Designing Formulations for Dermatological Indications

SKIN PRODUCT DEVELOPMENT UPDATE COURSE

REGISTRATION: http://events.r20.constantcontact.com/register/event?oeidk=a07e9res9m-k9a7dd8bf&llr=othusneab

FACULTY:

COURSE DIRECTOR: Otto Mills, PhD FCP, Rutgers Robert Wood Johnson Medical School

CDR DIRECTOR: Bozena Michniak-Kohn, PhD, M.R., Ernest Mario School Pharmacy

Jules Mitchel, PhD, MBA, Target Health

David Steinberg, FRAPS Steinberg Associates

Joel Zatz, PhD, Rutgers University
This is a course for researchers, product developers and evaluators of skin products. This course is a program of the Basic & Applied Dermatology Forum, cosponsored by the Center for Dermal Research and the New Jersey Center for Biomaterials.

This course is a condensed version of a 3-day course taught by the faculty in multiple locations throughout the year. It offers an overview of the key stages in new product design and development: formulation, regulatory, and advanced problem solving. In addition to presentations on specific topic areas, the faculty will share case examples to illustrate the concepts in a real-world context.

Interactive sessions will allow for discussion of challenges that researchers, formulation specialists, and business professionals may face.

**Cost:** CDR Members $100.00, Non-CDR Members $175.00, RU/UMDNJ Faculty $75.00, Students $50.00

**LinkedIn Group:** Basic and Applied Dermatology Forum

For more detail contact Louli Kourkounakis at Center for Dermal Research (848) 445-9614, or via email cbmfrontdesk@dls.rutgers.edu
ABSTRACTS

Joel L. Zatz, Ph.D.

Elements of Skin Product Quality

Product development begins with a clear statement of goals. Using a temple as a model, the four basic requirements: stability, efficacy, biocompatibility and patient/consumer acceptance are illustrated and described. Pharmaceutical and skin care professionals view the “active” ingredient in somewhat different ways and this can affect the relative weight given to each of the four requirements.

Skin Delivery

Optimization of skin delivery requires an understanding of the nature of the problem to be solved (or benefit to be achieved) and the location of the delivery target. Typically, the goal is to improve efficiency and/or increase product effectiveness. Measurements should focus on, or at least include, the target area. Both in vivo and in vitro methods are utilized. Utility of animals (in vivo) or animal tissue (in vitro) is limited by differences in structure and behavior between animal and human skin. The delivery rate depends on the nature of the biological system (skin), the active ingredient and the formulation/delivery system. The stratum corneum is important as a permeation barrier, a potential target for treatment and the locale of physical contact with an applied preparation. Certain aspects of delivery are under the control of the formulator and can be manipulated by the choice of delivery system and inactive ingredients.

David C. Steinberg, FRAPS

Critical Components of Skin Products

This will cover the current topics of preservation and preservatives including what works and what doesn’t and how to incorporate them, oxidation and chelation. The use of humectants & emollients and how they effect your formulation. Finally, how new ingredients are approved in the major markets of the world.

The Changing Regulatory Climate

What is the definition in the US of a drug or a cosmetics. What are the differences in these terms. A complete review of the OTC drug process will be covered including how to do Drug Facts labels and an update on the OTC Antiseptic Monograph, especially “body washes”. State regulations including California, Minnesota and what is happening with microbeads. Finally a brief review of the EU especially focusing on the their “PIF’s & Canada on their advertising claims.

Otto H. Mills, Jr., Ph. D., F.C.P.

Human Testing

This lecture provides insights into predictive testing by considering the phenomena and protocols used to evaluate safety and efficacy. In addition to clinical judgments, roles for non-invasive sampling and instrumental evaluations will be addressed. Included will be how to review data and what factors could influence the interpretation of results. Use of bio-statistical input pre and post will be outlined. Traditional assays and “specialty tests”, often used for claims, will be discussed. Ways to streamline testing will include understanding features of internet-based data collection systems.

 Paths to Innovations

Using “case studies” of early phases of development, this presentation will look for common steps on the path to innovation. Publications will be used to document early activity for: tretinoin, erythromycin and benzoyl peroxide, topically applied erythromycin, nonsteroidal anti-inflammatory agents, low strength benzoyl peroxide, vitamin E, salicylic acid and benzoyl peroxide, combination hyperpigmentation lighting cream, topical tocopheryl phosphates, follicular biopsy and topically applied isoleucine.

B. Michniak-Kohn, Ph.D. M.R. Pharm.S.

Designing Formulations for Dermatological Indications

A tunable family of tyrosine-derived triblock copolymers was synthesized with hydrophobic blocks composed of oligomers of desaminotyrosyl tyrosine esters and diacids and poly(ethylene glycol) as hydrophilic blocks. These triblock copolymers spontaneously self-assemble to produce TyroSpheres™ that act as an effective sink for binding paclitaxel and other hydrophobic drugs. TyroSpheres™ were found to be non-cytotoxic, provide enhancement of drug solubility and stability, effectively encapsulate therapeutically relevant amounts of various drugs, and release them in a rate-controlled manner. Skin distribution studies using a fluorescent dye (Nile Red) as a model compound confirm that: 1) TyroSpheres™ deliver significantly higher amounts of the payload (8-fold) to psoriatic skin compared to healthy skin in vitro, and 2) TyroSpheres™ deliver their payload to the basal layer of the epidermis, the target layer for treatment of psoriasis, and 3) TyroSpheres™ deliver drugs to hair follicles for treatment of acne and hair regeneration. Additionally, TyroSpheres™ can be incorporated into topically elegant viscous formulations with no impact on homogeneity, release, or skin distribution. These factors make our delivery system an excellent candidate for the treatment of psoriasis, acne or other dermatological diseases where topical drug delivery with limited systemic exposure is required. ACKNOWLEDGEMENTS: NIH (Grant #5R01AR056079) & Rutgers CDR for financial support of this study.
SPEAKERS

Joel L. Zatz, Professor Emeritus at Rutgers University, received his Ph.D. degree from Columbia University. He served three terms as chair of the pharmaceutics department, supervised the research of 30 graduate students and taught graduate and undergraduate courses in surface chemistry, pharmacokinetics, skin delivery, and the technology of liquid and semisolid topical delivery systems. He has presented short courses for the pharmaceutical and cosmetic industries in the United States and Europe for the past 25 years and participated in training programs for FDA inspectors.

Dr. Zatz has published widely in various pharmaceutical and cosmetic journals. His areas of research interest include skin delivery of drugs, preservatives and provitamins; skin technology of disperse systems; and penetration of antifungals through human nail. He is the author of Pharmaceutical 4th Calculations, a textbook now in its 4 edition and editor of Skin Permeation, published by Allured.

Dr. Zatz has consulted across a broad range of technical issues for many pharmaceutical and skin care companies. He has presented seminars on various aspects of delivery system technology, skin delivery and product evaluation. He served as an academic consultant to the FDA during development of the SUPAC-SS guidance. He is a Fellow of the Society of Cosmetic Chemists and has been chair of the NY chapter of the Society of Cosmetic Chemists, a former member of the editorial board of the Journal of Pharmaceutical Sciences and editor of the Journal Cosmetic Science.

David C. Steinberg has over 35 years experience in the cosmetic industry. In 1995 he founded Steinberg & Associates, Inc., a consulting company that specializes in cosmetic regulations, labeling, preservation and sunscreens. He founded the Masters Degree program in Cosmetic Sciences at Fairleigh Dickenson University and taught there from 1982 to 2000. He is a member of the American Chemical Society, Society of Cosmetic Scientists, Institute of Food Technologists, Regulatory Affairs Professional Society and is a Fellow member of the Society of Cosmetic Chemists. In 1991 he was the President of the US SCC. From 1992-5 he served on the Presidium of the e IFSCC. In 2009 he was elevated to Fellow status in the Regulatory Affairs Professional Society, the first person to be so honored who specializes in the regulations of OTC drugs and cosmetics.

He has written 4 books including Preservatives for Cosmetics, The Guide to the European Cosmetic Regulations and has authored many papers and chapters in books. He has lectured worldwide on how to preserve cosmetic products, regulations and many other topics. Since 1995, he has written a regular column on Cosmetic Regulations for Cosmetics Y& Toiletries magazine. David holds a BS in Chemistry from Drexel University and an MBA from Pace University.

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 Rutgers 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 fifty publications - www.pubmed.com (Mills O, Mills OH and Mills OH Jr.).

Dr. Mills has served as the Chair of Dermatologic and Allergic Diseases, American Society of Clinical Pharmacology and Therapeutics, and he is a Fellow of the American College of Clinical Pharmacology. His other memberships include: Sigma Xi (University of Pennsylvania), the American Federation for Medical Research, the Society for Experimental Biology and Medicine, the Society for Investigative Dermatology and the American Academy of Dermatology. Among the awards he has received for original research are those from the American Academy of Dermatology (1970, 1981, 1985), the College of Physicians of Philadelphia (1971), the Medical Society of New Jersey (1975), the American Medical Association (1975), the Southern Medical Association (1971) and the American Society of Clinical Pharmacology and Therapeutics (2002).
Rutgers University (Busch campus, Piscataway, NJ) has recently launched the new Center for Dermal Research (CDR) under the leadership of Prof. Michniak Kohn (Professor of Pharmaceutics, Ernest Mario School of Pharmacy).

The CDR offers professional courses, seminars, webinars, clinical workshops, annual symposia and networking events. Member companies receive discounted admission, in addition to having their logo on the CDR website and all CDR materials. Platinum members may exhibit at CDR events at no additional charge.

Additional opportunities for customized research interactions are developed on an individual basis with members, who enjoy reasonable fees for specialized training, collaborations, testing, and formulation support.

For more information please visit www.centerfordermalresearch.org

To find out more about the research, capabilities, members, and opportunities for students, post doctoral fellows and collaborators at Dr. Michniak-Kohn lab please visit www.michniaklab.org

The Basic & Applied Dermatology Forum has been providing informative programs for skin researchers for 19 years with support from Rutgers Robert Wood Johnson Medical School. www.dermatologyforum.org