

Steve J. Bannister, Ph.D.
Hightower Pharmaceutical Services Corp

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Dr. Bannister is a consulting chemist specializing in drug analysis. He is trained in the fundamentals of science and passionate about their application. Steve has focused on chemical analysis throughout his twenty-five year career in drug development and has been responsible for hundreds of analytical methods for the identification and quantitation of drugs and other substances in samples including blood, urine, tissue, excreta, powders, pills, lotions, potions, weeds, and seeds. He persistently challenges the commonly held belief that expensive technology insures the validity of analytical data. In fact, applying the challenge of the Scientific Method to every single step in an analysis – not just the instrument - is the only way to assess and demonstrate data validity. “Theory guides, experiment decides” I.M. Kolthoff, 1894-1993

Steve has more than twenty-five years of experience in the pharmaceutical industry, with broad responsibility for drug development, always including analytical chemistry. Both as a scientist and as a manager he has been accountable for the technical performance and regulatory compliance of drug-testing laboratory operations. He has extensive experience reviewing the development, documentation, and execution of methods of chemical analysis, and has audited service-providing laboratories.

Steve now has a consulting practice assisting scientists in drug development, executives in research and development strategy, and lawyers in civil and criminal litigation. He previously worked for Big Pharma (eg, Schering Plough), and for start-up (NaPro BioTherapeutics) and generic firms (Ivax). He received his BS in Pharmacy from the University of Georgia and his MS and PhD in Pharmaceutical Chemistry from the University of Kansas. More details are available at <http://www.linkedin.com/in/stevejbannisterphd>

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Experienced pharmaceutical-development scientist and leader; 26 years of experience applying the fundamentals of physical chemistry to the development, characterization, and analysis of drug formulations; proven ability to solve problems of solubility, stability and bioavailability; understanding of biological phenomena in drug absorption, distribution and clearance facilitates design and interpretation of pharmacokinetic studies and interpretation of drug-level patterns; highly analytical.

Ph.D., 1983 (M.S., 1977), Pharmaceutical Chemistry, University of Kansas. Rigorous fundamental training emphasizing physical and analytical chemistry of drugs formulated into products and drugs administered as therapeutic agents; dissertation research focused on analysis and pharmacokinetics of metal coordination complexes with activity in cancer

B.S., 1975, Pharmacy, University of Georgia. Broad program covering the science and practice of pharmacy; chose optional clinical term at the Medical College of Georgia

11/08 – **Hightower Pharmaceutical Services**, Tampa, Florida, **Owner & Principal Consultant**

Continuation of business-practice and product-development consulting practice.

- Assisting executives with planning and project valuation technical due diligence;
- Assisting scientists with experimental design, execution and interpretation; and
- Assisting attorneys as a subject-matter and testifying expert in civil and criminal litigation.

1/06 – 11/08 **Xcelience, LLC**, (was MDS until 05/06) Tampa, Florida, **Scientific Director and Principal Consultant**

- Responsible for consulting business practice within product-development contract research organization
 - Direct service to small and virtual clients extends capabilities by assisting in product concepts, development planning and project management
 - Consulting for large clients extends capacity by providing project-specific technical support including existing-technology review and project and document review
 - Projects include: drug formulation development; analytical method design, development, and validation; 510k diagnostic device development; CMC planning; and litigation support as a consulting and testifying scientific expert
- Support of Xcelience Technical Operations includes new-technology scouting and evaluation, participation in project teams and problem-solving consultation
- Business-development activities include joining territorial BD staff in meetings with potential customers of laboratory services and development of work scopes for broad projects combining multiple capabilities

4/04 – 1/06 **MDS Pharma Services, Inc / Pharmaceuticals**, Tampa, Florida, **Director of Analytical and Preformulation Services**

- Senior management staff member in contract service organization providing product development services to pharmaceutical industry
- Accountable for scientific integrity, technical capability, regulatory compliance and productivity of diversified analytical services group
- Directed team of 20 scientists including: 3 PhD; 7 MS; 12 BS; and 1 technician with 4 to 25 years of experience in pharmaceutical analysis (mean 11 / median 9)

- Responsible for all analytical services supporting formulation development, GMP manufacturing and product stability studies, including:
 - Preformulation characterization of drug substances – structure elucidation, solubility, partition coefficient, dissociation constant, polymorph screening, particle size, thermal behavior, stability of solid and solution, hygroscopicity and bulk powder properties
 - Analytical method development for drug substance and drug product – assay, related substances, degradation products, content uniformity, dissolution
 - Analytical methods included wet chemical, chromatographic and spectroscopic
 - Qualification and validation of analytical methods to rigorous scientific and compliance (FDA and ICH) standards
 - Design and execution of substance and product stability studies (stressed by heat, light and humidity) for submission to US and international regulatory authorities
 - Investigation of out-of-specification, out-of-trend, and unexpected results

4/03 – 7/04 **Hightower Pharmaceutical Consulting, Inc.**, Superior, Colorado, **Owner & Principal Consultant**

- Design, development and validation of analyses of drugs, formulations and biological samples
- New formulation development and reformulation to overcome stability problems
- Elucidation of physical characteristics and control mechanisms of delivery systems
- Coaching and mentoring of laboratory staff
- Development and management of effective and compliant laboratories
- Product and substance CMC
- Technical due diligence for acquisitions and startups

9/98 – 3/03 **NaPro BioTherapeutics, Inc.**, Boulder, Colorado Joined from Ivax - NaPro's former development partner

9/00 – 3/03 **Vice President**, Drug Development and corporate executive officer

- Accountable for drug R&D, process development and manufacturing technical services
- Member of corporate technical due diligence team
- In-house expert in the crafting and review of formulation patent defense strategies

Department accomplishments include:

- Approval of paclitaxel ANDA;
- Development of proprietary oral delivery systems for natural-product drugs;
- Design and synthesis of small focused libraries of proprietary modified natural products with specifically enhanced pharmacology;
- Development and installation of semisynthetic paclitaxel manufacturing process meeting or exceeding targets for cost, yield, purity, and impurity profile;
- Development and installation of extraction, isolation and purification processes for natural products from multiple biomass sources; and
- Numerous analytical methods, especially chromatographic, capable of specific determination of components in complex natural product mixtures

7/99-9/00 **Senior Director, Product and Analytical Development.** Formed new department combining internal resources for the development of sterile and oral formulated products with those of central analytical services.

9/98-7/99 **Director New Product Development.** Recruited from former development partner based on leadership of corporate technical interactions

6/95 – 9/98 **Ivax Corporation**, Miami, Florida

9/97-9/98 **Director, Preformulation Development**, 3/97-9/97 **Associate Director, Analytical Research and Development**, 6/95-3/97 **Section Head, Analytical Research and Development**.

Reinforced technical performance of central R&D analytical department. Participated in the Research & Development Committee (CSO's executive control of drug development), and the corporate new technology review committee, evaluating licensing opportunities and joint-venture proposals.

- Raised technical performance of Section and Department through the implementation of rational tools and techniques in analytical method development and optimization.
- Increased the level of collaboration of Section and Department with other development and regulatory units of Company.
- Assertively lead CMC collaboration between Ivax and partners NaPro BioTherapeutics (API supplier) and Faulding (product manufacturing).
- Increased effective utilization of department resources to complete a zero-deficiency Paxene NDA CMC section within project plan despite significant department staff reductions.
- Team developed proprietary solutions for formulation stability problems, and deformed and characterized competitor products

4/94-5/95 **LC Resources Inc**, McMinnville, Oregon. **General Manager Laboratory Services**.

Responsible for P&L of laboratory consulting and services business unit. Implemented GMP/GLP compliance programs for expansion of services beyond original method-development niche.

2/91-4/94 **Sandoz Research Institute**, East Hanover, New Jersey, **Group Leader, Bioanalytics**

Two laboratory units responsible for chromatographic methods applied to drug-safety and pharmacokinetics studies. US and Global Drug Safety representative on US and international product-management teams. Communicated effectively and persuasively with FDA on substantive technical issues. Permanent member of the US Drug Safety Management Committee (VP's senior staff), and permanent DS liaison to Pharma Development VP's staff. Project leader in international projects leading to global data-manipulation and data-management tools, and to harmonized reports.

4/90-2/91 **Fisons Pharmaceuticals**, Rochester, NY **Head, Development Analysis**, Divisional R&D.

Recruited to develop US product-development analytical resources. Left in collapse triggered by UK compliance failures.

2/87-3/90 **Beecham Laboratories**, Bristol, Tennessee, **Manager, Analytical Chemistry**.

Developed department from 7 to 22 professionals as part of expansion of US development resources.

- **Analytical Services** – Product and substance analytical methods and clinical supplies release;
- **Bioanalysis**- Methods for analysis of fluids and tissues for drugs and metabolites; and
- **Pharmacokinetics** – Bioavailability, bioequivalence, dose-proportionality, and drug-drug interaction studies were designed, interpreted and reported.

Projects included Augmentin®, Paxil®, Bactroban®, and Relafen®. The department prepared portions of PK and CMC sections of US and European investigational, new-drug, generic-drug and veterinary product registrations. Guided integrated implementation of new analytical and data-management technologies.

3/83-2/87 **Key Pharmaceuticals**, Miami, Florida, **Manager, Analytical Research and Services.**

Formed Key's first central analytical resource for drug-delivery product R&D. Products included TheoDur and drug-in-adhesive NitroDur.

Analytical methods and services included: *In-vitro* transport experiments; Product stability assessment; Drug release control characterization; Release of clinical-trial supplies; Determination of hazardous waste profiles and Technical services to production.

Served as liaison between R&D and engineering during specification, design and renovation of 70,000 sq.ft. factory - on-time and within budget – into laboratories for R&D use and as facility manager after construction.

7/82-3/83 **Milton Roy Company**, **Manager, Product Development**, Applied Science, State College PA, **Manager, Column Development**, LDC, Riviera Beach FL.

Directed R&D activities leading to new products in gas and liquid chromatography.

3/79-6/81 **Technicon Instruments Corporation**, Tarrytown New York, **Scientist**, Clinical Chemistry.

Member of team assembled by Lloyd Snyder developing methods, instruments and materials for high-throughput therapeutic drug monitoring by HPLC with automated sample pretreatment. Developed data for FDA diagnostic submissions. Served as liaison to engineering and production. Provided technical support to marketing including teaching, direct customer interactions, demonstrations, and troubleshooting.

ACADEMIC APPOINTMENTS

The University of Colorado Health Sciences Center, Denver, Colorado

2003 – 2004 **Advisor**, Technology Transfer Office. Provides technical and industry product development experience to multidisciplinary teams guiding commercialization of intellectual property developed by UCHSC faculty.

2003- 2004 **Collaborating Scientist**, School of Medicine, Department of Clinical Pharmacology.

Supervised postdoctoral research associate in development and validation of chiral bioanalytical methods for parent and metabolites in development of single-enantiomer new-drug analogs.

2000- **Adjoint Faculty Member**, School of Pharmacy, Department of Pharmaceutical Sciences. Lecturer in special topic graduate courses and dissertation committee member.

MEMBERSHIPS

- American Chemical Society
- American Association of Pharmaceutical Scientists,
- Controlled Release Society,
- AOAC International
- American Society for Clinical Pharmacology and Therapeutics

PUBLICATIONS

1. L.A. Sternson, A.W. Sternson and S.J. Bannister, "A Differential Pulse Polarographic Assay for O-Methylation of Catechols by Catechol-O-Methyltransferase, " *Anal. Biochem.*, **75**, 142-152 (1976).
2. L.A. Sternson, F. Hincal and S.J. Bannister, "Gas Chromatographic Analysis of Acetophenone Oxime and its Metabolites," *J. Chromatogr.*, **144**, 191-200 (1977).
3. S.J. Bannister, L.A. Sternson, A.J. Repta and G.W. James, "Measurement of Free-Circulating cis-Dichlorodiammineplatinum(II) in Plasma," *Clin. Chem.*, **23**, 2258-2262 (1977).
4. S.J. Bannister, Y. Chang, L.A. Sternson and A.J. Repta, "Atomic Absorption Spectrophotometry of Free-Circulating Platinum Species in Plasma Derived from cis-Dichlorodiammineplatinum(II) by Atomic Absorption Spectrometry," *Clin. Chem.*, **24**, 877-880 (1978).
5. T.F. Patton, K.S. Himmelstein, R. Belt, S.J. Bannister, L.A. Sternson and A.J. Repta, "Plasma Levels and Urinary Excretion of Filterable Platinum Species Following Bolus Injection and Intravenous Infusion of cis-Dichlorodiammineplatinum(II) in Humans," *Cancer Treatment Rep.*, **62**, 1359 (1978).
6. R.J. Belt, K.J. Himmelstein, T.F. Patton, S.J. Bannister, L.A. Sternson and A.J. Repta, "Pharmacokinetics of Non-Protein Bound Platinum Species Following Administration of cis-Dichlorodiammineplatinum(II)," *Cancer Treatment Rep.*, **63**, 1515-1521 (1979).
7. S.J. Bannister, L.A. Sternson and A.J. Repta, "Urine Analysis of Platinum Species Derived from cis-Dichlorodiammineplatinum(II) by High-Performance Liquid Chromatography following Derivatization with Sodium Diethyldithiocarbamate," *J. Chromatogr.*, **173**, 333-342 (1979).
8. S.J. Bannister, J.G. Stevens, D. Musson and L.A. Sternson, "High-Performance Liquid Chromatographic Analysis of Emetine After Oxidative Activation to a Fluorescent Product," *J. Chromatogr.*, **176**, 381-390 (1979).
9. J.W. Dolan, S.J. van der Wal, S.J. Bannister and L.R. Snyder, "On-Line Liquid-Chromatographic Analysis for Drugs in Serum with the Technicon 'FAST-LC' System: Performance Data for Theophylline and for Four Commonly Used Anticonvulsants and their Metabolites," *Clin. Chem.*, **26**, 871-880 (1980).
10. S.J. Bannister, S.J. van der Wal, J.W. Dolan and L.R. Snyder, "Liquid-Chromatographic Analysis for Common Tricyclic Antidepressant Drugs and Their Metabolites in Serum or Plasma with the Technicon 'FAST-LC' System," *Clin. Chem.*, **27**, 849-855 (1981).
11. S.J. van der Wal, S.J. Bannister, and L.R. Snyder, "Automated Analysis of Acetaminophen and Caffeine in Serum, Using the Technicon 'FAST-LC' System. Contributions to Assay Imprecision in Procedures Based on High Performance Liquid Chromatography with Sample Pretreatment," *J. Chromatogr. Sci.*, **20**, 260-265 (1983).
12. S.J. Bannister, L.A. Sternson and A.J. Repta, "Evaluation of Reductive Amperometric Detection in the Liquid-Chromatographic Determination of Antineoplastic Platinum Complexes," *J. Chromatogr.*, **273**, 301-318 (1983).
13. C.M. Riley, L.A. Sternson, A.J. Repta and S.J. Bannister, "Intact Cisplatin in Urine Following Intravenous Administration," *J. Pharm. Pharmacol.*, **34**, 826 (1983).
14. L.A. Sternson, K.C. Marsh, S.J. Bannister and A.J. Repta, "Detection Systems for Assay of Antineoplastic Platinum Complexes," *Anal. Proc. (London)*, **20**, 366-368 (1983).
15. S.J. Bannister, V.P. Houser, J.D. Hulse, J.C. Kisicki and J.G.C. Rasmussen, "Evaluation of the Potential for Interactions of Paroxetine with Diazepam, Cimetidine, Warfarin and Digoxin," *Acta Psychiatr. Scand.*, **Suppl.**, **350**, 102-106 (1989).

16. N.K. Jagota, S.J. Bannister, R.B. Poser, and J.T. Stewart, "HPLC Determination of Utibapril and its Diacid FPL 63674XX in Rodent Laboratory Diet Using Selective Extraction and Gradient Elution Chromatography," *J. Liq. Chromatogr.*, **14**, 2979-2991 (1991).
17. M.S. Alexander, M.M. Kiser, T. Culley, J.R. Kern, J.W. Dolan, J.D. McChesney, J. Zygmunt, S.J. Bannister, Measurement of Paclitaxel in Biological Matrices: High-Throughput Liquid Chromatographic-Tandem Mass Spectrometric Quantitation of Paclitaxel and Metabolites in Human and Dog Plasma, *J. Chromatogr. B*, **785**, 253-161 (2003).

PRESENTED PAPERS AND PUBLISHED ABSTRACTS

1. S.J. Bannister, L.A. Sternson, A.J. Repta, and Y. Chang, "Clinical Analysis of cis-Dichlorodiammineplatinum(II) (CDDP)," Academy of Pharmaceutical Sciences, Hollywood, FL. November 1978. Abstract P-31.
2. S.J. Bannister, S.J. van der Wal, J.W. Dolan and L.R. Snyder, "Critical Factors in the Precision of High-Performance Liquid Chromatography with Sample Pretreatment: Application in the Determination of Tricyclic Antidepressants in Serum using the Technicon 'FAST-LC' System," American Association for Clinical Chemistry, Boston, MA. July 1980. Abstract 245.
3. J.W. Dolan, S.J. van der Wal, S.J. Bannister and L.R. Snyder, "Determination of Several Cardiac Drugs by High-Performance Liquid Chromatography with the Technicon 'FAST-LC' System," American Association for Clinical Chemistry, Boston, MA. July 1980. Abstract 246.
4. S.J. van der Wal, S.J. Bannister, J.W. Dolan and L.R. Snyder, "Co-determination of Several Cardiac Drugs by High-Performance Liquid Chromatography on the Technicon 'FAST-LC' System," American Association for Clinical Chemistry, Boston, MA. July 1980. Abstract 247.
5. S.J. Bannister, L.A. Sternson and A.J. Repta, "Evaluation of Polarographic Detection in the Liquid Chromatographic Determination of Antineoplastic Platinum Complexes," Royal Chemical Society Autumn Meeting. "Spectrochemical Detectors in Chromatography," Edinburgh, Scotland. September 1982.
6. S.K. Govil, S. Farrell, C. Goetz, S.J. Bannister and C.H. Hsiao, "Effect of Receiver Composition on the Permeation of 17 Beta-Estradiol Through Hairless Mouse Skin," Academy of Pharmaceutical Sciences. Minneapolis, MN. November 1985.
7. S.J. Bannister, J.C. Kisicki, J.D. Hulse, V.P. Houser, "Pharmacokinetics of Paroxetine with Co-administered Diazepam," Paroxetine Symposium. Rome, Italy. October 1988.
8. S.J. Bannister, J.C. Kisicki, J.D. Hulse, V.P. Houser, "Effects of Cimetidine on the Steady State Pharmacokinetics of Paroxetine," Paroxetine Symposium. Rome, Italy. October 1988.
9. S.J. Bannister, J.C. Kisicki, J.D. Hulse, V.P. Houser, "Pharmacokinetics of Co-administered Paroxetine and Digoxin," Paroxetine Symposium. Rome, Italy. October 1988.
10. S.J. Bannister, J.C. Kisicki, J.D. Hulse, V.P. Houser, "Pharmacokinetics of Co-administered Paroxetine and Warfarin," Paroxetine Symposium. Rome, Italy. October 1988.
11. J.C. Hensley, M.K. Michaels, P.M. John and S.J. Bannister, "Determination of Taurine in Animal Nutrient Supplements," Pittsburgh Conference and Exposition on Analytical Chemistry and Applied Spectroscopy, Atlanta, GA. March 1989.
12. J. Gal, S. Dilmaghanian, L. Gera, and S. J. Bannister, "HPLC- And Fluorescence-Based Enantioselective Determination Of Ketoconazole (K) In Human Blood Plasma For Pharmacokinetic Studies," Chirality 2004 [International Symposium on Chiral Discrimination (ISCD16), New York, July 11-14th, 2004), oral presentation.

13. C. Pyrgaki, J. Gal, S. Bannister, J.G. Gerber, "Stereoselective Pharmacokinetics (Pk) Of Oral Itraconazole (ITZ) In Healthy Subjects" 44th Annual Interscience Conference on Antimicrobial Agents and Chemotherapy, American Society for Microbiology, Washington DC, October 30 – November 2, 2004, Poster A36.
14. S. Bannister, M. Talbott, F. Hanciles, R. Henry, "Rapid, Sensitive, General-Purpose Cleaning-Verification HPLC Methods Using Fused-Core™ Particle (FCP) Columns on Conventional Instrumentation," American Association of Pharmaceutical Scientists, San Diego, CA, November 2007.
15. J. Masselink, R. Ramineni, S. Bannister, T. Koontz, "Effect of Powder Characteristics and Operating Conditions on Filling 1mg Weights Using an Xcelodose™ 600 Micro-Dosing System," American Association of Pharmaceutical Scientists, San Diego, CA, November 2007.

CONFERENCE PRESENTATIONS

1. Steve J Bannister, PhD, "Accelerated First-in-Human Studies with Powder-in-Capsule Trial Supplies," 6th Contract Manufacturing for Pharmaceuticals - Utilizing Local and International Outsourcing to Gain and Sustain a Competitive Advantage, International Quality and Productivity Center, San Francisco, CA, June 25, 2007.
2. Steve J Bannister, PhD, "Accelerated Flexible-Dose Trial Supplies for Early-Stage Clinical Studies," Pharmaceutical & Biotech Outsourcing – Discovery to IND, International Institute for Business Information and Growth, LLC, Atlantic City, NJ, July 11, 2007.
3. Panel: James Prescott, PhD, Ravi Kiron PhD MBA, William J Lambert, PhD, Michael H Arenberg, Aaron F Barkoff, PhD JD, Moderator: Steve J Bannister, PhD, "Innovation & Success Strategies: Learning & Unlearning from Key Players," New Directions for Drug Delivery, International Institute for Business Information and Growth, LLC, Las Vegas, NV, October 29, 2007.
4. Panel: James Prescott, PhD, Ravi Kiron PhD MBA, Mark A Tracy, PhD, Patrick G Gattari, K. George Mooney, PhD, Moderator: Steve J Bannister, PhD, "The Business of Outsourcing: Strategic Innovation in Biopharma Partnerships," 2008 BioPharma Outsourcing – Partnerships with CRO's and Service Providers, International Institute for Business Information and Growth, LLC, Boston, MA, March 25, 2008.
5. Steve J Bannister, PhD, "Quality By Design: It's Within Reach Examples From Early Development," 4th Modern Drug Discovery & Development Summit, GTC Bio/Global Technology Community, LLC, La Jolla, CA, October 15, 2008.
6. W. Carl Lietz, Esq., and Steve J Bannister, PhD, "Understanding and Challenging Forensic Evidence in Federal Court," 4th Annual Saint Crispin's Day Continuing Legal Education Seminar, The Atlanta Federal Defender Program, Inc., Atlanta, GA, October 22, 2008
7. Panel: Alex Avdeef, PhD, Wendi Rodriguez, PhD, Grace Poon, PhD, Moderator: Steve J Bannister, PhD; "Discovery to Formulation," Partnering Workshop: Meeting R & D Challenges Through Strategic Alliances," Apelles Partners and Bentley University, Waltham, MA, March 31, 2009.
8. W. Carl Lietz, Esq and Steve J Bannister, PhD, "Understanding and Challenging Forensic Evidence in Federal Court," Northern District of Alabama's CJA Panel Attorney Training Program, Office of Defender Services Training Branch, Administrative Office of the United States Courts, Birmingham, AL, Scheduled April 24, 2009.