



## **Brian James, Ph.D.**

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### ***SUMMARY***

Brian provides broad development expertise across API, drug product and CMO sourcing. In addition to “hands-on” knowledge, he has successfully managed global teams for Rondaxe clients, both virtually and from the client’s site.

### ***PROFESSIONAL EXPERIENCE***

*Director, Strategic Development, Rondaxe: 2006-Present*

- Comprehensive management of pre-IND chemical and formulation development projects
- Complete vendor and supply chain management for pre-clinical and clinical stage products
- Build and evaluate cost model scenarios for Active ingredients
- Developed multiple defensible starting material strategies
- Process validation preparation, risk assessment and chemistry evaluation

*Associate Director, Global Actives and Intermediates, Bristol-Myers Squibb Company, 2004 - 2006*

*Senior Scientist, Technical Operations Planning and Sourcing, Bristol-Myers Squibb Company, 2004*

- Managed multiple sourcing projects.
- Responsible for \$10MM spend for validation raw materials.
- Negotiate Supply, Confidentiality and Quality agreements.
- Perform financial analysis related to projects.
- Evaluate technical and financial proposals from suppliers.
- Develop sourcing strategies for late development and commercial products.

*Senior Scientist, Chemical Development Laboratories, Bristol-Myers Squibb Company, 2003 - 2004*

*Scientist II, Chemical Development Laboratories, Bristol-Myers Squibb Company, 2002 - 2003*

*Scientist I, Chemical Development Laboratories, Bristol-Myers Squibb Company, 1999 - 2002*

- Developed cost effective synthetic routes for pharmaceutical ingredients.
- Process development using statistical methods.
- Transferred multiple projects from pilot to commercial facilities.
- Managed development kilo laboratory.

*National Institutes of Health Postdoctoral Fellow, Colorado State University, 1997 - 1999*

- Developed and executed multi-step synthetic routes toward natural products.
- Investigated methods for the addition of ethoxyvinyl lithium to unsaturated oxazolines.



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### ***EDUCATION***

MBA, LeMoyne College, 2005  
Major: Business Administration

Ph.D, University of California, 1996  
Major: Chemistry

B.S., California State University, 1992  
Major: Chemistry

### ***PUBLICATIONS***

James, B.; Meyers, A. I. "Diastereoselective Conjugate Addition of Ethoxyvinylolithium to Aromatic and  $\alpha,\beta$ -Unsaturated Oxazolines" *Tetrahedron Lett.* **1998**, 39, 5301.

Lipshutz, B. H.; James, B.; Vance, S.; Carrico, I. "A Potentially General Intramolecular Biaryl Coupling Approach to Optically Pure 2,2'-BINOL Analogs" *Tetrahedron Lett.* **1997**, 38, 753.

Lipshutz, B. H.; Buzard, D. J.; Carrico, I.; Dickson, D.; James, B.; Lindsley, C. Pecchi, S.; Vance, S.; Ullman, B. R "New Organometallic Solutions to Problems in Polyene Natural and Unnatural Products Synthesis" Proceedings of the 5th VW Symposium on Organic Synthesis *via* Organometallics (OSM 5), Heidelberg, 1996.

Lipshutz, B. H.; Aue, D. H.; James, B. "An *ab initio* Molecular Orbital Study on the Lewis Acidity of TMS-Cl and TMS-CN Toward an  $\alpha,\beta$ -Unsaturated Aldehyde: Are these Acid-Base Interactions Important in Organocuprate 1,4-Additions to Enones?" *Tetrahedron Lett.* **1996**, 37, 8471.

Lipshutz, B. H.; Stevens, K. L.; James, B.; Pavlovich, J. G.; Snyder, J. P. "Analyses of Cu(I) Complexes *via* Electrospray Mass Spectrometry: Implications for Organocuprate Reagents" *J. Am. Chem. Soc.* **1996**, 118, 6796.

Lipshutz, B. H.; James, B. "New  $^1\text{H}$  and  $^{13}\text{C}$  Spectral Data on 'Higher Order' Cyanocuprates. If the Cyano Ligand is not on Copper... Then Where is it?" *J. Org. Chem.* **1994**, 59, 7585.

Lipshutz, B. H.; James, B. "Effects of Additives on Cuprate 1,4-Additions: Gilman Reagents in the Presence of  $\text{Me}_3\text{SiCN}$ " *Tetrahedron Lett.* **1993**, 34, 6693.

Lipshutz, B. H.; Dimock, S. H.; James, B. "The Role of  $\text{Me}_3\text{SiCl}$  in Gilman Cuprate 1,4-Addition Reactions" *J. Am. Chem. Soc.* **1993**, 115, 9283.



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***PRESENTATIONS***

"Sourcing from China: Risk Mitigation Strategies" James B. Seminar presented October 29, 2008 at DCAT Strategic Sourcing Summit, New Brunswick, NJ

"Progress Toward the Asymmetric Formal Synthesis of Psuedoterosin A" James, B. Seminar presented April 25, 1997 at California State University, Chico.

"Analysis of Copper and Ruthenium Complexes by ESI-MS" James, B.; Stevens, K. L.; Buzard, D. J.; Keith, J. M., Pavlovich, J. G.; Lipshutz, B. H. Poster presented at the 44th Annual Meeting of the American Society for Mass Spectrometry, May 14, 1996. Portland, Oregon.

"Electrospray Ionization Mass Spectrometry: A Structural Probe of Organometallic Reagents" Lipshutz, B.H.; James, B; Stevens, K. L.; Pavlovich, J. G. Poster presented at the 8thIUPAC Symposium on Organometallic Chemistry Directed toward Organic Synthesis, August 6, 1995. Santa Barbara, California.

"The Effect of TMS-CI and TMS-CN on Cuprate Addition Reactions" James, B. Invited seminar presented November 18, 1994 at California State University, Chico.

***U. S. PATENTS***

"Method of Preparation of 21-Amino Epothilone Derivatives" Favreau, D.; Kant, J.; Levesque, K.; Wang, S.; Guo, Z.; James, B. L. WO 03/070170 A2, August 28,2003.

"Method of Producing N-[(2S)-Sulfanyl-4-(1,5,5-trimethylhydantoinyl)butanoyl]-L-Leucyl-L-tert-Leucine N-methylamide and intermediate thereof" North, J.; James, B. WO 03/048119 A2, June 12,2003.