Bernard A. Olsen, Ph.D.

Summary. Expertise in Chemistry, Manufacturing, and Control aspects for all phases of drug development, particularly for synthetic molecules. Specific areas of experience and expertise include:

- Analytical method development and validation
- Impurity investigation and control
- Genotoxic impurity assessment and control
- Regulatory filings, clinical trial and marketing authorizations
- Specification setting
- API physical property evaluation and control
- Support for patent litigation

Professional Experience

Olsen Pharmaceutical Consulting, LLC
2010-present

Aptuit Consulting
Managing Director: 2009

Eli Lilly and Company, Lilly Research Laboratories
Senior Research Fellow, Product Research and Development: 2007-2008
Research Fellow: 2002-2006
Senior Research Scientist: 1993-2001
Research Scientist: 1990-1992
Head, Bioanalytical Development: 1989-1990
Head, Analytical Development: 1987-1988
Research Scientist: 1986-1987
Senior Analytical Chemist: 1979-1985

Education

1975; BS, Nebraska Wesleyan University
1979; PhD, University of Wisconsin-Madison

Drug Development Experience

- Contributed to the development and/or support of over 25 marketed drugs including Prozac, Zyprexa, Gemzar, Evista, Cymbalta, Alimta, Cialis, Strattera, and Effient
- Technical advisor for cross-functional CMC aspects of Lilly small molecule drug portfolio in all phases of clinical development
- Experience responding to questions from worldwide regulatory authorities
- Produced expert reports for patent litigation matters, testified at deposition and trial
- Counterfeit drug analysis
- Published and lectured extensively on analytical method development, impurity investigation strategies, and regulatory strategies

Selected Publications

- Olsen, B.A.*; Sullivan, G.R., "Chemometric Categorization of Octadecylsilyl Bonded-Phase Silica Columns Using Test Mixtures and Confirmation of Results with Pharmaceutical Compound Separations", J. Chromatogr., 1995, 692, 147-159.
- Olsen, B.A.*; Argentine, M.D., “HPLC Method Development for Duloxetine Hydrochloride Using a Combination of Computer-based Solvent Strength Optimization and Solvent Selectivity Mixture Design”, J. Liq. Chromatogr. & Rel. Technol., 1996, 19, 1993-2007.
- Olsen, B.A.*; Perry, F.M.; Snorek, S.V.; Lewellen, P.L., “Accelerated Conditions for Stability Assessment of Bulk and Formulated Cefaclor Monohydrate”, Pharm. Dev. and Tech., 1997, 2, 303-312.
- Wirth, D.D.; Olsen, B.A.*; Hallenbeck, D.K.; Lake, M.E.; Gregg, S.M.; Perry, F.M., “Screening Methods for Impurities in Multi-sourced Fluoxetine Hydrochloride Drug Substances and Formulations”, Chromatographia, 1997, 46, 511-523.
- Olsen, B.A., “Hydrophilic Interaction Chromatography Using Amino and Silica Columns for the Determination of Polar Pharmaceuticals and Impurities”, J. Chromatogr. A, 913 (2001) 113-122.
- Olsen*, B.A.; Borer, M.W.; Perry, F.M.; Forbes, R.A. “Screening for Counterfeit Drugs by Near-Infrared Spectroscopy”, Pharm. Tech., 26 (2002) 62, 64, 66, 68, 70, 71, 95.
- Olsen, B.A.; Baertischi, S.W. “Strategies for Investigation and Control of Process and Degradation-Related Impurities”, in Handbook of Isolation and Characterization of Impurities in Pharmaceuticals, S. Ahuja and K. M. Alsante, Eds., Academic Press, San Diego, 2003, pp.89-117, invited chapter.
- Olsen, B.A., “Developing and Using Analytical Methods to Achieve Quality by Design and Efficiency in Drug Development”, Pharm. Tech., supplement on Scaling up Manufacturing Processes, 2005, S14, S16-S18, S20-S22, S24-S25. invited article.
- Olsen, B.A.*; Kiehl, D.E.; “Authentication and Fingerprinting of Suspect Counterfeit Drugs” Am. Pharm. Rev. 9 (2006) 115-118. invited article.
- Gavin, P.F.*, Olsen, B.A., Wirth, D.A., Lorenz, K.T.; “A quality evaluation strategy for multi-sourced active pharmaceutical ingredient (API) starting materials”, J. Pharm. Biomed. Anal., 41 (2006) 1251-1259.
- Argentine, M.D.; Owens, P.K.; Olsen, B.A.*, “Strategies for investigation and control of process-related impurities in drug substances”, Adv. Drug Del. Rev. 59 (2007) 12-28, invited article.
- Olsen, B.A.*, Gavin, P.F., Wozniak, T.J., “Quality by Design Considerations for Analytical Methods”, AAPS Newsmagazine, 10, Dec. 2007, 16-23.
- Pierson, D.A.*; Olsen, B.A.; Robbins, D.K.; DeVries, K.M; Varie, D.L.; “Approaches to assessment, testing decisions, and analytical determination of genotoxic impurities in drug substances”, Org. Process Res. Dev. 13 (2009) 285-291.
- Olsen, B.A., “Genotoxic Impurity Issues in Drug Development”, *Pharma Focus Asia*, 12 (2009) 20-22.

Professional Activities

- American Chemical Society (Analytical Division)
- American Association of Pharmaceutical Scientists
- Editorial Advisory Board: Journal of Pharmaceutical and Biomedical Analysis
- Reviewer: Journal of Chromatography A, Journal of Pharmaceutical and Biomedical Analysis, Journal of Pharmacy and Pharmacology
- United States Pharmacopeia, Committee of Experts, Vice chair of Committee for Monograph Development of Opthalmics, Oncolytics, and Dermatologicals and Chair, Monograph Development-Small Molecules 3 Committee
- Product Quality Research Institute, working group on Drug Substance Specifications
- Purdue University, Adjunct Professor, Department of Industrial and Physical Pharmacy
- Co-moderator, APQ open forum on QbD for Analytical Methods, AAPS National Meeting