

## **JAMES P. SAUNDERS**

2 Van Alstine Ave.  
Suffern, NY 10901  
845-369-6624 (home)  
845-270-8255 (cell)  
[Jpsaunders8658@aol.com](mailto:Jpsaunders8658@aol.com)

### **CAREER SUMMARY**

Strong analytical chemistry background in method development and validation, especially with LC/MS (8 years) and HPLC (2 years). Five years experience in designing and performing ADME studies of various rare sugars and other carbohydrates using rats and mice as experimental models.

### **TECHNICAL SKILLS**

LC/MS (ESI and APCI) –API 3000, API 4000, Micromass  
HPLC (UV, RI)-Shimadzu Prominence, Cohesive Technologies Aria, Waters 2795, Agilent 1100  
Laboratory automation - Tomtec Quadra 96, Perkin Elmer MultiProbe II, Tecan Genesis  
GC  
Liquid scintillation counting  
Atomic absorption spectrophotometry  
Computer Skills - Proficient with Analyst, MassLynx, Watson, NuGenesis, E-WorkBook, Microsoft Word, Excel, PowerPoint, Groupwise, Outlook, Internet

### **PROFESSIONAL EXPERIENCE**

#### **Pfizer (formerly Wyeth Research), Pearl River, New York**

May 2002 to Present: Senior Research Scientist I, Bioanalytical R&D, Drug Safety and Metabolism  
Provide analytical support by quantifying novel drug entities (primarily small molecules) in biological matrices, including tissues such as bone and skin, by LC/MS/MS and HPLC/UV in a GLP environment. Develop, validate, and optimize bioanalytical methods used for the quantitation of these compounds in support of pre-clinical and clinical studies. Routinely use laboratory automation such as Tomtec Quadra 96 and MultiProbe for sample extraction (protein precipitation, liquid-liquid, and SPE). Write LOGs and method validation and study reports. Troubleshoot equipment as needed. Calibrate, clean and maintain LC/MS. Prepare data for archiving. Responsible for ordering control plasma for entire Bioanalytical group. Received 5 individual and team awards. Co-author on three technical publications and co-inventor on one U.S. patent.

#### **Hoffmann-La Roche Inc., Nutley, New Jersey**

October 2000 to May 2002: Scientist (assignment through Adecco)  
Assisted with drug screening in the Discovery Pharmacology DMPK department, applying techniques such as LC/MS, LC/MS/MS, *in vitro* and *in vivo* (brain, rat models) microdialysis, and plasma protein binding assays by equilibrium dialysis. Programmed and operated automated robotic systems (Tecan Genesis Robotic Sample Processor 150) and autosampler fraction collectors. Performed assay and method development, optimization, and validation. Supported rat pharmacokinetic studies- prepared and analyzed dosing solutions, set up metabolism cages and dosing equipment, processed blood samples by centrifugation, performed sample analyses and data calculations, and created graphs with Excel.

#### **National Field Service Corporation, Suffern, New York**

October 1999 to October 2000: Biotech Consultant  
Provided scientific research and technology consultation to clients such as Biospherics Incorporated.

#### **Spherix Incorporated (formerly Biospherics Incorporated), Beltsville, Maryland**

February 1998 to September 1999: Manager, Biotech Programs  
As direct report to President of company, managed clinical and field research studies performed at two academic institutions. Worked closely with endocrinologist and registered nurse, analyzing data from normal and Type 2 diabetic patients in clinical studies of D-tagatose, a new low-calorie bulk sweetener, at the University of Maryland School of Medicine. Supervised University of Maryland field studies of non-toxic, carbohydrate-derived, and environmentally-safe pesticides. Coordinated activities of five consultants to Danish licensee (MD Foods Ingredients amba) on various aspects of D-tagatose development project. Provided

documentation for Generally Recognized as Safe (GRAS) determination process for D-tagatose to Danish licensee. Was primary author of two technical publications. Supervised Ph.D. biochemical engineer and lab technician in enzymatic process development research on D-tagatose and other research projects. Designed new laboratory facility. Administered \$250 K annual budget. Prepared corporate business plans and research proposals. Regularly prepared and delivered oral presentations to corporate management, Board of Directors, and scientific consultants. Served as corporate radiation safety officer and chemical hygiene officer.

1991 to 1998: Manager of Metabolic Studies, Biotech Programs

Designed and performed rodent dietary and metabolism studies of radiolabeled and unlabeled sugars such as D-tagatose. Prepared technical protocols and reports, including computer-generated graphics and data calculations; gave technical oral presentations to management; supervised animal care, dosing, sample analysis, and data collection. Managed contract laboratory animal toxicology studies. Developed and validated HPLC methods (following FDA GLP's) for homogeneity, stability, and concentration verification analyses of D-tagatose in dosing solutions and feed samples from toxicology studies. At Danish laboratory, assisted in development of new HPLC method for analysis of D-tagatose in blood, urine, and feces. Analyzed sugars in foods by GC and HPLC. Consulted for Danish licensee regarding development of D-tagatose process in their pilot plant. Co-inventor on three U.S. patents; two on the use of D-tagatose in the treatment of hyperglycemia and the complications of diabetes, and one on the use of carboxylic acids as larvicides.

1990 to 1991: Senior Chemist, Inorganic Laboratory

Performed metals analyses of water and soil samples using atomic absorption spectrophotometer for commercial analytical laboratory. Wrote SOP's for analytical methods.

1987 to 1990: Research Associate, Biotech Programs

Conducted dietary and metabolism studies of <sup>14</sup>C-labeled D- and L-sugars using rodents as experimental models (dosing by oral intubation or intravenously); synthesized commercially unavailable D- and L- (unlabeled and <sup>14</sup>C-labeled) sugars; purified sugars by liquid chromatography and recrystallization; analyzed sugars in foods by HPLC; and characterized sugars using FTIR spectrophotometry, polarimetry, and melting point determinations. Co-invented critical D-tagatose process and obtained two U.S. patents for novel process.

1985 to 1987: Research Assistant, Biotech Programs

Performed significant laboratory experiments with D- and L-sugars to study their metabolic fates in rodents. Prepared pivotal technical reports that set course for company's choice of low-calorie sweetener candidates.

## **EDUCATION**

M.S., Nutrition Research, University of Maryland, College Park, Maryland, 1984

B.S., Nutritional Sciences, Cornell University, Ithaca, New York, 1981

## **AWARDS AND PROFESSIONAL MEMBERSHIPS**

Wyeth Team of the Year Award - 2006

Wyeth Above and Beyond Award – 2004 - 2007

Roche Special Recognition Award – September 2001

Biospherics Incorporated Employee of the Month Award - July 1992

Biospherics Incorporated Outstanding Achievement Award - April 1991

Biospherics Incorporated Incentive Award - September 1987

American Chemical Society

American Society for Mass Spectrometry

## **PUBLICATIONS**

1. Ji, A.J.; Saunders, J.P.; Amorusi, P.; Stein, G.E.; Wadgaonkar, N.D.; O'Leary, K.; Leal, M.; and Fluhler, E.N., "Determination of Tigecycline in Human Skin Using a Novel Validated LC/MS/MS Method," *Bioanalysis*, in press.
2. Ji, A.J.; Saunders, J.P.; Amorusi, P.; Wadgaonkar, N.W.; O'Leary, K.; Leal, M.; Dukart, G.; Marshall, B.; Fluhler, E.N., "A Sensitive Human Bone Assay for Quantitation of Tigecycline Using LC/MS/MS," *Journal of*

- Pharmaceutical and Biomedical Analysis, 2008; 48:866-875.
3. Ji, A.J.; Saunders, J.P.; Wadgaonkar, N.W.; Petersen, P.J.; O'Leary, K.; McWilliams, W.E.; Amorusi, P.; Leal, M.; and Fluhler, E.N., "A Novel Antibiotic Bone Assay by Liquid Chromatography/Tandem Mass Spectrometry for Quantitation of Tigecycline in Rat Bone," *Journal of Pharmaceutical and Biomedical Analysis*, 2007; 44:970-979.
  4. Mallalieu, N.L.; Cavallo, G.C.; Hall, L.B.; Saunders, J.; Pamidimukkala, A.; and Renzetti, L.L., "Targeted Pharmacokinetics of Midazolam, Propranolol and Tenoxicam in the Lateral Ventricle of Rat Brain Using Microdialysis," *AAPS PharmSci*, 2001; 3(4) (suppl.).
  5. Saunders, J.P.; Donner, T.W.; Sadler, J.H.; Levin, G.V.; and Makris, N.G., "Effects of Acute and Repeated Oral Doses of D-Tagatose on Plasma Uric Acid in Normal and Diabetic Humans," *Regulatory Toxicology and Pharmacology*, 1999; 29:S46-S56.
  6. Saunders, J.P.; Zehner, L.R.; and Levin, G.V., "Disposition of D- [U – 14C] - Tagatose in the Rat," *Regulatory Toxicology and Pharmacology*, 1999; 29:S57-S65.
  7. Szepesi, B.; Levin, G.V.; Zehner, L.R.; and Saunders, J.P., "Antidiabetic Effect of D-Tagatose in SHR/N-cp Rats," *The FASEB Journal*, 1996; 10(3): A461.
  8. Levin, G.V.; Zehner, L.R.; Saunders, J.P.; and Beadle, J.R., "Sugar Substitutes: Their Energy Values, Bulk Characteristics, and Potential Health Benefits," *American Journal of Clinical Nutrition*, 1995; 62 (suppl.): 1161S-1168S.
  9. Ahrens, R.A.; Hsu, H.C.; Kim, S.S.; Saunders, J.P.; and Douglass, L.W., "The Disaccharide Effect of Sucrose Feeding on Excretion of Intravenously Injected [1,2-3H] Aldosterone and Conjugated Glucuronic Acid in Normotensive Rats," *Journal of Nutrition*, 1987; 117:689-693.

#### **PATENTS**

1. Ji, A., and Saunders, J.: "Determination of Antibiotic concentration for Tigecycline in Animal and Human bone Using LC/MS/MS," U.S. Patent 7,427,507, September 23, 2008.
2. Beadle, J.R.; Zehner, L.R.; Levin, G.V.; Saunders, J.P.; and Bozsa, R.C., "Insecticidal Aliphatic Carboxylic Acid Compositions," U.S. Patent 5,690,950, November 25, 1997.
3. Zehner, L.R.; Levin, G.V.; Saunders, J.P.; and Beadle, J.R., "D-Tagatose as Anti-Hyperglycemic Agent," U.S. Patent 5,447,917, September 5, 1995.
4. Zehner, L.R.; Levin, G.V.; Saunders, J.P.; and Beadle, J.R., "D-Tagatose as Anti-Hyperglycemic Agent," U.S. Patent 5,356,879, October 18, 1994.
5. Beadle, J.R.; Saunders, J.P.; and Wajda, T.J., "Process for Manufacturing D-Tagatose," U.S. Patent 5,078,796, January 7, 1992.
6. Beadle, J.R.; Saunders, J.P.; and Wajda, T.J., "Process for Manufacturing D-Tagatose," U.S. Patent 5,002,612; March 26, 1991.