

Despite advancements in contraceptive methods, nearly half of all pregnancies worldwide remain unplanned, highlighting an urgent need for better contraception options. Our group has been working on a new contraceptive technology using microneedle (MN) patches designed to enable long-term contraception, facilitate good patient access and compliance through self-administration, and offer low-cost solutions suitable for global use. Our efforts are underway to develop the long-acting contraceptive MN patch for human clinical trials, aiming for future use in clinical medicine and public health. This talk will highlight considerations and our efforts on achieving six-month contraceptive delivery with MN patches in terms of formulation, delivery of human dose, skin penetration and detachment, sterilization as well as the stability and acceptability/tolerability of the MN patches.

4:05 **Development of a User-informed, Long-acting Contraceptive Microneedle Product for Low Resource Settings**

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

The EMBED consortium, led by Cardiff University and funded by the Bill & Melinda Gates Foundation, have been developing a long-acting hormonal contraceptive suitable for low-and middle-income countries (LMICs) for the last 6 years. The product comprises biodegradable microneedles containing contraceptive and a simple, discreet, cost-effective and self-administrable applicator device with a design informed by both human factors studies in LMICs and in silico modelling. Preclinical studies have demonstrated complete and reliable delivery of the microneedles with a release profile relatively comparable to a commercial reference product, with no local or systemic tolerability issues. The project has now transitioned to lead candidate development, where product manufacturing and performance challenges are de-risked in advance of pivotal GLP-compliant preclinical studies and first-in-human testing. Cardiff University are also co-chairs of the Microneedle Array Patch Regulatory Working Group (MAP-RWG) and an update on the regulatory science of MAP products will be provided.

Panel Discussion

4:45 **MAPs & Global Health Needs**

Moderator: Dr. Michael Eakins, Eakins & Associates




Panelists:

Gülçin Arslan Azizoğlu, Georgia Tech

James Birchall, Cardiff University

Tycho Speaker, AbbVie

Discussants:

The Audience

Wednesday, September 18, 2024

7:15 ***Complimentary Breakfast***

Critical Issues—Solving the Supply Chain Problem

8:15 **Pushing the Envelope: Driving Meaningful Innovation in LMIC Vaccine Delivery**

Tycho Speaker, PhD, Senior Principal Research Scientist, AbbVie

Vaccination is among the most effective and vital interventions available to Global Health, and can be particularly impactful in Low- and Middle-Income Countries. Microneedle Array Patch (MAP) delivery offers a range of potential advantages that are in many ways well-matched to LMIC needs, yet progress has been slow. The MAP community has been highly innovative in producing delivery systems, but now must target the true bottlenecks of the supply chain to make meaningful gains.

9:00 **A Five-day Treatment Course of Zanamivir With a Single, Self-administered, Painless Microarray Patch (MAP): Revolutionizing Delivery of Poorly Membrane-Permeable Therapeutics**

Elke Lipka, President & CEO, TSRL, Inc.

Seasonal influenza virus infections cause a substantial number of deaths each year. While zanamivir (ZAN) is efficacious against oseltamivir-resistant influenza strains, the efficacy of the drug is limited by its route of administration, oral inhalation. Here we present the development of a hydrogel-forming microneedle ar-

ray (MA) in combination with a ZAN reservoir in a patch (MAP) for treating seasonal influenza, TSR-066. Our work to date has demonstrated that ZAN can be delivered over a five-day treatment course maintaining efficacious levels projected for humans. We have successfully developed and scaled-up the manufacturing of the drug free MAs, the ZAN reservoir formulation and have selected an application approach. TSR-066 delivers ZAN with a bioavailability of more than 60%, and the novel formulation approach has resulted in a PCT filing for this product candidate. The Phase 1 PK proof-of-concept and safety trial design has been finalized and the study will commence in 2H25. In addition, the regulatory strategy for the ZAN MAP development has been further refined and was discussed with the Emerging Technology team at the FDA. With reaching these important development milestones for the hydrogel-forming MA, we have also enabled the rapid development of follow-on products, predominantly therapeutics with poor membrane permeability, to bring this platform technology to its fullest potential.

9:45 *Morning Networking & Coffee Break*

Spotlight on Vaccine Product Development—Lessons Learned from Phase 1-2

10:15

Dissolving Microneedle Technology for Drug and Vaccine Administration

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 others in planning stages, Micron's technology is on a rapid path to commercialization. In this presentation, we will provide an overview of Micron's technology, discuss the status of ongoing programs, and steps taken by Micron to close the commercialization gap.

11:00

A Skin Patch for Improved Thermostability and Accessibility of mRNA Vaccines for All

Tom Lake, Senior Vice President, Strategic Alliances & Commercialization, Vaxxas

mRNA vaccines can play an important role in rapid response to pandemics and other disease outbreaks. Rapid and equitable access to mRNA vaccines is essential to reduce morbidity and mortality, especially in underserved or hard-to-reach communities, and to reduce the global spread and impact of disease. Cold chain requirements and the need for skilled administration are significant factors in this accessibility divide.

Vaxxas has developed a high-density microarray patch (HD-MAP) and associated vaccine formulation and manufacturing technology that has been proven in Phase 1 studies to effectively deliver a variety of vaccine types (e.g., seasonal influenza, measles rubella, subunit proteins) that can be stored at temperatures up to 40°C for extended periods of time – in some cases, over a year. This eliminates or reduces the need for cold chain in shipping and storage, reducing the cost and complexity of providing vaccines. The HD-MAP delivers dried vaccine material directly into the epidermis and upper dermis, which in many cases enables a lower dose of vaccine compared to intramuscular formulations. The device is easy to use by minimally trained administrators. Here we will share new data demonstrating improved thermostability of mRNA encapsulated in several LNP formulations on the HD-MAP, ranging from 2-8°C to 40°C conditions. The approach to formulation screening, liquid dispensing using a novel process technology, and drying of mRNA formulations will be described, along with methods used to assess quality. We will also share preclinical data demonstrating in vitro protein expression, in vivo uptake, and immune response to an HD-MAP delivered model influenza mRNA antigen. Based on these foundational data, an mRNA vaccine candidate has been selected to advance into a Phase I clinical program. This platform approach can be applied to other antigens and LNP formulations, supporting CEPI's "100 days" target and general mRNA vaccine development.

11:45 *Complimentary Lunch, Sponsored by*

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Technology Spotlight—Polymeric Microneedles

12:50

Ultra-precision Tooling and Molding for Polymer Microneedles

Vijay Kudchadkar, Director of Business Development and Innovation, Isometric Micro Molding, Inc.

Microneedles offer significant advantages in numerous applications including biosensing, fluid extraction and medical drug delivery. Their micro size allows for precise and minimally invasive delivery, reducing patient discomfort and the risk of tissue damage. While microneedles can be made from a variety of materials such as silicone, ceramics, metals, this presentation will focus on polymer microneedles.

Thermoplastic materials provide excellent mechanical strength and compatibility with a wide range of drugs, ensuring efficient delivery. Polymer microneedles offer versatility in design and manufacturing, enabling

customized solutions for specific drug delivery needs, ultimately improving patient compliance and treatment outcomes. In addition, when delivering a drug from inside the body, bioresorbable thermoplastic needles will dissolve safely within the body, eliminating the need for needle removal and reducing the risk of infection.

Injection molding polymer needles presents notable challenges due to their thin-wall sections, sharpness, and delicate annular sections. In this presentation, Isometric will demonstrate how ultra-precision innovative tooling and molding techniques have overcome these obstacles - by pushing the boundaries of conventional injection molding and successfully manufacturing microneedles with geometries previously considered unattainable. This breakthrough opens new avenues for precise and efficient drug delivery, underscoring the transformative potential of polymer microneedles in advancing medical care.

1:20 **Extractable and Leachable Testing of Transdermal Delivery Systems (TDS)—What is Special About Microneedle Systems? Regulatory Aspects and Practical Considerations for Testing**

Gyorgy Vas, PhD, Business-Technical Scientific Liaison, Intertek, USA

Transdermal drug delivery systems are relatively complex pharmaceutical products. The formulations typically contain multiple excipients along with a dermal contact adhesive. The performance of the delivery systems depends on the quality of the dermal adhesive and the formulation, which delivers the drug on a pre-determined rate.

2:05 ***Afternoon Break***

The dermal delivery route is increasingly popular, since the effect of the delivered drug can be localized, which may reduce the systemic side effects. However, since the formulation has extended contact time and the drug is delivered with excipients, degradation products and packaging related components can also be "delivered" with the same route of administration.

Extractable testing of transdermal systems is straightforward and does not require "out of box" thinking. Leachable testing requires more complex approaches, as a skin exposure have to be simulated with a solvent and in addition, the regulatory expectation is to test the finished products with biologically relevant extraction media.

2:20 **The Development Journey of an Intradermal Delivery System Packaged with an Ampoule**

Jorge Capurro, Director of Drug Delivery, Archimedic

Archimedic is developing a novel intradermal delivery system designed to mitigate known microneedle technology challenges with drug storage stability, dosing inaccuracies, and complex manufacturing. The easy-to-use delivery system incorporates the following: (1) an ampoule as the primary container that can provide lasting stability of the drug, (2) a mechanism for breaking the ampoule, (3) a filter to isolate glass particles from the drug injection, (4) a mechanism to enable the diffusion of the drug, (5) a microneedle array for intradermal delivery, and (6) an adhesive patch. This presentation will provide an overview of the development efforts from concept through feasibility phases and next steps.

3:05 ***Close of Program***

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