Location, Logistics & Special Invitation

The course will be held in Rohnert Park, CA, at the DoubleTree by Hilton Hotel Sonoma Wine Country located approximately 40 miles north of San Francisco.

Overnight accommodations can be arranged at the DoubleTree. Special room rates are available for course attendees. Booking details will be provided at the time of registration.

Airport transportation directly to/from Sonoma County is available from both SFO and OAK : www.airportexpressinc.com.

A welcome reception for attendees will be held on the evening of Tuesday, April 17th 2018 from 5 — 7 pm at Dow Development Labs. If travel allows, plan to attend this causal gathering.

Course registration includes lecture, Q & A, all course materials including digital and hard copies of presentations and reference materials, two hands-on interactive sessions, as well as continental breakfast and lunch each day.

Course Sponsors:

DowDevelopmentLabs.com

DOW DEVELOPMENT LABORATORIES, LLC

Croda.com

CRODA

Registration Form Dermatological Product Development Course

Name: _____

Title: _____

Company: _____

Address: _____

Address: _____

Address: _____

Email: _____

Phone: _____

Space is limited - Registration will be accepted on a first come basis.

Registration Fee: $1,100/person
$950/person for 3 or more attendees from same company.

Payment Options:
1. Check Made Payable to: Dow Development Laboratories, LLC
2. Pay by Credit Card*: contact khanley@dowdevelopmentlabs.com
*$50 additional fee/person, totaling $1,150

Return Registration Form & Payment to:
Dow Development Laboratories, LLC
ATTN: Karen Hanley
1031-A North McDowell Blvd.
Petaluma, CA 94954

Refunds: Registration fee, less $300/person, is available for any cancellation received in writing prior to April 2, 2018.

This course is sponsored by:
Dow Development Laboratories, LLC and Croda Inc

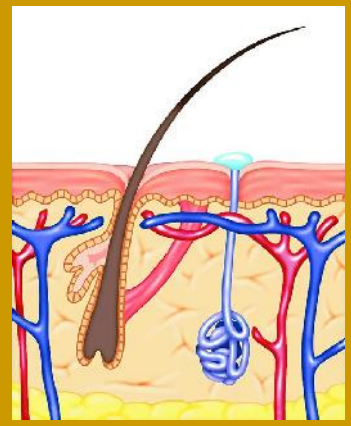
This course is presented by:
Dow Development Institute—*advancing topicals research through education, collaboration and financial support*

April 18-19, 2018
Sonoma County, CA

DERMATOLOGICAL PRODUCT DEVELOPMENT

CURRENT ISSUES FOR TOPICAL PRODUCTS

with interactive sessions for hands-on learning



Presented by

David Osborne, PhD

DOW DEVELOPMENT INSTITUTE

Advancing topicals research through education, collaboration and financial support

OVERVIEW

The aim of this course is to provide a working knowledge of topical product development for industry professionals both new to dermatological products, as well as to those having worked in the field. Emphasis will be on aspects of topical drug delivery that are significantly different from parenteral or solid products. In addition to providing a solid understanding of the skin and formulations for the skin, a detailed listing of the pitfalls unique to semisolid product development will be provided.

The skin, hair and nails represent unique delivery advantages and challenges for the application of therapeutic agents. The first day of the course will provide fundamentals of skin structure and function and the basics of the formulations used to treat healthy and diseased skin. *In vitro* skin permeation techniques are often used to characterize and select formulations. Since this evaluation method readily produces biased or erroneous results, a critical methodology review will be completed. Techniques for enhancing skin penetration will be discussed with an emphasis on pharmaceutical and regulatory implications.

The remaining course hours will be devoted to strategies and development issues faced during development of topical products. Topics such as: when should the final, to-be-marketed formulation be developed, advantages of offshore clinical development, and bridging strategies for formulation changes will complement descriptions of typical product development programs. Practical guidance concerning preclinical; chemistry manufacturing and controls; and clinical product development will be provided. Finally, the regulatory paths for dermatological product development and unique aspects of semisolid patents and the FDA Dermatology and Dental division will be presented.

Two interactive hands-on sessions by Croda, Inc will be integrated into the course.

COURSE OUTLINE

Wednesday, April 18, 2018

8:00 am Basics of Skin Structure, Function and Microbiome

9:15 am Introductions of Participants and Short Break

9:30 am Basics of Topical Pharmaceuticals

10:30 am Quality by Design (QbD) and *Interactive **"HLB"** Hands-on Session**

Noon Lunch

1:00 pm Analytical Methods

1:45 pm *In-Vitro* Skin Permeation and Skin Penetration Enhancement

3:30 pm Break

3:45 pm Topical Product Formulation Development

Thursday, April 19, 2018

8:00 am *Interactive **"Demystifying Emulsions"** Hands-on Session**

8:45 am Nonclinical and Clinical Dermatological Product Development

9:45 am Break

10:00 am Regulatory Paths for Topical Products to Reach the Market

10:45 am Overview of Skin Diseases

Noon Lunch

12:45 pm Designing Clinical Trials for Dermatological Products

1:45 pm Unique Aspects of FDA Dermatology and Dental Division

2:45 pm Break

3:00 pm Topical Product Patents

3:45 pm Wrap-up

**Interactive sessions sponsored by Croda Inc*

Course Instructor

David Osborne received his BS in Chemistry from Missouri State and a PhD in Chemistry from Missouri University of Science and Technology under the direction of Professor Stig E. Friberg. Dr. Osborne honed his skills while employed at the Upjohn Company (now Pfizer) and Calgon Vestal Labs (a Merck subsidiary). He became Vice President of R&D for ViroTex Corp which was acquired by Atrix Laboratories. Dr. Osborne was VP of the Dermatology Division at Atrix, then moved to Dow Pharmaceutical Sciences as VP of Product Development from 2003 until 2008. Dr. Osborne then lead Product Development at TOLMAR, Inc. until retiring as Chief Scientific Officer in May 2016.

David Osborne has over 100 issued patents and 45 publications primarily in the areas of surfactants, formulations and skin delivery. He edited the book *Topical Drug Delivery Formulations* (Marcel Dekker, 1990) and is the developer of Orajel® Ultra, Eucalyptamint® 2000, and Rx product Aczone® (5% dapsone topical gel). Under his leadership Viractin® Cream and Gel (Combe), Eligard® treatments for prostate cancer, Clobex® Spray, MetroGel® 1% (Galderma) and fifteen generic topical products (Sandoz) were developed.

He was the 1992 Chairman of the ACS Division of Colloid and Surface Chemistry, North American Editor of the journal *Colloids and Surfaces: Biointerfaces* and the 2001 Missouri State University Outstanding Young Alumnus.

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