Microneedle & Transdermal Drug Delivery Virtual Conference 2020
Advanced Design, Development and Delivery of Skin-Mediated Therapies and Vaccines
October 27–28, 2020, Online Eastern Daylight Time

Featuring Lessons Learned & 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, including Sterilization Concerns
- Scaling It Up—Key Manufacturing Experiences and Challenges for MN arrays
- Understanding the Commercial Value Proposition for Microarray Patch Products
- Target Product Profiles for Microarray Patches of Global Public Health Importance
- Industry Group Updates—PATH & The MAP Center of Excellence Regulatory Working Group
- Key Regulatory Considerations for Microneedle and Transdermal Systems, Including the recent FDA Guidance
- Emerging Science: Transdermal Microneedle Sensors and Diagnostics
- Microneedle Dermatotoxicology: Knowns and Unknowns
- Key Formulation Considerations for Skin-Mediated Therapies and Vaccines

With Representation From:

Contact: Kim Hubbard
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Tuesday, October 27, 2020

8:00  Chairperson’s Welcome and Opening Remarks

The Landscape of Microneedle Drug Delivery—Challenges and Opportunities

8:15  Intradermal Delivery: An Overview

Brian K. Meyer, Principal Scientist, Merck

Abstract coming soon

8:55  Novel Applications of Microneedle Technology in Dermatology, Pediatrics and Vaccines

Mark Prausnitz, Regents’ Professor, Georgia Institute of Technology

In this talk, we will address novel forms of microneedle technology for three different medical applications. Because it is difficult to apply microneedle patches over large areas of skin, which might be needed to treat dermatological conditions, we developed microneedles protruding from particles (i.e., STAR particles) that can be incorporated into topical formulations and rubbed on the skin to increase its permeability by orders of magnitude. Specific challenges associated with drug delivery and diagnostics by microneedle patch in the pediatric population will also be addressed, and a novel approach to DNA vaccination by microneedle patch will be presented.

Conference Keynote

9:35  Zosano’s Microneedle Technology: Changing Traditional Dosing Paradigms

Hayley Lewis, Senior VP of Operations, Zosano Pharma

Commercial dosage forms, oral, injectable, and passive transdermal delivery while well-established, present barriers to compliance. Oral delivery of therapeutics undergoes first pass metabolism, poor absorption during nausea and vomiting. Furthermore, there is extensive gastric and intestinal degradation especially for biologic therapeutic drugs. Oral dosage forms, while economical and well accepted have other disadvantages when it comes to their suitability for certain patient populations including; pediatric, geriatric and those with cognitive impairment. Injectable delivery, while certainly effective in the targeted delivery of products, often requires medical supervision, and is associated with poor patient compliance due to needle phobia. Additionally, oftentimes reconstitution prior to administration can be a challenge, and in the case of a rescue type setting, requires presence of mind. Injectables require aseptic manufacturing and can pose some supply chain limitations as well as the need to dispose of the spent syringes properly as they are a biohazard. Traditional transdermal delivery does provide constant administration of drug, is mostly easy to apply and wear, but the limitations exist due to the barrier properties of the skin and the physicochemical properties of drugs. These systems can be large, and some, not discreet. Additionally, the risk of overdose of patches have been reported, and given the medications that are delivered this way, can be fatal.

Microneedles have been in development for about 100 years now, with the first patents being filed in the 70s. Microneedles have been in development to mitigate the existing dosing limitations of current dosage forms. With the ability for microneedle patches to be unit dose, reconstitution is no longer required. From a distribution perspective, the elimination of cold chain offers a significant advantage over refrigerated products. Additionally, the elegant form factor and the intuitiveness of self-administration sets the stage for microneedle-mediated therapies to transform how vaccines and other therapies can be dosed. In today’s new world of the avoidance of crowds, and the reluctance to visit doctors’ offices for a single dose administration, having the ability to send medications to patients’ houses and trusting that their application and dose delivery is as simple as applying an adhesive patch, changes the way we ought to think about ensuring patients have access to needed medications.

Morning Break & Sponsor Presentations

10:15  Tissue Target Considerations for Microneedle Delivery

Tycho Speaker, Director, Drug Delivery, AbbVie

Skin is often viewed as a single target tissue/organ in the context of sub-cutaneous or intradermal injections. Microneedle-mediated delivery requires a more nuanced understanding of this organ, and its unique vascular structure. Further, microneedle penetration and subsequent API delivery can be profoundly influenced by insertion dynamics, underlying tissue types, and microneedle array dimensions. Comprehensive consideration of these aspects and their interactions are critical to developing an effective delivery platform appropriate to the API and to navigating an appropriate regulatory approach toward a safe and effective product.

10:30  Spotlight on Regulatory Considerations—Agency and Industry Perspectives

Product Development and Quality Considerations for Transdermal Systems and Microneedle Systems: A Regulatory Perspective

Caroline Strasinger, Master Reviewer, FDA

Abstract coming soon.

11:10  Lunch Hour. Visit the Networking Chatroom
12:50 Technology for Continuous, Invasivelyless and Wearable Access to the Interstitial Fluid for Biomedical Science, Drug Delivery, Drug Monitoring & Drug Development

**Dr. Samia Bensalem, Kiffik Biomedical, Inc.**

Abstract coming soon

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1:00 The MAP Center of Excellence Regulatory Working Group: An Update and a Chance to Participate!

**Dr. Sion Coulman, Lecturer, Cardiff University**

As part of this Center of Excellence, PATH has partnered with Cardiff University to Chair a group that aims to provide independent scientific opinions and recommendations that help define the regulatory pathway for Microneedle Array Patches (MAPs) and thus expedite clinical translation of the technology. This Regulatory Working Group (RWG) includes representatives with MAP expertise in both the commercial and academic sectors, vaccine development experts and representatives from national regulatory authorities, international pharmacopoeia and the WHO pre-qualification of medicines program. The group have begun work in four key areas; (i) defining the delivery system; (ii) identifying critical quality attributes; (iii) developing test methods for MAPs; and (iv) evaluating the sterility requirements for MAP products. This talk will provide an update on progress to date and, most importantly, will highlight online mechanisms that we have recently established to enable you, as a stakeholder in the MAP community, to contribute to this work. This is a truly collaborative endeavor that aims to get MAP technology out of the laboratory and into the clinic and so if you are interested and/or want to contribute then please visit www.microneedleregulatory.org for more detail.

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1:40 Microneedle Dermatotoxicity: Knowns and Unknowns

**Dr. Howard Maibach, Professor of Dermatology, UC San Francisco**

Microneedles have had a long and painful gestation period—from the Alza patents to the recent NDA filing of a drug. One (controllable) part of the delay relates to potential toxicities, real and imagined. This presentation will summarize the experimental and clinical data on dermatotoxicology—and place it into a regulatory/product liability perspective, as well as dealing with the unexpected, namely what will use by many millions teach us.

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2:20 Panel Discussion: Ask the Experts

**The Changing Regulatory Landscape for Microneedle Products—What You Need to Know**

**Moderator: Michael Eakins**

Panelists:
- Caroline Strasinger, FDA
- Sion Coulman, MAP Center for Excellence
- Darin Zehrung, PATH
- Tycho Speaker, AbbVie

Discussionists: The Audience

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3:00 Afternoon Break & Networking Chat

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3:20 Research Spotlight—Emerging Uses for MNs

**Exploring the Oral Route for the Delivery of Microneedle-Based Systems**

**Dr. Ester Caffarel-Salvador, Senior Scientist, Leo Pharma**

While microneedles have mainly been investigated for transdermal delivery, they also offer great potential for therapeutic drug monitoring and for oral drug delivery. The first part of the talk will describe the properties of the gastrointestinal tract and the boundary conditions for the oral administration of drug delivery devices. The second part will be devoted to exploring the use of microneedle-based devices in different organs of the gastrointestinal tract.

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4:00 Allergy Desensitization: An Emerging Use of Coated Microneedles

**Dr. Harvinder Gill, Whitacre Chair of Science & Engineering, Texas Tech University**

Allergies have increased worldwide. Although respiratory allergies such as those caused by pollen grains can be treated through allergy shots, food allergies have limited treatment options. Over the recent years, microneedles coated with allergens have been investigated for the treatment of both respiratory and food allergies. In this presentation, the relevance of the transdermal route for allergen desensitization will be discussed. Case studies involving the use of microneedles coated with house dust mite and peanut allergen will be presented to demonstrate the effectiveness of microneedles for both allergy treatment and allergy prevention.

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4:40 End of Day One
**Wednesday, October 28, 2020**

**8:05**  
Chairperson's Welcome & Opening Remarks

**Research Spotlight—Next Generation Microneedle Technologies & Applications**

**8:20**  
Transdermal Sensing with Microneedles—From Metabolites to Proteins to Drugs  
**Dr. Tony Cass, Department of Chemistry, Imperial College London**

Continuous monitoring of both endogenous and exogenous molecules in the dermal interstitial fluid has applications in disease management, lifestyle modification and environmental exposure. To achieve these, the devices need to meet the 3 A’s of Accurate, Acceptable and Automated. Accuracy is a technical issue, Acceptability is a user experience issue and Automation a systems design requirement that links the device to the Internet of Things.

In this presentation I will describe examples of microneedle sensor arrays for metabolite measurements and therapeutic drug monitoring with a focus on integrating suitable molecular recognition chemistry with microneedle fabrication methods. The talk will conclude with a description of how the sensing components can be integrated with the other systems elements.

**9:00**  
Microarray Patches: Poking a Hole in the Challenges Faced When Delivering Poorly Soluble Drugs  
**Dr. Ryan Donnelly, Chair, Pharmaceutical Technology, Queens University, Belfast**

Poorly soluble drugs constitute more than 60% of currently marketed pharmaceuticals and more than two-thirds of promising new chemical entities never enter the clinic due to solubility issues. Although oral formulations have made some impact, alternative enhancement strategies for administration of such molecules are actively sought. Over the last decade, innovation on a global scale has enabled the expansion of the frontiers of microarray patches (MAPs) further than ever before. Initially designed to load low doses of hydrophilic and potent therapeutic agents, MAPs are now becoming a viable strategy for the immediate and long-acting delivery of poorly soluble drugs through the skin. This together with the advantages of transdermal administration over the oral and parenteral routes, make of MAPs an appealing platform for the development of products with increased patient compliance. Undoubtedly, MAPs will soon become an available therapeutic alternative, and experts from academia, industry and regulatory bodies are working together to facilitate progression of MAPs towards safe and effective clinical use. This presentation will highlight the ability of MAPs to deliver poorly soluble actives, discuss the mechanisms behind in-skin drug and evaluate the future direction of this aspect of the field.

**9:40**  
Innovations in Alternative Routes of Vaccine Administration  
**Tanima Sinha, Lead Interdisciplinary Scientist, US Dept of HHS/BARDA**

Abstract coming soon

**10:15**  
Morning Break and Sponsor Presentations

**10:25**  
PATH Microarray Patch Center of Excellence: Target Product Profiles for Microarray Patches of Global Public Health Importance  
**Courtney Jarrahan, Portfolio Leader, Packaging and Delivery Technologies, Co-director, MAP Center of Excellence**

PATH’s Microarray Patch (MAP) Center of Excellence is a four-year initiative to mobilize efforts to accelerate the development of MAPs for critical vaccines and essential medicines and to ensure that the MAP delivery technology platform can maximize its impact by meeting global public health needs. The Center of Excellence is collaborating with global stakeholders and partners with the aim of facilitating the potential of this innovative delivery technology platform as a whole, as well as specifically advancing priority applications for the diseases and use cases that have the greatest health impact in low-resource settings. MAP applications that PATH has prioritized include vaccines against measles-rubella (MR), human papillomavirus (HPV), rabies, and hepatitis B. These vaccines were selected since they are delivered in campaigns and through special strategies outside routine immunization clinic visits where MAP delivery could improve access and equity. For essential medicines, high-priority applications include hormonal contraception and long-acting antiretroviral drugs for HIV where MAP delivery could enable self-administration of long-acting formulations to improve access, as well as support adherence and continuation of use.

PATH has developed draft target product profiles (TPPs) for several of these priority MAP products, including MAP vaccines for rabies and HPV and MAP delivery of antiretrovirals for HIV, and has contributed to the World Health Organization/UNICEF TPP for MR MAPs. These TPPs have been informed by literature reviews, interviews with expert stakeholders, and in-country user assessments that gathered input from health care workers, potential recipients, and program managers. The TPPs include minimum and optimal targets for parameters—such as the intended use case, target population, safety, efficacy, dosage, dosing regimen, stability, and disposal—with a focus on the needs of users and health program priorities in low- and middle-income countries.
PATH has established a Center of Excellence (CoE) for microarray patch (MAP) technology. The overall goal of the CoE is to advance the MAP technology platform to transform delivery of vaccines and essential medicines for diseases of global health significance. Through the CoE, PATH is collaborating with MAP developers, pharmaceutical companies, public health stakeholders, and other partners to develop a value proposition for priority MAP products and to support product development activities. These activities include developing well-informed target product profiles, determining user needs, supporting technical development, advancing manufacturing processes, articulating the business case and public health value proposition, and collaborating with regulatory experts to define regulatory pathways for MAPs.

Technical proof-of-concept studies are underway for two key MAP products—measles-rubella (MR) vaccine and long-acting hormonal contraception—but a long-range commercialization plan remains to be completed. To address this gap, PATH has developed business cases for these two MAP products from a commercial perspective. Results of this work include demand estimation under various use case scenarios, net-present-value modeling, identification of potential partners, definition of the market opportunity, and review of incentives for commercialization partners and global health stakeholders (e.g., donors, procurers) to engage in commercialization partnerships and undertake the substantial investment required to move a MAP candidate through clinical development, regulatory approval, manufacturing scale-up, and eventual program introduction in low- and middle-income countries.

**Lunch Hour. Visit the networking chat room.**
In this presentation, will we describe two case studies to convert existing marketed products to microneedle versions. The first is a pre-clinical case study on the small molecule dutasteride. Dutasteride was first launched as a daily oral softgel capsule to treat benign prostate hyperplasia. It is a low dose, low bioavailability and long half-life molecule. Dutasteride was developed and evaluated as a dissolving microneedle patch with dutasteride particles distributed through the patch. Once administered, it was envisioned that the dutasteride particles would slowly dissolve due to the low solubility of the molecule and naturally create a prolonged release of the drug. Pre-clinical data will be shared to demonstrate the performance of the prototypes and the potential for a weekly microneedle patch product for dutasteride. The second case study is a clinical case study on a small peptide, Abaloparatide. Abaloparatide is a PTHrP analog and is used to treat postmenopausal osteoporosis. It was first launched as a daily 80 microgram subcutaneous injection. Due to the low dose, it was an ideal candidate to convert to a coated microneedle patch, however achieving a bioequivalent pharmacokinetic profile was unexpectedly challenging. Pre-clinical and clinical pharmacokinetic data will be presented from the Abaloparatide microneedle product development efforts which resulted in a bioequivalent product.

End of Program
In the Age of COVID, the Show Must Go Online

In response to overwhelming audience and speaker feedback, and in view of the current health and safety concerns involving the novel coronavirus COVID-19, we’re taking our events online (at least for the foreseeable future; we do hope to see you again soon in person when all this is over!) Microneedle & Transdermal Drug Delivery Virtual Conference 2020 is an entirely online event, complete with insightful presentations from leading researchers, 1:1 networking opportunities, live question & answer sessions, and sponsored informational presentations that highlight how vendors are tackling some of the key issues facing the Microneedle market today. Just sit back and enjoy this online learning experience from the safety and comfort of your home or office. Missed a session or two? No worries—the full program will be archived and available for post-conference viewing and download.

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