

# Steve Davio, Ph.D.

---

Pharmaceutical Development Technical Consultant,  
PO Box 246, Fairport, NY 14450 | 585-698-7067 | Steve@DavioPharmaConsulting.com

## Summary:

---

Steve is a career pharmaceutical scientist with 30+ years of hands-on experience developing a wide range of pharmaceutical products including biologics, oral dosage formulations, and, most recently, ophthalmic products. He is a development specialist with advanced leadership and technical skills in Chemistry, Manufacturing, and Control (CMC) functions beginning with formulation development, also including analytical methods, and process development, clinical supply manufacture, scale-up, technology transfer, specifications development, and CMC regulatory documentation. Steve possesses well-developed partnering skills with the other disciplines required to develop pharmaceutical products: clinical, regulatory, marketing, etc. His science background includes biochemistry, protein chemistry, drug delivery, pharmaceuticals, and pharmacokinetics. Steve's breadth of experience in the ophthalmic area includes Rx, generic, and over-the-counter (OTC) products, as well as due-diligence assessments for new business opportunities.

## Current Position:

---

DAVIO PHARMA CONSULTING, LLC | OCT 2013-PRESENT | PRINCIPAL



Founder, Davio Pharma Consulting (DPC), dedicated to helping clients through specialized knowledge and experience in development of pharmaceutical products for eye health. Davio Pharma Consulting works with clients anywhere in the world ranging from virtual companies to large pharmaceutical companies.

Areas of business interest include:

- Rx and Gx Ophthalmic Drug Products, new or re-purposed drugs, assisting virtual to large companies developing their first ocular pharmaceutical product. The product scope can include topical or injectable, biotechnology (protein) or small molecule.
- Non-Prescription Eye Products, bringing specialized expertise on the surface of the eye, the underlying structural issues of dry eye, and the non-prescription eye drop market to develop the next exciting product for treatment of mild to moderate dry eye.
- "Claims Strategy", helping non-scientists maximize market value by capitalizing on the scientific basis for their product, and helping marketers communicate this value to their customers.
- Expert Witness services for legal proceedings involving patent disputes on ophthalmic drug formulations.

## Scientific and Technical Experience:

---

### BAUSCH & LOMB | 2006-AUG 2013 | RESEARCH FELLOW

- Successfully led a CMC team in developing Lotemax Gel®, a novel gel formulation for a Bausch & Lomb flagship product, resulting in FDA approval and market launch.
- Directed a CMC team in formulation development for a recombinant proteolytic enzyme, tested in clinical trials by intra-vitreous injection. Developed IP around a device for back-of-the-eye injections.
- Organized and led a team of formulators and cell biologists in a program to discover natural ingredients with potential benefit in OTC dry eye drops. Discoveries resulted in new IP.
- Led a team in development of functional models of tear film, *in vitro* models of the corneal epithelium, and, through collaboration with an esteemed academic team, clinical measurements of the integrity of the human tear film.
- Led a CMC team in development of an improved formulation for Soothe XP, an OTC dry eye product.
- Performed multiple due-diligence/business development assessments of biotech and conventional ophthalmic drug candidates.

### PHARMACIA/PFIZER | 1996-2005 | ASSOCIATE RESEARCH FELLOW

- Developed dissolution methods for several products including multi-drug combinations in novel dosage forms.
- Elucidated factors controlling drug release from tablets, enhancing predictions of *in vivo* performance.
- Successfully developed and transferred *tipranavir*, a life-saving drug in soft gelatin capsule, to a licensee.
- Led a solid oral dosage form development project in collaboration with a Japanese partner, managing accelerated tech transfer and scale-up to a contract manufacturer in Puerto Rico.

### THE UPJOHN COMPANY | 1985-1996 | RESEARCH SCIENTIST II/III/IV

- Developed formulations for multiple protein products including bovine growth hormone releasing factor, a human fibrinolytic protein, a cytotoxic anti-HIV protein, a blood-substitute product, and a recombinant vaccine antigen.
- Developed and published a method to assess the potential for intravenous precipitation of insoluble peptide-mimetic drugs.

### THE US ARMY, MEDICAL SERVICE CORPS | US ARMY, FT DETRICK, MD | 1981-1985 | CAPTAIN

- Led the Army Medical Research Institute program on the detection and medical intervention upon exposure to the marine neurotoxins saxitoxin (red tide toxin) and tetrodotoxin (Fugu or 'puffer' fish toxin)

## Education:

---

PH.D | 1981 | PURDUE UNIVERSITY: Physical protein biochemistry, red blood cell membranes.  
B.S. | 1976 | MICHIGAN STATE UNIVERSITY: Physical Science.

## Technical credentials & 'soft' skills:

---

- Solid technical background + Strong "people" orientation.
- Flexibility and rapid adoption of new technical areas.
- Full-spectrum product experience, sterile solutions through oral tablets, Rx to OTC.
- Wide range of technical competency from small molecule through protein therapeutics.
- Experienced CMC team leader, CMC team builder, mentor, coach.
- Ph.D. in physical protein biochemistry: 3 book chapters, 34 papers and posters, 5 patents, > 50 technical presentations to audiences covering the spectrum of technical background.

## Select Bibliography:

---

- Marlowe, Z.T. and **Davio, S.R.**, Dose Uniformity of Loteprednol Etabonate Ophthalmic Gel (0.5%) Compared with Branded and Generic Prednisolone Acetate Ophthalmic Suspensions (1%), *Clinical Ophthalmology* 2014:8, 23-29.
- **Davio, S.R.**, Cavet, M.E., Harrington, K.L., Walsh, A., Marlowe, Z., Glass, B., and Sarkar, P. "Corneal Epithelial Cell-protective and Wettability-enhancing Properties of Hyaluronic Acid + PEG 8000 in an Artificial Tear Product," ARVO 2013 Program #6000.
- Sarkar, P., Marlowe, Z., Walsh, A., Glass, B., Kleiber, T., Cavet, M.E., Harrington, K.L., and **Davio, S.R.** "A Comparative Evaluation of Lipid-based Formulations for Dry Eye Therapy using a Corneal Epithelial Cell Desiccation Model and Physicochemical Measurements," ARVO 2013 Program # 4318.
- Tung, C.I, Kottaiyan, R., Koh, S., Wang, Q., Yoon, G., Zavislan, J.M., **Davio, S.R.**, and Aquavella, J.V. (2012), Noninvasive, Objective, Multimodal Tear Dynamics Evaluation of 5 Over-the-counter Tear Drops in a Randomized Controlled Trial. *Cornea* 31(2): 108-114.
- Coffey, M.J, and **Davio, S.R.**, "Viscoelastic and Sedimentation Characterization of Loteprednol Etabonate Ophthalmic Gel, 0.5%," ARVO 2012 Program # 6283.
- Bandyopadhyay, P., Marlowe, Z., Kleiber, T., and **Davio, S.R.**, "Unique Rheologic Properties of a Lubricant Eye Drop Containing Propylene Glycol and Glycerin (Active Ingredients) and Sodium Alginate," ARVO 2011 Program # 377.
- Wang, H., Marlowe, Z. and **Davio, S.R.** "Properties of OTC Dry Eye Products in the US Market", ARVO 2009 Program# 4650.
- **Davio, S.R.**, Maxwell, R., and Smith, M.A. "A Model System to Relate Water Penetration and Solute Dissolution with Drug Release of a Soluble Drug from a Hydrophilic Polymer Matrix Tablet." Abstract T2152. Presented at the American Association of Pharmaceutical Scientists Annual Meeting, Baltimore, MD, November 9, 2004.
- **Davio, S.R.** and Grimmer, J. "Drug Release Characterization of a Highly-Soluble Drug from an HPMC-Based Matrix Tablet: Implications for an In Vivo-In Vitro Correlation." Abstract W5191.

Presented at the American Association of Pharmaceutical Scientists Annual Meeting, Salt Lake City, UT. October 29, 2003.

- **Davio, S.R.** (1995). Differential Scanning Calorimetry (DSC) as a Research Tool in the Development of Protein Formulations. An invited symposium presentation to the Midwest Regional Meeting of the American Association of Pharmaceutical Scientists, Chicago, IL, May 1995.
- **Davio, S.R.**, Kienle, K.M., and Collins, B.E. (1995). Interdomain Interactions in the Chimeric Protein Toxin sCD4(178)-PE40: A Differential Scanning Calorimetry (DSC) Study. *Pharm. Res.* 12: 642-648.
- Harris, J.S., Epps, D.E., **Davio, S.R.**, and Kezdy, F.J. (1995). Evidence for Transbilayer, Tail-to-Tail, Cholesterol Dimers in Dipalmitoylphosphatidylcholine Liposomes. *Biochemistry* 34: 3851-3857.
- **Davio, S.R.**, Kienle, K.M., and Haluska, C.E. (1994). A Study of the Mechanism of sCD4(178)-PE40 Aggregation. Presented at the American Association of Pharmaceutical Scientists Ninth Annual Meeting, San Diego, CA, Nov., 1994.
- **Davio, S.R.** and Hageman, M.J. (1993). Characterization and Formulation Considerations for Recombinantly Derived Bovine Somatotropin. Stability and Characterization of Protein and Peptide Drugs: Case Histories. Eds: Wang, Y.J. and Pearlman, R. Plenum Press, New York. pp. 59-89.
- McShane, M.M. and **Davio, S.R.** (1992). Hydroxypropyl  $\beta$ -Cyclodextrin May Decrease Intra-vascular Precipitation of Drugs: Application to the HIV Protease Inhibitor U-75875. Proceedings of the Sixth International Cyclo-Dextrin Symposium, Chicago, IL, April 21-24, 1992.
- **Davio, S.R.**, McShane, M.M., Kakuk, T.J., Zaya, R.M., and Cole, S.L. (1991). Precipitation of the Renin Inhibitor Ditekiren Upon IV Infusion; in Vitro Studies and Their Relationship to in Vivo Precipitation in the Cynomolgus Monkey. *Pharm. Res.* 8: 80-83.
- **Davio, S.R.** (1984). Medical Defense Against the Potential Biological Warfare Agent, Saxitoxin. Proceedings of the Army Science Conference, Vol I. West Point, NY. pp. 197-205.
- **Davio, S.R.** and Fontelo, P. (1984). A Competitive Displacement Assay to Detect Saxitoxin and Tetrodotoxin. *Anal. Biochem.* 141: 199-204.
- **Davio, S.R.** and Low, P.S. (1982). Anesthetic-Ion Channel Interactions: The Effect of Lidocaine on the Stability and Transport Properties of the Membrane-Spanning Domain of Band 3. *Arch. Biochem. Biophys.* 218: 421-428.

### Patents/Applications:

---

- US 20130210912 A1 and WO2013122801 A1, Ophthalmic pharmaceutical compositions and methods of making and using same, Davio, Sarkar, Marlowe, Glass, Kleiber, August 15, 2013.
- US 8420648 B2, Polymorphs of brimonidine pamoate, Wang, Davio, McIntire, Hall, Suchit, Summersett, Whitehead, April 16, 2013.
- WO 2009/089409 A2, Intravitreal injection system having coaxial cannulae and use thereof, Valenti, Bartels, Davio, Rotoli, Levy.
- US 20080293728 A1, Complexes comprising alpha-2 adrenergic receptor agonists and compositions, McIntire, Davio, Harms, and Wang.

- US 20070134231 A1, Method for prolonging activity of auto-degradable enzymes and compositions thereof. Jani, Kwok, McIntire, Pfeffer, Shafiee, Shi, Venkatesh, Wang, Huang, and Davio. June 14, 2007.
- CA 2675500 A1, Ophthalmic compositions comprising diglycine. Burke, Xia, Kwok, and Davio, April 24, 2008.

[Steve's LinkedIn Profile](#)