Microneedle & Transdermal Delivery Forum 2022
Advanced Design, Development and Delivery of Skin-Mediated Therapies and Vaccines
September 13–14, 2022 Philadelphia PA

Featuring Lessons Learned and Case Studies from Industry Experts:

And Comprehensive Coverage On:

- Latest Advances in Dissolvable Microneedle Technology for Drugs & Biologics
- Key Considerations for Microneedle and Microarray Patch Development
- Scaling It Up—Key Manufacturing Experiences and Challenges for MN arrays
- Key Regulatory Considerations for Microneedle and Transdermal Systems
- Identifying Critical Quality, Material and Design Attributes for MNs & TDDs
- Key Formulation Considerations for Skin-Mediated Therapies and Vaccines
- In Vitro Permeation Testing of Dermal Products
- Why IVPT—and Not In Vivo?
- In Vitro Release Test (IVRT): Principles and Applications
- Evaporative Metamorphosis in Topical Products
- Delivering Biologics Using Oral Devices—An Overview
- Dissolving Microneedle for Advanced Alopecia Treatment
- Laser-based Manufacturing and Coating of Microneedle Devices
- Clinical Development and Manufacturing of the First Sustained-Release, Patch-Based Influenza Vaccine
- And More!

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Tuesday, September 13, 2022

8:00 Why IVPT—and Not In Vivo?
Dr. Howard Maibach, Professor of Dermatology, School of Medicine, University of California, San Francisco

Prior to the late 1960s-conventional wisdom suggested that the human skin was impermeable to most chemicals/drugs—as the chemical analytics at the time suggested the same—i.e., limited sensitivity. With the advent of post-World War II chemistry, the opposite turned out to be the case. Today in vivo penetration data documents that many drugs are absorbed up to 500 Daltons—and some up to 800—through the skin. The presentation will analyze the similarities and differences in flux-comparing IVPT to in vivo data, allowing the investigator to choose the system most relevant for their regulatory and clinical needs.

8:40 In Vitro Release Test (IVRT): Principles and Applications
Dr. Vinod Shah, Founder, VPS Consulting, LLC

In vitro drug release test has become one of the most important tools for drug development and approval process of semisolid dosage forms. In vitro release reflects the combined effects of several physico-chemical characteristics, particle or droplet size, viscosity, microstructure arrangement of the matter and state of aggregation of dosage form. Principles of IVRT and its rank order relationship with vasoconstriction and DPK results and test requirements for regulatory approval will be highlighted.

Determining the bioequivalence of topical drug products is challenging, complicated and cumbersome. Topical Drug Classification System (TCS), based on established scientific principles of SUPAC-SS and in vitro release (IVR) has been developed to simplify regulatory pathway for generic topical drug approval. TCS classification is similar to well-established Biopharmaceutics Classification System (BCS). The TCS system along with evolving concept for topical dermatological drug products from Q1, Q2, Q3 sameness to Q1, Q2, Q3 similar allowing greater permissiveness in formulation will be discussed. Validation of TCS concept using Acyclovir 5% cream products will be presented. TCS simplifies the regulatory requirements and reduces the regulatory burden, maintains drug product quality and increases the availability and affordability.

9:20 Advanced Harmonization Techniques Result in Accurate Establishment of In Vitro–In Vivo Relationships for Drug Permeation from Complex Dermal Formulations
Audra Stinchcomb, Professor/CEO, University of Maryland/F6 Pharma

Abstract coming soon

10:00 Morning Networking & Coffee Break

10:30 Evaporative Metamorphosis in Topical Products
S. Narasimha Murthy, CSO, Topical Products Testing, LLC

Topical products may lose the solvents and volatile components at the site of application leading to several changes in their composition and characteristics. The drug concentration can change, leading to changes in the degree of saturation. The key quality attributes such as pH, viscosity, globule size and particle size can undergo significant changes over time due to the loss of solvents. The interplay between all the changes in the degree of saturation and the key quality attributes impacts the bioavailability of drugs from a topical product. This presentation will discuss the process of metamorphosis, the potential changes in the key quality attributes and degree of saturation of drug and its impact on performance of topical products in case of APIs with different physicochemical properties.

11:10 Role of Skin Penetration and Permeation Enhancers in Drug Delivery
Jasmine Musakhanian, Scientific & Marketing Director, Gattefossé USA

A wide range of excipients have been referenced in the literature as enhancers for drug penetration and permeation to/via the skin. Selection of the right enhancer requires attention to safety followed by the efficacy of the excipient(s) used. Although the efficacy of the excipient and formulation system are ultimately defined by the clinical end point, it is imperative for the development scientist to define and demonstrate the mechanism(s) of action for every component of the delivery system. To this effect, the enhancer efficacy needs to be defined and decrypted by the mechanism(s) by which enhancement occurs: the chemistry, concentration, and function of an enhancer(s) vis-à-vis the formulation system, the skin structures, and formulation metamorphosis post application. This presentation delves into the key mechanisms of enhancement by type of excipient/drug chemistry, concentration, and formulation type.

11:50 Complimentary Lunch
1:15

**Conference Keynote—The Promise of Crosslinked Polymer MN Arrays**

*Ryan F. Donnelly, Chair, Pharmaceutical Technology, 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, the utility of these hydrogel-forming microneedles for sustained delivery, for up to 14 days from a single patch application will be described, with applications in infectious diseases, schizophrenia, HIV treatment and cardiovascular disease all discussed in depth.

1:55

**Micro Transdermal Interface Platforms (MicroTIPs) for Minimally Invasive Drug Delivery**

*Conor O’Mahony, Principal Scientist, Tyndall National Institute, Ireland*

Arrays of hollow microneedle arrays will ultimately be integrated with microelectronic technologies such as miniaturized actuators, power sources, control electronics, embedded sensors and wireless communication protocols. The resultant microdosing platforms, that we refer to as Micro Transdermal Interface Platforms (MicroTIPs), will have patch-like form factors and will unobtrusively interact with the body for applications in transdermal drug delivery and diagnostics. High-performance micropumps will play a key role in these microneedle-based systems. However, since MicroTIPs technology will facilitate a level of closed-loop fluidic control that is not currently available with conventional delivery devices, it is crucial to have a deeper understanding of the strategies needed to optimize delivery of therapeutic agents via the microneedle/micropump route. This talk highlights the potential use of micropump-microneedle assemblies for transdermal drug delivery, and the opportunities and challenges associated with these closed-loop infusion systems.

2:35

**Laser-based Manufacturing and Coating of Microneedle Devices**

*Roger Narayan, Professor, Joint Department of Biomedical Engineering, University of North Carolina and North Carolina State University*

In this presentation, the use of laser-based methods such as two photon polymerization and matrix assisted pulsed laser evaporation for microneedle manufacturing applications will be considered. For example, the use of two photon polymerization for manufacturing of microneedles out of photosensitive polymers (e.g., acrylate-containing materials) and organically-modified ceramic materials will be described. In addition, the use of matrix assisted pulsed laser evaporation for coating the surfaces of microneedles will be considered. Biological and functional studies involving laser-processed microneedles will be reviewed. Appropriate steps in the development of laser methods for commercially scalable manufacturing will be discussed.
5:00 Happy Hour Mixer, sponsored by GATTEFOSSÉ

7:15 Complimentary Breakfast

8:00 Pandemic Perspective: Considerations for Scalable, Market-appropriate Microneedle Products for Mass-vaccination and Global Health

Tycho Speaker, Director, Drug Delivery & Biomaterials, AbbVie

The COVID-19 pandemic has profoundly impacted all of our lives in myriad ways, calling to the forefront yet again the needs that are so often discussed at this conference. Nevertheless, the user needs driving product configurations for different patient groups, cultures, and economic contexts are very different. This talk attempts to consolidate previous work in the field and to put forth some principles that may be of service as we work to develop platforms adaptable to both high-income as well as low- and middle-income countries.

9:20 PATH's Microarray Patch Center of Excellence

Collrane Frivold, Technical Officer, PATH

The goal of PATH’s Microarray Patch (MAP) Center of Excellence (CoE) is to advance the MAP technology platform to transform delivery of vaccines and essential medicines for diseases of global health importance. PATH’s dual approach aims to develop MAPs as an innovative delivery technology platform and for specific priority applications for the diseases and use cases that have the greatest impact in low-resource settings. Through the MAP CoE, PATH collaborates with global stakeholders and partners to develop well-informed target product profiles, support technical development, advance manufacturing processes, clearly articulate the business case and public health value proposition, and create regulatory pathways for MAPs. Recently, PATH has been preparing for clinical trials of measles-rubella vaccine MAPs; understanding the potential role of MAPs in COVID-19 response; and progressing the regulatory pathway through the Regulatory Working Group.

9:40 Strategic Partnerships for Microarray Patch Development

Tanima Sinha, Lead Interdisciplinary Scientist, Influenza & Emerging Diseases Division, BARDA, US Department of Health & Human Services

Within the U.S. government, Department of Health and Human Services, Administration for Strategic Preparedness and Response, the Biomedical Advanced Research and Development Authority (BARDA) invests in the innovation, advanced research and development, acquisition, and manufacturing of medical countermea-
sures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to respond to public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks; pandemic influenza (PI), and emerging infectious diseases (EID).

The new BARDA strategic plan, released in May 2022, is built on four strategic 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

Within Goal 1, Objective 1.3, BARDA intends to support the development and commercialization of alternative delivery technologies that will reduce the need for cold chain distribution and manufacturing of needles and syringes, with the goal of having at least one alternative vaccine delivery/administration product FDA-licensed and integrated into a vaccine.

Although there are several technologies that offer alternatives to traditional needles and syringe administration of vaccines, BARDA is currently focusing on microarray patch (MAP) technology. Vaccine (antigen) technology could include recombinant, whole inactivated or nucleic acids, and may include adjuvant if required to mount a more robust immune response. BARDA is interested in supporting innovative technologies like microarray patches to expand access to life saving vaccines, especially for pandemic mitigation.

9:40 Impact and Challenges of Developing Microneedle Array Patches to Advance Immunizations in Global Health

David K. Robinson, PhD, Deputy Director, Vaccine Development, The Bill and Melinda Gates Foundation

Vaccines represent one of the most impactful medical advances with billions of doses delivered and tens of millions of lives saved. Vaccination with measles vaccines alone has prevented more than 15 million deaths in the past 20 years. Improvements in delivery of measles vaccines could result in the prevention of an additional hundreds of thousands to million infant deaths in the next 20 years. Based on these needs, the foundation conducted a careful assessment of delivery technologies and identified MAPs as potentially one of the most impactful improvements in delivery of measles vaccine. The author will review this assessment and highlight both the impact and challenges associated with development and deployment of MAPs for measles vaccination campaigns.

10:00 Morning Networking & Coffee Break

10:30 Delivering Biologics Using Oral Devices—An Overview

Ester Caffarel-Salvador, PhD, Associate Director, Strategic Innovation, Rare Diseases at Chiesi USA

Biologics have revolutionized disease treatment. However, their rapid degradation and poor absorption in the gastrointestinal (GI) tract generally limit their administration to injection delivery methods. This talk will review the landscape of oral devices designed to selectively target different organs of the GI tract to deliver biologics.

11:10 The Top Challenges (and Solutions) to Develop and Commercialize Intradermal Drug Delivery Devices

Lisa Dick, MTS Technology Platform Leader, Kindeva Drug Delivery

Commercial intradermal drug delivery is a long-standing goal and many new technologies are being developed to address it, but few have overcome the development and manufacturing challenges to enable mainstream and cost-effective implementation. Kindeva’s microstructured transdermal systems are designed to meet the market needs and have not only been through benchtop, preclinical, and human clinical evaluation, they are also manufactureable at scale. Development expertise will be shared regarding: microstructured arrays, adhesives, scale-up, analytical methods, design, sourcing, packaging, quality, and regulatory pathway considerations. Real-world learnings in the form of short case studies will be reviewed and recommendations from the viewpoint of an experienced drug delivery systems expert will be provided.

11:50 Complimentary Lunch

12:55 Clinical Development and Manufacturing of The First Sustained-Release, Patch-Based Influenza Vaccine on the MIMIX Platform

Michael Schrader, Co-founder & CEO, Vaxess Technologies

Vaxess is developing the MIMIX™ sustained release patch technology, originally conceived at MIT and Tufts University. MIMIX™ uses the unique qualities of silk proteins and breakthrough immune activating biology to enable best-in-class vaccines. Vaxess has raised more than $60M in grant and venture capital funding from groups such as The Engine, BARDA, DARPA, NIH, NSF and the Gates Foundation.
Recent studies have shown that modulating the kinetics of antigen presentation to mimic those of a natural infection can drive more potent and broadly protective immune responses (Cirelli et al., Cell 2019). To achieve sustained vaccine delivery, Vaxxas has developed a microneedle patch composed of silk tips (MIMIX) encapsulating antigen and a dissolving base (Stinson et al., Vaccine 2021). Upon application, silk microneedle tips are implanted in the dermis and slowly deliver antigen over two weeks. Using the MIMIX platform, Vaxxas is developing a more broadly protective influenza vaccine that is shelf-stable and easily administered.

A Phase 1 proof-of-concept trial of this first program, MIMIX-Flu, is underway in 2022. To support this program, Vaxxas conducted a number of key development efforts, including the construction of a wholly-owned GMP Pilot Manufacturing facility, establishment of an in-house quality system, development of 27 different release assays, and successful completion of a wide range of pre-clinical safety, toxicity, and immunogenicity studies. This talk will present an overview of the product and the development efforts required to support clinical entry.

Opportunities & Challenges for Commercializing Microarray Patches for Vaccination from a MAP Developer’s Perspective

Tom Lake, SVP, Strategic Alliances and Commercialization, Vaxxas

Continued advances in microarray patch (MAP) technology are starting to make needle-free delivery of a broad range of vaccines an achievable goal. The drivers and potential benefits of a MAP platform for pandemic response and routine vaccination are clear and include dose-sparing, cold-chain elimination, increased safety, and potential self-administration. MAP technology is regarded as a priority innovation to overcome vaccination barriers, ensure equitable access, and improve effectiveness of vaccines. Vaxxas, a global leader in this technology, has built a strong evidence-base for the commercial application of their (HD) MAP platform, and is rapidly advancing scale-up of the manufacturing process for HD-MAPs. A greater awareness and understanding of the implications of the technology amongst supply-chain participants, regulatory authorities, and global healthcare organizations and foundations is needed to accelerate adoption and, particularly, to prepare for MAP use in pandemics. Key challenges remain in the commercialization of MAP technology and its adoption, including market acceptance, scale-up of production, regulatory approval, and the availability of capital to build advanced manufacturing infrastructure ahead of late-stage clinical trials.

Panel Discussion

Meeting Regulatory Challenges to Intradermal & Microneedle Product Development

Moderator: Michael Eakins, Eakins & Assoc.

Panelists:
- Tycho Speaker, AbbVie
- Lisa Dick, Kindeva Drug Delivery
- Michael Schrader, Vaxxas
- Tom Lake, Vaxxas

Discussants: The Audience

Afternoon Break

Manufacturing Spotlight—Scale Up & Product Development

Dissolvable Microarray Patches – A Versatile Dosage Form Ideal for Delivering Biologics

Dr. Frank Theobald, Managing Director, MAP-Program, LTS Lohmann Therapie Systeme AG

Developing alternative dosage forms for biologics has widely known challenges. Due to the low oral bioavailability and blocked for transdermal passage by the Stratum corneum the prominent delivery form is an injection. Despite advancements in the field of injections, key challenges remain. Typically, health care professionals must do the treatment or are involved in the treatment. Even if the product allows self-treatment, injections are painful and the solutions and prefilled syringes in many cases are requiring storage and transport in a cool chain. For the past decade, innovation in microneedles has been a focus within the pharmaceutical world. Today, microneedles are seen as a viable option for the delivery of drugs such as biologics and difficult-to-deliver small molecules through the skin, in both immediate-release and long-acting products. The widely recognized benefits of transdermal administration in terms of pharmacokinetics, pain-free delivery, convenience, and patient compliance, make microneedles an ideal platform for an increasing number of therapeutic areas. In the introduction of the presentation, you will get an insight into the options of transdermal applications. A brief comparison of a variety of transdermal application including injection systems will provide a better understanding of problems faced while using such system. In addition to current designs and compositions we will investigate the development, manufacturing, and analytical testing of dissolvable microarray patch systems. The final part of the presentation will include in-house case studies with a focus on biologics and the unique challenges faced during the development and manufacturing.
3:35 Clinical Development of a Fully Dissolvable Micro-Array Technology for the Simple Administration of Drugs and Vaccines
Sebastien Henry, MS, MBA, Vice President, Operations, Micron Biomedical, Inc.

Micron Biomedical is developing a fully dissolvable micro-array technology for the simple administration and distribution of drugs and vaccines. A micro-array technology with attributes to provide convenience, confidence and improved compliance for self, caregiver and physician administration of drugs and vaccines. Micron is a clinical-stage biopharmaceutical company, developing drugs and vaccines that are formulated into a proprietary technology that simplifies and improves the way actives are delivered, stored, and distributed. With one clinical trial completed and five underway or in planning stages, Micron’s technology is on a rapid path to commercialization.

In this presentation, we will discuss preclinical and clinical activities ongoing at Micron, related target product profiles and describe how key attributes of our technology are being leveraged to develop a broad range of drug and vaccine products.

4:15 Realizing the Promise of Intradermal Delivery
Nicky Bertollo, Co-founder, Pharma Latch

Intradermal delivery holds great promise as a delivery site for a multitude of drugs, vaccines and therapies, the potential benefits of which are becoming more apparent from an ever-growing body of evidence. Existing delivery technologies including microneedles (solid-coated, hollow and dissolvable) and jet-injectors, however, present a range of technical, manufacturing, regulatory and clinical challenges. In some cases, these arise from the limitations posed by the variable biomechanical properties of skin itself. Pharma Latch, with its novel and patented arrays of hollow angled microneedles overcomes many of these challenges, offering an easy-to-use, rapid, reliable, repeatable and cost-effective intradermal delivery device capable of handling both small and large volumes of low-to-high viscosity solutions.

By changing the intradermal delivery paradigm, Pharma Latch will allow the potential of Intradermal delivery to be realized across a wide range of applications, from vaccines, through to biologics and cell and gene therapies. This talk will provide an overview of the Pharma Latch hollow technology and supporting data.

End of Program
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