



Brian James Ph.D., M.B.A.

SUMMARY

Experienced pharmaceutical professional with in-depth current knowledge of the fine chemical industry including intermediates, active ingredients, drug product, impurity marker and analytical providers. Participated in more than fifty technical, capacity and capability audits. Broad process development expertise using statistical optimization techniques and experience in technical transfer of process knowledge between sites. Excellent communication skills and ability to integrate technical and business objectives in order to achieve development goals.

PROFESSIONAL EXPERIENCE

Vice President Operations and Managing Director, Rondaxe: 2006-Present

- Comprehensive management of pre-IND chemical and formulation development projects
 - Review technical details from out-licensing company
 - Identify technical requirements and match to potential CRO and CMO as appropriate
 - Identify gaps in development history to date
 - Assist in writing CTD documents for regulatory filing
- Complete vendor and supply chain management for pre-clinical to commercial products
 - Convert sponsor technical information into a technical transfer enabling document
 - Draft RFPs on behalf of sponsors
 - Assist in vendor selection, and technical audit
 - Manage technical transfer activities
 - Oversee development, transfer and manufacturing activities
 - Review and approve technical documents (batch records, specifications, etc.)
- Process validation preparation, risk assessment and chemistry evaluation
 - Quality, safety and chemistry based approach to determining critical process parameters
 - Review validation protocols provided by CMO
 - Evaluate chemistry for the potential formation of genotoxic impurities
- Build and evaluate cost model scenarios for Active ingredients
 - Extrapolate current process to a launch or commercial process for costing
 - Identify key cost drivers to guide development activities
- Developed multiple defensible starting material strategies
 - Coordinated with vendors to develop robust specifications
 - Developed new suppliers of key materials



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Associate Director, Global Actives and Intermediates, Bristol-Myers Squibb Company, 2004 - 2006
Senior Scientist, Technical Operations Planning and Sourcing, Bristol-Myers Squibb Company, 2004

- Develop sourcing strategies for late development and commercial products.
 - Determine key technology requirements
 - Identify multiple sources to better supply security
 - Negotiate Supply, Confidentiality and Quality agreements.
- Managed multiple sourcing projects.
 - Primary responsibility for Phase-III and early commercial products
 - Evaluate technical and financial proposals from suppliers.
 - Conducted capability and capacity audits
 - Perform financial analysis
- Member of commercial launch team
 - Direct oversight of process validation
 - Responsible for \$10MM spend for validation raw materials.

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.
 - Experience working in HPAPI facility
 - Designed robust and reproducible crystallization procedures
- Transferred multiple projects from pilot to commercial facilities.
- Managed development kilo laboratory.
 - Responsible for budget, operation and scheduling

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

M.B.A., 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 Ethoxyvinyl lithium to Aromatic and α,β -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 α,β -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 ¹H and ¹³C 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 Me₃SiCN" *Tetrahedron Lett.* **1993**, 34, 6693.

Lipshutz, B. H.; Dimock, S. H.; James, B. "The Role of Me₃SiCl in Gilman Cuprate 1,4-Addition Reactions" *J. Am. Chem. Soc.* **1993**, 115, 9283.

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 Pseudoterosin A" James, B. Seminar presented April 25, 1997 at California State University, Chico.



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"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 8th IUPAC Symposium on Organometallic Chemistry Directed toward Organic Synthesis, August 6, 1995. Santa Barbara, California.

"The Effect of TMS-Cl 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.