

Transdermal & Intradermal Drug Delivery Systems 2016

Advanced Design, Development & Delivery of Skin-Mediated Therapies & Vaccines
September 12-13, 2016, Racquet Club of Philadelphia, PA

Featured Speakers Include:



Ajay Banga
Mercer University



Bobby Singh
Corium



Lisa Dick
3M



Yash Kapoor
Merck



Mikolaj Milewski
Merck



Narisimha Murthy
Ole Miss

With Comprehensive Coverage On:

- Phase I & Phase II Clinical Trials using Passive TD and Microneedle Technology
- Modeling and Simulation of In Vivo Absorption of Large Molecules for ID Delivery
- Bioavailability Considerations for TDDS
- Key Regulatory Issues for TDDS & IDDS, Including Recent FDA & USP Guidance Documents
- Key Formulation Considerations for Skin-Mediated Therapies and Vaccines
- Latest Advances in Microneedle Patch Design
- Optimizing TDD & IDD for Efficacious Delivery and Patient Compliance
- Enhancement of Skin Permeation Using Supersaturation
- Effects of Hypothermia in TDD
- Lowering Production Costs for TDD & IDD Therapies and Vaccines
- Mechanisms of Dermal and Transdermal Absorption of Drugs
- And more!

The growing interest in alternative routes of drug administration has experts predicting that the market for transdermal and intradermal drug delivery systems will exceed \$30 billion in 2016. The industry is on the threshold of bringing into commercial production a new generation of transformative TDD and IDD therapies and delivery systems. That is why you cannot afford to miss this two-day intensive conference. Pharma Ed brings together leading researchers in the field to share the most recent advances in the design, formulation, and delivery of skin-mediated therapies and vaccines.

With Representation From:



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Monday, September 12, 2016

8:00 Complimentary Breakfast & Chairperson's Welcome and Opening Remarks

The Transdermal Landscape—Challenges and Opportunities

8:30 Overcoming Challenges Facing Skin Delivery Systems

Dr. Ajay Banga, Chair & Professor of Pharmaceutical Sciences, Mercer University

Moderately lipophilic drugs typically have good skin permeation flux but face challenges such as drug crystallization in patches. Extremely lipophilic drugs may not partition past the stratum corneum. Hydrophilic molecules and macromolecules do not normally pass through the skin unless enabling technologies are used. Some of the enabling physical enhancement technologies include iontophoresis, phonophoresis, laser energy, or the various skin microporation approaches. Recent innovations in these technologies, especially for iontophoresis, ablative and non-ablative fractional laser, and microneedle based devices, will be presented. Application, limitations, challenges, and commercialization of these technologies will be discussed. Key takeaways include:

- Learn about challenges facing passive patch development such as drug crystallization in the adhesive.
- Learn how new technologies are expanding the scope of transdermal delivery to include hydrophilic macromolecules
- Learn the success and failures of iontophoretic delivery systems developed and marketed over the years and the recent excitement and activity centered on microneedle based research

9:10 Keynote: Advancing Transdermal Technologies to Enable New Market Opportunities

Bobby Singh, Ph.D., Chief Technology Officer, Corium International

KEY NOTE

Transdermal drug delivery is a useful and proven alternative route of administration to oral and parenteral modes of administration. It overcomes the pain and fear of needles, bypasses GIT and hepatic first pass effects, enhances bioavailability, and improves safety and efficacy by providing sustained and controlled drug plasma levels. This presentation will cover:

- Transdermal technology landscape review
- Recent advancements in transdermal technologies, and
- Positive clinical Proof-of-Concept results demonstrating therapeutically effective delivery of potential new product candidates

9:50 Networking Coffee Break

Technology Spotlight—Recent Advances in Microneedles

10:15 Phase-Based Development for a Commercializable Microneedle Product
Lisa Dick, Ph.D., MTS Platform Manager, 3M Drug Delivery Systems

As developers of transdermal drug delivery products, 3M Drug Delivery Systems has expertise in both existing patch systems and new technologies. This talk addresses big-picture considerations of microneedle technology development, from technical, manufacturing, and regulatory points of view. Following development of specific types of microneedle systems, preclinical and tolerability aspects are highlighted. Then, quality and regulatory considerations are presented in the context of developing products for global approval. Examples of product development learnings from 3M's solid and hollow microstructured transdermal systems are discussed in the context of phase of development from lab scale to commercialization. As microneedle and delivery system technology matures, technical, regulatory, quality and manufacturing will all come together for successful commercialization of this promising dosage form.

10:55 Microneedle Particles for Drug Delivery to Large Surface Area Tissues

Dr. Andrew R. Tadros, Georgia Institute of Technology, School of Chemical and Biomolecular Engineering [Contributing Author: Dr. Mark Prausnitz, Georgia Tech]

CASE STUDY

There are many advantages to using microneedles (MN) over other conventional delivery strategies; however, MN patches are limited by the relatively small surface area they cover (e.g., <5cm²). This limitation hinders the use of MN patches in numerous medical indications, especially dermatological ones. To overcome this limitation, we have developed a novel technology platform that we are calling STAR MN particles. STAR particles function similarly to non-dissolving MN patches (i.e., "poke and patch" approach), but STAR particles differ in that they can be incorporated, as an inert additive, to a topical formulation, which (1) simplifies the MN application process to a single step and (2) enables treatment of surface areas that conventionally cannot be easily accessed with conventional MN patches.

Within the present study, STAR particle properties are characterized in relation to their effects on increasing the permeability of cutaneous tissue to topically applied compounds. STAR particle geometry, concentration, application time, size, and thickness were investigated in full-thickness porcine ear skin ex vivo. Measurements of gentian violet (GV) staining area and skin electrical resistance provided insight into reduction of skin barrier properties after STAR particle application. Treated skin samples were exposed to sulforhodamine B in a vertical diffusion cell setup, and cumulative permeation

was measured for up to 48 hours. Fluorescence images of histological cross sections were obtained for up to 24 hours of exposure to sulforhodamine B.

- Application of STAR particles by gentle rubbing on the skin was able to create micropores in the skin similar to those created by MN found on conventional patches as shown by GV staining.
- Skin pre-treatment with STAR particles induced a significant increase in skin permeability and resulting permeation of sulforhodamine B into the skin when compared to intact and MN patch controls.
- Quantitative measurement of sulforhodamine B penetration across the skin in Franz cells showed that transport rates up to $2.1 \times 10^{-2} \mu\text{g}/\text{cm}^2/\text{h}$ and $1.5 \times 10^{-2} \mu\text{g}/\text{cm}^2/\text{h}$ were achieved after STAR particle and MN patch pre-treatment, respectively.

These results demonstrate for the first time that STAR particles have the potential to significantly increase the delivery of topically applied therapeutics over large surface areas of skin and potentially other tissues as well. In this way, STAR particles represent a new class of MN that may enable this technology to be used in the treatment of a broader range of medical needs.

11:35 *Brief Presentation and Lunch Sponsored by*



How to Progress from Lab Development to Pilot Scale While Keeping Repeatability for Validation

Ryan Schooley, Business Development, Delta ModTech

It can be a difficult task going from formulation and hand assembly of transdermals to pilot scale manufacturing for testing, trials and FDA approval. How is this accomplished without going to full production, large scale manufacturing? Although many of processes are the same and cannot be removed, there are solutions offered that take the large scale process and scale it down to smaller production rates. Delta ModTech provides lab/pilot scale coating and converting equipment that maintains the process and precision required for validation when transferring to larger scale production.

1:00

CASE STUDY

Microneedles for Allergy Immunotherapy

Dr. Harvinder Gill, Associate Professor & Whitacre Endowed Chair of Sciences and Engineering, Texas Tech University

Allergy immunotherapy, also known as allergy shots, involves subcutaneous injections to treat allergies. The entire treatment lasts many years and cumulatively involves 50–80 injections. The long duration and the associated pain acts as a deterrent for many patients and they do not even start immunotherapy; while many others who do start, do not complete the therapy. Us-

1:40

Polymeric Microneedles: Patient Considerations and Future Perspectives

Dr. Helen Quinn, Research Fellow, School of Pharmacy, Queen's University, Belfast

Microneedles are one of the most promising innovations in drug delivery, with great potential to yield tangible benefits for both patients and industry in the coming years. Our research group at Queen's University Belfast is focused on the design and physicochemical characterisation of advanced polymeric microneedle systems for transdermal drug delivery, with a strong emphasis on improving therapeutic outcomes for patients. Transdermal administration of what are typically known as 'difficult-to-deliver' drugs has been demonstrated *via* a hydrogel-forming microneedle platform, alongside delivery of biotherapeutics, vaccines and photosensitisers, highlighting the versatility of the technology. Investigations have now progressed to *in vivo* delivery of clinically relevant doses of drugs and biotherapeutics, whilst simultaneously considering usability factors and acceptance of a microneedle product by key stakeholders. It has been recognised that consideration of regulatory issues, as well as long-term safety studies, will speed the progress to commercialisation. Manufacture has, therefore, been a strong focus, including for example, scaled-up microneedle production and design and validation of industry-ready quality control tests. Key points of this talk include:

- Delivery using hydrogel-forming microneedles is not limited to hydrophilic, small molecule drugs of high potency
- Hydrogel-forming microneedles can also be used for minimally invasive monitoring and diagnosis
- Manufacturing scale-up of our polymeric microneedle formulation has been demonstrated to be feasible
- Continuing interaction with regulatory authorities and consideration of patient safety will drive the microneedle field forward

2:20

Afternoon Networking Break

2:45

Product Development Trends: Insourcing and Outsourcing

Ken Miller, Ph.D., ISYN Consulting LLC

The pharmaceutical industry is an ever-changing landscape of ideas, innovation, technology, and techniques. A company may dominate a particular field, but rarely reigns supreme for long. This is because there are so many variables affecting the market and so many individuals affecting those variables that it is impossible to accurately predict where the next opportunity will surface with any regularity.

Any established pharmaceutical company will have many minds dedicated to finding and exploiting business opportunities, but these minds typically think in terms of existing products and technology while expecting lightning-fast response to changing market conditions. But, that's not how product development works.

Successful product development requires steady commitment of resources, clear and stable objectives, millions of dollars, years of uninterrupted work and patience. Still, the principles of 'for-profit' business do apply to R&D because R&D is an investment that may have little present value, but potentially enormous future value. A 'for-profit' company invests in R&D with the expectation that it will ultimately receive a positive return on that investment. But how much time and money should a company invest in a potential product and where should that investment be made?

One option is to fund existing personnel currently working on similar products or hire experienced personnel and SMEs as an on-going expansion of internal development activities (insourcing). Alternately, a company may choose to invest in (and share the risk with) an outside partner with anything from a turn-key product to an unrealized concept (outsourcing).

We will explore some of the factors and consequences that drive the decision to invest/expand internally or partner with an outside team.

3:25

USP Requirements for Product Quality and Performance Testing of Transdermal Products

Michael N. Eakins, Ph.D., Principal Consultant, Eakins & Associates

The presentation will outline some of the USP chapters that are relevant to transdermal systems and topical dosage forms. The focus will be on new chapters, and chapters under revision that have been published recently in the USP's Pharmacopeial Forum for comment. For example, new chapters include <1663> Assessment of Extractables Associated with Pharmaceutical Packaging/Delivery Systems, <1664> Assessment of Leachables Associated with Pharmaceutical Packaging/Delivery Systems and the proposed revision of chapter <661> Plastic Packaging Systems and their Materials of Construction. In addition the recent proposed changes in <3> Topical and Transdermal Products—Product Quality Tests will be addressed.

Regulatory Spotlight—Evaluating the New FDA Draft Guidance for TDDS

3:50

Draft Guidance on Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs—Pros & Cons/Q&A

Ken Miller, ISYN Consulting LLC

Earlier this year, the US FDA released its Draft Guidance on *Assessing Adhesion with Transdermal Delivery Systems and Topical Patches for ANDAs* along with a

request for comments. Although it will take time for the FDA to evaluate the comments and respond, we will take this opportunity to review the draft guidance in its original form to identify and discuss the merits and potential weaknesses as a benchmark for new generic patches.

Among the aspects we will address:

- The true impact of adhesion quality on product performance relative to other bioequivalence criteria
- The validity of the assumptions in the Draft Guidance
- Whether the proposed adhesion scoring scale is adequate and fair
- Do product-specific considerations (API, patch design, patient population) affect the validity or interpretation of the adhesion scores?
- Is there too much or too little flexibility in the Draft Guidance (i.e., is there opportunity for developers to devise a meaningful comparison study for their product or is this a one-size-fits-all protocol?)

4:15

Open Forum Discussion—Regulatory Considerations for TDD & IDD Systems

Moderators: Ken Miller, ISYN Consulting, Inc., and Michael Eakins, Principal Consultant, Eakins & Associates
Participants: The Audience

Regulatory bodies continue to develop procedures and acceptance criteria for critical quality attributes in transdermal, intradermal, and topical drug delivery systems, including uniformity of dosage, uniformity in containers, and drug performance characteristics. Harmonization of criteria across the various regulatory bodies is a central concern as well. This open forum discussion will survey key areas of the regulatory landscape, and provide opportunities to raise questions and gain insights from others in the industry on a range of current issues, including: QbD for TDDS; Cold Flow; Shear Testing; In Vitro Drug Release Testing; Harmonization; Uniformity in Containers; and much else. Bring your questions and share your stories.

5:00

Poster Presentation: Pre-Clinical and Clinical Performance of a Novel Intradermal Injection System

Minami Matsuura, Yoichiro Iwase, Kazunori Koiwai, Naoki Akatsuka, and Hidehiko Oshima, Terumo Corporation

Various studies have demonstrated that intradermal (ID) vaccination induces more potent immune responses compared to standard intramuscular and subcutaneous (SC) vaccination. The Mantoux technique as the conventional ID injection method, however, requires specific skills and does not always ensure accurate or consistent ID delivery. To overcome these difficulties, we have developed a novel ID injection system (IDS) for reliable ID vaccination. The IDS has a needle 1.15 mm in length inserting perpendicularly into the skin. To evaluate the

IDS for performance in animals and humans, we first conducted pre-clinical study using swine skin model to clarify the distribution of the contrast media by X-ray imaging after ID injection. The contrast media after injection with IDS were located only in the dermis, while the Mantoux technique resulted in frequent fluid distribution also in the SC layer. In the clinical study, the performance of IDS was evaluated using two criteria; wheal formation and absence of fluid leakage on the skin surface. The subjects receiving ID injection presented a wheal with high frequency (no less than 96%) and no leakage was observed at the injection site. In the usability test, all of the participants scored positive for its handling. This test also showed that the IDS do not require specific training to perform. These results suggest that the IDS provide the advantages in terms of consistency and accuracy of ID injection.

9:10

Intradermal Delivery of Biologics: Understanding Absorption & Pharmacokinetics

Yash Kapoor, Ph.D., Associate Principal Scientist, Merck

Biologics such as peptides and proteins are not amenable for oral delivery and thus, the primary delivery methods for these larger molecules are limited to subcutaneous (SC), intramuscular (IM) or the intravenous (IV) injections. Apart from these routes, intradermal (ID) delivery has gained acceptance and popularity especially with technologies like microneedles gaining momentum over the past decade. Comparing ID and SC delivery for various peptides highlights a very atypical pharmacokinetics response of high maximum plasma concentration (C_{max}) and shorter time to reach the maximum concentration (T_{max}) for ID delivery. This clearly suggests that the physiological differences between these two routes of administration lead to a varied absorption kinetics.

To understand these differences from the first principles, we adapted a physiological-based mathematical model developed for ID delivery and modified it further for determining the absorption kinetics through the ID and SC routes. This model incorporates multiple relevant features such as protein binding, differences in absorption due to the physiochemical properties of the drug and basic understanding of blood vs. lymphatic absorption. Apart from understanding the absorption, it was also the intent to understand the changes in pharmacokinetic response if we allow for diffusion in the tissues and treat the dermis and the subcutis as a continuous layer. This lends to the idea that the absorption differences between the ID and the SC route can be utilized to tune the pharmacokinetic response and a more precise control can be envisioned for personalized medicine.

9:50

Networking Coffee Break

Critical Issues: In Vitro— in Vivo Correlation

10:15

IVIVC in Transdermal Drug Delivery: Streamlining the Drug Approval Process

Audra Stinchcomb, Ph.D., Chief Scientific Officer and Founder of F6 Pharma Inc.; Professor, University of Maryland

Clinical studies are expensive and time consuming. Even pharmacokinetic-based clinical studies for transdermal dosage forms can slow the development process of generic products and burden the healthcare system with extra costs that are ultimately passed onto the patients. These limitations provide an opportunity for the development of surrogate bioavailability and bioequivalence methods. Regulatory agencies will only recognize surrogate methods that are validated and relevant to clinical application scenarios. Several surrogate in vitro permeation testing (IVPT) studies will be discussed, including

CASE STUDY

CASE STUDY

5:20

End of Day One

Tuesday, September 13, 2016

8:00

Complimentary Breakfast & Chairperson's Remarks

Research Spotlight—Bioavailability & Pharmacokinetics in TDD and IDD

8:30

Demystifying Transdermal Doses: Marketed Patches Vs. Oral Counterparts

Mikolaj Milewski, Ph.D., Associate Principal Scientist, Merck

The conventional transdermal market is limited to a narrow range of drugs given the formidable barrier properties of the skin. However, transdermal drug delivery is also commonly regarded as a method that exhibits several specific pharmacokinetic advantages over oral drug delivery. Some of the most cited pharmacokinetic benefits include profiles devoid of high peak-to-trough ratios, common in oral drug delivery, and avoidance of gastric and hepatic first-pass metabolism. Both of them can potentially result in lower transdermal therapeutic doses as compared to oral administration route. Here we examine this thesis in detail by 1) finding marketed transdermal patches which have oral drug counterparts (i.e. drugs used for the same therapeutic indication that exist in the market in both patch and oral forms), and 2) comparing transdermal and oral doses. It is worth mentioning that the notion of a transdermal dose can be confusing as, depending on the source, it may refer to the total drug amount formulated in the patch, or drug amount that is released from the patch during patch wear time, or the drug amount that is delivered into the systemic circulation from the patch during patch wear time. Here we first compare transdermal doses defined as the drug amount released from the patch during application time against oral tablet doses and then focus on the comparison of doses absorbed into systemic circulation i.e. bioavailable doses.

the corresponding healthy human subject data obtained, and the potential in vitro-in vivo correlation (IVIVC). Additionally, a study was completed in order to examine the effect of heat on drug delivery in humans and in vitro, and to evaluate the influence of key variables with which the heat interacts, including the drug, the formulation, and the membrane used in the in vitro study. Residual drug analysis in patches paralleled the results from IVPT and healthy human subject studies, suggesting its potential as a surrogate measure to determine the extent of drug delivery and/or absorption from certain products.

10:55

Effect Of Hyperthermia On Dermal/Transdermal Delivery Of Drugs

Dr. Narasimha Murthy, Associate Professor of Pharmaceutics, Ole Miss

Temperature is known to influence the formulation characteristics and skin permeability, which, in turn could impact drug delivery across the skin. The magnitude of effect of temperature on the permeation of a therapeutic agent is also predominantly determined by the inherent physicochemical characteristics of the active ingredient. In some cases, exposure to elevated temperature has been utilized as a mode of enhancement of drug delivery to improve the therapeutic outcome. On the contrary, in a few cases, heat induced drug permeation enhancement has also been known to have led to severe toxicity. In this presentation, we will discuss the effect of hyperthermia on skin permeation of some of the candidate drugs from their topical and transdermal products. The potential solutions to overcome the negative consequences will also be discussed.

11:35

Brief presentation and lunch sponsored by



Critical Issues—Moving From Lab Formulation to Full Scale Manufacturing

1:05

How to make a Million...Patches: From Lab Formulation to Full Scale Production

Andy Rensink, Ph.D., President, Tapemark

Once you have achieved good pK data, what does it take to scale up, commercialize and produce one million patches? We'll discuss the science and process of taking a lab formulation with promising results through a series of defined steps to achieve full scale production, including what the agency is looking for in the CMC section of the filing beyond statistically significant clinical results. It costs millions to make the first successful transdermal patch for a given molecule, now how much is it going to take scale up the process to be robust and statistically repeatable. What are the pitfalls of process scale up and how can they be avoided. Invariably

1:45

Chemistry, Manufacturing And Controls (CMC) In Transdermal Delivery Systems (TDS)—A Generic Product Development Perspective

Tarun Goswami, Ph.D., Senior Manager, Transdermal Product Development, Amneal Pharmaceuticals

The development and manufacturing of transdermal systems (TDS) is a complex, multidisciplinary and expensive affair. Over the years there have been numerous issues reported with respect to TDS quality and performance. Some of these problems have resulted in product recalls, temporary or permanent removal of the product from the market. These problems can be eliminated by suitably addressing chemistry, manufacturing and controls requirements, which would result in development of robust transdermal formulation and processes.

Especially in generic product development, even minor formulation and manufacturing differences can impact the bioequivalence requirements for that product. Due to the change of scale between pilot and submission batches, certain process parameters may need to be optimized to ensure successful manufacturing. Even after commercialization, special care is needed to ensure that the product retains its performing quality attributes (delivery, adhesion, crystallization, minimal cold flow) during its entire shelf life.

Under current regulatory environment, a complete characterization of the generic product in terms of its qualitative and quantitative similarity along with pharmacokinetic and/or pharmacodynamic, adhesion and skin irritation potential is required. The purpose of this talk is to highlight critical drug and excipient attributes along with critical process parameters and their impact on critical quality attributes of the drug product. Understanding these critical parameters and using a 'Quality by design' in the development can guide the generic companies to optimize the formulation and process design in reduced time intervals.

A few case studies will be presented to emphasize the importance of robust CMC controls to reduce hurdles that need to be overcome and how various aspects of the development can lessen the risk of failure both from a clinical and commercial standpoint.

2:25

Afternoon Networking Break

2:40

Supersaturation To Enhance Drug Delivery— Is It Commercially Viable?

*Lakshmi Raghavan, Ph.D., President & CEO,
Solaris Pharma Corporation*

Presently, it is well known that supersaturated solution of different chemical compound & drugs molecules has been shown to improve delivery in form of membrane flux or otherwise, in transdermal and other non-transdermal systems. The real challenge in maintaining a supersaturated state of chemical in solution is to tailor the solvent system through use of antinucleant polymers to achieve the maximum thermodynamic activity while still maintaining the compound stability in solution. Use of antinucleant polymers has been tested and found effective, however the concepts behind selection of an appropriate polymer for a particular supersaturated system in order to achieve maximum drug delivery are still not well understood. In addition, there are challenges in scale-up, manufacture and stability. In spite of the huge challenges in developing a stable supersaturated product that can be commercialized, extensive research & development efforts as well as innovative designs can exploit the potential advantages of the technology.

3:20

Enhancing Transdermal Drug Delivery System Stability and Extending Shelf Life thru Packaging Head-Space Management

*Craig Voellmicke, Vice President, Business
Development, CSP Technologies*

Current and developing TDD technologies face stability challenges related to moisture, oxygen, carbon dioxide, volatile organic compound and residual solvent interactions. Thus, effective head-space management in the confined space of thin transdermal pouches and in packaged applicator cartridges is key to solving these issues in order to extend product shelf life.

Headspace management options for TDD have been available for some time, and include gas flushing and adhesive labels containing granular desiccants and scavengers. Both of these options can be effective to some level but also have drawbacks; for example, nitrogen flushing does not address ingress over time. Similarly, labels can break and include an adhesive that can introduce unwanted residual organic solvent impurities.

Engineered polymers (extruded or molded parts) can be a more effective and efficient head-space solution, and address a wider range of desiccant and scavenging needs. These solutions can be adhesive free, provide higher capacity and also have the ability to combine

different capabilities such as moisture and oxygen scavenging into a single solution. At the end of this presentation, audience members will:

- Understand the options and benefits of engineered polymers for head-space management, including adhesive-free and combination film options
- Learn considerations for assessing head-space needs and evaluating solutions
- Learn real-world examples of stability challenges and engineered solutions

4:00

Extractable And Leachable Testing For Transdermal Drug Delivery Systems

*Gyorgy Vas, Louis Fleck, Howard Carpenter,
Trace Organic Analytical Group, Intertek
Pharmaceutical Services*

Transdermal drug delivery systems are relatively complex pharmaceutical products. The formulation contains multiple excipients and in addition 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 at a pre-determined rate.

The dermal delivery route is getting more and more 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, besides the drug being delivered includes excipients, degradation products and packaging related components can also be "delivered" with the same route of administration.

The extractable testing of transdermal systems are straightforward and does not require "out of box" thinking. The leachables testing requires more complex approaches, as the regulatory expectation is to test the finished products with biologically relevant extraction media.

The presentation will focus on different test approaches, to present options for leachable testing, how to evaluate the actual leachables and validate analytical methods, what requires non-routine extraction methods, and detection capability down to ppb level.

The complex formulation combined with the low level testing requirement are very challenging analytical tasks. Component identification, analytical method development and validation are not as simple as for the components present at a ppm level or above.

4:40

End of Program

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