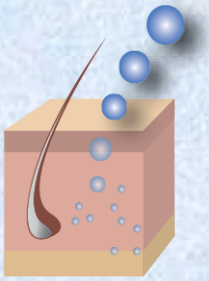
RUTGERS

Center for Dermal Research

2020-2021 ANNUAL REPORT



10th Anniversary 2011-2021

2007/2008

- June 25, 2007
  1st Annual Skin Workshop
- September 30, 2008
  2nd Annual Skin Workshop

2011

- March 3, 2011
  Official launch of the
  Center for Dermal Research/CDR
- May 24, 2011
  First BADF/CDR Skin Course
  offered
- October 12, 2011
  4th Annual Skin Workshop
- September launched LinkedIn page

2012

- By 2012 we had a total of
  30 students graduate with a
  PhD or Masters degree from CDR
- Launch of the CDR Website
- Dermaceutics Course
  switched from Fall to Spring
  in 2012
- Sponsor of the Year 2012:
  Target Health

2013

- September 24, 2013
  First CDR/TRI Joint Seminar
- Fall 2013 First Innovations in
  Dermatological Sciences
  Conference
- Sponsor of the Year 2013: Avon

2014/2015

- Sponsor of the Year 2014:
  Galderma
- Spring 2015 3rd time
  Dermaceutics
  course offered
- Sponsor of the Year 2015:
  Advancing Innovations in
  Dermatology

2016

- CDR 5th Anniversary
  celebration during 4th
  Innovations in Dermatological
  Sciences event in Fall 2016
- Sponsor of the Year 2016:
  BASF Pharma

2017

- January 2017
  42 students graduate
  with PhD or Masters degree
- Fall 2017 1st annual joint
  CDR/BASF Workshop in
  Tarrytown, NJ
- Sponsor of the Year 2017:
  Colgate Palmolive Company

2018

- 4th Dermaceutics Course
  Spring 2018
- Sponsor of the Year 2018:
  Tergus Pharma

2019

- 5th Innovations in
  Dermatological
  Sciences event
- Sponsor of the Year 2019:
  Rodan and Fields

2020 2021

- November 2020 CDR Workshop
  "CBD Wonder Ingredient or Potential Snake Oil" held remotely
- Spring 2021 5th Dermaceutics Course offering remote
- September 2021 6th Innovations in Dermatological Sciences
  Conference remote
- Sponsor of the Year 2021: Estee Lauder
- Four Lifetime Honorary Members Added: Dr. Gopi Menon;
  Dr. Otto Mills; Dr. David Steinberg and Dr. Phil Wertz
- October 2021 over 1,000 LinkedIn followers!

Director's Message

In spite of the significant obstacles posed by Covid-19, the Center for Dermal Research CDR not only survived but had a number of important achievements. For example, our publication numbers were unaffected by the pandemic and we maintained a good level of visibility at scientific conferences. We were able in 2020 to attend the AAPS PharmSci 360, October 26 – November 5, and in 2021 we attended the Biotech Meeting: 2nd Global Virtual Summit on Biotechnology & Bioengineering, April 5-6, https://biotechconference.mindauthors.com, the Controlled Release Society Virtual Annual Meeting, July 25-29, as well as the AAPS PharmSci 360, October 17-20.

ORBIS, the successful scientific exchange of scientists with Europe, was placed on hold in 2021 with a European Union approved extension into 2022-2023. However, before the shut-down we had four ORBIS visitors at CDR namely: Drs. Anna Froelich, Paulina Skupin-Mrugalska, Tomasz Osmalek and Pavel Kovacic. From these collaborative scientific exchanges we have already published five papers in peer-reviewed journals.

In November 2020 we offered remotely our two-day Workshop (postponed from March 2020) entitled "CBD-Wonder Ingredient or Potential Snake Oil?" with Dr. Daniel Siegel MD, MS from Suny Downstate as the plenary speaker. The CDR Annual "Innovations in Dermatological Sciences" conference took place remotely on September 28th and 29th, 2021 with plenary speakers Drs. Peter Elias and Zoe Draelos who gave informative and exciting presentations.

In addition, in late 2021 we even had some travel opportunities ….

As the 2021 winner of the City of Poznan Public Annual Lecture by Eminent Global Scientist competition I presented a lecture entitled "Understanding the Skin to Preserve your Health" at the Polish Library-Congress Center, Poznan in November, 2021. In addition, I gave two other lectures at the Poznan University of Medical Sciences "*Microneedles: a new skin device for drug delivery*" presented to the Student Division of the International Society of Pharmaceutical Engineering (ISPE) and "*Designing formulations for the skin: facts and challenges*" to the Faculty of Pharmacy. I am grateful for the assistance and encouragement of Prof. Janina Lulek (P.I. for the ORBIS scientific exchange program) and recommendation from the Chancellor of the Poznan University of Medical Sciences, Poznan, Poland, who made the travel funds available from the City of Poznan as well as the University.

Statistics on some 2020-2021 CDR successes:

- There were nine CDR seminars offered in 2020 and 12 in 2021 to attendees from around the world and examples include India (Indian Institute of Technology, Bombay), Belgium, England (Nottingham, Bath), Pakistan and Spain (Barcelona).
- A CDR two-day Workshop was offered November 5th and 9th 2020 entitled "CBD-Wonder Ingredient or Potential Snake Oil?" with 30 attendees.
- The CDR Annual "Innovations in Dermatological Sciences" conference took place in September 28th and 29th, 2021 with plenary speakers: Drs. Peter Elias and Zoe Draelos who gave excellent presentations. Since this was a remote event we were able to record the presentations with access for all registrants for up to 3 months after the event. Arrangements offered flexibility to registrants and poster presenters as well as speakers who could easily prerecord their talks. We had 150 attendees representing 60 corporations and 9 universities!! We delayed our "in person" 10th anniversary celebration to the Fall of 2022 and of course we missed our "in person" networking that cannot be replaced easily on the screens of our devices…
- The Dermaceutics Graduate Course was offered in the Spring semester 2021 and we had 87 participants from industry and academia. The largest enrollment for this class!
- In 2020-2021 we had a total of 6 poster presentations, published 21 peer-reviewed papers and 2 book chapters.
- We graduated six Ph.D. students: Drs. Anika Haq Alam, Dina Ameen, Benjamin Goodyear, Vinam Puri, Parinbhai Shah and Julia Zhang. Congratulations to the group!!!!
- We added five new Ph.D. students to the research group, Namrata Matharoo, Hana Moh'D, Robert Falcone, Anna Shternin from Merck and Amgad Saleh from Boehringer Ingelheim. A sixth, Nubul Albayati will join in Spring 2022.
- We welcomed new CDR Honorary Members: Drs. David Steinberg, Gopi Menon and Philip Wertz.

The CDR managed to survive the ups and downs of the Covid-19 surges with laboratory research, student teaching and training, CDR remote events and student graduations /interviews and other changes at Rutgers University. After all, 2021 was the official year of celebrations: the 10th anniversary of the launch of CDR!!! We plan to celebrate in style in Fall 2022!!!

On a wonderful note we welcomed two new additions to the CDR family, Yusur Moh'd, son of Hana Moh'd was born March 11, 2020 and Ella Rose Shternin, the daughter of Anna Shternin born on December 10, 2021. Congratulations!!

Dr. Bozena Michniak-Kohn
Director, Center for Dermal Research/Laboratory for Drug Delivery

CDR Staff and Lab Members 2020-2021

Nirali Dholaria
Part-time PhD Student

Namrata Matharoo
PhD Student
Skin Formulation Scientist

Hana Moh'd
PhD Student

Karen Mooney
Executive Assistant to
Dr. Michniak-Kohn

Keyaara Robinson
PhD Student
LDD Lab Manager

Amgad Saleh
Part-time PhD Student

Anna Shternin
Part-time PhD Student

Amitkumar Virani
Part-time PhD Student

Our Lab Members Receiving PhDs in 2020-2021

Dr. Anika Haq Alam
March 2020
Dr. Alam is currently working as an ORISE Fellow
CDER/OGD/ORS/DTP
U.S. FDA

Dr. Dina Ameen
June 2020
Dr. Ameen is currently working as a Senior Scientist, Skin Biodelivery
Skin Health Translational Sciences
Johnson & Johnson Consumer Inc.

Dr. Benjamin Goodyear
September 2021
Dr. Goodyear is a Global Technical Manager for BASF Pharma Solutions

Dr. Vinam Puri
September 2021
Dr. Puri is a Research Scientist II, Formulation for Solaris-Pharma

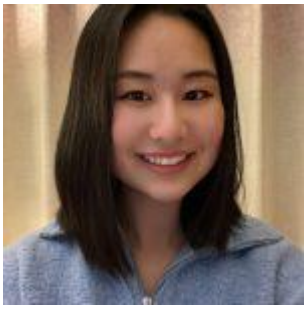
Dr. Parinbhai Shah
September 2020
Dr. Shah is currently the Sr. Manager/Head of Product Development at Cosette Pharmaceuticals Inc.

Dr. Julia Zhang
October 2020
Dr. Zhang is currently the Director of Pharmaceutical Development at ASPIRE Pharmaceutical

Undergraduate Students in CDR 2020-2021

The Center for Dermal Research/Laboratory for Drug Delivery (LDD) participates in numerous programs to offer undergraduate students laboratory experience. We are proud to have had the following students be a part of our group!

Kevin Chen joined the LDD Team as part of the SURF Program. The SURF (Summer Undergraduate Fellowship) Program is offered through the Ernest Mario School of Pharmacy. The program is intended for highly motivated undergraduates interested in a research career in the pharmaceutical and environmental sciences. Students are provided with an opportunity to conduct full-time research in areas related to Pharmacology and Toxicology, Environmental Health Sciences, Pharmaceutics, Medicinal Chemistry, Chemical Biology, and Clinical Pharmacy. Kevin is also a senior in the Honors Program at Rutgers



Joyce Cui joined the LDD in the Spring 2021 and we are very happy to have her as part of our team at the LDD!

Joyce is a junior at the Honors Program at Rutgers University, majoring in Biological Sciences and minoring in Spanish and Cognitive Science. She is hoping to gain experiences from a wonderful team at LDD prior to starting her honors thesis.

Katrina Tun joined the LDD for the academic year 2020/2021 as our Aresty Student. The Aresty Research Assistant (RA) Program enables students to gain their first authentic research experiences by supporting faculty research projects during the academic year. RAs learn valuable research skills by working side by side with professors on forefront research projects, while professors benefit from a structured program to recruit and train the next generation of researchers.

Due to Covid, our Summer 2020 participants from the RISE (Research Intensive Summer Experience) and Project SUPER (Science for Undergraduates: A Program for Excellence in Research) were not able to come to campus but we were fortunate to have them work with us remotely.

RISE: Celymar Valentin,
University of Puerto Rico

Project SUPER: Sophia Mordan
Rutgers University

Visiting Scientists in CDR 2020-2021

Daphne Benderly, Ph.D. from Presperse, NJ specializing in polymer chemistry and characterization.
July 2016-present.

Kavita Beri, M.D. practicing clinician dermatologist from Ocean City, NJ.
Spring 2015-present.

Samuel Gurion-Arsiquaud, Ph.D. spectroscopist from TRI, Princeton NJ.
Spring 2015-present.

Benjamin Goodyear, PhD. Global Tech Manager for BASF Pharm
October 2021-present

ORBIS at Rutgers University

The Center for Dermal Research (CDR) at Rutgers, The State University of New Jersey is a partner hosting site for Visiting Scientists from Europe from both academia and pharmaceutical companies. In 2019, the CDR hosted seven ORBIS (Open Research Biopharmaceutical Internships Support) scientists. In the initial year, 2018, nine scientists visited the CDR. During the four years of the proposal, ending in 2023, Rutgers University's CDR will host 98-person months of visiting scientists from the ORBIS consortium from many locations in the European Union. The P.I. at Rutgers University is Dr. Bozena "Bo" Michniak-Kohn, Professor of Pharmaceutics at the Ernest Mario School of Pharmacy and Director of the CDR.

The current process of drug development is lengthy and inefficient. Only 1 out of approximately 10,000 drug molecules enters the market. Therefore, more effective medicines, demanded by society, cannot be provided by pharmaceutical industry. To fill this gap, ORBIS proposes that the high attrition rate of new drug candidates might be reduced by over 20% by improving early stage R&D productivity. The overarching objective of ORBIS is therefore to form an international and inter-sectoral academic and industrial network. The action is aimed at improving the preclinical pathway of medicine development concentrating on processes and technologies. The goal is to integrate multidisciplinary research by involving academia and industry from EU (Poland, Ireland, Finland, Germany and Czech Republic), EU associated country (Ukraine) and the US to address the poor drug bioavailability as 70% of actives have solubility and/or membrane permeability problems. The action is addressed at selected molecules of class II and IV of Biopharmaceutics Classification System, to improve their pharmaceutical potential. The complementary consortium comprises experts in computations, physical chemistry, material science, nanotechnology, pharmacy, pharmacology and bioanalysis. The secondments (training periods) will create a stimulating environment for early stage researchers to advance their individual career and soft skills. EU scientists will amalgamate their expertise in drug synthesis and dissolution, oral formulations, and bioanalytical methods with the knowledge on dermal research provided by the US partner. ORBIS will consolidate the existing links, promote long-term cooperation and exchange of knowledge between beneficiaries and partners. ORBIS will also enhance dissemination of new research outcomes and raise the awareness among the general public of the importance of drug delivery research that makes new drugs more accessible and affordable for society.

The ORBIS Project is a response to the current scientific, economic and social challenge of increasing the effectiveness and productivity of drug development process, both for innovative and (super)generic drugs. This goal can be achieved by interdisciplinary cooperation between the academics from different fields of pharmaceutical sciences and the employees of R&D sector in commercial enterprises. The core of ORBIS is constituted by international, intersectoral exchange of researchers between academic centers and pharmaceutical companies – the consortium partners

ORBIS Visitors in CDR 2020-2021

Professor Anna Froelich, Ph.D., Assistant Professor, Department of Pharmaceutical Technology, Poznan University of Medical Sciences, Poznan, Poland. Funded by Orbis RISE grant. March, 2019- March, 2020.

Paulina Skupin-Mrugalska, Ph.D., Department of Inorganic &Analytical Chemistry, Poznan University of Medical Sciences, Poznan, Poland. Funded by Orbis RISE grant. September, 2019-February, 2020

Professor Tomasz Osmalek, Ph.D., Associate Professor, Chair and Department of Pharmaceutical Technology, Poznan University of Medical Sciences, Poznan, Poland. Funded by Orbis RISE grant. December, 2019-March, 2020.

Pavel Kovacic, Formulation Manager Zentiva, k.s. (Prague, Czech Republic) January – March 2020

CDR Lifetime Honorary Members

William Ju
Advancing Innovations in Dermatology

Gopi Menon
Fellow, California Academy of Sciences, SF

Otto Mills
Rutgers
Robert Wood Johnson Medical School

Kishore Shah
Polytherapeutics, Inc.

David Steinberg
President, Steinberg & Associates

Paul Thau
Formerly with PaCar Tech, LLC

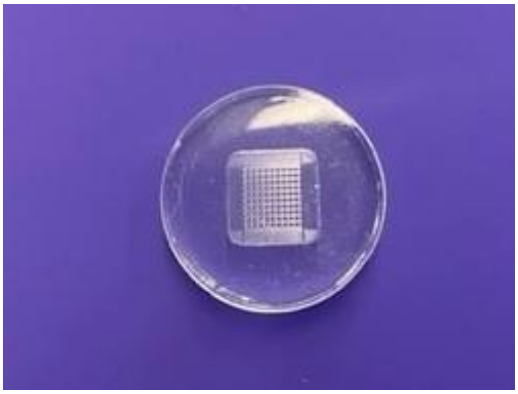
Phil Wertz
University of Iowa – retired

Microneedle Array Patches as Transdermal Delivery Vehicles for Chronic Diseases

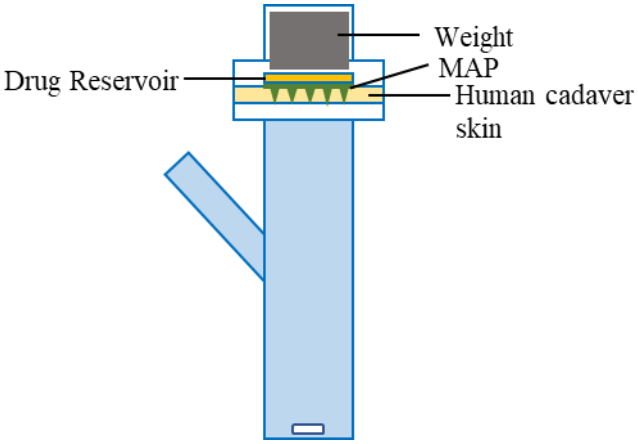
Microneedle Array Patches (MAPs) are small medical devices consisting of micron-sized needles which are arranged onto a small patch, and have been extensively studied to overcome the limitations of conventional transdermal delivery approaches. The needles impart their effect by creating micron-scale pores which disrupt the barrier properties of the stratum corneum (SC), thereby increasing its permeability and providing enhanced transdermal drug delivery. Due to their length, typically between 150 – 1500 µm, they reduce the risk of stimulating nerve endings and can provide efficient, pain-free delivery of many drugs through the skin for entry into systemic circulation. The advantages of MAPs, including their minimally invasive nature, ability to provide controlled release of drugs, and relative simplicity to manufacture make them ideal drug candidates for delivering hydrophilic compounds, vaccines and potent compounds. However, their small size limits the amount of active that can be loaded and makes them a challenging application for molecules that are required in large doses to impart their effect. Levodopa (LD) is one such compound, and its administration via MAPs could overcome some of the disadvantages of its current administration via the oral route.

LD is the "platinum" standard for Parkinson's disease treatment but it is rapidly converted to dopamine in the peripheral tissues, which is responsible for the accompanied nausea and adverse reactions after oral administration. Due to its rapid conversion, it is administered in large doses and only 1-3% of its initial dose is available to the brain.

Studies using MAPs for transdermal drug delivery at the Center for Dermal Research are expanding significantly with interest in developing high-drug loaded, long-acting MAP-based delivery systems for use in treating chronic diseases. We are working with a variety of nanocarriers and microneedle compositions to achieve effective delivery. After establishing initial analytical and physical characterization of nanocarriers and microneedles prototypes, we are using Franz diffusion cells to assess their drug release behavior. Currently, we are focusing on developing various formulation strategies with molecules to treat Alzheimer's and Parkinson's Disease, including galantamine hydrobromide and levodopa which are currently administered via the oral route.



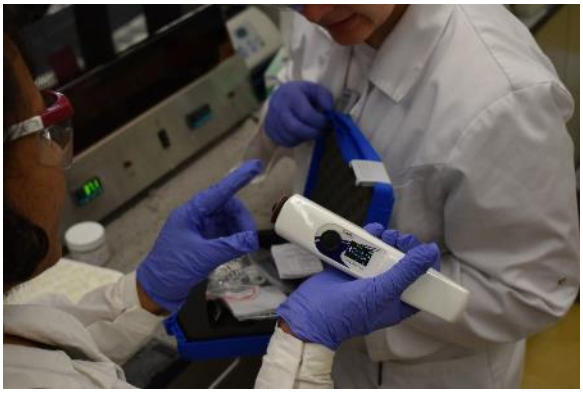
Microneedle Array Patch Molds



Example FDC setup for MAPs

In-Vitro Release (IVRT) and In-Vitro Skin Permeation Testing (IVPT)

In vitro permeation testing (IVPT) or skin permeation testing is a critical tool for evaluating drug delivery into the various skin layers and for understanding the formulation selection for topical or transdermal application. The Center for Dermal Research (CDR) is well equipped with Franz diffusion permeability testing equipment, which includes water-jacketed models as well as heat block models. FDC-24 heat blocks have the capacity to handle up to 24 Franz diffusion cells which allows the evaluation of six replicates for three different formulations with a control in a single heat block. We develop and validate suitable HPLC analytical methods for screening drugs as well as personal care and cosmetic actives. Optimized formulations are evaluated for drug/active distribution in different skin layers. The flux of actives across human cadaver skin can be determined by quantifying levels of compounds in the Franz cell receptor medium, collected at various time intervals. We have access to various U.S. accredited tissue banks and companies specializing in donated skin samples and disease-state tissue models. Depending on the project needs, an appropriate model can be selected for testing. We have explored various skin models including freshly-excised human skin (mostly from abdominal surgeries), human cadaver skin, skin from porcine ears (to study anti-acne drugs), tissue engineered skin models (EpidermFT for example), Strat-M (MilliporeEMD) and in-vitro disease-state skin such as the atopic dermatitis model. Stratum corneum (SC) the uppermost layer of the skin forms a major barrier to permeation of topically applied compounds. It is important to use undamaged skin samples in our permeability experiments where the SC is intact and performing as it would in vivo. Thus, a skin integrity test is always performed as part of any IVPT protocol.



At CDR, we use a fairly sophisticated, wireless, portable and easy-to use instrument Vapometer (Delfintec, Finland) to measure transepidermal water loss (TEWL) as an indicator of skin integrity. Vapometer data is stored for every IVPT experiment we perform at the Center. Release studies of actives through polymeric synthetic membranes such as polysulfone, cellulose acetate/nitrate mixed ester is termed in-vitro release testing (IVRT). This is performed in order to understand and establish the release kinetics of a drug from the formulations such as polymer or lipid based nanoparticles, organogels, complexes and liposomes. IVRT studies can be performed either by mounting cellulose acetate membranes on Franz diffusion cells to closely simulate topical application or by using dialysis tubes or dialysis cassettes with appropriate molecular weight cut-off values. Rates of drug release from particular formulations and fluxes through human cadaver skin are important data required for research and development endeavors and FDA filings.

Nanocarriers as Drug Delivery Vehicles

Nanoparticles as drug delivery carriers have been explored for various topical and transdermal applications for more than two decades. Nano-sized particles are utilized as beneficial drug carriers to address various challenges of poor penetration/permeation in topical and transdermal drug delivery. These nanostructures can provide a protective polymeric or lipid coating to help stabilize certain photosensitive drug molecules and to reduce skin irritation caused by their direct topical contact. Nanocarriers have the potential to improve the solubility of hydrophobic drugs that are suitable for skin permeation but a challenge to incorporate in adequate amounts in the final formulation. Nanocarriers can be further modified to provide controlled release, targeted treatments and can serve as reservoirs in skin layers or hair follicles, which facilitates the distribution of the drug molecules throughout the skin including into the deeper layers. For many years, the research group of Dr. Michniak-Kohn has focused on the design, development and testing of polymeric and lipid based nanoparticles (nanosuspensions, nanoemulsions, liposomes, solid lipid nanoparticles and ethosomes) for topical and transdermal drug delivery. Research efforts have been directed towards targeting several disease states including atopic dermatitis, psoriasis, skin cancer and skin aging issues, and for systemic (transdermal) delivery using gels and patches for treatment of Alzheimer's disease, epilepsy, and for anti-inflammatory and antioxidant effects. At the Center, we characterize these nanocarriers for particle size and surface charge, and evaluate in-vitro drug release, skin permeation, skin irritation as well as pro-inflammatory cytokine release. We are implementing computer modeling and Quality by Design (QbD) approaches to complement experimental protocols in order to achieve better design space and gain a greater understanding of the effects of critical processes and formulation parameters on final product characteristics. Some examples of our studies are provided below:

Niosomes development via QbD approach

Niosomes are non-ionic surfactant-based carriers for enhanced drug delivery for topical and transdermal applications. Niosomes can modify drug properties and increase drug stability by holding drug within the niosomal matrix. We have performed extensive research work to develop corticosteroid drug loaded niosomes. We have used a systematic QbD approach and utilized quality by design principles to develop and optimize the most suitable niosomal dispersion. Using quality by design concept, we have extensively studied the various CMA's and CPP's that impact on the product quality. We have used statistical software to develop prediction profiles for the formulation to evaluate impact of the process change on the final formulation. The aim is to utilize advanced techniques to develop the niosomes and to minimize failure risk and maximize scale up feasibility.

Liposomes

Liposomes are self-assembled structures formed by lipids. The use of lipid vesicles in topical delivery systems has many advantages, such as: increases drug permeation through stratum corneum; reduced skin irritation caused by drugs and metabolites; prolonged the effective time within the skin by interaction of phospholipid bi-layer with the similarly structured cell membrane; for hydrophobic drugs, a liposome formulation increases overall solubility without the use of skin irritating solvents. However, it has been proven that classic liposomes are of little or no value as carriers for transdermal drug delivery because they do not deeply penetrate the skin, but rather remain on the upper layer of the stratum corneum. For liposomes to pass through and reach to the deeper layers of the skin, many new strategies have been developed. Among these, deformable liposomes have gained much attention in the past twenty years. Deformable liposomes are prepared by combining a lipid, e.g., a phosphatidylcholine (PC) with a denaturant such as a surfactant or an alcohol.

We have conducted extensive research to develop various deformable liposomes using NSAIDs as model drugs. Liposomes were prepared by the thin film hydration method followed by sonication (Figure 1). These deformable liposomes were composed of phospholipid, edge activator, cholesterol and/or permeation enhancer.

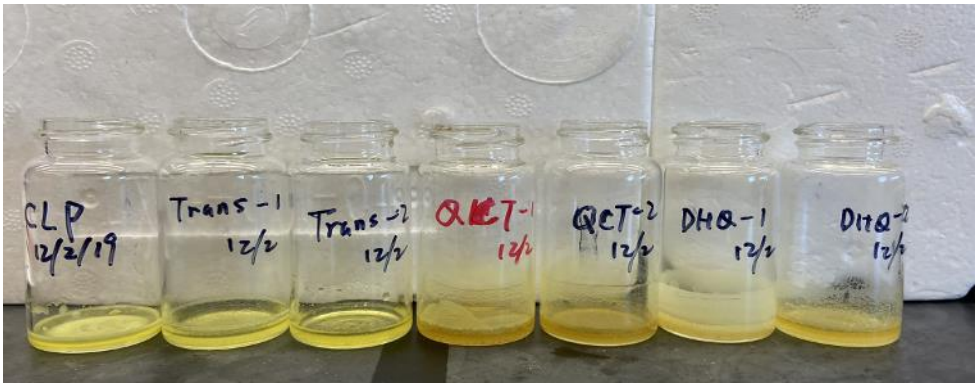


Figure 1: Lipid film of various liposomal formulations

These NSAID loaded liposomes demonstrated high drug entrapment rate, homogeneous particle size and improved solubility and skin permeability compared to classic liposomal formulations. Figure 2 shows the TEM image of the deformable formulations.

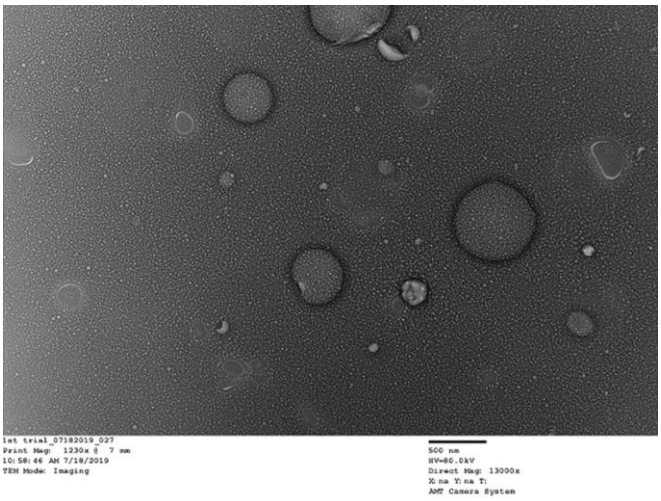


Figure 2: TEM image of deformable liposomes

The dermal and transdermal delivery using deformable liposomes can be a promising alternative to conventional oral delivery of NSAIDS with enhanced local and systemic onset of action and reduced side effects. Our current research goal is to incorporate these liposomal suspensions into a delivery vehicle, such as hydrogels, creams or transdermal patches to eventually develop a commercially viable formulation.

Microemulsions for micro-and nanocarriers

Microemulsions are liquid nanodispersions composed of polar and non-polar phases stabilized with surfactant and usually a co-surfactant. Because of their advantageous properties, they are frequently investigated as potential carriers useful in topical and transdermal drug delivery. According to numerous scientific reports, microemulsions reveal good solubilizing properties, which is particularly important in formulations containing poorly soluble drugs. Moreover, microemulsions can enhance the permeation process, improving the bio-availability of the incorporated drug. In our laboratory we investigate microemulsions and microemulsion-based polymer gels as potential carriers for topical and transdermal delivery of non-steroidal anti-inflammatory drugs. One of the most important aims of our studies is to assess the physicochemical factors which are crucial for the skin permeation and determine the therapeutic efficiency of the formulation.

Transdermal Delivery of Drugs for Neurodegenerative Diseases

The transdermal route possesses several advantages over other routes, such as avoidance of first pass effect metabolism and gastrointestinal side effects and/or metabolism, improved efficacy and decreased toxicity. Also, it presents a very appealing choice for the treatment of Alzheimer's disease (AD). Indeed, transdermal patches offer exceptional advantages for the AD patients by reducing the pill burden, thus improving compliance. Moreover, a study involving 1059 AD patients' caregivers revealed that 70% of them preferred the rivastigmine patch over capsules. The preference was based on the patch ease of application and less interference with everyday life. In addition, there is an advantage to being able to see the applied patch as opposed to remembering if the patient has or has not taken their oral medication especially in patients who have impaired memory.

The objective of this research is to develop transdermal patches for delivery of drugs for some neurodegenerative diseases such as Alzheimer's disease and multiple sclerosis. First, through investigating the effect of chemical penetration enhancers on the improving the transdermal delivery of the drugs. Several penetration enhancers with different mechanisms of action at different concentration were compared to determine the enhancer with maximum enhancement ratio (Figure 3).

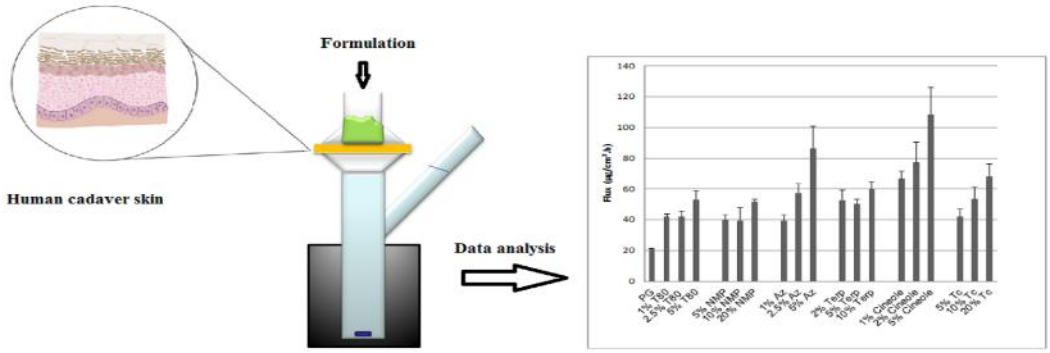
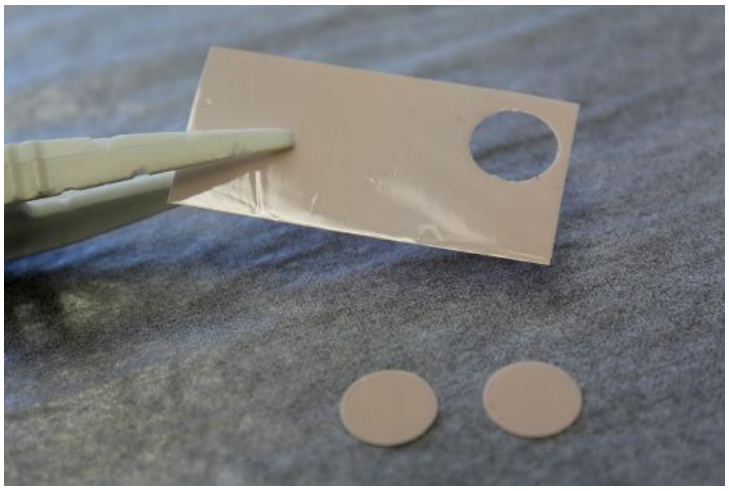


Figure. 3: Using Franz diffusion cells to test the transdermal permeation of drug molecules with the presence of different penetration enhancers.

Second, formulating the drug into a transdermal drug delivery system. Basically, there are two different types of patches; reservoir type and matrix type. Our focus is to formulate and characterize a transdermal patch of a drug for Alzheimer's disease, which is available as oral tablets. A drug in adhesive type of patch is formulated by dissolving the drug in an acrylate polymer matrix containing a penetration enhancer. For this purpose, several acrylate and silicon polymers were investigated to choose a candidate polymer that offers highest delivery of drug. In addition, 10 different penetration enhancers were compared in terms of enhancement effect. The optimization of the formulation included a study of the effect of concentration of the API on the flux, and effect of addition of crystallization inhibitor. All permeation experiments were done using vertical Franz diffusion cell mounted with human cadaver skin (Figure 4). The developed patches are designed to be applied once daily to deliver the drug at the therapeutic level with minimum irritation.

Figure 4: A schematic describing the process of developing and characterizing drug-in-adhesive patch.



A transdermal patch

Transungual (Nail) Drug Delivery

Transungual drug delivery refers to the drug transport across the nails to achieve targeted drug delivery for treatment of nail diseases. Onychomycosis is a fungal disease of the nail that is growing rapidly worldwide especially in the older population. The condition involves discoloration, brittleness and thickening of the nails. It is a recurring disease seen more in toenails than in fingernails and the challenge is to achieve effective drug delivery topically rather than by the oral route, the latter posing greater risks of systemic adverse effects. A transungual drug transport system provides a better delivery route than oral or systemic treatment of fungal infections due to its better adherence, localized action and minimum systemic side effects.

Transungual drug delivery studies at the Center for Dermal Research have been expanded significantly with interest in deep nail layer delivery. We are working with novel formulations containing different anti-fungal drugs to achieve effective delivery. After establishing initial analytical characterization of anti-fungal drugs and human cadaver nails, we have begun permeation studies using modified Franz Diffusion Cells with nail adapters (Figure 6, Figure 7).

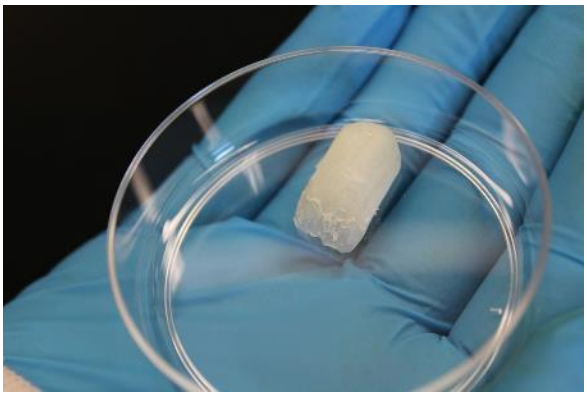


Figure 6: Human cadaver nail

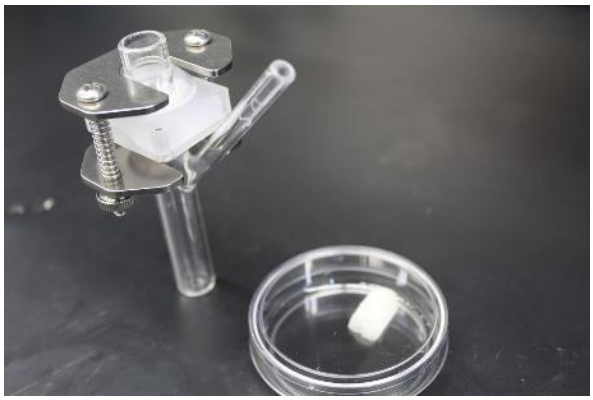


Figure 7: Franz diffusion cell with nail adapters

Efforts are being made not only towards achieving drug permeation through the nail, but also understanding lateral diffusion of drugs in the nail layers. We have collaborations with our partners at TRI Princeton and other research groups with the latest technology platforms and testing capabilities to enhance our efforts in this area. Currently, we are focusing on developing different formulation strategies with potential antifungal molecules such as terbinafine hydrochloride, econozaole, ketoconazole, and others to target the disease and achieve effective antifungal therapies. We are exploring various formulations such as microemulsion/nanoemulsion gels, lipid nanostructures and nail lacquers for treating fungal infections.

Innovations in Dermatological Sciences Conference
Held Remotely in 2021

RUTGERS

Center for Dermal Research

"Innovations in Dermatological Sciences"

Celebrating the 10th Anniversary of the CDR - Annual Conference - Remote

September 28 & 29, 2021

Speakers – September 28th

Dr. Michael Zwick, Rutgers University
Dean Joseph Barone, Rutgers University
Dr. Zoe Diana Draelos, Dermatology Consulting Services PLLC *Plenary Speaker
Dr. Vijendra Nalamothu, Tergus Pharma
Dr. Greg Hillebrand, Amway
Dr. Eduardo Perez, Signum Biosciences, Inc.
Dr. Kaushik Chakravarty, VeriSIM Life, Inc.
Dr. Jim Simon, Rutgers University
Dr. Kavita Beri, BE Mind Body Skin
Dr. Kristen Labazzo, Rutgers University

Speakers – September 29th

Dr. Peter Elias, San Francisco VA Health Care System *Plenary Speaker
Dr. Philip Wertz, University of Iowa
Dr. David Moore, Tioga Research Inc
Dr. Geert Cauwenbergh, Legacy Health Care
Dr. Giuseppe Valacchi, North Carolina State University *Keynote Speaker
Dr. Ian Myles, National Institute of Health (NIH)
Dr. Suzie Chen, Rutgers University
Dr. Mayumi Ito, NYU Langone Health
Dr. Sam Raney, United States Food and Drug Administration
Dr. Markham Luke, United States Food and Drug Administration
Dr. Tannaz Ramezanli, United States Food and Drug Administration
Dr. Priyanka Ghosh, United States Food and Drug Administration

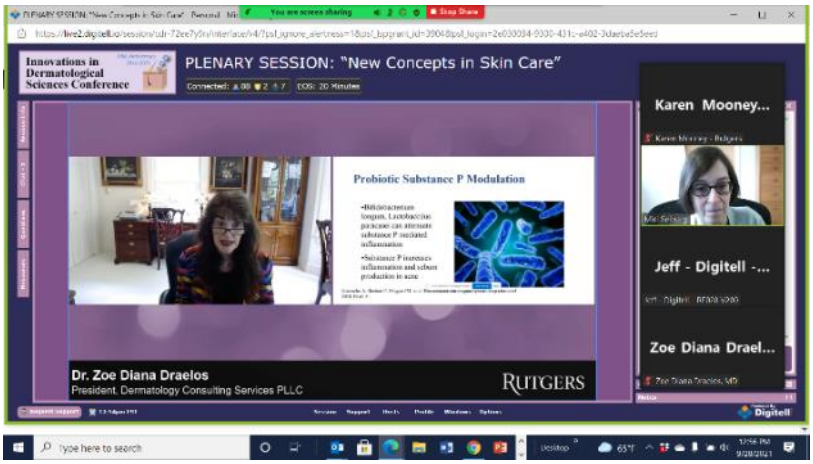
10th Anniversary 2011-2021

Registration is now open! Visit our website for more details:
https://sites.rutgers.edu/centerfordermalresearch/cdr-events/ids-conference/

Dr. Michniak-Kohn welcomes the 154 attendees representing 60 corporations and 9 universities!

Dr. Wilson Lee accepts the CDR Sponsor of the Year Award – Estee Lauder!

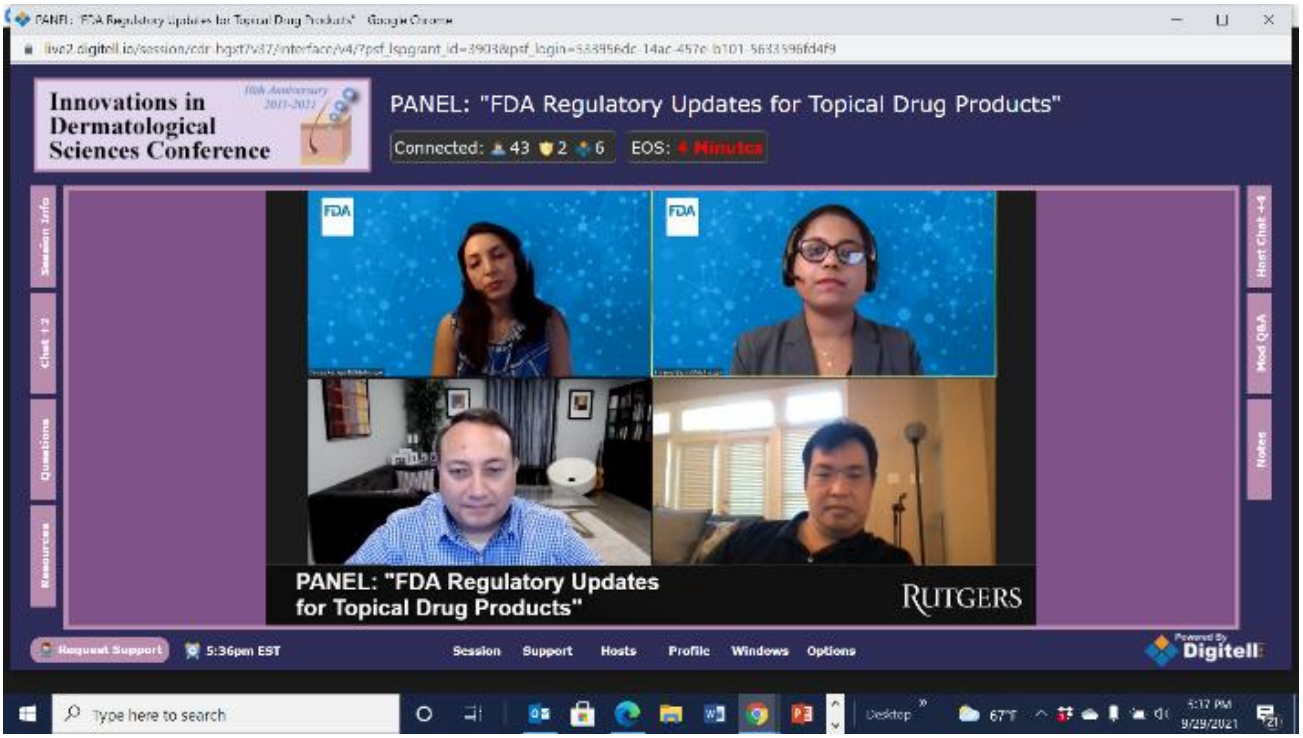
Dean Joseph Barone, Rutgers Ernest Mario School of Pharmacy welcomes the attendees.



Dr. Zoe Diana Draelos, our September 28th Plenary Speaker discusses "New Concepts in Skin Care"

Dr. Peter Elias, our September 29th Plenary Speaker presenting "Impact of Aging on Skin Function"

Dr. Giuseppe Valacchi, our Keynote Speaker presents "NLRP1 Inflammasome involvement in Cutaneous Responses to Pollution"



We wrapped up our conference with an FDA Panel discussing "FDA Regulatory Updates for Topical Drug Products". The panel featured **Dr. Sam Raney**, **Dr. Markham Luke, Dr. Priyanka Ghosh** and **Dr. Tannaz Ramezanli**

Thank you to all of our 2021 Conference Sponsors:

Thank you to our 2021 Planning Committee:

Kavita Beri – BE Mind Body Skin

Thomas Boyd – Colgate Palmolive Company

Jamie Breslin – Advancing Innovation in Dermatology, Inc.

Suzie Chen – Rutgers University

Giorgiana Giancola – Colgate Palmolive Company

Vincent Gruber – Jeen International

Peter Landa – Estee Lauder

Bill Ju – Advancing Innovation in Dermatology, Inc.

Laurie Joseph – Rutgers University

Bozena Michniak-Kohn – CDR- Rutgers University

Otto Mills – Rutgers University

Karen Mooney – CDR – Rutgers University

Vijendra Nalamothu – Tergus Pharma

Amy Pappert – Rutgers University

Miri Seiberg – Seiberg Consulting

Summary of our Conference Attendees:

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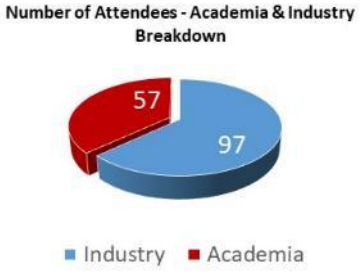
Center for Dermal Research
"Innovations in Dermatological Sciences Conference 2021"
September 28 & 29, 2021 (remote)

Conference Attendees: 154

Companies Represented: 60
Universities Represented: 9

- COMSTAT University (Pakistan)
- Long Island University
- New York University
- North Carolina State University
- Rutgers University
- UNIVERSITÀ DEGLI STUDI DI FERRARA (Northern Italy)
- University of Iowa
- University of Texas
- University of York (England)



CDR Workshop – November 5th & 9th, 2020

Our CBD Workshop originally scheduled for March 2020 was postponed due to Covid and held remotely on November 5th & 9th, 2020. We welcomed 30 attendees to our workshop!

Thank you to Fox Rothschild LLP for sponsoring this event!

Fox Rothschild LLP
ATTORNEYS AT LAW

Center for Dermal Research Presents:

CBD - Wonder Ingredient or Potential Snake Oil?

Thursday, Nov 5th and Monday Nov 9th. Times shown are EST
Remote Workshop

Thursday, November 5th

1:00-1:10pm Opening Remarks
1:10-2:10pm Plenary Speaker: "Therapeutic Potential of Cannabinoids in Dermatology and Beyond" Daniel Siegel, MD, MS (Management & Policy), SUNY Downstate
2:10-2:45pm CBD Regulatory Overview – David Steinberg, President, Steinberg & Associates
2:45-3:00pm Break
3:00-4:00pm CBD CMC – Chemistry, Manufacturing, and Controls Challenges; Keith Woelfel, Director of Research and Development, Caliper Foods
4:00-4:45pm Intellectual Property Issues Relating to CBD Industry; Shahnam Sharareh, PharmD, RAC, Partner, Fox Rothschild LLP

Monday, November 9th

1:00-1:15pm Questions/Follow-up from Day 1
1:15-2:00pm Corporate Banking, Employment, and Investment Considerations Panel; Jonathan Lagarenne, JD, Partner, Fox Rothschild LLP; Bob Nagle, JD, Partner, Fox Rothschild LLP; Mark Yacura, JD, Partner, Fox Rothschild LLP
2:00-2:45pm CBD Update on the Latest Importation, Transportation and Intrastate Sales and the Ever-evolving Matrix of State Compliance Regulations; Joshua Horn, JD, Partner, Fox Rothschild LLP
2:45-3:00pm Break
3:00-3:45pm FDA and USDA Perspectives on CBD and Hemp Derived CBD Products; Robert Falcone, PhD, Prestige Consumer Healthcare
3:45-4:00pm Closing Remarks

Thank you to Fox Rothschild LLP for sponsoring this event!

For more information: cdr_frontdesk@dls.rutgers.edu

Dermaceutics Course 2021

The Dermaceutics Course is an in-depth full semester course designed for graduate level students as well as scientists in the pharmaceutical/personal care and cosmetic industries who need to learn more about the fundamentals of skin, skin absorption, topical/transdermal compound delivery and methodologies for testing the penetration of compounds into skin. This course is held every three years at Rutgers University.

In the Spring 2021, due to Covid, all 14 lectures of the course were held remote which allowed us to have our largest class every with **87 students in attendance**!

RUTGERS

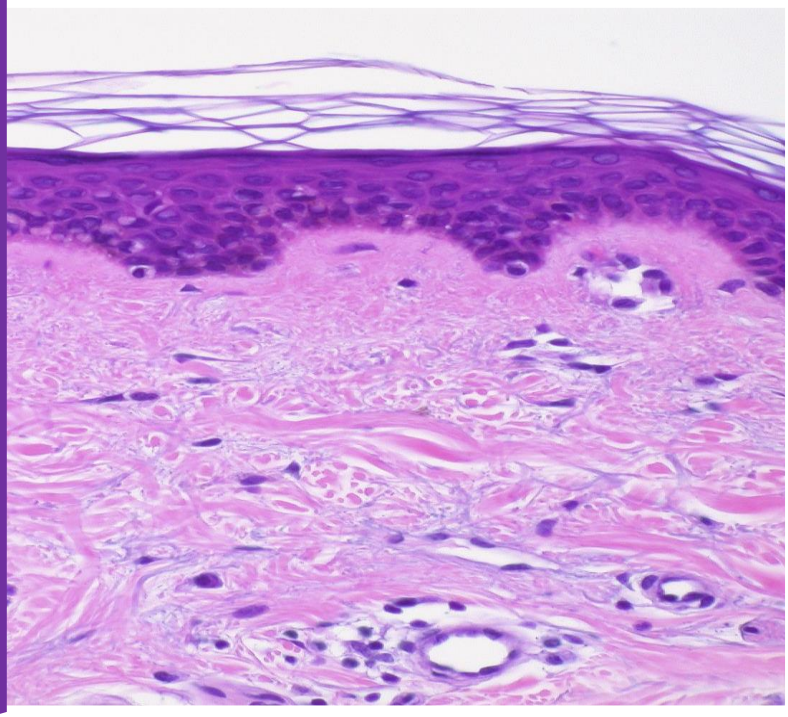
CENTER FOR DERMAL RESEARCH TRAINING PROGRAM

DERMACEUTICS

SPRING 2021

WEDNESDAYS; 6PM-9PM

Offered Remotely



GOALS OF THE COURSE

"Dermaceutics" is an in-depth full semester course designed for graduate level students as well as scientists in the pharmaceutical/personal care and cosmetic industries who need to learn more about the fundamentals of skin, skin absorption, topical/transdermal compound delivery and methodologies for testing the penetration of compounds into skin. We will cover in vivo clinical testing as well as issues with regulatory and intellectual property/patent aspects of formulations and actives applied to the skin.

LEARNING OBJECTIVES

Upon completion of this course, you will be able to:

- Explain general in vitro testing procedures for topicals and transdermals
- Discuss regulatory requirements for in vitro absorption testing
- Understand the complexities in setting up in vivo testing panels
- List the different stages of percutaneous absorption

- Be familiar with skin penetration parameters
- Understand the approaches of enhancing and retarding percutaneous absorption of actives
- Discuss the barrier properties of skin, skin biology, skin metabolism of actives

WHO SHOULD ATTEND

- Skin research and development scientists
- Formulation chemistry experts
- Toxicology and regulatory affairs specialists
- Technical sales and marketing professionals
- New employees needing introductory background
- Legal professionals dealing with I.P., patent litigation in the topical/transdermal areas

*Industry participants and those currently not enrolled as Rutgers students will receive a certificate of completion in lieu of academic credits.

Topics Covered:

- Basic Principles I: *"Skin Structure and Function"* by Dr. Bozena Michniak-Kohn
- Basic Principles II: *"The Stratum Corneum and Lipids"* and *"Biochemistry of the Skin"* by Dr. Gopi Menon
- Skin Aging and Photodamage: *"Skin Aging and Photodamage"* by Dr. Linda Rhein
- Principles of Percutaneous Absorption I*: "Skin of Color"* by Dr. Seiberg and *"Skin Penetration Pathways"* by Dr. Bozena Michniak-Kohn
- Principles of Percutaneous Absorption II: *"Enhancement of Drug Permeation I"* by Dr. Bozena Michniak-Kohn
- Principles of Percutaneous Absorption III: *"Enhancement of Drug Permeation II"* by Dr. Bozena Michniak-Kohn
- Formulation Patents, I.P. & Obviousness: *"Formulation Patents, I.P. & Obviousness"* by Dr. Shahnam Sharareh
- Skin Diffusion & Dissolution: "*Fick's Laws of Diffusion*"; "*Percutaneous Penetration Parameters*" and "*Drug Release Studies*" by Dr. Michniak-Kohn
- In Vitro and In Vivo Clinical Testing I: "*In Vitro Cellular Skin Models*" and "*In Vitro & In Vivo Animal Models*" by Dr. Bozena Michniak-Kohn
- In Vitro and In Vivo Clinical Testing II: "*Clinical Testing in Humans*" by Dr. Neelam Muizzuddin and "*Antiperspirants & Deodorants*" by Dr. Peter Hilliard
- Delivery Systems: "*Transdermal Delivery Systems*" by Dr. Bozena Michniak-Kohn
- Skin Diseases, Clinical Treatment & Commercialization: "*Overview & Treatment of Common Skin Diseases*" by Dr. Otto Mills and "*From the Clinic to Commerce*" by Dr. Jeffrey Mills
- Delivery Systems & Toxicology: "*Topical Delivery Systems*" by Dr. Indu Pal Kaur and "*Toxicology and the Skin*" by Dr. Laurie Joseph
- Hot Topics: "*Fundamentals of Hair Science*" by Dr. Trevor Evans and "Vibrational Spectroscopy, Microscopy & Imaging of Skin and Hair" by Dr. Samuel Gourion- Arsiquaud

CDR Seminars in 2020

January 27: Dr. Tomasz Osmalek presented *"Design and Studies on Semi-Solid Systems for Topical Delivery of Anti-Inflammatory Drugs"*

February 24: Norman Richardson, BASF Pharma Solutions presented *"Excipients for Human Skin Permeation Enhancement of Topical Drugs"*

March 9: Dr. Pascal Yvon, Alban Muller presented *"5 Key Considerations in Developing Natural Cosmetics"*

Due to Covid, our CDR Seminars were cancelled for April and May. The remaining seminars were held remotely for 2020.

June 29: Dr. Laurie Joseph, Rutgers University presented *"Skin and Eye: Targets for Vesicant Induced Injury"*

July 27: Dr. Jemima Shultz, DSM Nutritional Products presented *"Natural Clay Minerals and Cosmetic Applications, In Vitro and Ex Vivo Evaluations on Topical Delivery and Cell Viability Study"*

September 21: Dr. Samiul Amin, Manhattan College presented *"Engineering Complex Fluid Formulations for Enhanced Sustainability in Cosmetic and Personal Care Products"*

October 21: Norman Richardson, BASF Pharma Solutions presented *"Functional Pharmaceutical Excipients for Optimized Transdermal Drug Delivery System (TDDS) Design and Development"*

December 1: CDR/BADF joint seminar Dr. Robert Verdicchio presented *"Nanospace the Next Industrial Revolution"*

December 7: Dr. Sonia Trehan, Johnson & Johnson presented *"Topical Delivery: A Pragmatic Vision"*

CDR Seminars in 2021 – held remotely

January 19: BADF/CDR joint seminar featuring Dr. Laurie Joseph and Dr. Krishnan Tamareselvy presenting *"What's in a Name: 2021 Update of the International System of Uniform Cosmetic Ingredient Names"*

January 25: Dr. Robert Falcone, Prestige Consumer Health presented *"How to Leverage Real World Data for Claim Substantiation?"*

February 22: Benjamin Goodyear, BASF Pharma Solutions – Skin Delivery presented *"Lipid-Based Excipients for Skin Drug Permeation Using IVPT Studies"*

March 22: Dr. Manpreet Randhawa, Syntheon LTD. Dr. Randhawa's topic *"From Traditional Knowledge to Efficacy Driven Modern Day CBD"*

April 5: Dr. Inayet Ellis, Gattefosse, presented *"Microemulsions to Enhance Percutaneous Absorption in Dermal Delivery"*

May 10: Dr. Audra Stinchcomb, University of Maryland, presented *"Translational Transdermal Delivery from Complex Drug Products"*

June 14: Dr. Joanna Wu, Colgate Palmolive, presented *"Amino Acid Complex (AAComplex) Benefits in Cosmetic Products"*

August 2: Dr. Narasimha Murthy; University of Mississippi, School of Pharmacy, *"Noninvasive Approaches of Sampling Analytes and Drugs from The Skin"*

September 13: Dr. Mark Chandler, ACT Solutions Corporation. *"Pandering to Polar Actives"*

October 18: Dr. Isabel Diaz and Dr. Junhong Mao from Colgate Palmolive presented *"Topical Delivery of Vitamins C & E and Their Skin Benefits"*

November 8: Stephanie Wheeler, Genemarkers presented *"Evaluating the Efficacy of CBD in Topical Skincare Products"*

December 6: Dr. David Moore, Tioga Research, presented *"Biophysical Methods to Characterize Deposition and Delivery from Topical Wash-Off Formulations"*

RUTGERS

Center for Dermal Research

CDR is a dedicated research center at Rutgers, The State University of New Jersey (Busch Campus, Piscataway, NJ) providing skin formulation expertise and testing facilities (pharmaceutical, cosmetic and personal care). Project scope ranges from formulation screening to interdisciplinary development programs.

Capabilities

- Design and testing of novel formulations for skin delivery of actives (pharmaceutical and cosmetic)
- Formulation design, characterization, optimization and evaluation of topical, transdermal and transmucosal actives delivery
- Visualization of skin transport pathways of actives using spectroscopy, electron and confocal microscopy
- Development of human tissue cultured skin equivalents for permeability testing of actives
- Design and evaluation of novel dermal penetration enhancers and retardants & their structure-activity relationships
- Physical approaches to enhancing dermal delivery of actives
- Biorelevant actives release/dissolution testing of semisolids and transdermal pharmaceutical dosage forms
- Exploring various skin relevant biomarkers for potential anti-ageing and anti-inflammatory activity
- Evaluation of penetration of actives in different skin layers using microtoming of skin samples
- Skin surface pH studies following skin application of actives and formulations
- Cytotoxicity evaluations for skin actives in cellular models as well as skin equivalents
- Research, technical and regulatory support by experienced and proficient scientists with hands on experience and more than a decade of experience in pharmaceutical industry
- Design and development of SOPs for topical and transdermal studies, preparation of SOW & proposals, stability protocols, budgets and scientific reports.
- The CDR has expanded its research capabilities into the area of nail drug delivery and has been using a Quality by Design approach to design and formulate products, followed by effective testing of delivery into the nail unit.

cdr_frontdesk@dls.rutgers.edu

CDR Facilities

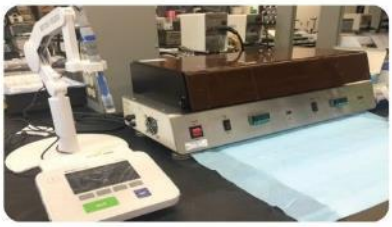
The Center for Dermal Research houses the "Laboratory for Drug Delivery" (LDD) dedicated towards topical and transdermal drug delivery. It occupies 1400 sq. ft. and is housed within the Life Sciences Building on Rutgers University Busch campus.

LDD is equipped with:

- Three Agilent 1100 HPLCs with diode array and ChemStation software, autosamplers, UV/vis and fluorescent detectors
- Ten water jacketed Franz diffusion cell modules
- Four heat block FDC-24 Franz cell modules for skin penetration studies
- Leica® Cryotome instrument (Leica® CM1850, Nussloch, Germany)
- Mettler Toledo pH meter with InLab® micro and surface pH electrodes for skin surface pH studies
- Light and stereomicroscopes
- Vankel VK 7010 Dissolution Test Station with VK 8000 Sampling Station
- Buchler vortex evaporator
- Mettler electronic balances
- 8 foot chemical fume hood
- Upright freezers, refrigerators, dishwashers & autoclaves
- Shared Biology Suite (Room 207, 720 sq. ft.) with four Biosafety II hoods located adjacent to the LDD
- Double CO2 incubator, ultra & regular centrifuges, PCR equipment, plate readers, etc.
- Deionized water, vacuum, and compressed air facilities

CDR has access to:

- Confocal laser scanning (Zeiss LSM410) and confocal multiphoton microscopy (Leica TCS S2 AOBS), TEM, SEM, skin and other tissue imaging (Raman confocal, etc.)
- NMRs, AFM-atomic force microscopy, LC-MS-liquid chromatography mass spectrometry and FTIR analytical techniques
- UV-Vis Spectroscopy
- GPC-gel permeation chromatography
- DSC-differential scanning calorimetry
- Mechanical tester with environmental chamber, quartz crystal microbalance with dissipation monitoring
- TGA-thermogravimetric analyzer & DMA-dynamic mechanical analyzer
- Polymer synthesis and characterization facility
- In-vivo studies facility
- Rheological and histological facilities
- Conference and event facilities (auditorium, three conference rooms & poster/exhibit areas in lobby) in the Life Sciences Building, Busch campus.



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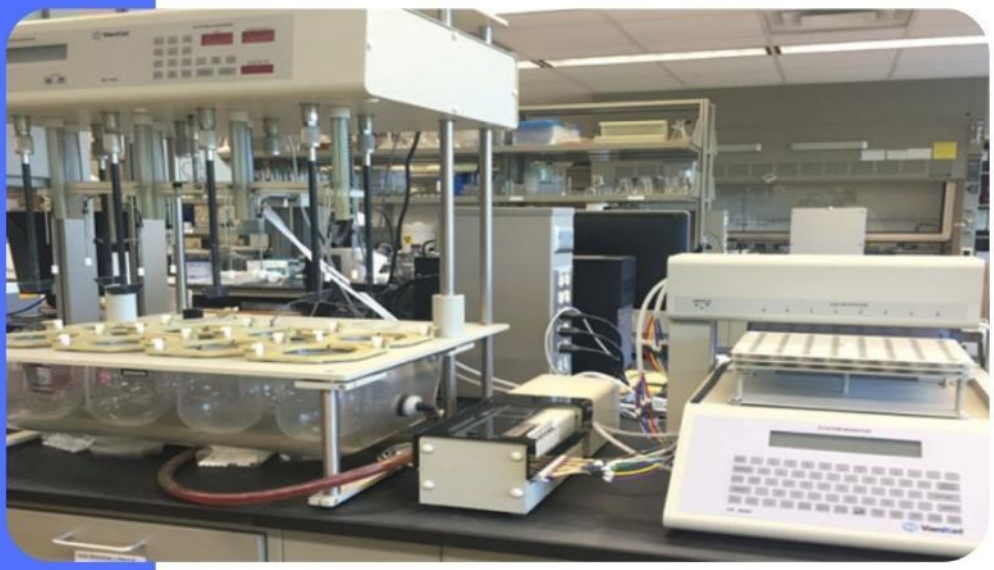
CDR Collaborations

CDR has close collaborations with the Dermatology Department of the Robert Wood Johnson Medical School at Rutgers University with access to patients for skin biopsies and other clinical protocols. Research group of Dr. Michniak-Kohn consists of around 20-25 members including Laboratory Manager for industrial projects, Ph.D. students, post-doctoral associates, and undergraduates from several Rutgers University graduate programs including Pharmacy, Biomedical Engineering, Masters Program in Business and Science, Chemistry & Chemical Biology (CCB) and Chemical Engineering.



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2020-2021 PEER REVIEWED PUBLICATIONS

1) de Oliveira, E.C., Salvador, D.S., Holsback, V., Shultz, J.D., **Michniak-Kohn, B.B.**, Leonardi, G.R. Deodorants and antipersirants: identification of new strategies and prespectives to prevent and control malodor and sweat of the body. International Journal of Dermatology (2021) doi: 10.1111/ijd.15418.
2) Lin, H., Lin, L., Choi, Y. **Michniak-Kohn, B.** Development and evaluation of co-loaded berberine chloride and evodiamine ethosomes for treatment of melanoma. International J. Pharmaceutical Sciences (2020) May 15 581:119278 doi: https://doi.org/10.1016/j.ijpharm.2020.119278. PMID 32229284.
3) Xu, Q., Jalilian, E., Fakhoury, J.W., Manwar, R., **Michniak-Kohn, B.**, Elkin, K.B., Avanaki, K. Monitoring the topical delivery of ultrasmall gold nanoparticles using optical coherence tomography. Skin Research & Technology (2019) September 25. doi: 10.1111/srt.12789. PMID 31556193.
4) Shah, P., Goodyear, B., Haq, A., Puri, V., **Michniak-Kohn, B.** Evaluations of Quality by Design (QbD) elements impact for developing niosomes as a promising topical drug delivery platform. Pharmaceutics Special Edition "Quality by Design (QbD) for Topical Dermatological & Transdermal Product Development" (2020) 12,246; doi:10.3390/pharmaceutics120302246. www.mdpi.com/journal/pharmaceutics. PMID 32182792.
5) Shah, P. Goodyear, B., Dhoralia, N., Puri, V., **Michniak-Kohn, B.** Development and evaluation of a desoximetasone nanostructured non-ionic surfactant carrier-based gel for topical drug delivery. International J. Molecular Sciences (2021) 22,1535. https://doi.org/10.3390/ijms22041535.
6) Zhang, Z.J., Froelich, A., **Michniak-Kohn, B.** Topical delivery of meloxicam using liposome and microemulsion formulation approaches. Pharmaceutics Special Edition "Nanosystems as Drug Delivery Carriers: From Nature to the Medication" (2020) 12, 282; doi:10.3390/pharmaceutics120302282 www.mdpi.com/journal/pharmaceutics. PMID 32245190.
7) Zhang, Z. J., **Michniak-Kohn, B. B.** Flavosomes, novel deformable liposomes for the co-delivery of anti-inflammatory compounds to skin. Int. J. Pharm. (2020) 585, 119500. PMID 32512226.
8) Zhang, Z., Osmalek, T., **Michniak-Kohn, B.B.** Deformable liposomal hydrogel for topical delivery of meloxicam. Int. J. Nanomedicine (2020) 15, 9319-9335. PMID 33262590.
9) Anantaworasakul, P., Chaiyana, W., **Michniak-Kohn, B.B.,** Rungseevijitprapa, W., Ampasavate, C. Enhanced transdermal delivery of concentrated capsaicin from chili extract-loaded lipid nanoparticles with reduced skin irritation. Pharmaceutics (2020) 12,463; doi:10.3390/pharmaceutics12050463 www.mdpi.com/journal/pharmaceutics. PMID 32438539.
10) Jakubowska, E., Davin, S., Dumicic, A., Garbacz, G., Juppo, A., **Michniak-Kohn, B.,** Rudzki, P. J., Smulek, W., Strachan, C., Syarkevych, O., Tajber, L., Lulek J. ORBIS (Open Research Biopharmaceutical Internships Support)- building bridges between academia and pharmaceutical industry to improve drug development. J. Med. Sci. (2020) 89 (1), e419.
11) Shah, P., Goodyear, B., Haq, A., Puri,V., **Michniak-Kohn, B.** Quality by Design: A systematic approach using an advanced statistical tool for optimization of niosomes preparation for the topical delivery of desoximetasone. World Journal of Pharmacy & Pharmaceutical Sciences WJPPS (2020), 9, (7), 251-277.
12) Haq, A., Kumar, S., Mao, Y., Berthiaume, F., **Michniak-Kohn, B.** Thymoquinone loaded polymeric films and hydrogels for bacterial disinfection and wound healing. Biomedicines (2020) 8, 386: doi: 10.3390/biomedicines8100386. PMID 32998437.

13) Shariat-Madar, Z., Rahman, A., **Michniak-Kohn, B.,** Da Motta, G., Rahman, A. Camera-less terahertz imaging investigation of the interaction of Factor XII protein with the human stratum corneum. J. Membrane Sci. Technol. (2020) 10:213 doi: 10.35248/2155-9589.2020.10.213.
14) Sandhu, S. K., Raut, J., Kumar, S., Singh, M., Kaur, S., Sharma,G., Roldan, T., Trehan, S., Holloway, J., Wahler, G., Laskin, J.D., Sinko, P., Berthiaume, F., **Michniak-Kohn, B.,** Rishi, P., Ganesh, N., Kaur, I.P. Systematic development and characterization of novel, high drug loaded, photostable, curcumin solid lipid nanoparticle hydrogel for wound healing. Antioxidants (Basel) (2021) May; 10(5): 725. Published online 2021 May 5. doi: 10.3390/antiox10050725 PMCID: PMC8148018.
15) Ramzan, M., Gourion-Arsiquaud, S., Hussain, A., Gulati, J.S., Zhang, Q., Trehan, S., Puri, V., **Michniak-Kohn, B.,** Kaur, I.P.In vitro release, ex-vivo penetration, and in vivo dermatokinetics of ketoconazole-loaded solid lipid nanoparticles for topical delivery. Drug Delivery and Translational Research (2022) Published online January 7th 2022 https://doi.org/10.1007/s13346-021-01058-6.
16) Ramzan, M., Kaur, G., Trehan, S., Agrewala, J.N., **Michniak-Kohn, B.,** Hussain, A., Mahdi, W.A., Gulati, J.G. Mechanistic evaluations of ketoconazole lipidic nanoparticles for improved efficacy, enhanced topical penetration, cellular uptake (L929 and J774A.1), and safety assessment: In vitro and in vivo studies. J. Drug Delivery Science & Technology (2021), 65, 102743. https: doi.org/10.1016/j.ddst.2021.102743.
17) Chen, K., Puri, V., **Michniak-Kohn, B.** Iontophoresis to Overcome the Challenge of Nail Permeation: Considerations and Optimizations for Successful Ungual Drug Delivery. The AAPS Journal Special Edition "Celebrating Women in the Pharmaceutical Sciences" (2021), 23:25 doi: 10.1208/s12248-020-00552-y.
18) Froelich, A., Osmalek, T., Jadach, B., Puri, V., **Michniak-Kohn, B.** Microemulsion-based media in nose-to-brain drug delivery. Pharmaceutics (2021),13, 201. https://doi.org/10.3390/pharmaceutics13020201.
19) Osmałek T., Froelich A., Jadach,B., Tatarek, A., Gadzinski, P., Falana, A., Gralinska, K., Ekert, M., Puri, V., Wrotynska-Barczynska, J., **Michniak-Kohn B.** Recent advances in polymer-based vaginal drug delivery systems. Pharmaceutics (2021) 13, 884. https://doi.org/10.3390/pharmaceutics13060884.
20) Tang, X., Dong, Q., Li, J., Li, F., **Michniak-Kohn, B.B.,** Ho, C-T., Huang, Q. Anti-melanogenic mechanism of tetrahydrocurcumin and enhancing its topical delivery efficacy using a lecithin-based nanoemulsion. Drug Delivery & Controlled Release (2021) 13, 1185. https://doi.org/10.3390/pharmaceutics13081185.
21) Schultz, J.D., Carita, A.C., Mohd, H., **Michniak-Kohn, B.,** Aiello, L.M., Leonardi, G.R. Cosmetic formulations containing Vitamin C and the instability challenge. Int. J. of Pharmacy & Pharm. Sci (IJPSS) 2021 (*submitted*).

2020-2021 ABSTRACTS

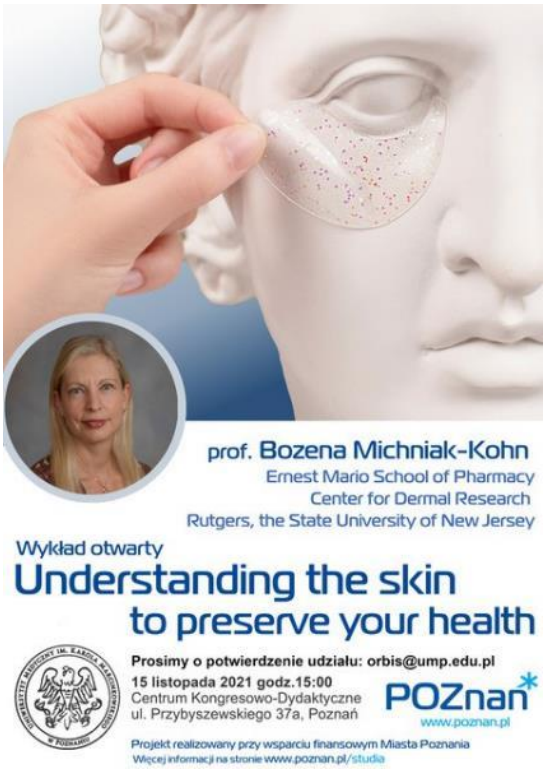
1) Haq, A., Chandler, M., **Michniak-Kohn, B. B.** Solubility-physicochemical-thermodynamic theory of penetration enhancer mechanism of action. AAPS Annual Meeting & Exposition 2020 PharmSci 360, October 26 – November 5, 2020.
2) Puri, V., Froelich, A., **Michniak-Kohn, B.B.** A systematic process for synthesis of nanospheres for the ungual delivery of terbinafine hydrochloride. AAPS Annual Meeting & Exposition 2020 PharmSci 360, October 26 – November 5, 2020.
3) Shariat-Madar, Z., Rahman, A., **Michniak-Kohn. B.,** Da Motta, G., Rahman, A. Terahertz camera-less imaging of human stratum corneum-protein interactions. Biotech Meeting, 2nd Global Virtual Summit on Biotechnology & Bioengineering, April 5-6, 2021 https://biotechconference.mindauthors.com.
4) Matharoo, N., Garimella, H.J., Uppal, G., **Michniak-Kohn, B.** Comparative evaluation of the transdermal activity of desoximetasone using cream and ointment. Controlled Release Society Virtual Annual Meeting, July 25-29, 2021.
5) Matharoo, N. Uppal, G., Garimella, H.J., **Michniak-Kohn, B.** Comparative evaluation of kinetics and dermal bioavailability of adapalene from three marketed gel formulations using human cadaver skin. 2021 AAPS PharmSci 360, October 17-20, 2021. Poster ID #1053387.
6) Maphalle, L.N.F., Wesley-Smith, J., Ogunrombi, M.O., **Michniak-Kohn, B.B**., Adeleke, O.A. Fabrication, morphological examination, and *in vitro/ex vivo* analyses of a novel rifampicin loaded matrix type skin delivery patch. 2021 AAPS PharmSci 360, October 17-20, 2021.

2020-2021 BOOKS

1) Kumar, S., Haq, A., Berthiaume, F., **Michniak-Kohn, B. B.** Chapter 6. Preclinical Research Designs in "Principles of Research Methodology and Ethics in Pharmaceutical Sciences" in series "Drugs in the Pharmaceutical Sciences" Anthony Hickey (Editor) CRC Press (Taylor & Francis) (2021).
2) Ameen, D., Goodyear, B., Robinson, K., Dhoralia, N., Mahmoud, H., Shah, P., Zhang, Z. **Michniak-Kohn, B.** "Transdermal products" in "Time-proof Perspectives on Bioequivalence". Vitorio, C., Miranda, M., Sousa, J., Almeida, A. Nova Science Publishers, Inc., Hauppage, NY (2021).

MICHNIAK-KOHN WINS EUROPEAN COMPETITION

Dr. Michniak-Kohn was invited as the 2021 winner of City of Poznan Public Annual Lecture by Eminent Global Scientist competition. The lecture was entitled "*Understanding the Skin to Preserve your Health*" at the Polish Library-Congress Center, 37a Przybyszewskiego Street, Poznan, Poland. November 15th, 2021.



Basic&Applied Dermatology Forum

CDR Membership

The CDR gives its members valuable networking opportunities and access to a range of speakers in intimate settings. Members may attend CDR events for free or at a reduced cost. For information about becoming a member, please contact us at cdr_frontdesk@dls.rutgers.edu

Annual Membership Levels:

Double-Diamond Level ($50,000)

This membership affords companies with more say in how their membership funds are spent and grants them further access to resources at the CDR.

- Sponsor a student or graduate student who will present a talk at the company once a semester (two presentations per membership year)
- Opportunity for an employee to shadow a Lab Tech or Researcher for a week
- Attendance for two new employees at a lab training session
- Two seats on the CDR Advisory Board
- Complimentary/discount registration at a CDR event for six attendees.
- 1/2 day per month face time with Dr. Bozena Michniak-Kohn and/or key lab members
- Two seats on CDR Program Committees
- Your firm will be able to present a premium table top exhibit at annual conference, your company representative will have the opportunity to present a 15-minute talk to the attendees, and your company logo will also be featured prominently in meeting and event marketing materials.
- Special seating at the VIP table during the reception with CDR leadership and speakers of the event.
- Opportunity to be a speaker for a CDR Seminar.
- CDR Seminar presentation recorded, profiled and archived on CDR website
- Register for the Spring 2021 Dermaceutics course at a discount rate.

Diamond Level ($20,000)

This level opens up a whole new realm of opportunities and level of involvement for members of the CDR.

- One seat on the CDR Advisory Board
- Complimentary/discount registration at a CDR event for six attendees.
- 1/4 day per month face time with Dr. Bozena Michniak-Kohn and/or key lab members
- One seat on CDR Program Committees
- Your firm will be able to present a premium table top exhibit at annual conference, your company representative will have the opportunity to present a 10-minute talk to the attendees, and your company logo will also be featured prominently in meeting and event marketing materials.
- Special seating at the VIP table during event reception with CDR leadership and speakers of the event.
- Opportunity to be a speaker for a CDR Seminar.
- CDR Seminar presentation recorded, profiled and archived on CDR website
- Register for the Spring 2021 Dermaceutics course at a discount rate.

Platinum Level ($5000)

- Complimentary/discount registration at a CDR event for four attendees.
- Your company logo will also be featured prominently in meeting and event marketing materials.
- Opportunity to be a speaker for a CDR Seminar.
- CDR Seminar presentation recorded, profiled and archived on CDR website
- Your firm will be able to present a basic level table top exhibit at annual conference.
- Register for the Spring 2021 Dermaceutics course at a discount rate.
- Special seating at the VIP table during the reception with CDR leadership and speakers of the event.
- Company representative will have the opportunity to present a 5-minute talk to attendees at annual conference.

Gold Level ($2500)

- Complimentary/discount registration at a CDR event for two attendees.
- Your company logo will also be featured prominently in meeting and event marketing materials.
- Opportunity to be a speaker for a CDR Seminar.
- CDR Seminar presentation recorded, profiled and archived on CDR website
- Your firm will be able to present a basic level table top exhibit at annual conference.
- Register for the Spring 2021 Dermaceutics course at a discount rate.

Silver Level ($1000)

- Complimentary/discount registration at a CDR event for one attendee.
- Your company logo will also be featured prominently in meeting and event marketing materials.
- Opportunity to be a speaker for a CDR Seminar.

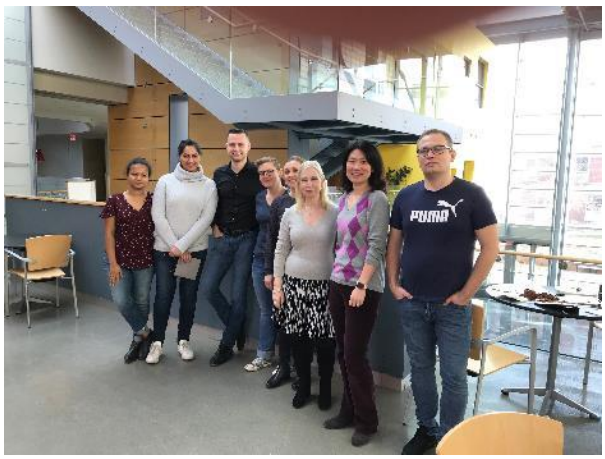
Individual Memberships ($250)

This membership level is for self-employed individuals or small companies with less than 10 employees.

- Complimentary/discount registration at a CDR event for one attendee.

Thank you to all of our CDR Members for 2020/2021

CDR Photos outside the lab…

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