# DAVID W. OSBORNE, Ph.D.

DOsborne@arcutis.com
david.wade.osborne@gmail.com
970-691-3452

## EDUCATION and TRAINING

2005 **Professional Degree in Chemistry (Honorary)**
University of Missouri-Rolla, Rolla, Missouri

1985 **Ph.D.** in **Physical Chemistry**
University of Missouri-Rolla, Rolla, Missouri
Research Advisor: Professor Stig E. Friberg
Dissertation: The interaction of a glyceridacid with lipids of the stratum corneum

1982 **Bachelor of Science** in **Chemistry (ACS Certified), Math Minor**
Southwest Missouri State University, Springfield, Missouri

## PROFESSIONAL EXPERIENCE

### 2017-Present ARCUTIS Inc

2018-present **Chief Technical Officer**

2017-2018 **Senior Vice President, Product Development**
Venture capital (Frazier Healthcare) funded start-up virtual company developing topical dermatological products. Full time employment began April 11, 2017.

### 2016-Present DAVID W. OSBORNE PHD CONSULTING INC

2016-Present **President**
S-Corporation formed in late August of 2016 providing consulting and educational services in pharmaceutical product development including intellectual property and serving as an expert witness in Paragraph 4 litigations.

### 2008-2016 TOLMAR Inc. (Retired in June 2016—TOLMAR had about 650 total employees with 105 employees reporting to the CSO)

2014-2016 **Chief Scientific Officer**
Responsible for managing Formulation & Process Development, Analytical Development, Polymer Development, Clinical Development, and Tech Services. In addition to continuing development of generic topical and specialty injectable products,

TOLMAR developed a pipeline of proprietary dermatology products and in-licensed a specialty injectable technology (one active advanced into the clinic prior to 2017). Worked closely with TOLMAR and external patent attorneys concerning intellectual property. Implemented a QbD adoption campaign.

2008-2014 **Vice President, Product Development**

Responsible for managing the Formulations Development, Analytical Development, Clinical Development, and Regulatory groups within TOLMAR. Between October 2008 and March 2010, this team filed five First-to-File topical product ANDAs requiring clinical endpoint bioequivalence studies. All five products successfully navigated litigation, were approved and launched. In addition to generic topical dermatology products (ANDAs filed: 2 in 2009, 3 in 2009, 1 in 2010, 1 in 2011, 1 in 2012, 6 in 2013, 1 in 2014, 2 in 2015, and 2 in 2016), generic specialty injectable product development was added as a second product development focus in 2010.

## 2003-2008 Dow Pharmaceutical Sciences

**Vice President, Product Development**

Managed Formulations & Product Development (FPD), Clinical Labeling, Skin Biology Laboratory, and the Internal Development Program (IDP) at Dow. FPD developed dermatological products from pre-formulation through scale-up and commercial manufacturing for Dow clients. Clinical Labeling provided randomization, labeling and product kits for clinical studies. The Skin Biology Lavatory completed in-vitro skin and membrane permeation studies to guide formulation selection. IDP selected development opportunities, established defendable intellectual property, and coordinated initial development of products that were then out-licensed to marketing partners (Valeant acquired DPSI and the IDP pipeline in 2008 for $285 million).

## 1993-2003 Atrix Laboratories, ViroTex Corporation

(ViroTex was acquired by Atrix on November 30, 1998)

2002 – 2003 **Vice President, Dermatology Division, Atrix**

- Responsible for establishing Atrix as a leading developer of generic and proprietary topical formulations and forward integrating this business unit to become a specialty pharmaceutical company focused on Dermatology.

Operational duties include:

- Selection and Management of generic product development with an ever-increasing number of annual ANDA filings (2 in 2001, 5 in 2002, and 7 in 2003). Marketing partner for this program was Geneva (Sandoz/Novartis).
- Directed all proprietary dermatology product development including being chairman of the Joint Development Management Committee between Atrix and Fujisawa that

directed the development of 5% Aczone Topical Gel. The dapsone development program had a 2003 budget of $18 Million.
- Directed all business development activities related to dermatology products and provide a strategy for the creation of a specialty pharmaceutical company focused on Dermatology.
- Managed both proprietary and generic analytical methods development and validation groups for all Atrix products
- **Responsible for overseeing worldwide patenting of all dermatology related Atrix intellectual property.**

1998 – 2002 **Vice President, Pharmaceutical Development, Atrix**
- Transition of ViroTex technologies into Atrix following the November 30, 1998 acquisition. Managed product and analytical development groups for all products. Managed approximately 20-25% of Atrix Employees for this period of time

Operational duties include:
- Oversight of patent applications;
- Product development from formulation selection to commercial scale-up
- Analytical methods development and validation
- **Project Team Leader for Dapsone Topical Gel**

Laboratory responsibilities included:
- New dermatological and mucosal product development
- Novel delivery system evaluation
- Transfer of Atrigel products from Drug Delivery to Process Development

1993 – 1998 **Vice President, Research & Development, ViroTex**
**(3rd Employee, ~ 22 employees in R&D when acquired)**
- Designed and equipped a product development laboratory, quality control laboratory, virology/microbiology laboratory and a GMP manufacturing area.

Operational duties included:
- Oversight of patent applications, contract manufacture of both OTC and Rx products, contract toxicology testing, animal pharmacology/efficacy testing, human clinical trials.

Laboratory responsibilities included:
- New product research, topical drug delivery research, analytical methods development, product stability testing, quality control release of raw materials, and antiviral mechanism of action studies.

**1991 – 1993** **Calgon Vestal Laboratories, Subsidiary of MERCK & CO. (Product Development ~45 employees)**

**Group Leader, Skin Care**

Development of:
- Routine and high-risk handwashing products for preventing the spread of infection;

- Development of skin conditioning products for maintaining healthy, normal and aging skin in hospitals and nursing homes;
- Development of topically applied products to treat diseased skin or relieve skin discomfort.
- Development efforts included evaluation of potential actives/products for licensing, formulation design including stability and efficacy testing, manufacture of GLP and GMP supplies for use in toxicological evaluations, and support of clinical studies.

## 1985-1991 THE UPJOHN COMPANY (~7,000 employees)

1988 – 1991 **Research Scientist, Drug Delivery R&D-Specialty Products**

- Areas of specialization included: topicals, transdermal delivery systems (patches), and suppositories.
- Typical activities were: pre-formulation characterization, bulk drug stability, formulation design, final formulation stability, Phase I, II and III clinical supply manufacture, GLP pathology/toxicology supply manufacture and preparation of the corresponding sections of the IND and NDA.

1985 – 1988 **Research Scientist, Pharmaceutical Manufacturing Technical Services**--Group was reorganized into Drug Development R&D in January 1988

- Areas of specialization included: topicals
- Responsible for scale-up, manufacturing phase-in and marketed product support including validation of packaging and raw material changes.

## COMMERCIALIZED PRODUCTS

**Inventor/Developer**
**PrimaHex Foam** (Approved "NDA" marketed by CV Ltd)
**Orajel Ultra** (OTC marketed by Del Laboratories)
**Eucalyptamint 2000** (OTC marketed by Heratige)
**Aczone** (Approved NDA marketed by Allergan)
**Onsolis** (BEMA-Fentanyl NDA marketed by Meda Pharmaceuticals)

**Named Inventor on Orange Book listed patent**
**Bunavail** (BEMA-Buprenorphine and Naloxone) US 6,159,498 and 7,579,019
**Belbuca** (BEMA-Buprenorphine) US 6,159,498 and 7,579,019

**Developer**
**Viractin Cream** (OTC marketed by Combe Inc)
**Viractin Gel** (OTC marketed by Combe Inc)
**Aloe Vestal Antifungal Ointment** (OTC marketed by ConvaTec)
**Cleocin Vaginal Ovules** (Approved NDA marketed by Pfizer)
**Eligard 1 month** (Approved NDA marketed by TPI, Astellas, and others)
**Eligard 3 month** (Approved NDA marketed by TPI, Astellas, and others)
**Eligard 4 month** (Approved NDA marketed by TPI, Astellas, and others)
**Eligard 6 month** (Approved NDA marketed by TPI, Astellas, and others)
**MetroGel 1%** (Approved NDA marketed by Galderma)

**Clobex Spray** (Approved NDA marketed by Galderma)
**Desonate Gel** (Approved NDA marketed by Bayer AG)
**Ziana Gel** (Approved NDA marketed by Medicis)
**Acanya Gel** (NDA marketed by Arcutis/Valeant)
**Erythromycin Benzoyl Peroxide Gel** (Approved ANDA marketed by Sandoz)
**Fluticasone Cream** (Approved ANDA marketed by Sandoz)
**Lidocaine/Prilocaine Cream** (Approved ANDA marketed by Impax)
**Mometasone Ointment** (Approved ANDA marketed by Impax)
**Betamethasone Dipropionate Cream** (Approved ANDA marketed by Impax)
**Ketoconazole Shampoo** (Approved ANDA marketed by Sandoz)
**Metronidazole Topical Gel** (Approved ANDA marketed by Impax)
**Metronidazole Vaginal Gel** (Approved ANDA marketed by Sandoz)
**Mometasone Cream** (Approved ANDA marketed by Impax)
**Mometasone Lotion** (Approved ANDA marketed by Impax)
**Orajel Protective Mouth Sore Discs** (OTC marketed by Del Laoratories)
**Clindamycin Benzoyl Peroxide Gel** (Approved ANDA-BenzaClin marketed by Mylan)
**5% Imiquimod Cream** (Approved ANDA marketed by Impax)
**Calcipotriene Cream** (Approved ANDA marketed by Sandoz)
**Diclofenac Gel, 3%** (Approved ANDA marketed by Impax)
**Calcipotriene 0.005% and Betamethasone Dipropionate Ointment**
(Approved ANDA marketed by Sandoz)
**Adapalene Gel, 0.03%** (Approved ANDA marketed by Sandoz)
**Jublia (efinaconazole) Topical Solution 10%** (Approved NDA marketed by Valeant)
**Clindamycin Benzoyl Peroxide Gel** (Approved ANDA-Duac marketed by Impax)
**Naftifine Cream 2%** (Approved ANDA marketed by Impax)
**Clindamycin Benzoyl Peroxide Gel** (Approved ANDA-BenzaClin marketed by Impax)
**Acyclovir Ointment 5%** (Approved ANDA marketed by Impax)
**Azeleic Acid 15%** (Approved ANDA marketed by Impax)

Combined annual sales of developed products exceeded $1.2 billion in 2015

## PROFESSIONAL SOCIETIES

American Chemical Society
American Academy of Dermatology
American Association of Pharmaceutical Scientists (inactive)
The Society for Investigative Dermatology (inactive)
Skin Pharmacology Society (inactive)

## PROFESSIONAL ACTIVITIES AND HONORS

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|---|---|
| 2016-2019 | Chair, Q3 Working Group |
| 2015-2016 | CSU Advisory Board Member for developing a Professional Science Master's degree in Biodata Analytics in the Department of Biochemistry and Molecular Biology |
| 2011-present | Member of the UMKC School of Pharmacy Research Advisory Council |
| 2005 | Chair AAPS Dermatopharmaceutics Focus Group |

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