Edwin G. Moore, Ph.D.

Curriculum Vitae

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Career Objectives: Research and development activities of biopharmaceutical and pharmaceutical technologies for new product development and life cycle management.

Professional Experience:

1/14 – present	Principal Consultant, BioPhia Consulting
8/13 – present	Visiting Scientist, University of Illinois, Chemistry Department
8/94 – 7/13	Baxter Healthcare Corp.,
2011 – 2013	Sr. Director, R&D, Technology Resources, Medical Products
2005 – 2011	Sr. Director, R&D, Pharmaceutical R&D, Medication Delivery
2002 – 2004	Sr. Director, Research and Development, Renal Pharmaceuticals
1998 – 2002	Director, Chemical Sciences, Hemoglobin Therapeutics
1997 - 1998	Director, Analytical Research and Testing, Blood Substitutes Div.
1994 - 1997	Manager, Analytical Research and Testing, Blood Substitutes Div.
10/78 - 8/94	Abbott Laboratories, Abbott Diagnostics Division, Abbott Park, IL
1993 - 1994	Project Manager for Extramural Research Activities (Diagnostics Division R&D)
1990 - 1993	R&D Manager (Diagnostics Division R&D).
1989 - 1990	R&D Manager (Venture Business Unit)
1987 - 1989	R&D Manager (Consumer Diagnostics venture).
1984 - 1987	R&D Manager (Therapeutic Drug Monitoring business unit)
1983 - 1984	R&D Lab Manager (Diagnostics Division R&D)
1980 - 1983	Section Head (Diagnostics Division R&D)
1978 - 1980	Project Manager and Lead Scientist (Diagnostics Division R&D)
1/76 - 9/78	University of Michigan, Department of Biological Chemistry, Ann Arbor, MI. Post-doctoral fellow studying flavoprotein enzyme mechanisms using chemically modified flavins.

Professional Responsibilities and Accomplishments:

- Assist with teaching undergraduate courses in organic chemistry and in special topics at University of Illinois.
- Direct analytical method development activites for global product development and product support activites for Medical Products division. Responsibilities include 29 analytical chemistry professional in the US and Europe developing and validating analytical methods used in the production of IV parenteral products. The group includes analytical method development and validation for raw materials, finished product, stability indication methods, extractable studies and leachable methods for containers and devices.

- Global reseach and development experience establishing and managing an R&D group in China to develop new pharmaceutical parenteral products. Management of the China group was the responsibility of the site director in China. My group provided training and direct technical interaction with the R&D teams to develop and guide new product development.

- Leadership experience in international scientific societies – currently co-chairing the Well Characterized Biopharmaceutical conference (WCBP) co-sponsored by CASSS and FDA, and participating in the programming committee for AAPS National Biotech Conference.

- Taught special topics course at University of Illinois, Champaign-Urbana, under Prof. Jeff Moore, Chemistry Department. Focus was for student to create white paper guidance for pharmaceutical / biopharmaceutical product families not covered by ICH Q3A and Q3B.

- Directed analytical development of parenteral pharmaceutical product in Baxter Pharmaceuticals and Technology with a group of 13 scientific professionals as direct reports and with indirect reports of the remaining product development staff of approximately 30 scientific professionals. Developed premix product in flexible containers and insoluble drugs formulated as soluble suspensions. Designed and directed research to demonstrate the protein compatibility of flexible containers and plastic pre-filled syringes. Led development of residual solvent testing strategy for compliance for Baxter BPT products to USP monograph. Contributed to the Heparin recall investigation by leading a team of scientific professionals that isolated and characterized the contaminant in heparin product that became known as over-sulfated chondroitin sulfate. Contribute to WWPP technology assessment and to Baxter BPT innovation process with 5 new innovation ideas submitted.

- Assumed interim duties of VP Product Development during extended medical leave including developed and managed expense and capital budget. Led the integration R&D product development functions from New Providence and Cherry Hill into Round Lake (Project Grow). Designed and developed China Premix mentoring program to assist

China R&D Premix team in developing quality product development system.

- Directed R&D product development of erythropoietin product in Baxter Renal Division. Led a cross-divisional team of scientists from Technology Resources, BioScience, and Renal divisions that enhanced the recombinant cell bank to be cGMP compliant, developed and validated a manufacturing facility for the API, characterized the erythropoietin cell bank and API, and validated release methods of the finished product. Designed, developed, and managed the expense and capital budget.

- Directed analytical, biochemical, and chemistry research for Baxter Hemoglobin Therapeutics for both first-generation blood substitute and second-generation recombinant hemoglobin. Developed analytical testing for in-process and release testing as well as biochemical characterization that support regulatory submission for phase II and III of first generation product and phase I for second generation recombinant product.

- Led the R&D team at Abbott Diagnostics Division that successfully explored new biochemical markers of disease that could become diagnostic products for the clinical laboratory. Disease areas explored included Alzheimers, lipid metabolism, cardiovascular, and immune disorders. Products were developed for homocysteine (first automated method for this cardiovascular risk marker), fibrin degradation products, and high sensitivity C-reactive protein (inflammatory and myocardial infarct risk marker).

- Designed and developed a team of R&D scientists to innovate and develop diagnostics that could be used by consumers in US and Europe. Participated in a marketing venture team that evaluated market opportunities for consumer diagnostic products. Home pregnancy testing was developed from technology developed at Abbott Diagnostics Division. Developed technologies for cholesterol and glucose testing.

- Led the R&D team at Abbott Diagostics Division that successfully expanded the menu of the TDx therapeutic drug monitoring instrument system. TDx was a recently introduced and quickly adopted clinical chemistry instrument and reagents that provided ease-of-use and superior analytical capabilities to the clinical laboratory. Directed the R&D activities of 50 that grew to 90 scientific/technical professionals with responsibilities for product development and rare reagent manufacturing including antibody development, chemical synthesis, assay optimization and validation, clinical evaluation, instrument software development, and production of the chemicals and biologics that went into commercial product. Developed and managed budget.

- Contributed to TDx business leadership team implementing strategic initiatives that drove dramatic growth in the business by growing the number of products on the TDx system from 18 to 53 products, by delivering new products more expeditiously and on time, and by increasing the supply of all product rare reagents to a minimum 1 year supply and no days off-market. Two additional platforms were added to the system for clinical chemistry methods and abused drug testing. TDx strategy resulted in increases

in instrument placements, greater than 15 to 25% growth in sales, and profit margins greater than 85%.

Professional Organization Achievements:

Co-chaired session on Biopharmaceutical Development at 8th Baxter Science and Technology Symposium, September 1999.

Co-chaired session on Protein Characterization and Analytical Methods at 9th Baxter Science and Technology Symposium, May 2001

Taught Chem 397/497 special topics course at University of Illinois under Prof. Jeffrey Moore, Chemistry Department. Course focused on pharmaceutical / biopharmaceutical product impurities and included lectures and student project to develop industry guidance white papers on control of impurities in various categories of pharmaceutical products, Fall 2012.

Human Proteomics Organization (HUPO) – member of the Plasma Proteomics Project committee, 2002

Well Characterized Biopharmaceutical – workshop co-chair for protein biopharmaceutical chemical modification and glycosylation, January 2003.

NIH Study Section reviewer for Reparative Medicine Study Section, March 12-13, 2003.

NIH Study Section reviewer for Research Opportunities in Tissue Engineering, August 7-8, 2003.

Organizing committee for Well Characterized BioPharmaceuticals conference, co-sponsored by California Separation Society and FDA, 2003 – present.

Well Characterized BioPharmaceuticals – workshop co-chair for adventitious agents, January 2004.

Invited speaker at Well Characterized Biopharmaceuticals Conference on "Protein Aggregate – Why do we care?", January 2004.

Invited speaker at Barnett Institute conference on Immunogenicity Testing for Therapeutics, February 9-10, 2004. Topic: "Immunogenicity of Chemically Modified Proteins".

Invited keynote speaker at Barnett Institute conference on Protein Aggregation, September 9 – 10, 2004. Topic: "Examining the Consequences of Protein Aggregation on Pharmaceutical Quality".

Invited speaker and co-chair at Barnett Institute conference on Immunogenicity Testing for Therapeutics, September 30 – October 1, 2004. Topic: "Immunogenicity of Chemically Modified Proteins".

Invited speaker at IBC conference on Drug Delivery and Formulation of Proteins and Peptides, October 4 – 6, 2004. Topic: "Analytical Characterization – Bricks and Mortar for Product Development".

Invited speaker at Wyatt Technology Light Scattering Colloquium, October 11 – 12, 2004. Topic: "Hemoglobin Therapeutics – Macromolecular Sizing".

NIH Study Section reviewer for Musculoskeletal Tissue Engineering, March 17-18, 2005.

Invited speaker at AAPS Biotechnology Conference, Open Forum, June 5-8, 2005. Topic: "Impact of Protein Aggregation on Protein Quality".

NIH Study Section reviewer for Musculskeletal Tissue Engineering, July 11-12, 2005.

Lecture at University of Illinois, Chicago, School of Pharmacy, *Special Topics in Biopharmaceutical Sciences, Course 594*, "Analytical Characterization of Biopharmaceuticals – Bricks and Mortar of Biopharmaceutical Product Development", June 22, 2006, and October 19, 2011.

Invited speaker at Well Characterized BioPharmaceuticals, January 29-31, 2007, "Protein Compatibility – Container Interactions and Leachables".

Co-chaired CMC Forum on Extractables and Leachable for Biopharmaceutical, January 27, 2008.

CASSS associate director, January 2010 – present.

Lead industry working group through the IQ Consortium on Impurities in Pharmaceutical and Biopharmaceutical products. January 2012 – present.

"Case Study: Contamination of Heparin with Oversulfated Chondroitin Sulfate," Chess, E. K.; Bairstow, S.; Donovan, S.; Havel, K.; Hu, P.; Johnson, R. J.; Lee, S.; McKee, J.; Miller, R.; Moore, E.; Nordhaus, M.; Ray, J.; Szabo, C.; Wielgos, T. in Heparin – A Century of Progress, Lever, R. et al. (eds.) Handbook of Experimental Pharmacology 207, Springer-Verlag, Berlin; 2012.

Co-chair WCBP 2013 conference, January 2012 – present

Invited Speaker AAPS Workshop on Predicting and Monitoring Impurities in API and Drug Product, *"Update from IQ Impurities Working Group"*, October 13-14, 2012.

Invited speaker AAPS conference, Risk Based Design of Stability Studies symposium, *"Making Good Enough Even Better: Enhanced Analytical Chemistry Technologies for Improved Efficiency and Quality in Product Testing"*. October 17, 2012.

Co-chaired WCBP 2013, 2014, 2015 conference.

Professional Memberships:

American Association for the Advancement of Science
American Association for Clinical Chemistry
American Society of Biochemistry and Molecular Biology (FASEB)
American Chemical Society
American Association of Pharmaceutical Scientists
Biophysical Society
California Separation Sciences Society (CASSS), serves as Associate Director
Parenteral Drug Association

Education:

Ph.D. Biochemistry (1976) Cornell University, Ithaca, NY
minor in Physical Organic Chemistry
major advisor – Prof. Quentin Gibson
Thesis: "Cooperativity in the Binding of Nitric Oxide to Hemoglobin"

B.S. Biochemistry (1972) University of Illinois, Champaign, IL
Senior thesis advisor: Prof. Robert Switzer

Publications:

E.G. Moore and Q. Gibson, "Cooperativity in the Dissociation of Nitric Oxide from Hemoglobin" (1976) J. Biol. Chem. 251: 2788-2794.

E.G. Moore, E. Cardemil, and V. Massey, "Production of a Covalent Flavin Linkage in Lipoamide Dehydrogenase" (1978) J. Biol. Chem. 253: 6413-6422.

E.G. Moore, S. Ghisla, and V. Massey, "Properties of Flavins Where the 8-methyl Group Is Replaced by Mercapto Residues" (1979) J. Biol. Chem. 254: 8173-8178.

V. Massey, S. Ghisla, and E.G. Moore, "8-mercaptoflavin as Active Site Probes of Flavoenzymes" (1979) J. Biol. Chem. 254: 9640-9650.

G. Blankenhorn and E.G. Moore, "Sulfoxylate ion (HSO2-), the hydride donor in dithionite-dependent reduction of NAD+ analogs" (1980) J. Am. Chem. Soc. 102: 1092-1098.

P.N. Hawkins, M.N. Rossor, J.R. Gallimore, B. Miller, E.G. Moore, and M.B. Pepys, "Concentration of Serum Amyloid P Component in the CSF as a Possible Marker of Cerebral Amyloid Deposits in Alzheimer's Disease" (1994) BBRC 201: 722-726.

J. Wilkins, J.R. Gallimore, G.A. Tennent, P.N. Hawkins, P.C. Limburg, M.H. van Rijswijk, E.G. Moore, and M.B. Pepys, "Rapid Automated Enzyme Immunoassay of Serum Amyloid A " (1994) Clin. Chem. 40: 1284-1290.

M.T. Shipchandler and E.G. Moore, "Rapid, Fully Automated Measurement of Plasma Homocyst(e)ine with the Abbott IMx Analyzer" (1995) Clin. Chem. 41: 991-994.

Z. Yu, G. Friso, J.J. Miranda, M.J. Patel, T. Lo-Tseng, E.G. Moore, A.L. Burlingame, "Structural Characterization of Human Hemoglobin Crosslinked by bis (3,5-dibromosalicyl) fumarate Using Mass Spectrometric Techniques" (1997) Protein Science 6: 2568-2577.

M.J. Patel, E.J. Webb, T.E. Shelbourn, C. Mattia-Goldberg, A.J.T. George, F. Zhang, E.G. Moore, and D.J. Nelson, "Absence of Immunogenicity of Diaspirin Cross-Linked Hemoblobin in Humans" (1998) Blood 91: 710-716.

L.A. Dick, G. Heibel, E.G. Moore, and T.G. Spiro, "UV Resonance Raman Spectra Reveal a Structural Basis for Diminished Proton and CO_2 Binding to α,α-cross-linked Hemoglobin" (1999) Biochemistry 38: 6406-6410.

X Zhao, G. Balakrishnan, E.G. Moore, T.G. Spiro, "Kinetics of hemoglobin allostery from time-resolved UV resonance Raman spectroscopy: effect of a chemical cross-link" (2000) J. Raman Spectroscopy 31: 349-352.

S.A. Dragon, K.W. Olsen, E.G. Moore, A. Fitch, "Spectroelectrochemical Study of Hemoglobin A, alpha- and beta- fumarate crosslinked hemoglobin; implications to autoxidation reaction" (2008) Bioelectrochemistry 73:55-63.

S.E. Lee, E. Chess, B. Rabinow, G.J. Ray, C.M. Szabo, B. Melnick, R.L. Miller, L.M. Nair, E.G. Moore, "NMR of Heparin API: investigation of unidentified signals in the USP-specified range of 2.12-3.00 ppm" (2011) Anal Bioanal Chem 399:651-662.

Abstracts:

E.G. Moore and V. Massey, "Importance of Charge Transfer Interactions During Catalysis by Lipoamide Dehydrogenase" (1978) Fed. Proc. 37

S. Budz, E. Moore, and P. Zieske, "Consistency in the Potency and Pharmaceutical Quality Profiles of Diaspirin Crosslinked Hemoglobin 10% and Electrolyte Injection" (1996) Aritificial Cells, Blood Substitutes and Immobilization Biology 24: 312.

S. Bush, R. Knight, M. Kray, and E. Moore, "DCLHb (Diaspirin Crosslinked Hemoglobin) 10% and Electrolyte Injection: Significant and Consistent Deliverable Oxygen Content" (1996) Aritificial Cells, Blood Substitutes and Immobilization Biology 24: 313.

T. Shelbourn, M. Patel, and E.G. Moore "Characterization of Diaspirin Crosslinked Hemoglobin (DCLHb) by Spectroscopic Techniques" (1996) Aritificial Cells, Blood Substitutes and Immobilization Biology 24: 423.

E. Webb, T. Shelbourn, E. Moore, C. Mattia-Goldberg, and M. Patel, "Evaluation of the Immunogenicity of Diaspirin Crosslinked Hemoglobin (DCLHb)" (1996) Aritificial Cells, Blood Substitutes and Immobilization Biology 24: 457.

E.G. Moore, C. Mattia-Goldberg, J. Pettersson, G. Marchand, E. Webb, S. Samandar, P. Zieske, N. Albala, S. Johansson, and M.J. Patel, "Validation of Spectrophotometric Systems for Measurement of Plasma Levels of Diaspirin Crosslinked Hemoglobin (DCLHb)" (1997) Clin. Chem.

E.G. Moore, M. Patel, S. Samandar, T. Shelbourn, G. Heibel, L. Dick, and T. Spiro, "Spectral Characterization of Diaspirin Crosslinked Hemoglobin" (1997) Second European Symposium of the Protein Society

M.J. Patel, Z. Yu, F. Fiso, T. Lo-Tseng, E. Webb, E.G. Moore, and A.L. Burlingame, "Structural Characterization of a Hemoglobin Based Blood Substitute: Diaspirin Crosslinked Hemoglobin" (!997) Second European Symposium of the Protein Society

Patents:

S.D. Stroupe and E.G. Moore, "Determination of Glycosylated Hemoglobin in Blood", April 29, 1980, U.S. Patent 4,200,435.

S.D. Stroupe and E.G. Moore, "Reagent and Test Kit for Determining Glycosylated Hemoglobin", March 10, 1981, U.S. Patent 4,255,385.

E.G. Moore, "Glycosylated Hemoglobin Standards", April 7, 1981, U.S. Patent 4,260,516.

E.G. Moore, "Standards for Determining Glycosylated Hemoglobin", June 23, 1981, U.S. Patent 4,274,978.

D. Looker, I. Apostol, E. Brucker, M. Doyle, D. Foster, C. Glascock, J. Hartman, G. Lee, D. Lemon, E. Moore, J. Richards, M. Schick, S. Trimble, D. Pereira, T. Hai, K. Burhop, B. Kerwin, “Reduced Side-effect Hemoglobin Compositions”, May 1, 2007, US Patent 7,211,560.