BRADLEY A. CLARK, R.PH., PH.D.

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SUMMARY

An industrial pharmacy veteran recently taking the opportunity to move into an academic role. Over 29 years of postgraduate experience in pharmaceutical and analytical sciences, clinical supply and commercial manufacture, and pharmaceutical production technical support. Extensive experience in the practice of pharmaceutical sciences in preformulation, formulation and process development, analytical and bioanalytical development and technical problem solving. Experienced in building and managing scientific organizations of BS, MS, and PhD-level scientists and engineers, as well as leading multi-disciplinary teams in activities supporting Chemistry, Manufacturing, and Control sections of regulatory dossiers. Presented numerous invited lectures on various pharmaceutical science topics both domestically and internationally.

EDUCATION

Ph.D., Pharmaceutics, University of Georgia College of Pharmacy, 1987.

B.S. Pharmacy, University of Georgia College of Pharmacy, 1982 - Georgia Board of Pharmacy Licensure 1982.

TEACHING AND ACADEMIC EXPERIENCE

HIGH POINT UNIVERSITY, High Point, NC **2015-present**

High Point University is creating a new School of Pharmacy with the first class of students to matriculate into the PharmDprogram Fall 2016. A new pharmacy building is under construction and is expected to come on line in Spring 2017.

Associate Professor, Basic Pharmaceutical Sciences

Faculty member of newly created Fred Wilson School of Pharmacy with teaching emphasis on pharmaceutics and pharmaceutical sciences. Research focus in Drug Delivery Systems and Dosage Form Design. Committee assignments include School of Pharmacy Assessment and Outcomes, Admissions, Academic and Professional Conduct, Faculty Search Committee (chair) and Executive Committees, and University-wide Information Technology Advisory Committee.

Additional academic activities

- PhD committee member, Dr. Mychael Scoggins, Mercer University Department of Pharmaceutics, 2004-2009.
- Invited Lecturer, Mercer University Department of Pharmaceuticals graduate pharmaceutics course, 2007.
- Center for Professional Advancement, course faculty member, "Pharmaceutical Process Development", New Brunswick, NJ, 1995-2008, Chicago, IL, 2002, Winnipeg, Manitoba, 1998, Amsterdam, The Netherlands, 2007.

- Invited Lecturer, University of Wisconsin Extension Service course entitled "Fundamentals and Advanced Concepts in Tableting", 1999-2000.
- Division of Pharmaceutical Sciences, School of Pharmacy, University of Missouri – Kansas City, Adjunct Assistant Professor, 1989.

INDUSTRIAL EXPERIENCE

NPS PHARMACEUTICALS, Bedminster, NJ **2013-2015**

NPS Pharmaceuticals is a global biopharmaceutical company of approximately 350 people focusing on products for rare diseases, with a recently approved global product for the indication of treatment of patients with short bowel syndrome, a product pending approval to treat adult hypoparathyroidism, and and early stage compound with potential application in rare calcium receptor disorders.

Senior Director, Pharmaceutical Development & Clinical Supplies Management

Provide pharmaceutical development leadership for Chemistry, Manufacturing, and Controls (CMC) activities of clinical candidates from preclinical to commercialization, including CMC team leadership & core team membership, contract development, manufacturing and packaging coordination. Also manage the clinical supply process including interfacing and coordinating with clinical research, manufacturing, and contract manufacturers / packagers / labelers / logistics organizations to ensure NPS clinical studies are optimally supplied with Investigational Product.

- **Led CMC team** in virtual preparation of drug substance and IV drug product for the company's first-in-human trials of a small molecule NCE, including GMP synthesis of the drug, GMP manufacture of the drug product, clinical packaging and labeling, and preparation of the CMC section of the IND to enable clinical studies
- **Head of Clinical Supplies Management function** overseeing preparation, labeling, packaging, and shipment of investigational products for multiple studies in North America, Europe, and Japan
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TRANSTECH PHARMA, High Point, NC **2011-2013**

TransTech Pharma is a privately held clinical-stage development pharmaceutical company of approximately 100 people focused on the discovery and early development of human therapeutics in the areas of central nervous system disorders, cardiovascular disorders, diabetes, obesity, and cancer.

Vice President, Pharmaceutical Development
Head of pharmaceutical development unit, including first-in-human and early clinical product formulation development, GMP analytical development, clinical supply manufacture, packaging and logistics, successfully supporting 8 preclinical and clinical programs.

- **Led and trained scientists** in all aspects of pharmaceutical sciences including preformulation, solid state characterization, early formulation, analytical development, drug

substance sourcing, drug product clinical supply production and packaging, and GMP sourcing and contracting.
- Responsible for **development of formulation and analytical methodology** to be transferred to contract API and drug product manufacturers.
- Oversight of **regulatory CMC dossier preparation** and **Good Manufacturing Practices quality assurance,** including support of three initial IND filings and two Phase 2 IND amendments.
- Strong working relationship with **chemistry, toxicology, and clinical** groups in order to rapidly move New Chemical Entities into clinical development to proof-of-concept Phase 2 studies.

ABBOTT PRODUCTS / SOLVAY PHARMACEUTICALS, Marietta, GA **2003-2011**

Head, Drug Delivery Systems Development, Pharm Tech Platform, Product Development & Support (2009-2011)

Led a multidisciplinary group of pharmaceutical and analytical scientists in the feasibility and proof of concept assessment of drug delivery technologies applied to existing molecules and clinical candidates; served as site head of the global Product Development and Support organization in the US, including operational, budget, and administrative oversight.

- **Trained and mentored scientists** in all aspects of pharmaceutical sciences including preformulation, solid state characterization, early formulation, full development, analytical development, tech transfer into production, and pharmaceutical manufacturing support.
- Transition team responsible for **design of new Technology Platform** of PDS organization from former CPD and TPS organizations, resulting in successful implementation of new 160 person global organization in under 5 months.
- **Lead pharmaceutical scientist** and resource manager supporting CMC team for novel gel based drug delivery system: achieved a four-fold reduction in degradation and improvement in stability by simultaneously implementing multiple formulation strategies.
- Primary **pharmaceutical science support** on multiple CMC teams: approval of NDA of an in-licensed gastric retentive tablet product with no CMC deficiencies.
- Due to Abbott site closure, **led shutdown of technical building** in Marietta including staging, packing, and shipping of essentially all analytical and pharmaceutical instrumentation and equipment, cleaning and decommissioning of facilities, and closure of building controlled substance registration in 4 months.

Director – Pharmaceutical Development, Chemical & Pharmaceutical Development – US (2003-2009)

Head of the Pharmaceutical Development function within Global Chem & Pharm Development at the Solvay Pharma US site, including pharmaceutics development, clinical supply logistics, packaging engineering, and production technical support functions.

- Led PhD, MS, and BS level scientists in both US and Germany in **developing drug product technology** for clinical and commercial supplies, successfully supporting 7 development programs including one approved NDA for a transdermal product.
- **CMC Leader** representing Chem and Pharm Development on two corporate development teams based in both the US and Europe (Netherlands and Germany): successfully filed new low dose hormone product e-CTD to MHRA.
- Chaired the Solvay Pharma PAT Expert Working Group across US and Europe and led an international task force resulting in adoption of a position paper on the integration of **Quality by Design, PAT, and Design to Cost** concepts into development of all new Solvay Pharma products.
- Part of a 5-person team charged with designing and implementing a site wide **innovation process**: resulted in successful roll-out of "I-Site" computer-based system and installation of corresponding governance structure.

SEARLE / PHARMACIA, Skokie, IL **1998-2003**

Director – Project Management, Global Pharmaceutical Sciences (2002-2003)
Director – Solids Formulation Development and Clinical Supply Manufacture, Global Pharmaceutical Sciences (2001-2002)
Section Head – Solid Dosage Formulation and Process Development (2000-2001)
Group Leader – Solid Dosage Formulation and Process Development (1998-2000)

THE R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE / JOHNSON & JOHNSON, Spring House, PA / Raritan, NJ **1993-1998**

Research Manager – Technology Transfer Group, Product Development/Technical Service Department (1998)
Interim Manager – Production Technical Services, Ortho-McNeil Pharmaceuticals, Manati/Dorado PR (1996)
Group Leader – Solid Dosage Forms, Product Development/Technical Service Department (1995-1998)
Principal Scientist – Solids Dosage Forms, Process Development/Technical Service Department (1993-1995)

SOLVAY PHARMACEUTICALS, Marietta, GA **1989-1993**

Senior Research Scientist, Pharmaceutical Development Department

MARION MERRELL DOW, Kansas City, MO **1986-1989**

Senior Pharmaceutical Investigator / Scientist, Technical Development Department

APPOINTMENTS, COMMITTEES, AND MEMBERSHIPS

- Member, Editorial Board, Journal of Analytical and Pharmaceutical Research.

- American Association of Pharmaceutical Scientists, Pharmaceutical Technologies Section
  - Section Chairman 2007/Chair-Elect 2006/Vice Chair 2005, Membership Committee Chairman, Poster Screening Committee Chairman – 2001, 2002, and 2003 National Meetings, Committee on Graduate Education, '93
  - Microwave Focus Group – '94, Program Committee for 2000 meeting – '99,
  - Arden House Conference Faculty (1995) and Committee (1995, 2000)
  - Philadelphia Pharmaceutical Forum ('94, '95, '96, '97 Program Committees
- Member, Editorial Advisory Board, *The Encyclopedia of Pharmaceutical Technology*.
- Advisory Board, Mercer University Center for Drug Delivery.

AWARDS AND RECOGNITION

- Phi Eta Sigma Honor Society
- Rho Chi Pharmaceutical Honor Society
- Recipient of J&J Achievement Awards for approval and launch of Perindopril (ACEON™) NDA ('94), Tramadol (ULTRAM™) NDA ('95), and Topiramate (TOPAMAX™) IRD ('95)
- Solvay Pharmaceuticals – US: QUEST I & II Leadership Development Programs ('07, '09)

PATENTS

A. Mjalli, B. Clark, D. Polisetti, Jr., J. Quada, C. Valcarce Lopez, R. Andrews, S. Davis, T. Yokum, US Patent Application Publication US 2015/0313908 A1, "Combinations of a GLP1R Agonist and Metformin and Use Thereof for the Treatment of Type 2 Diabetes and Other Disorders, " published Nov 2015.

M. Gibler, M. Bennet, K. Waeber, K. Hogue, C. Gillum, P. Harrell, D. Parrott, S. Mackey, R. Conjeevaram, T. Rebne, B. Clark, J. Hemingway, J. Zhou, B. Weisner, US Patent Application PublicationUS 20130102994 A1, "Sealing arrangement for syringe," published Apr 2013.

B. Clark, U. Shah, D. Dubash, P. Curry, and M. Scoggins, US Patent Application 12/245,399 / International Patent Application PCT/US2008/078765, "Pharmaceutical Compositions Comprising Esterified Estrogens and Methyltestosterone and Method of Using Same," published Apr 2009 (WO/2009/046310).

T. Schultz, B. Clark, and A. Falzone, Patents EP 1 361 881 B1 (granted Oct 2005) and US 7,867,990 B2 (granted Jan 2011), "Steroid Hormone Products and Methods for Preparing Them".

PUBLICATIONS

"Drying and Driers", A.J. Hlinak and B. A. Clark, in *The Encyclopedia of Pharmaceutical Technology*, 2nd edition, Marcel-Dekker, 1018-1032, 2002.

"In-Vitro / In-Vivo Evaluation of a Liquid Sustained Release Dosage Chlorpheniramine", O.L. Sprockel, J.C. Price, R.N. Jennings, R.L. Tackett, S. Hemingway, B. A. Clark and R.E. Laskey. Drug Development and Industrial Pharmacy, 15(9), 1393-1404, 1989.

"Stability Indicating HPLC Analysis of Dibromodulcitol in Aqueous Solutions", B. A. Clark, D.E. Caldwallader, and M.J. Salamone, Analytical Letters, 21 (3), 411-422, 1988.

"Size Exclusion Chromatographic Determination of PEG 3350 in Human Plasma and Urine", B.A. Clark, J.T. DiPiro and D.E. Cadwallader, Analytical Letters, 20(2), 293-301, 1987.

"Absorption of Polyethylene Glycol after Administration of a PEG – Electrolyte Solution", J.T. DiPiro, K.A. Michael, B.A. Clark, P. Dickson, J.J. Vallner, T.A. Bowden Jr., and F.J. Tedesco. Clinical Pharmacy, 5, 153-155, 1986.

ABSTRACTS AND PRESENTATIONS

"Intraduodenal Drug Delivery Optimizes Disease Specific Therapy", Invited lecture presented at the 3rd Annual Drug Repositioning and Pipeline Enhancement Conference, Philadelphia, PA, September 2010.

"Fluid Bed Granulation: Identifying Critical Process Parameters and Developing Design Space", S. Sathigari, S. Wilson, M. Scoggins, H. Vera, A. Melendez, B. Clark, and U. Shah; Poster presented at AAPS, Los Angeles, CA November 2009.

"Dynamic Vapor Sorption as a PAT Tool to Assess Tablet Coating", J. Vieta, A.R. Garcia, D. Burnett, D. Dubash, E. Heintz, B. Clark, and U. Shah; Poster presented at AAPS, Los Angeles, CA November 2009.

"A Novel Approach to Addressing Segregation Challenges in Directly Compressible (DC) Formulations", M. Scoggins, D. Dubash, J. Vieta, B. Clark, and U. Shah; Poster Presented at AAPS, Atlanta, GA, November 2008.

"Effects of Process Variables on Film Quality Using Opadry® fx™ Film Coating System", J. Vieta, A. Melendez, M. Scoggins, G. Kristen, D. Dubash, B. Clark, and U. Shah; Poster presented at AAPS, Atlanta, GA, November 2008.

"Application of Tangential and Vertical Velocities As Scale-Up Parameters For Directly Compressible Tablets – Two Case Studies," R. Conjeevaram, A. Melendez, R. Malladi, B. Clark, U. Shah; Poster presented at AAPS, Atlanta, GA, November 2008

"Science and Engineering Principles Applied to Pharmaceutical Technology for Solid Formulations," Organizer / Moderator, AAPS Short Course, AAPS Annual Meeting, San Diego, CA, November 2007.

"Opportunities in the Pharmaceutical Industry for Pharmaceutical and Biomedical Sciences Students", B. A. Clark, Invited lecture presented as part of the AAPS Visiting Scientist seminar program, University of Georgia College of Pharmacy, September 2004.

"Training in Pharmaceutical Sciences: An Industrial Pharmacist's Perspective", B. A. Clark, Invited lecture presented at GRASP 2004, Mercer University, Atlanta, GA, June 2004.

"Keys to Ensure Success in International Technology Transfer," A. Cavallo, M. Adami, B. Clark, et al, 4th World Meeting ADRITELF/APV/APGI, Florence, Italy, April 2002.

"Formulation Development: Scale-up Considerations", B. A. Clark, Invited lecture presented at AAPS Eastern Regional Meeting Formulation Feasibility Short course, New Brunswick, NJ, June 1997.

"Mixing and Blending", B. A. Clark, Invited lecture presented at the University of Wisconsin Extension Service course entitled "Fundamentals and Advanced Concepts in Tableting", Las Vegas, NV, 1999 and 2000.

"Powder Blend Sampling in Blend Uniformity Testing"' B. A. Clark, Invited lecture presented to R.W. Johnson Pharmaceutical Research Institute Product Development/ Technical Service "Science Day", Lambertville, NJ, April 1997.

"Scale-Up / Technology Transfer of Particle Coating Processes," B. A. Clark, Invited lecture presented at 30th Arden House Conference, Harriman, NY, February 1995.

"Cubic Spline Interpolation in Particle Size Analysis", B. A. Clark and A. G. K. Sobe, Poster presented at 7th Annual AAPS Meeting, San Antonio, TX, November 1992.

"The Clinical Supply Manufacturing Process", B. A. Clark, Invited lecture presented to R&D Division Therapeutic Area Teams, Solvay Pharmaceuticals, July 1991.

"Calorimetric and Conductimetric Determination of Collapse Temperatures of Collagen Co-Precipitates and Application to Lyophilization Development", B. A. Clark and A. Yaman, Poster Presented at 4th Annual AAPS Meeting, Atlanta, GA, October, 1989.

"Scale-Up Aspects of Integra®", B. A. Clark, Invited lecture presented to Development Division, Marion Laboratories, January 1989.

"Base Catalyzed Degradation of Dibromodulcitol in Aqueous Solutions",
B. A. Clark and D.E. Cadwallader, Poster Presented at the First National AAPS Meeting, Washington, DC, November 1986.