# Steve J. Bannister, Ph.D.

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Experienced pharmaceutical-development scientist, leader, teacher and entrepreneur with more than 30 years of experience applying the fundamentals of physical and analytical chemistry to the design, development, and analysis of drugs, drug delivery systems, and medical devices. Proven ability to solve problems of solubility, stability, release, bioavailability, and biocompatibility based on a thorough understanding of physical and biological phenomena.

**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 of products administered as therapeutic systems; dissertation research focused on the bioanalysis and pharmacokinetics of platinum 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

## EXPERIENCE

03/14 – **Cloaked Therapeutics, LLC**, Oxford, Mississippi, **Cofounder and member of the board of managers**
One of six founding members of firm formed to be the exclusive world-wide licensee of Arbor's TumorSelect® technology applied to certain existing anticancer drugs. Currently raising funds to support development activities necessary for regulatory approval to begin clinical trials.

05/12 - **Arbor Therapeutics, LLC**, Oxford, Mississippi, **Cofounder and member of the board of managers**
Firm formed for the discovery and development of animal proof-of-concept data for TumorSelect® intravenous drug delivery technology which combines actively targeted nanoparticles and optimized oncolytic prodrugs to achieve intracellular delivery to tumors while sparing healthy tissues. General management responsibilities are shared with four other founding members. Specific technical responsibilities include the design and optimization of the nanoparticle formulation and manufacturing processes.

11/08 – **Hightower Pharmaceutical Services**, Tampa, Florida, **Owner and Principal Consultant**
Continuation of technical product-development consulting practice.

- Assists executives with technical due diligence, program and project technical review, guidance, and regulatory submission, including as examples:
    - Technical due diligence team member for one of the parties to the proposed merger of two small natural-products drug-discovery firms. Evaluated R&D productivity record and possible benefits of asset combination.
    - Review of program targeted to develop nanoemulsion consumer product using a complex mixture of very poorly soluble natural products. Work product included a detailed analysis of significant unmet challenges, a conclusion of infeasibility within resource constraints, and a recommendation against the undertaking.
    - Review of existing drug-substance manufacturing, formulation-screening, and bioavailability data for a very lipophilic small molecule development candidate and assessment of regulatory gaps; direction of the necessary analytical work and of the creation of the CMC component of the pre-IND meeting briefing package.
- Assists technical management with analytical and delivery-system technology selection and development including as examples:

    - Review and presentation of technology options for an intravenous formulation of a drug with an aqueous solubility of less than one nanogram per milliliter. Recommended nanoparticle technology using phospholipid surfactants and Microfluidizer processing. Successfully demonstrated feasibility, optimized the formulation, and scaled the process to support IND-enabling preclinical studies.
    - Pre-IND drug-discovery client needed a high-bioavailability formulation of a BCS Class II compound to insure adequate animal exposure in safety studies. Recommended the use of a surfactant-free lipid formulation. Toxicology and toxicokinetics studies ongoing.
- Assists scientists with experimental design and execution, data interpretation, and problem-solving;
    - Medical-device client, in execution of ISO 10993 biocompatibility testing on a polymer implanted device, received mass spectrometry data from contract laboratory originally interpreted as suggesting the surprising presence of extractable compounds completely unrelated to the polymer or to the polymer additives. Examined the MS data in the context of known additives and concluded that an ionization artifact combined with blind library-matching algorithms had led to conclusions of nonsensical compounds. Re-interpretation of data was consistent with presence of unsurprising polymer-additive degradation products.
    - Generic developer of a peanut oil topical solution received an ANDA deficiency letter from FDA noting the inadequate performance of a quantitative peanut-antigen limit test. Directed the development and successful validation of a method based on the combination of antigen hydrolysis, fluorescent amino-acid derivatization, and reverse-phase HPLC.
- Assists litigators as a consulting and testifying expert in civil and criminal litigation by teaching fundamental concepts to attorneys, analyzing technical issues and explaining opinions in court.
    - Evaluation of the likelihood of successful development of a particular coated-pellet controlled-release formulation and process and the expression of opinions in testimony
    - Pharmaceutical-chemistry testifying expert retained by the patent holder in a series of patent-infringement lawsuits in which the issues were related to fundamental physical phenomena

4/04 – 11/08 **Xcelience®, LLC,** (was MDS Pharma Services 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 extending capabilities by assisting in product concepts, development planning and project management
    - Consulting for large clients extending capacity by providing project-specific technical support including existing-technology review and project and document review
    - Projects included: 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 including new-technology scouting and evaluation, participation in project teams and problem-solving consultation
- Activities in support of broader laboratory service business development include joining territorial BD staff as a consulting expert in client meetings and development of work scopes for broad projects combining multiple capabilities

**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 problem-solving performance and effective 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**.

- Lead multidiscipline analytical unit
- Developed methods to characterize new-drug and generic immediate and extended-release oral solid dosage forms and used data in collaborative product optimization.
- Reinforced technical performance of central R&D analytical department. Member of 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 manufacturer).
- Increased effective utilization of department resources to complete a zero-deficiency Paxene (paclitaxel) NDA CMC section within project plan despite significant department staff reductions.
- Team developed proprietary solutions for formulation stability problems, and deformulated and characterized competitor products

4/94-5/95 **LC Resources Inc**, McMinnville, Oregon. **General Manager Laboratory Services**.
Responsible for P&L of pharmacokinetic 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 corporate collapse triggered by UK manufacturing 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 Theo-Dur, an extended release oral solid delivering theophylline, K-Dur, an extended-release oral solid delivering potassium chloride, and the drug-in-adhesive Nitro-Dur nitroglycerin transdermal.
Analytical methods development and services applied to:

- Drug substance and drug product testing;
- Drug release control characterization and release-mechanism elaboration;
- Collaborative optimization of formulation and process to achieve in-vitro and in-vivo release targets;
- *In-vitro* transport experiments;
- Product stability assessment;.

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 South Florida**, Tampa, Florida
2013 – **Mentor** to start-ups housed in the Tampa Bay Technology Incubator

**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 – 2004 **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
- International Society for Biomedical Polymers and Polymeric Biomaterials

**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. *Analytical Biochemistry* **75**: 142-152 (1976).
2. L. A. Sternson, F. Hincal, and S. J. Bannister. Gas chromatographic analysis of acetophenone oxime and its metabolites. *Journal of Chromatography A* **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. *Clinical Chemistry* **23**: 2258 (1977).
4. T. F. Patton, K. J. 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 iv infusion of cis-dichlorodiammineplatinum (II) in man. *Cancer Treatment Reports* **62**: 1359 (1978).
5. 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). *Clinical Chemistry* **24**: 877 (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 Reports* **63**: 1515 (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. *Journal of Chromatography A* **173**: 333-342 (1979).
8. S. J. Bannister, J. Stevens, D. Musson, and L. A. Sternson. High-performance liquid chromatographic analysis of emetine after oxidative activation to a fluorescent product. *Journal of Chromatography A* **176**: 381-390 (1979).
9. J. W. Dolan, S. 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. *Clinical Chemistry* **26**: 871 (1980).
10. S. J. Bannister, S. 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. *Clinical Chemistry* **27**: 849 (1981).
11. C. M. Riley, L. A. Sternson, A. J. Repta, and S. J. Bannister. Intact cisplatin in urine following intravenous infusion. *Journal of Pharmacy and Pharmacology* **34**: 826-826 (1982).
12. S. J. Van der Wal, S. J. Bannister, and L. R. Snyder. Automated Analysis of Acetaminophen and Caffeine in Serum Using the FAST-LC System: Contributions to Assay Imprecision in Procedures Based on HPLC with Sample Pretreatment. *Journal of Chromatographic Science* **20**: 260-265 (1982).
13. S. J. Bannister, L. A. Sternson, and A. J. Repta. Evaluation of reductive amperometric detection in the liquid chromatographic determination of antineoplastic platinum complexes. *Journal of Chromatography B: Biomedical Sciences and Applications* **273**: 301-318 (1983).
14. L. A. Sternson, K. C. Marsh, S. J. Bannister, and A. J. Repta. Detection systems for assay of antineoplastic platinum complexes. *Analytical Proceedings* **20**: 366-368 (1983).
15. S. J. Bannister, V. P. Houser, J. D. Hulse, J. C. Kisicki, and J. Rasmussen. Evaluation of the potential for interactions of paroxetine with diazepam, cimetidine, warfarin, and digoxin. *Acta Psychiatrica Scandinavica* **80**: 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. *Journal of Liquid Chromatography* **14**: 2979-2991 (1991).
17. M. S. Alexander, M. M. Kiser, T. Culley, J. R. Kern, J. W. Dolan, J. D. McChesney, J. Zygmunt, and S. J. Bannister. Measurement of paclitaxel in biological matrices: high-throughput liquid

chromatographic-tandem mass spectrometric quantification of paclitaxel and metabolites in human and dog plasma. *Journal of Chromatography B* **785**: 253-261 (2003).

18. C. Pyrgaki, S. J. Bannister, L. Gera, J. G. Gerber, and J. Gal. Stereoselective determination of the epimer mixtures of itraconazole in human blood plasma using HPLC and fluorescence detection. *Chirality* **23**: 495-503 (2011).

**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, Sj. 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, Sj. 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, "Codetermination of ethosuximide and valproate 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. Gal, Joseph; Pyrgaki, Christina; Bannister, Steve J; Gera, Lajos; Gerber, John G. Stereoselective Determination Of The Antifungal Agent Itraconazole In Human Blood Plasma Using Hplc With Two Chiral Stationary Phases And Fluorescence Detection. Ninth International Congress of Therapeutic

Drug Monitoring and Clinical Toxicology. Louisville, Kentucky April 23-28, 2005. Proceedings: *Therapeutic Drug Monitoring* **27**: 219 (2005).

15. 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.
16. 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.
17. J. Gal, C. Pyrgaki, L. Gera, S. Bannister, J. Gerber, "Stereoselective Determination of Itraconazole in Human Blood Plasma Using HPLC and Fluorescent Detection," American Chemical Society Northwest Regional Meeting, Portland, OR, June 2011.

## 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 Rodrigueza, 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.

## PATENT

1. McChesney JD, Nikoulin I, Bannister SJ, Rodenburg DL, Inventors; Arbor Therapeutics, LLC, assignee. Nanoparticulate Compositions for Targeted Delivery of Acid Labile, Lipophilic Prodrugs of Cancer Chemotherapeutics and Their Preparation. United States patent US 9,468,603. 2016 2016/10/18