The course will be held in Denver, CO, at the Courtyard Marriott Denver, Downtown.

Overnight accommodations can be arranged at the Courtyard Marriott.

Course registration includes lecture, Q & A, all course materials including digital and hard copies of presentations and reference materials, as well as continental breakfast, lunch and snack the day of the course.

**Location & Logistics**

**FORMULATION BOOTCAMP**

Presented by:
David Osborne, PhD

Sponsored by:

**DOW DEVELOPMENT LABORATORIES, LLC**

**DERMATOLOGICAL PRODUCT DEVELOPMENT**

November 13, 2016
Denver, CO

*Registration Form*

Dermatological Product Development
November 13, 2016

Name: ____________________________

Title: ____________________________

Company: _________________________

Address: __________________________

Address: __________________________

Address: __________________________

Email: ____________________________

Phone: ____________________________

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

Registration Fee: $950/person
$850/person for 3 or more attendees from same company.

Check Made Payable to:
Dow Development Laboratories, LLC or PayPal* to:
jholley@dowdevelopmentlabs.com

* $50 additional fee/person, totaling $1000

Return Registration Form & Check to:
ATTN: Jared Holley
Dow Development Laboratories, LLC
1031-A North McDowell Blvd.
Petaluma, CA 94954  p: 707.202.6361

Refunds: Registration fee, less $300/person, is available for any cancellation received in writing prior to November October 28, 2016.
The aim of this course is to detail how to formulate topical gels, creams and ointments for optimal skin permeation. This one-day course will benefit the formulation scientist having years of dermatological product development experience as well as the pharmaceutical professional new to formulating topical products. In addition to providing a solid understanding of the skin and formulations for the skin, a listing of potential pitfalls unique to semisolid product development will be provided.

The course will begin by focusing on the critical quality attributes typical for topical gels. The inactive ingredient database listed excipients that can be used will be detailed and a strategy for how to formulate a topical gel with specific product examples will be presented. Critical Process Parameters, Critical Material Attributes, and other Quality by Design aspects of a topical pharmaceutical gel and its container/closure system will be thoroughly discussed. Analogous in-depth discussion of USP Emulsions (Creams and Lotions) and USP Ointments will follow.

Human skin represents unique delivery advantages and challenges for the application of therapeutic agents. The skin’s natural barrier to the penetration of external molecules must be overcome by the formulator in order to have an effective product. The physical properties of the active pharmaceutical ingredient combined with the volatility/skin penetration of excipients determines how much of the applied dose becomes systemically available after application. To facilitate the course participant’s ability to optimize a topical pharmaceutical formulation, a thorough description of both healthy and diseased human skin will be provided. Techniques for enhancing skin permeation will be reviewed. The concept of the “secondary” formulation (the residual film remaining on the surface of the skin after “rub-in”) will be introduced to provide course participants a conceptual framework for optimizing skin delivery.

The course will end with a presentation on topical product patents. What is required for a formulation to become an invention that is not obvious to one of normal skill in the art? It is the opinion of the course instructor that a truly optimized topical product, developed using the Quality by Design paradigm, will provide additional layers of intellectual capital to the owner of the active pharmaceutical ingredient.

**Sunday, Nov. 13, 2016**

9 am—4 pm

1. Introduction
2. USP Definition of a Gel
3. Gel excipients: IID and CMAs
4. How to formulate a topical gel
5. QTPP for topical Gels: List of things to consider
6. Topical Gel CQAs, CPPs, and other QbD considerations
7. Container Closure System: Leachables and Extractables
8. Scale-up and Commercialization
9. USP Definition of an Emulsion (Creams and Lotions)
10. Cream excipients: IID and CMAs
11. How to formulate a topical cream
12. QTPP for topical Creams: List of things to consider
13. Topical Cream CQAs, CPPs, and other QbD considerations
14. Container Closure System: Leachables and Extractables
15. Scale-up and Commercialization
16. USP Definition of an ointment
17. Ointment excipients: IID and CMAs
18. How to formulate a topical ointment
19. QTPP for topical ointments: List of things to consider
20. Topical ointment CQAs, CPPs, and other QbD considerations
21. Container Closure System: Leachables and Extractables
22. Scale-up and Commercialization
23. Suspended drug, crystal habit and Ostwald ripening
24. Skin Structure and Function
25. Barrier properties of the healthy skin
26. Barrier properties of diseased skin
27. Transfollicular skin penetration
28. Skin penetration enhancement
29. Skin permeation enhancement
30. Primary formulation versus secondary formulation
31. Functional excipients
32. Topical product patents

**Course Instructor**

David Osborne received his BS in Chemistry from Missouri State and a PhD in Chemistry in 1985 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). In 1993 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 50 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 inventor and developer of Aczone® (5% dapsone topical gel). Under his leadership Viractin® Cream and Gel (Combe), Eligard® treatments for prostate cancer, Clobex® Spray, MetroGels® 1% (Galderna) and over twenty generic topical products were developed and launched.

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 MSU Outstanding Young Alumni

**Contact Information:**

Jared Holley
Dow Development Laboratories
707-202-6361
jholley@dowdevelopmentlabs.com