Center for Dermal Research
2019 Annual Report
June 25, 2007 – 1st Annual Skin Workshop

September 30, 2008 – 2nd Annual Skin Workshop

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

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

September 24, 2013 – First CDR/TRI Joint Seminar

Fall 2013 – First Innovations in Dermatological Sciences Conference

April 2015 – Sonia Trehan hired as CDR’s Industrial Project Manager

Spring 2015 – 3rd time Dermaceutics course was offered

CDR 5th Anniversary celebration during 4th Innovations in Dermatological Sciences event in Fall 2016

January 2017 – 42 students total graduate with PhD or Masters degree

Fall 2017 – First annual joint CDR/BASF Workshop launched in Tarrytown, NJ

5th Innovations in Dermatological Sciences event

4th Dermaceutics Course – Spring 2018
Center for Dermal Research, 145 Bevier Road, Room 107
Piscataway, New Jersey 08854 – Tel: 848.445.3589

As we move into the next decade it is interesting to see some highlights of what we have accomplished at the Center for Dermal Research CDR and the Laboratory for Drug Delivery LDD:

- The Life Sciences Building at Rutgers Busch campus opens its doors 2005
- LDD moves from UMDNJ Medical School, Newark Summer 2005
- First Annual Skin Workshop June 2007
- First Dermaceutics Graduate Course offered Spring 2009
- CDR founded in March 2011
- Annual CDR Seminar Series launched 2011
- First Joint CDR/BADF event May 2011
- First “Innovations in Dermatological Sciences” conference Fall 2013
- First CDR/TRI Princeton Joint Seminar Series launched Fall 2013
- First series of training Webinars offered by CDR in 2013
- Annual Joint CDR/BASF Skin Workshop launched in Tarrytown NY Fall 2017
- First Joint CDR/Colgate Palmolive Seminar Series launched 2017
- First Joint CDR/J&J Joint Seminar Series launched Fall 2019
- 15 ORBIS Grant funded scientists hosted by LDD 2018-2019
- 22 Ph.Ds graduated in LDD and 6 Masters 2005-2019
- 126 undergraduates trained in LDD 2005-2019
- 82 CDR Seminars 2011-2019

As I am writing this message in March 2020, we are all dealing with an extraordinary and difficult situation globally with the COVID-19 issues. Rutgers - The State University of New Jersey has already sent all undergraduates home and many faculty and Ph.Ds are working already remotely from home. It is hard at this stage to write about all the “good and successful” times we had at the CDR in 2019 while looking out of my office at pretty empty parking lots and texts beeping in constantly with information about the next set of COVID closures, curfews, and cases...

However, looking back at more happier times… 2019 was a very successful year for CDR (the Centers’ eighth year since being founded) as well as the Laboratory for Drug Delivery (LDD). The annual two day conference “Innovations in Dermatological Sciences” has been established by now as a Fall event of the CDR and this year we decided to no longer focus on one broad topic for the two days but allow sessions to cover many “hot topics” in skin actives delivery research. We have a dedicated Programming Committee which each year selects outstanding speakers and session topics. Due to renovations at the Route 1 Marriott Renaissance this year, we moved to the Doubletree by Hilton in Somerset, NJ (September 8, 9 & 10th). Our Plenary Session was given by Dr. David Fisher from the Massachusetts General Hospital/ Harvard Medical School on the understanding and manipulation of skin pigmentation. Other sessions focused on: Epigenetics-roots of inheritance & effects on skin health, sun care and hair aging, microbiome and skin nutrition, development of complex generic products (FDA session), formulations, delivery challenges and testing methods, together with a scientific poster and a vendor exhibit. CDR Sponsor of the Year 2019 award was given to Rodan and Fields-congratulations!! A novel addition to the conference this year was the introduction of the Young Scientist Mentor Program that included a dinner on Sept 8th and then Mentor Circles at the conference lunchbreaks each day. This is intended for all scientists early in their career and the aim is to provide opportunities for mentorship, discussion forums and networking. A big thank you to all our speakers, sponsors, programming committee and contributors as well as staff at the Center, LDD members for all their assistance & support… Hopefully everyone is looking forward to the next Innovations in Dermatological Sciences conference…

During the year the CDR participated in the Joint CDR/BASF Tarrytown NY Skin Workshop in Spring, conducted 13 CDR Seminars and one Spring 2019 Workshop. This event was a continuation of our scientific discussions from our 2018 two day conference. The subject was “Personal Care + Cosmetics: Regulatory and Compliance Elements” held at the Richard Weeks Hall Rutgers Busch campus. Our plenary speaker was Representative Frank Pallone, NJ 6th congressional district, Chairman of the House Energy & Commerce Committee. Other speakers included: Edward Glynn (Locke, Lord LLP), Anu Gokhale (National Advertising Division), Jennifer Martin (Colgate Palmolive), Neelam Muzzuddin (Skin Clinical Research Consultants), Robert Schiff (Schiff & Company, Inc.) Ronald Levine (Herrick, Feinstein LLP) and David Steinberg (Steinberg Associates, Inc.).

CDR/LDD hosted ORBIS exchange scientist Professor Anna Froclich, Ph.D., Assistant Professor, Department of Pharmaceutical Technology, Poznan University of Medical Sciences, Poznan, Poland for one year starting in March, 2019. Other scientists that participated in the ORBIS exchange program with CDR/LDD were Michał Gażdowski, Ph.D. Formulation Specialist, Pharmaceutical Development, Zentiva Group, Prague, Czech Republic (Sept.-Nov. 2019), Marta Napierala, Ph.D., Laboratory of Environmental Research, Department of Toxicology, Poznan University of Medical Sciences, Poznan, Poland, for one year starting in March, 2019. Other scientists that participated in the ORBIS exchange program with CDR/LDD were Michaela Gażdowska, Ph.D. Formulation Specialist, Pharmaceutical Development, Zentiva Group, Prague, Czech Republic (Sept.-Nov. 2019), Professor Franciszek Glowka, Ph.D., D.Sc. Vice-Dean, Professor & Head of Dept. of Physical Pharmacy & Pharmacokinetics, Poznan University of Medical Sciences, Poznan, September, 2019 and Paulina Skupin-Mragalska, Ph.D., Dept. of Inorganic & Analytical Chemistry, Poznan University of Medical Sciences, Poznan, (Sept.-Nov. 2019-Feb. 2020). More research laboratories are being added to the CDR group with opportunities in aspects of pharmacokinetics, biomedical sciences, 3D printing, and toxicology. We enjoyed meeting all of you and hosting you at the CDR/LDD and keep in touch!!

Other successes of international visitors included two Ph.D. students from Thailand: Phunsuk Anantaworasakul whose thesis title was “Chili extract delivery system for minimizing skin irritation” and whose thesis defense was at Chiang Mai University, Chiang Mai, Thailand, June 2019 and Panikchar Wichayapreechar whose thesis title was “Modulation of NF-KappaB and SIRT-1 protein expression in psoriatic cell model by anti-inflammatory herbal extract-encapsulated nanoparticles” and whose thesis defense took place at Chiang Mai University, Chiang Mai, Thailand, June 2019. Both conducted their entire last year of PhD studies at the LDD. Panikchar went on to become a faculty member at another well-known Thai university. Congratulations to both ladies!!

Finally, in 2019 the CDR/LDD welcomed Ms. Karen Mooney in the Fall as the new Executive Assistant to Dr. Michniak-Kohn. Welcome Karen!!
Our CDR Advisory Council includes the following members:

- Abhijit Bidaye – Croda
- Angela Christiano – Dermatology, Columbia University
- Gary Cleary – Cape Therapeutics, Inc.
- Adam Friedman – George Washington School of Medicine and Health Sciences
- Vince Gruber, JEEN International
- William Ju – Advancing Innovation in Dermatology, Inc.
- Peter Landa – Estee Lauder
- John Lyga – Avon
- Gopi Menon – Consultant
- Amy Pappert – Rutgers, RWJ Medical School
- Miri Seiberg – Seiberg Consulting

The Center for Dermal Research offers pharmaceutical, personal care, cosmetic and other companies an opportunity to participate in its programs and meetings. Membership affords companies and their key employees opportunities to learn about the latest developments at the Center for Dermal Research at Rutgers and to meet scientists and researchers who are making progress in developing new concepts and products in the science. Through their participation members also have the opportunity to contribute to the research that is being conducted by the Center.

Double-Diamond Level ($50,000). The 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
- Six attendees at CDR events held through the membership year
- 1/2 day per month face time with Dr. Bozena Michniak-Kohn and/or key lab members
- Two seats on CDR Program Committees
- Full access to Archived Lectures
- Your company will be able to present an exhibit at most events, 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 all meeting and event marketing materials.
- Special seating at the VIP table during the reception with CDR leadership and speakers of the evening.
CDR Membership Program

**Diamond Level** ($20,000). This member 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
- Six attendees at CDR events held through the membership year
- 1/4 day per month face time with Dr. Bozena Michniak-Kohn and/or key lab members
- One seat on CDR Program Committees
- Full access to Archived Lectures

Your company will be able to present an exhibit at most events, 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 all meeting and event marketing materials.

**Platinum Level** ($5000). Your company will be able to present an exhibit at most events, your company representative will have the opportunity to present a 5-minute talk to the attendees, and your company logo will also be featured prominently in all meeting and event marketing materials. Attendance of up to four company representatives at reduced or no cost for all CDR events held through the membership year. * In addition, special seating at the VIP table during the reception with CDR leadership and speakers of the evening.

**Gold Level** ($2500). Your company will be able to present a tabletop exhibit at most events and your company logo will also be featured in all meeting and event marketing materials. Attendance by up to two company representatives at reduced or no cost for any CDR event held through the membership year.

**Silver Level** ($1000). Your company’s logo will be featured in all meeting and event marketing materials. Attendance by one company representatives at any CDR event held through the membership year at reduced or no cost.

**Individual Memberships** ($250). Attendance at any CDR event held through the membership year at reduced or no cost.
LAB MEMBERS 2019

Graduate Students

Anika Haq Alam
PhD Student

Keyaara Robinson
PhD Student

Dina Ameen
PhD Student

Parin Shah
Part-time PhD Student

Nirali Dholaria
Part-time PhD Student

Jemima D. Shultz
PhD Student/Industrial Project Scientist

Ben Goodyear
Part-time PhD Student

Amitkumar Virani
Part-time PhD Student

Namrata Matharoo
PhD Student Skin Formulation Scientist

Julia Zhang
PhD Student/Industrial Project Manager

Vinam Puri
PhD Student/ LDD Lab Manager
Staff Members 2019

Malak Awad
Senior Accountant,
NJCBM

Hannah Carter
Outreach Events
Specialist, NJCBM

Suzanne Squires
Associate Director,
NJCBM

Srilekha Vangala
Personnel Administrator,
CCB

Dana Downer
Executive Assistant to
Joachim Kohn, NJCBM

Sangya Varma
Chief Operating Officer,
NJCBM

Jacob Holober
Administrative Assistant
to Sangya Varma,
NJCBM

John Watkins
IT Specialist, NJCBM

Karen Mooney
Executive Assistant to
Bozena Michniak-Kohn,
CDR
Visiting Scientists in CDR 2019

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

**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.

**Aaron Cohen, Ph.D.**
from Colgate-Palmolive, NJ, specializing in personal care products.
March 2019-present.

**Maria Garcia, Ph.D.**
from Kanalis Consulting, L.L.C. in Edison NJ.
Specialties: Membrane biochemistry and biophysics, Ion channels and transporters, Pharmacology, HTS assays.

**Sharon Haynie, Ph.D.**
from Hypatia Technology Works, LLC, Philadelphia, PA. Specialist in drug delivery systems.
Fall 2018-present.

**Greg Kaczorowski, Ph.D.**
from Kanalis Consulting, L.L.C. in Edison NJ.
Specialization ion channels and transporters as drug targets and the subject of drug safety.

**Arsalan Khan, Ph.D.**
from Croda, NJ specializing in polymers and personal care products for skin.
September 2016-present.

**Allyson Maron, Ph.D.**
from Croda, NJ specializing in polymers and personal care products for skin.
September 2017-present.

**Jagruti Rana, Ph.D.**
from Cosette Pharmaceuticals, NJ specializing in Invitro Bioequivalence testing for semi solids, topicals using diffusion apparatus.
August 2019-present.

**Amra Tabakovic, Ph.D.**
from Croda, NJ specializing in polymers and personal care products for skin.
July 2018-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 2021, Rutgers University’s CDR will host 98-person months of visiting scientists from the ORBIS consortium from many locations in the European Union. The PI 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.
During the secondments planned in the project, young and experienced scientists will cooperate with the hosting institutions on the most relevant and up-to-date issues of drug development process, such as: synthesis and optimization of new active ingredients, preformulation studies, development of novel oral, dermal and transdermal dosage forms, as well as their biopharmaceutical evaluation with new analytical methods.

ORBIS Background

On July 5, 2017 the European Commission awarded € 2,268 million for the realization of a prestigious, international and intersectoral project no. 778051 entitled ORBIS (Open Research Biopharmaceutical Internships Support). The four-year-long (2018-2022) grant was favorably evaluated in the Research and Innovation Staff Exchange (RISE) call under the Maria Skłodowska-Curie Actions of Horizon 2020 Framework Program (H2020-MSCA-RISE-2017). The consortium lead is Dr. Janina Lulek of the Faculty of Pharmacy, Poznan University of Medical Sciences (PUMS) and the US partner is Dr. Bozena Michniak-Kohn, Ernest Mario School of Pharmacy and the Center for Dermal Research (CDR) at Rutgers-The State University of New Jersey.

Four universities, one research institute and four pharmaceutical companies from seven countries are participating in the ORBIS project. The University partners are: Trinity College Dublin (Ireland); University of Helsinki (Finland), Poznan University of Medical Sciences/Poznan University of Technology (Poland); and Rutgers University, The State University of New Jersey (USA), The Center for Dermal Research – founded and lead by its Director, Dr. Bozena Michniak-Kohn. The research institute partner is the Pharmaceutical Research Institute (Poland). The four pharmaceutical companies are: Applied Process Company Ltd. (Ireland); Farmak JSC (Ukraine); Physiolution GmbH (Germany) and Zentiva k.s. (Czech Republic).

ORBIS visitors in CDR 2019:

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.


Marta Napierala, Ph.D., Laboratory of Environmental Research, Department of Toxicology, Poznan University of Medical Sciences, Poznan, Poland. Funded by Orbis RISE grant. September, 2019-November, 2019.

Professor Franciszek Glowka, Ph.D., D.Sc. Vice-Dean, Professor & Head of Dept. of Physical Pharmacy & Pharmacokinetics, Poznan University of Medical Sciences, Poznan, Poland. Funded by Orbis RISE grant. September, 2019.


Professor Tomasz Osmalek, Ph.D., Assistant Professor, Department of Pharmaceutical Technology, Poznan University of Medical Sciences, Poznan, Poland. Funded by Orbis RISE grant. October, 2019-January, 2020.
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 to 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

Nanocarriers 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 Prof. 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 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 proved 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 too 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. 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.

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, microemulsion 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 tablet burden, thus improving compliance. Moreover, a study involving 1059 AD patients’ caregivers revealed that 70% of them preferred 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 neurodegenerative diseases such as Alzheimer’s disease and multiple sclerosis. Several penetration enhancers with different mechanisms of action at different concentrations were compared to determine the enhancer with maximum enhancement ratio (Fig. 3). Second, we formulated 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 performed using vertical Franz diffusion cell mounted with human cadaver skin (Fig. 4). The developed patches are designed to be applied once daily to deliver the drug at the therapeutic level with minimum irritation.

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

Figure 4: A schematic describing the process of developing and characterizing drug-in-adhesive patch.
Transdermal Delivery of ACTIVES for the Treatment of Skin Infections

*Staphylococcus aureus* is one of the most important human and veterinary pathogens and is the causative agent for the majority of primary skin infections. It causes infections ranging from benign to life threatening diseases. Skin and soft tissue infections (SSTIs) encompass a wide variety of clinical outcomes, ranging from mild cases of cellulitis, erysipelas, trauma, subcutaneous tissue infections, wound related infections to complicated deep-seated infections with systemic sign of sepsis. SSTIs may lead to severe complications and hospital admission when associated with co-morbidities and/or bacteraemia. The most commonly reported cause of SSTIs is *Staphylococcus aureus* followed by β-haemolytic streptococci (BHS). *Staphylococcus aureus* can internalize by a variety of nonphagocytic host cells and can contribute to the development of persistent or chronic infections and may lead to deeper tissue infections or dissemination. The skin of patients with atopic dermatitis (AD), eczema and psoriasis show a striking susceptibility to colonization with *Staphylococcus aureus*. There is a relationship between disease severity, extent and *Staphylococcus aureus* colonization of lesional and non-lesional skin and the density of *Staphylococcus aureus* has been shown to correlate with cutaneous inflammation. SSTIs including atopic dermatitis (AD), eczema, psoriasis and wound healing all rely on efficient antibiotic therapies.

The objective of this study was to synthesize and characterize a bio compatible novel topical polymeric film system (Figure 5) that has the potential to deliver antibacterial agent of medicinal plant origin directly at the skin target site that may be useful for the treatment and management of *Staphylococcus aureus* related bacterial skin infections and for the wound management. To achieve this objective, antibacterial agent loaded polyvinyl pyrrolidone (PVP) films were prepared using solvent casting method. The prepared films were characterized for physical parameters, permeability and stability studies. Its biocompatibility was assessed, and the antibacterial efficacy of films were evaluated in vitro and ex vivo against *Staphylococcus aureus*. Further, in vitro scratch assay models using HDF (fibroblast) and HaCat (keratinocytes) cell lines were used to demonstrate its wound healing properties.
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).

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, econazol, 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.
2019 Innovations in Dermatological Sciences

Our seventh annual conference on dermatology took place on Monday and Tuesday, September 9-10, 2019 at the Doubletree by Hilton Hotel in Somerset, NJ. Throughout the two-day program speakers addressed epigenetics, the delivery challenges and testing methods, and the regulatory standards of topical formulations when developing products.

PROGRAM COMMITTEE

Bozena Michniak-Kohn
Rutgers, The State University of New Jersey
Center for Dermal Research

Kavita Beri
BE MIND BODY SKIN

Robert Bianchini
Rodan + Fields, LLC

Tom Boyd
Colgate Palmolive Company

Angela Christiano
Columbia University

Laurence Du-Thumm
Colgate Palmolive Company

Angelike Galdi
L'Oreal

William Ju
Advancing Innovation in Dermatology, Inc.

Pankaj Karande
Rensselaer Polytechnic Institute

Peter Landa
Estee Lauder

Jon Lenn
MedPharm

Frank Liebel
Avon Products, Inc.

Carine Mainzer
SILAB Inc.

Otto Mills
Rutgers, The State University of New Jersey

Amy Pappert
Rutgers, The State University of New Jersey
RWJMS

Sam Raney
FDA Office of Generic Drugs, Office of Research and Standards, Division of Therapeutic Performance

Miri Seiberg
Seiberg Consulting

Joel Sunshine
Advancing Innovation in Dermatology, Inc.
2019 Innovations in Dermatological Sciences — continued
Our Personal Care + Cosmetics: Regulatory & Compliance Elements took place on June 18th, 2019 at Richard Weeks Hall at Rutgers University New Brunswick Campus. This workshop was created as a spin-off from the discussions about compliance and ingredient guidelines at our annual Innovations in Dermatological Sciences conference in the fall. We were honored to have Representative Frank Pallone be in attendance and give a presentation.
CDR Seminar Series 2019

Carine Mainzer, SILAB, Inc., “Recycle” your knowledge about autophagy: focus on the skin”

Neelam Muizzuddin, Skin Clinical Research Consultants, “Balancing skin microbiome: fact or fiction?”

Lakshmi Raghavan, Solaris Pharma Corporation, “Characterization methodologies in generic dermatologicals development”

Robert Falcone, HRA Pharma, “The advantages of leveraging patient reported outcomes for cosmetics’ claim substantiation”

Kristine Kannheiser/Daphne Benderly, Presperse Corporation, “Particulates offering multifunctional benefits – boosting UV performance and soft focus”

Tracy Wang, Johnson & Johnson, “Understanding the different stages of skin development is key for addressing age-specific skin needs”
CDR outside of the lab...

Annual NJCBM & CDR Summer BBQ

Holiday Party 2019

CDR Birthday Celebration

Dr. Joachim Kohn, Dr. Bozena Michniak-Kohn, and Dr. Kavita Beri at the Summer BBQ

ARESTY students sharing their work

New NIH/FDA Grant Approved
CDR outside of the lab...

Award for CDR/Colgate from NJCT, NJ

SCC Meeting in New York City

SID in Chicago, IL

AAPS San Antonio, TX

AAPS San Antonio, TX

AAPS San Antonio, TX
Calendar of Events 2019

February 12th CDR Seminar Series – Carine Mainzer, SILAB, Inc., “Recycle” your knowledge about autophagy: focus on the skin

February 19th CDR Seminar Series – Kristine Kannheiser/Daphne Benderly, Presperse Corporation, “Particulates offering multifunctional benefits - boosting UV performance and soft focus”

March 12th CDR Seminar Series – Lakshmi Raghavan, Solaris Pharma Corporation, “Characterization methodologies in generic dermatologicals development”

April 16th CDR Seminar Series – Nava Dayan, Dr. Nava Dayan, LLC, “Is there a connection between UV induced immunosuppression and skin microbiome?”

May 7th CDR Seminar Series – Gloria Ho, BASF, “The role of excipient selection in formulating topical therapies for atopic dermatitis and psoriasis”

May 28th CDR Seminar Series joint with Colgate – Min Li, Colgate Palmolive, “Skin microbiome: the frontier in skin care”

June 18th Personal Care + Cosmetics: Regulatory & Compliance Elements Workshop

June 24th CDR Seminar Series – Karin Hermoni, Lycored, “Beauty from within and the cycle of glow: How carotenoids create a healthful foundation for beauty to thrive”

July 15th CDR Seminar Series – Vince Gruber, Jeen International Corporation, “Another technological success and commercial failure! Avoiding the pitfalls of commercial ingredient development”

September 9-10th Innovations in Dermatological Sciences Conference 2019

September 23rd CDR Seminar Series join with Colgate – Vinay Bhardwaj, Colgate Palmolive – “Applications of raman and surface-enhanced raman spectroscopy (SERS) in health and beauty”

October 28th CDR Seminar Series – Robert Falcone, HRA Pharma, “The advantages of leveraging patient reported outcomes for cosmetics’ claim substantiation”

October 29th CDR Seminar Series joint with BADF – David Steinberg, Steinberg & Associates, “Sunscreen innovation act, TEAs for UV filters, the February 2019 TFM, the JAMA MUST paper and the status of bemotriznol”

November 18th CDR Seminar Series – Neelam Muizzuddin, Skin Clinical Research Consultants, “Balancing skin microbiome- fact or fiction?”

December 9th CDR Seminar Series – Tracy Wang, Johnson & Johnson, “Understanding the different stages of skin development is key for addressing age-specific skin needs”
CDR Capabilities

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

- Design and testing of novel formulations for skin delivery of actives
- Formulation design, characterization, optimization and evaluation of topical, transdermal and transmucosal delivery
- Visualization of skin transport pathways using Raman, Fourier Transform Infra-Red spectroscopy, electron and confocal microscopy
- Development of novel 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 drug release/dissolution testing of semisolid and transdermal pharmaceutical dosage forms
- Protein extraction from different skin layers and proteomic evaluations
- Exploring various skin relevant genes for potential anti-ageing and anti-inflammatory activity
- Evaluation of penetration of actives in different skin layers using microtoming
- Skin surface pH studies using Mettler Toledo In-Lab Surface pH electrode and confocal laser scanning imaging system
- Cytotoxicity evaluations for skin actives: cellular as well as skin equivalents
- Research, technical and regulatory support by experienced and proficient research 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, prepare proposals, stability protocols, budgets and scientific reports.
2019 Peer Reviewed Publications

2019 Abstracts

2019 Books

Michniak-Kohn Appointments 2019

Michniak-Kohn Lab Member Awards since 2011
Michniak-Kohn Ph.D. student Zhang “Julia” Zhang received the 2019 AAPS Best Poster Award for her contribution entitled “Dermal and transdermal delivery of oxicams using deformable liposomes” at the AAPS PharmSci360 annual conference, November 3-6, 2019 in San Antonio, TX.
Michniak-Kohn Ph.D. student Anika Haq Alam received the Rutgers University Pharmaceutical Research Award in 2019.
Michniak-Kohn Ph.D. student Anika Haq Alam received the AAAS member (American Association for the Advancement of Science), AAAS/Science Program, Excellence in Science Award 2018-2019.
TRI Princeton is an independent, non-profit scientific research and education organization founded in 1930 by an act of US Congress. Over the decades, TRI has evolved into a full-service independent research and testing facility, specializing in porous materials, textiles, fibers, bio-materials, polymers, and films. TRI provides research solutions to a wide variety of domestic and international industrial companies, governmental organizations, and academic institutions.

With the range of instruments and methodologies, characterization goes well beyond just visualization, but deeper into the analysis, identification, and localization of molecular and structural components within the sample. The technical platform encompasses a powerful set of cutting-edge tools and techniques along with complementary approaches for material characterization and analysis, especially well-suited for the study of biomaterials such as hair, skin, nail, bone and/or teeth. These analyses and information can then be correlated to a host of different biophysical parameters. Furthermore, the techniques are exceptional in applications for testing, understanding and comparing variations or changes in biomaterials with relation to specific conditions like aging, diseases, environmental stresses (e.g. UV exposure), chemical exposure, and product treatments (product application or drug therapy). More importantly, changes that occur in these biomaterials and bio-substrates as a function of various factors (whether extrinsic or intrinsic influences) can be established and monitored in specific areas of interest such as at the surface or deep inside the structures of interest.

Contact Info: SGourion@triprinceton.org

Basic and Applied Dermatology Forum (BADF)
The Forum brings speakers with new/challenging topics to the Rutgers community. Now in its 24th year, it succeeds an annual full day multi-speaker conference (1984-1996).

Capitalizing on Rutgers’ unique environment, The Forum seeks to identify individuals working with skin in academic, industrial and clinical settings and bring them together for a talk, discussions and lunch. Partnering with the Center for Dermal Research brings the Forum ideas, advice, logistical support and helps it continue to offer attendance with little or no fee.

Otto H. Mills Jr., PhD, F.C.P. Adjunct Professor, Department of Dermatology Rutgers -Robert Wood Johnson Medical School. Otto Mills joined the University of Pennsylvania’s Graduate Group on Molecular Biology in 1965 and the Department of Dermatology, School of Medicine in 1967. His first appointment at the University of Medicine and Dentistry of New Jersey, Robert Wood Johnson Medical School was in 1984, where he is a member of the Department of Dermatology. He has lectured by invitation at universities and medical meetings in the United States, Europe and Asia and authored or co-authored over two hundred and fifty publications.

Contact info: Otto H. Mills at Otto@ohmills.com

Contact Info: SGourion@triprinceton.org

2018 CDR Sponsor of the Year
TERGUS PHARMA

2019 CDR Sponsor of the Year
RODAN + FIELDS

Director Bozena Michniak-Kohn pictured with Rodan + Fields, receiving the award for sponsor of the year 2019. Pictured from left to right: Cheng Hwang, Taylor Oswald, Christine Crane, and Robert Bianchini.

Director Bozena Michniak-Kohn and Jean-Phillippe Therrien from Tergus Pharma, receiving the award.

RODAN +FIELDS
The Master of Business & Science Degree (MBS) WITH A CONCENTRATION IN PERSONAL CARE SCIENCE

The Professional Science Master’s program at Rutgers offers a Master of Business & Science (MBS) degree in Personal Care Science. The degree combines science and business courses which better aligns with today’s careers. The MBS Personal Care Science focuses on the chemistry and sciences relevant in cosmetics, skin care, hair care, fragrances and other consumer health, pharmaceutical and specialty chemical industries. Our curriculum provides an extensive education for a career in the personal care industry whether in R&D and Formulations, Product Development, Marketing, Quality, Regulatory, Supply Chain or other areas. Our science and business courses along with executive coaching and many experiential opportunities through internship and externship prepare our graduates to become the next generation of personal care leaders.

PERSONAL CARE COURSES

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BUSINESS COURSES

Finance/Accounting, Marketing, Communication/Leadership, Ethics, Intellectual Property, Project Management, Supply Chain, Others
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