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# Jeff Sailstad

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## ***SIGNIFICANT QUALIFICATIONS***

- A leader in the field of analytical chemistry, especially the development, validation and application of biological and immunological based techniques for pre-clinical and clinical pharmaceutical studies
- Extensive experience supervising, training and mentoring research teams
- Expertise in initiating and implementing analytical automation techniques to enhance efficiency and accuracy
- Extensive background with diverse analytical techniques, including immunologic, chromatographic and biologically based methods.

## ***KEY AREAS OF TECHNICAL AND MANAGERIAL EXPERTISE***

- Management responsible for a GLP (good laboratory practice) compliant laboratory (3-12 scientists; supporting up to 24 studies per year)
- Extensive experience working with contract research organizations to develop, validate and apply regulatory compliant methods. This has been both as “the client” or as a liaison between pharmaceutical or biotec companies and CRO analytical laboratories.
- Developed and managed analytical assays for a broad range of therapeutic agents including: anticonvulsants, antidepressants, antidiarrheal, antibody therapy, biologicals, cardiovascular agents, antihistamines and decongestants, chemotherapeutics, antivirals
- Extensive experience mentoring and working with research project teams wishing to move projects from research to full development, specifically how to meet the increased regulatory requirements for bioanalytical methods.
- Recognized as a leader in the field of “fit for purpose” analytical method validation.

## ***PROFESSIONAL EXPERIENCE***

*Sailstad and Associates, Durham, NC*

### **President, Owner September 2002-Current**

- Scientific consultant – in the area of bioanalytical regulatory compliant methods
  - PK/PD, biomarkers, immunogenicity
  - Bioequivalency
  - Bioassays and Potency Testing
  - Laboratory automation
  - Needs assessment and solutions for the development of a GxP regulated laboratory
- Provides expertise in the areas of: regulatory compliance (GLP/GCP/GMP), Pharmacokinetics, Toxicology, Pharmacology and Clinical Trial Design.

*Trimeris Inc. Durham, NC*

### **R&D Quality Manager and Manager Bioanalytical Chemistry February 2006- December 2006**

- Successfully leveraged experience with quality programs in the development of a GMP initiative, charged with in-house synthesis of an API (active pharmaceutical ingredient) for upcoming toxicology and first-time in-man studies.
- Oversight of GMP activities in both production and analytical chemistry groups.
- Continued management of Bioanalytical Chemistry Group
- Member of Trimeris/Roche project team charged with immunogenicity testing efforts in support of next generation fusion inhibitor.

*Trimeris Inc. Durham, NC*

### **Group Manager, Discovery/Bioanalytical Chemistry February 2003- February 2006**

- Continued management of Bioanalytical Chemistry Group
- Additional responsibilities in the drug discovery, overseeing assay development in molecular screening/high throughput area.
- Management responsibility for laboratory automation group as well as line-management responsibility for compound registration/distributions systems.

*Trimeris Inc. Durham, NC*

### **Manager, Bioanalytical Chemistry December 2002 – February 2003**

- Directing a group of six scientists, providing bioanalytical services for the pre-clinical through clinical support of novel antiviral therapeutics.
- Responsible for the enhancement and maintaining of this GLP laboratory.
- As a member of the Trimeris Research Management Committee responsible for the enhancement of immunogenicity testing for ongoing clinical trials.

*Glaxo SmithKline Research Triangle Park, NC*  
*Joint appointment with Worldwide Bioanalysis and Experimental Medicine*

### **RTP Site Head Pharmacodynamic Exploratory Research Lab (PERL)**

#### **Senior Research Investigator / Team Leader January 2001 – August 2002**

- Directed major company efforts to support the analysis of biologicals (peptides, proteins, antibodies)

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- Identified critical unmet need for regulatory acceptance, redirected a portion of team to support immunogenicity testing for ongoing clinical trials
- Developed and supervised the analysis of pharmaceuticals in neurology and virology areas, this resulted in cost savings to the company in excess to \$2.5 million/year
- Project leader for software validation project to assured part 11 compliance

*Glaxo Wellcome Inc. Research Triangle Park, NC  
International Bioanalysis*

#### **Research Investigator / Team Leader 1997-2001**

- Led the effort to redirect immunoassay team to support biomarker analysis  
17 biomarker assays established and validated under GLP
- Introduced electrochemiluminescence (ECL) assays to the repertoire of methodologies used with the company. Resulted in increased sensitivity and assay flexibility; 4 ECL assays developed and implemented
- Served as departmental representative on Research and Development (R&D) promotion review board- Assured consistency in promotion criteria across diverse functions in R&D

#### **Sr. Research Scientist 1995-1997**

- Developed semi-automation of immunoassays that were implemented as the world-wide company standard for analysis
- Converted tube-based radioimmunoassays to multiwell format for scintillation proximity radioimmunoassays compatible with automation. These methods were successfully implemented in both the US and UK and reduced time and error potential

*Burroughs Wellcome Co. Research Triangle Park, NC  
Department of Pharmacokinetics and Drug Metabolism*

#### **Research Scientist 1991-1995**

- Developed assays for pre-clinical and clinical trials for 2 project level compounds
- Department Project team representative for two clinical projects provided both Bioanalytical ADME (Absorption, Distribution, Metabolism and Excretion)
- Supervised multi-departmental team which successfully validated and applied a novel folate bioassay to support of numerous toxicology studies
- Recognized for expertise on validation questions, with particular emphasis on immunoassays
- Instrumental on a committee developing the international LIMS (laboratory information management system), the first analytical techniques supported were immunoassays

#### **Research Specialist II 1987-1991**

- Supervised and mentored research technicians and students
- Supported preclinical pharmacokinetics in animal models protocols through authorship of the final internal reports
- Developed methods for quantitative analysis of numerous compounds from many types of tissues (brain, fetal tissue, amniotic fluid, etc.) generated during toxicology studies

#### **Research Scientist II 1983-1987**

- Responsible for the development and application of immunoassays and the subsequent transfer of methodology to the drug assay laboratory for use in clinical studies

#### **Scientist I 1981-1983**

- Assisted in the development and utilization of radioimmunoassays

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**Research Assistant 1978-1981**

- Performed routine immunoassays and assisted senior scientist in assay development

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## ***EDUCATION***

Belmont Abbey College, Belmont, NC 1978

Bachelor of Science, Chemistry

North Carolina State University, Raleigh, NC

Graduate coursework in areas of toxicology and biochemical toxicology, 1978-1980

## ***Special Training***

Advanced Labeling Techniques – Wallac Inc. - Tutu, Finland

Advanced Automation Development – Tecan Inc. - Zurich, Switzerland

BIA Basics – Biacore, Inc.

Computer assisted experimental design – taught by GW senior statisticians

Management Training – such as: performance management, targeted selection, how to deal with difficult employees

## ***LEADERSHIP IN PROFESSIONAL ORGANIZATIONS***

American Association of Pharmaceutical Scientists (AAPS)

- Founding member of Ligand Binding Assay Bioanalytical Focus Group (LBABFG)  
Vice Chair 1999 - 2002  
Chairman 2002 – 2004
- Biotec Section representative on planning committee for the National Biotec Meeting in 2007 and 2008.
- Co-Chair - for “AAPS/FDA Third Bioanalytical Workshop on Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays”
- Co-Guest Editor AAPS Journal – themed issue - Bioanalytical Method Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays, 2007

## **PUBLICATIONS**

Quantitative Bioanalytical Methods Validation and Implementation: Best Practices for Chromatographic and Ligand Binding Assays, C.T. Viswanathan, Surendra Bansal, Brian Booth, Anthony DeStefano, Mark Rose, Jeffrey Sailstad, Vinod P. Shah, Jerome P. Skelly, Patrick G. Swann, and Russell Weiner **The AAPS Journal 2007; 9 (1) Article 4** (<http://www.aapsj.org>) also accepted for publication in **Pharmaceutical Research**.

Fit-for-Purpose Method Development and Validation for Successful Biomarker Measurement, Jean W. Lee, Viswanath Devanarayan, Yu Chen Barrett, Russell Weiner, John Allinson, Scott Fountain, Stephen Keller, Ira Weinryb, Marie Green, Larry Duan, James A. Rogers, Robert Millham, Peter J. O'Brien, Jeff Sailstad, Masood Khan, Chad Ray and John A. Wagner, **Pharmaceutical Research 23 (2)** 312 - 328, (2006)

Method Validation and Measurement of Biomarkers in Nonclinical and Clinical Samples in Drug Development. A Conference Report, Jean W. Lee, Russ S. Weiner, Jeff M. Sailstad, Ronald R. Bowsher, Dean W. Knuth, Peter J. O'Brien  
An AAPS Conference in Salt Lake City Oct 24-25,( 2003), **Pharmaceutical Research 22 (4)** 499–511 (2005)

Workshop on Bioanalytical Methods Validation for Macromolecules: Summary Report, Krys J. Miller, Ronald R. Bowsher, Abbie Celniker, Jacqueline Gibbons, Shalini Gupta, Jean W. Lee, Steve J. Swanson, Wendell C. Smith, Russell S. Weiner, Dan J. A. Crommelin, Ira Das, Binodh S. DeSilva, Robert F. Dillard, Michael Geier, Han Gunn, Masood N. Khan, Dean W. Knuth, Michael Kunitani, Gerald D. Nordblom, Rene J. A. Paulussen, Jeffrey M. Sailstad, Richard L. Tacey and Ann Watson, **Pharmaceutical Research 18 (9)** 1373-1383, (2001)

Disposition of phenacetin in dog and man determined by a sensitive and specific radioimmunoassay, J.W.A Findlay, R.L. DeAngelis, R.F. Butz, J.M. Sailstad, R.M. Welch, **J. Pharm. and Experimental Therapeutics. 210(1)** 127-133, (1979).

Pseudoephedrine and triprolidine in plasma and breast milk of nursing mothers, J.W.A. Findlay, R.F. Butz, J.M. Sailstad, J.T. Warren, R.M. Welch, **Br. J. Clin. Pharmac. 18**, 901-906, (1984).

Treatment of digoxin intoxication in a renal failure patient with digoxin-specific antibody fragments and plasmapheresis, G.M. Rabetoy, C.A. Price, J.W.A. Findlay, J.M. Sailstad, **Am. J. Nephrol. 10(6)**: 518-21, (1990).

Clinical and pharmacokinetic profiles of digoxin immune Fab in four patients with renal impairment, N.M. Allen, G.D. Dunham, J.M. Sailstad, J.W.A. Findlay, **DICP 25(12)**: 1315-20, (1991).

Immunofluorometric assay for lamotrigine (Lamictal) in human plasma, J.M. Sailstad, J.W.A. Findlay, **Ther. Drug. Monit. 13(5)** : 433-42, (1991).

Influence of digoxin immune Fab therapy and renal dysfunction on the disposition of total and free digoxin, M.R. Ujhelyi, MR, S. Robert, D.M. Cummings, R.D. Colucci, P.J. Green, J.M. Sailstad, **Ann. Intern. Med. 119(4)**: 273-7, (1993).

Radioimmunoassay for the chemical stable prostacyclin analog, 15AU81: a preliminary pharmacokinetic study in the dog, J.W.A. Findlay, M.J. McNulty, T.L. Page, S.Y. Chang, J.M. Sailstad, **Prostaglandins Leukot. Essent. Fatty Acids. 48(2)**: 167-74, (1993).

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The pharmacokinetics and pharmacodynamics of the prostacyclin analog 15AU81 in the anesthetized beagle dog, M.J. McNulty, J.M. Sailstad, R.P. Steffen, **Prostaglandins Leukot. Essent. Fatty Acids**, **48(2)**: 159-66, (1993).

Disposition of digoxin immune Fab in patients with kidney failure, M.R. Ujhelyi, R.S. Cummings, R.D. Colucci, J.M. Sailstad, P.H. Vlasses, J.W.A. Findlay, B.J. Zarowitz, **Clin Pharmacol Ther.** **54(4)**:388-94, (1993).

Pharmacokinetics and hematological effects of the PEGylated thrombopoietin peptide mimetic GW395050 in rats and monkeys after intravenous or subcutaneous administration, M. de Serres M., R.L. Yeager, J.E. Dilberger, G. Lalonde, G.H. Gardner, C.A. Rubens, A.H. Simkins, J.M. Sailstad, M.J. McNulty, J.L. Woolley, **Stem Cells** **17(6)** 316-26 (1999)

A phase I and pharmacokinetic study of 1843U89, a noncompetitive inhibitor of thymidylate synthase, in patients with advanced solid malignancies, G. Schwartz, T.R. Johnson, A. Goetz, H. Burris, L. Smetzer, T. Lampkin, J. Sailstad, J.A. Hohnaker, D.D. Von Hoff, E.K. Rowinsky, **Clin Cancer Res.** **7(7)**:1901-11 (2001)

**Abstracts**

Validation of an Immunoradiometric Assay (Irma) For the Detection of Anti-CJC-1295 Antibodies in Monkey Serum

Khan Pham, Julie Woo, Dominador Calamba, Bill Nowatzke, Megan Freeman, Jeff Sailstad, Ronald Bowsher, and J P Castaigne

**AAPS National Biotec Conference 2005**

Evaluation of Binding of Protein La to Rabbit, Monkey, Dog, and Human Immunoglobulins

Jeff Sailstad, Khan Pham, Bill Nowatzke, Vihra Iordanova, Jean-Paul Castaigne, Stella Wen, and Ronald Bowsher

**AAPS National Biotec Conference 2005**

Investigation of Three Immunogenicity Methods to Detect Antibodies to CJC-1295

Nowatzke B, Pham K, Sailstad J, Baganoff M, Salfen B, Iordanova V, Castaigne J, Bowsher RR,

**AAPS National Biotec Conference 2005**

Automation of immunoassays using a Tecan Genesis® running Logic® and Facts® Software, E.H.

Culverhouse, M. O'Mara, J. Bruner, J. Sailstad., **Clinical Ligand Assays Society National Meeting 2000**

Automatic Calibration of Tecan Genesis, A.H. Simkins, M. O'Mara, J. Bruner, J. Ormand, J. Sailstad,

**Clinical Ligand Assays Society National Meeting 2000**

Immunofluorometric assay for acrivastine in human plasma, J.M. Sailstad, K.H. Yeowell, F.R. Nelson, S.Y. Chang, J.W.A. Findlay, **J. Clin. Immunoassay. 13(1): 53, (1990).**

Radioimmunoassay for anti-digoxin Fab fragments (Digibind) in human plasma, J.M. Sailstad, J.W.A. Findlay, **J. Clin. Immunoassay. 13(1): 53, (1990).**

The Pharmacokinetic of Digoxin Immune Fab, Total Digoxin and Free Digoxin in Patients with Renal Impairment, R.D. Colucci, M. Chow, J. Kluger, J. Sailstad, J. Findlay and R. Long, **10th Annual Meeting, American College of Clinical Pharmacy**, August (1989).

Pharmacokinetics of the Antidiarrheal Pentapeptide, BW-942C, in Dog, Monkey, and Man Determined by a New Radioimmunoassay, J.M. Sailstad, S. Wilkinson and J.W.A. Findlay, **Fed. Proc., 46, 867 (1987).**

The Pharmacokinetic Study of the Antidiarrheal Pentapeptide, BW-942C, In Many by Radioimmunoassay, J.W.A. Findlay, J.M. Sailstad, D.F. Kirksey, R.F. Fleck, B.A. Boucher and W.A. Wargin, presented at **III Wld. Congress on Clin. Pharmacol. and Therap.**, Stockholm, Sweden, July, (1986) (abstr. 194).

Pharmacokinetics of d-Pseudoephedrine (PE) in Dogs and Rats, J.W.A. Findlay and J.M. Sailstad, **Fed. Proc., 42, 1139 (1983).**

Pharmacokinetics and Bioavailability of Mebentine Sulfate in Man, J.W.A. Findlay, E.L. Michelson, R.A. Long, J.M. Sailstad, T.L. Wenger, S.T. Liao, K.W. Hamblen and M.R. Blum, **Pharmacologist, 24, 240 (1982).**

Metabolism of Phenacetine(P) to N-Hydroxyphenacetin (N-OHP) in Hamster and Man, R.M. Welch, P.B. Rolfe, J.M. Sailstad and J.W.A. Findlay, **Pharmacologist, 23, 197 (1981).**

## ***Invited Presentations***

Immunogenicity Testing - "The Devil in the Details" - UK Focus Group sponsored by BioVeris, Oxford, UK, February 2007

Bioanalytical Method Validation of Ligand-Binding Assays to Support Pharmacokinetic Assessments of Macromolecules: A Post-Crystal City III Perspective, AAPS Annual Meeting, October 2006

Bioanalysis Using ECL Detection "An Important Tool in the Toolbox"  
BioVeris Workshop, Nashville, TN, AAPS Annual Meeting, Nov. 2005

How to Implement the Recent "Recommendations for the Design and Optimization of Immunoassays used in the Detection of Host Antibodies against Biotechnology Products" Barnett Conference, Immunogenicity Testing for Therapeutics (Philadelphia, PA), Sep. 2005

Immunogenicity Testing Using ECL Detection - A User's Viewpoint IIR Immunogenicity Conference  
BioVeris Workshop, Boston, Oct. 2005

Improving Bioanalytical Method Validation for Macromolecules using Non-Chromatographic Method,  
World Bioanalytical Congress, Philadelphia, September, 2005

How to Implement the Recent "Recommendations for the Design and Optimization of Immunoassays used in the Detection of Host Antibodies against Biotechnology Products," Drug Information Association, Washington, DC, June 2005

Automation: A Measured Approach – *How to Start Small, Show Value, Expand, Remit and Get Promoted* AAPS Short Course titled Automation of Ligand Binding Assays to Support Demanding Drug Development Programs: Strategies for Success, Nov. 2004

Special Topic – How to Implement the Recent "Recommendation for the Design and Optimization of Immunoassays used in the Detection of Host Antibodies against Biotechnology Products", Barnett Conference, Immunogenicity Testing for Therapeutics (Brussels, Belgium), Sep. 2004

Immunogenicity Testing Using ECL Detection – Advantages and Disadvantages, Barnett Conference, Immunogenicity Testing for Therapeutics (Brussels, Belgium), Sep. 2004

Immunogenicity Testing Using ECL Detection – Advantages and Disadvantages, Barnett Conference, Immunogenicity Testing for Therapeutics, Feb. 2004

Pre-Study Validation: What to do and How to do it: AAPS Annual Meeting Short Course titled GLP-Compliant Validation of Ligand Binding Assays: A Practical and Rational Approach, Oct. 2003

AAPS Workshop on Method Validation and Measurement of Biomarkers in Nonclinical and Clinical Samples in Drug Development, Planning Committee (Organizer and Moderator of Clinical portion of Program), Salt Lake City, UT Oct. 2003

Understanding Additional Validation: What Do We Accept, Repeat or Extend? Barnett Conference, Bioanalytical Methods, Feb. 2003

New Technology – So many new techniques, what should we use? Part of symposium dealing with the application of biomarkers in clinical drug development, AAPS National Biotechnology Conference, June 2002, San Diego, CA.

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Acceptance Criteria: "What Makes Sense?" AAPS/FDA Workshop Bioanalytical Methods Validation for Macromolecules, March 1-3, 2000 Arlington, VA.

Panelist at APQ Open Forum titled "Bioanalytical Methods: What you don't know will hurt you" AAPS National Meeting November 2, 2000.

Where are the Dams? A rational look at automation in the bioanalytical laboratory US Environmental Protection Agency (Office of Research and Development), July 1999.

Immunoassays: It is not really magic! The basics and validation considerations. US Environmental Protection Agency (Office of Research and Development), November 1997.