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SMi Group Proudly Presents the Annual Conference on...

Transdermal and Microneedle Drug Delivery

Latest innovations in drug delivery beyond the needle

Venue to be confirmed, London, UK

CONFERENCE:
24TH - 25TH
WORKSHOPS: 26TH

JAN 2022

HIGHLIGHTS FOR 2022:

- **Gain** insight into developments in microneedles for drug delivery and diagnostics, with highlights from Zosano Pharma on In-Home administration and LEO Pharma on dissolving polymeric needles
- **Discover** advances in design and application of transdermal patches, including the development of the Covid-19 vaccine patch
- **Engage** in insights into micro-array patches for developing countries from WHO and the MAP Regulatory Working Group
- **Explore** and benchmark against industry developments through case studies and real-world examples in device development for microneedle drug therapeutic delivery
- **Develop** an understanding of the global importance of going beyond the needle in BARDA's interactive post conference-workshop

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CHAIRS FOR 2022:



Sanjiv Sharma,
Senior Lecturer in Medical Engineering,
Swansea University



Tycho Speaker,
Director, Drug Delivery and Biomaterials,
AbbVie

FEATURED REGULATORY SPEAKERS:

- **Caroline Strasinger**, Master Reviewer, Office of Pharmaceuticals Quality, **CDER/FDA**
- **Bridgitte Giersing**, Team Lead, Vaccine Prioritization and Platforms, World Health Organisation.

FEATURED 2022 SPEAKERS INCLUDE:

- **Marion Menozzi-Arnaud**, Senior Specialist, Market Shaping, Gavi, The Vaccine Alliance
- **Hayley Lewis**, Senior Vice President, Zosano Pharma
- **Courtney Jarrahian**, Program Advisor, PATH
- **Michael Schrader**, CEO, Vaxess Technologies, Inc.
- **Clemens Guenther**, Director of Senior Expert Nonclinical Safety, Bayer AG
- **James Birchall**, Professor of Pharmaceutical Sciences and Deputy Head of School, Cardiff University

and many more...

PLUS TWO INTERACTIVE POST-CONFERENCE WORKSHOPS
WEDNESDAY 26TH JANUARY 2022, LONDON UK

A: Beyond the Needle – (Division of Research, Innovation, and Ventures DRIVE)

Workshop Leader:

Kerry DeMarco, DRIVE Start Program Innovation & Alliance Lead,
Biomedical Advanced Research & Development Authority

8.30 - 12.45

B: Microneedles - tiny objects that make a huge impact

Workshop Leader:

Ryan Donnelly, Chair in Pharmaceutical Technology,
Queen's University Belfast Medical Biology Centre

13.30 - 17.30

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Transdermal and Microneedle Drug Delivery

Day One | Monday 24th January 2022

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LETTER FROM THE CHAIRS:

Dear Colleagues,

It is with great pleasure that we invite you to SMI's Transdermal and Microneedle Drug Delivery conference, taking place on the 24th – 25th January 2022 in London.

As part of SMI's leading series of Drug Delivery conferences, this year's event will bring together expertise from individuals in multiple disciplines in the field of transdermal drug delivery and MicroArray Patches. The two-day conference will offer a series of presentations, through which you will gain insight into real world applications of microneedles in drug delivery and strategies for device design. The conference will consider key developments in the transdermal drug delivery field, including the innovations in microneedle technology for a COVID-19 vaccine, opportunities for development in cancer vaccine delivery, advances in microarray patches, and microneedle-based diagnostics.

Following the main event, 2 post-conference workshops will be held on Wednesday 26th January 2022. There will be an opportunity to discuss moving beyond the needle with drive ... and to explore the potential of manufacturing microneedle patches with Ryan Donnelly and LTS. As chairs of this conference, we look forward to welcoming you to this must-attend event in London this January.

Yours Sincerely,



Sanjiv Sharma,
Senior Lecturer in
Medical Engineering,
Swansea University



Tycho Speaker,
Director, Drug Delivery
and Biomaterials,
AbbVie

08.00 Registration & Coffee

09.00 Chairs' Opening Remarks

Sanjiv Sharma, Senior Lecturer in Medical Engineering, **Swansea University**
Tycho Speaker, Director, Drug Delivery and Biomaterials, **AbbVie**

MICRONEEDLE PATCHES FOR VACCINE DELIVERY

09.10 OPENING ADDRESS

Prioritisation of microarray patches (MAPs) for vaccine delivery in low and middle-income countries

- Compelling attributes of MAPs for vaccine delivery, and potential public health impact
 - MAPs, priority #1 as part of the Alliance Vaccine Innovation Prioritisation Strategy – methodology and rationale
 - The Alliance 5-year strategy and action plan for MAPs
 - Prioritisation of antigens for MAPs' use in low and middle-income countries
- Birgitte Giersing**, Team Lead, Vaccine Prioritization and Platforms,
World Health Organization
Marion Menozzi-Arnaud, Senior Specialist, Market Shaping,
Gavi, the Vaccine Alliance



09.50 **PATH Microarray Patch Center of Excellence**

- Overview and update from PATH's Microarray Patch (MAP) Center of Excellence, an initiative to mobilize efforts to accelerate the development of MAPs for critical vaccines and essential medicines
- How the MAP delivery technology platform can maximize its impact by meeting global public health priorities.
- Evaluations of user needs, human factors, cost-effectiveness modeling, and manufacturing approaches.

Courtney Jarrahian, Program Advisor, **PATH**



10.30 Morning Coffee

11.00 **GMP production of vaccine microneedles for clinical trials**

- Recent KFDA guidance on medical microneedle
 - Choosing the right vaccine for MAP technology; why is the birth dose of hepatitis B vaccine microneedle important?
 - Aseptic process development and quality control for hepatitis B vaccine microneedle
 - Analysing strategies for developing vaccine microneedle
- Jung-Hwan Park**, Chief Technical Officer,
QuadMedicine, Inc.



11.40 **Advances in Vaccine Adjuvants and RNA Vaccines**

- Licensed vaccines with adjuvants
 - RNA vaccines
 - Delivery systems
 - Discovery of next generation adjuvants
- Derek O'Hagan**, Senior Advisor Vaccines R&D, **GSK**

12.20 **Development of Smart Vaccine Patch for COVID19 vaccination**

- Repurposing microneedle technology for a COVID vaccine
 - Monitoring biomarkers in the skin compartment to assess efficacy of the vaccination
 - Microneedle patches for diagnostics and drug delivery
 - Evaluating advantages of microneedle technology: allowing for lower doses of the vaccine which contributes to low-cost manufacturing
 - Beyond the pandemic: expanding research to other diseases
- Sanjiv Sharma**, Senior Lecturer in Medical Engineering, **Swansea University**



13.00 **Networking Lunch**

14.00 **Developing differentiated, transdermal forms of high-value drugs**

- How does the Hero Patch work? A technology overview
- Current challenges in the sustained delivery of macromolecules
- A new class of microneedle – the cutting edge technology behind improved drug loading
- Pre-clinical data and future possibilities of the Hero Patch delivery platform

Jake Lombardo, CEO and Co Founder, **Anodyne Technologies Inc.**

REGULATORY INSIGHT IN THE TRANSDERMAL SPACE

14.40 **Considerations for Microneedle System Development: An FDA Assessor's Perspective**

- An overview of FDA perspectives on combination products, specifically transdermal and microneedle systems
- Considerations for the manufacturing process and ensuring product quality of microneedle systems
- Enhancing communication to move microneedle technology to the commercial market

Caroline Strasinger, Master Reviewer, **FDA**



15.20 **The MAP Center of Excellence Regulatory Working Group: A collaborative approach to help define the regulatory pathway for MAPs**

- A background to the MAP Regulatory Working Group (RWG)
- An update on the activities of the MAP RWG, to include:
 - Laboratory Developments; Developing new standardised Test Methods for MAP critical quality attributes
 - Guidance; Helping to define the regulatory pathway for MAP development

Sion Coulman, Senior Lecturer, **Cardiff University**

16.00 **Afternoon Tea**

16.30 **Transdermal and Microneedle Drug Delivery – Regulatory requirements in the EU**

- General requirements for topical products in the context of a regulatory submission
 - Aspects to consider with respect to applications with Microneedle technology
 - Transdermal and Microneedle Drug Delivery Systems in paediatrics
- Janet Koenig**, German CHMP Alternate, Head of the Unit
Anaesthesiology, Algesiolog, Rheumatology, Pneumology, ENT, **Federal Institute for Drugs and Medical Devices, Germany**

17.10 **Transdermal Delivery Systems as Drug Device Combination Products - Considerations for the biocompatibility testing program**

- Insight into biocompatibility evaluations supporting regulatory submissions of DDCP
- Evaluating biocompatibility of Transdermal Delivery Systems / Microneedling Devices
- How to comply with requirements on extractable and leachable testing
- Toxicological Risk Assessment approaches for E&L

Clemens Guenther, Director Senior Expert Nonclinical Safety, **Bayer AG**

17.50 **Chair's Closing Remarks and Close of Day One**

Sanjiv Sharma, Senior Lecturer in Medical Engineering, **Swansea University**
Tycho Speaker, Director, Drug Delivery and Biomaterials, **AbbVie**

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Transdermal and Microneedle Drug Delivery

Day Two | Tuesday 25th January 2022

www.transdermal-microneedle-delivery.co.uk

08.00 Registration & Coffee

09.00 Chairs' Opening Remarks

Sanjiv Sharma, Senior Lecturer in Medical Engineering, **Swansea University**
Tycho Speaker, Director, Drug Delivery and Biomaterials, **AbbVie**

NOVEL APPLICATIONS OF MICRONEEDLE TECHNOLOGY

OPENING ADDRESS

09.10 **Methods of Microneedle Drug Delivery**

- Dissolving polymeric microneedle arrays
- Coupling microneedles with iontophoresis for transdermal delivery
- A microneedle platform for macromolecule delivery
- The landscape for oral delivery and microneedles

Ester Caffarel-Salvador, Associate Director, Regenerative Medicine, **LEO Pharma**



09.50 **Advanced microneedle patches for drug delivery**

- Perspective on microneedle field as a whole
- Novel microneedle patch designs
- Case study on microneedle patch for drug delivery

Mark Prausnitz, Regents' Professor, **Georgia Institute of Technology**

10.30 Morning Coffee

11.00 **Enabling More Efficacious and Accessible Vaccines with the MIMIX Patch Platform**

- Introduction to the biology of sustained intradermal delivery
- Introduction to the MIMIX sustained intradermal delivery platform
- Pre-clinical data review
- Manufacturing and clinical trial program status

Michael Schrader, CEO, **Vaxess Technologies, Inc.**

11.40 **Vaxxas HD-MAP Update**

- Pre-clinical & Clinical Studies
- Insights into Vaxxas' needle-free vaccination technology
- Manufacturing of Vaxxas' HD-MAP

Tom Lake, SVP, Strategic Alliances and Commercialization, **Vaxxas**

CHALLENGES IN DESIGN, DEVELOPMENT AND MANUFACTURING OF TRANSDERMAL PRODUCTS

12.20 **Nanoengineered microneedle arrays**

- Nanocrystal-loaded microneedles for long-acting delivery
- Chemically-crosslinked hydrogel networks for sustained delivery
- Drug targeting to specific body sites

Ryan Donnelly, Chair in Pharmaceutical Technology, School of Pharmacy, Queen's University Belfast, **Medical Biology Centre**

13.00 Networking Lunch

14.00 **Tissue Role in MAP Insertion Dynamics**

- Discussion of complex physical phenomena influencing MAP insertion
- Tissue-specific considerations in development of a delivery system
- Path to clinical studies and model selection

Tycho Speaker, Director, Drug Delivery and Biomaterials, **AbbVie**



14.40 **Human centred design of microneedle products**

- User studies and human factors in microneedle product development
- Addressing challenges in contraception technologies in low and middle income countries
- Evaluating the usability and acceptability of a microneedle-based contraceptive

James Birchall, Professor of Pharmaceutical Sciences, Deputy Head of School, **Cardiff University**

15.20 **Microneedle-Mediated Application and Delivery of Vaccines as a Dose-Sparing and In-Home Alternative to Traditional Administration**

- A presentation on the formulation and delivery of vaccine candidate(s) via microneedles to demonstrate the efficiency and ease of use
- An outline of the program from concept to in vivo data
- Key points demonstrating the versatility and validity of microneedle delivery as a potential to respond to current challenges in vaccine distribution and roll out

Hayley Lewis, Senior Vice President, **Zosano Pharma**

16.00 Afternoon Tea

PANEL DISCUSSION

16.30 **Future outlook of transdermal drug delivery systems**

- Recent advances of microneedles for biomedical applications
- Commercial opportunities in developing transdermal delivery systems
- Overcoming challenges in scale up of manufacturing
- Future uses of microneedles in pandemics: what would it take to make the technology ready?
- Is the market ready for microneedle patch technology? Weighing the benefits and costs of transdermal delivery

Panel Moderators:

Sanjiv Sharma, Senior Lecturer in Medical Engineering, **Swansea University**
Tycho Speaker, Director, Drug Delivery and Biomaterials, **AbbVie**

Panelists:

Courtney Jarrahian, Portfolio Leader: Packaging & Delivery Technologies, **PATH**

Ester Caffarel-Salvador, Associate Director, Regenerative Medicine, **LEO Pharma**

Hayley Lewis, Senior Vice President, **Zosano Pharma**

Michael Schrader, CEO, **Vaxess Technologies, Inc.**



17.10 **Delivery of macromolecules into and across the skin**

- Currently available delivery options for macromolecules
- Non-invasive and minimally invasive transdermal techniques
- Iontophoresis for intra and transdermal delivery of proteins
- Laser poration and its tandem use with iontophoresis

Sachin Dubey, Head of Drug Product and Analytical Development, **Ichnos Sciences**

17.50 **Chair's Closing Remarks and Close of Day One**

Sanjiv Sharma, Senior Lecturer in Medical Engineering, **Swansea University**
Tycho Speaker, Director, Drug Delivery and Biomaterials, **AbbVie**

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Transdermal and Microneedle Drug Delivery

Wednesday 26th January 2022

POST-CONFERENCE WORKSHOP A 08.30 - 12.45

Workshop Leader:
Kerry DeMarco, DRiVE Start Program Innovation & Alliance Lead,
Biomedical Advanced Research & Development Authority



Beyond the Needle - (Division of Research, Innovation, and Ventures DRiVE)

Workshop Overview:

DRiVE as a section of Biomedical Advanced Research and Development Authority (BARDA), present the new technology behind their 'beyond the needle' programme. With an introduction to the programme, conversations about the challenges and the ability to ask questions about this new area of technology. This interactive session will have discussions about manufacturing, regulations and the costs associated with moving away from the needle and syringe method of delivery. Join us to discover more about needless delivery and the potential impact this can have across the world.

This workshop will explore:

- Discover the potential to move to needless administration with conversations on manufacturing and costs
- Understand and evaluate the current market with relevant case studies
- Interact with industry professionals with Q&A sessions
- Speak with BARDA about moving towards the needless future with an opportunity to obtain funding

About the workshop leader:

Kerry DeMarco has been with BARDA since 2019 and currently leads the BARDA DRiVE Program & Innovation activities and runs the Beyond the Needle program. Prior to her time at BARDA, Dr. DeMarco was the Program Manager for the jointly funded BARDA/State of Texas pandemic response facility, the Texas A&M Center for Innovation in Advanced Development and Manufacturing (CIADM). Dr. DeMarco also spent over fifteen years supporting the U.S. Department of Defense Science & Technology development activities. Dr. DeMarco earned her Ph.D. in Kinesiology/Psychophysiology from the University of Maryland.

About the organisation:

The Biomedical Advanced Research and Development Authority (BARDA), within the Office of the Assistant Secretary for Preparedness and Response in the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies such as chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases.

Together with our industry partners, BARDA promotes the advanced development of medical countermeasures to protect Americans and respond to 21st century health security threats.

Programme

08.30 Registration and Coffee

09.00 Opening Remarks and Introductions

09.10 A review and discussion of the 'Beyond the Needle' programme

- The vision and need for change
- The challenges to overcome – talking logistics

09.50 Current areas of application and focus

- A look into real world examples of moving away from needle-based administration
- Case studies:
 - Enesi Pharma and the Covid-19 Pandemic Vaccine
 - Vaxxas and their needle free patches

10.30 Morning Coffee

11.00 How to go needle free, an interactive session

- Discussion on how to move current products away from needlebased administration, the costs vs the impact
- Understanding the barriers to face, including the skin
- Alternative methods of manufacturing – how BARDA can help

12.00 A future outlook and open discussion.

- An opportunity to ask questions about moving 'beyond the needle'
- The overall importance of needle free administration and the shortfalls of the need to inject medications around the world
- How to collaborate with BARDA moving forward and learn about their funding opportunities

12.30 Closing Remarks

12.45 End of Workshop

POST-CONFERENCE WORKSHOP B 13.30 - 17.30

Workshop Leader:
Ryan Donnelly, Chair in Pharmaceutical Technology,
Queen's University Belfast Medical Biology Centre



Microneedles - tiny objects that make a huge impact

Workshop Overview:

This interactive workshop will give an insight into the manufacturing of nanoengineered microneedles. With workshop leader Ryan Donnelly having successfully manufactured his microneedles, join discussions and learn how to move your work into the next stage.

Why you should attend this workshop:

- Discover the steps involved in moving to microneedle manufacture.
- Gain insight into current work within the nanoengineering microneedles
- Discuss the possibilities around manufacturing
- Join an open discussion and participate in a Q&A with those in the manufacturing industry

About the workshop leader:

Professor Ryan Donnelly holds the Chair in Pharmaceutical Technology at Queen's University Belfast and is Director of QUB's interdisciplinary research programme Materials & Advanced Technologies for Healthcare (MATCH). His personal research is centred on design and physicochemical characterisation of advanced polymeric drug delivery systems for transdermal and intradermal drug delivery, with a strong emphasis on improving patient outcomes. He is currently developing a range of novel microneedle technologies through independent research, but also in collaboration with several major pharma partners. He has obtained substantial UK Research Council, charity and industrial funding and authored over 300 peer-reviewed publications (H-index = 58), including 6 patent applications, 6 textbooks, 23 book chapters and approximately 250 full papers. He has been an invited speaker at numerous national and international conferences. Professor Donnelly is Europe/Africa Editor of Drug Delivery & Translational Research and the Controlled Release Society's Communications Chair. He has won the Academy of Pharmaceutical Science's Innovative Science Award (2020), Evonik's Resomer Award (2018), the Controlled Release Society's Young Investigator Award (2016), BBSRC Innovator of the Year and the American Association of Pharmaceutical Scientists Pharmaceutical Research Meritorious Manuscript Award (2013), the GSK Emerging Scientist Award (2012) and the Royal Pharmaceutical Society's Science Award (2011).

Programme

13.30 Registration and Coffee

14.00 Opening Remarks and Introductions

14.10 Current work within the Polymeric Microneedles Field

- The enhanced delivery of high dose medicines
- Considerations in the formulation of biomolecules
- An overview of other possible applications

14.50 Working with manufacturers – an interactive session

- The steps involved in moving to scalable manufacturing
- Attendees to break out into groups to discuss main steps of manufacturing
- Attendees to regroup for larger discussion about the considerations involved in manufacturing

15.30 Afternoon Tea

16.00 Quality control and in microneedle manufacturing importance of adopting optimal quality controls for your microneedle device

- Defining critical quality attributes and assessing the potential parameters
- Open discussion - applying the appropriate quality controls for your manufacturing process

16.50 An outlook and open discussion

- An opportunity to ask questions about polymeric microneedles research and moving to manufacturing stages
- Highlighting the potential importance of polymeric microneedles and their properties
- Understanding of microneedles in the world of healthcare innovation

17.20 Closing Remarks

17.30 End of Workshop

Register online at www.transdermal-microneedle-delivery.co.uk

TRANSDERMAL AND MICRONEEDLE DRUG DELIVERY

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Workshops: Wednesday 26th January 2022, Venue To Be Confirmed, London UK

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