Edwin G. Moore, Ph.D.

Curriculum Vitae

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

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Professional Experience:

10/16 – present — Entrepreneur-in-Residence Program, EnterpriseWorks, University of Illinois Research Park, LLC
Responsibilities – Provide technical mentorship for start-up companies. Mentorship includes consulting on product development, business aspects, regulatory requirements, funding options. Mentorship also includes training including seminars to groups of start-up employees.

1/14 – present — President and Principle Consultant, BioPhia Consulting, Inc.
Responsibilities – Review and sign all contracts. Provide leadership to consulting group. Maintain communications with affiliate consulting groups. Evaluate and liaison with CROs who can potentially meet client needs. Consult with clients in my areas of expertise.
Accomplishments – co-founded company. Grew company from 4 original consultants to 14 SME consultants and 2 associates. Formed affiliations with more than 10 other consulting groups with different skill sets. Grew client base and sales.

8/13 – present — Visiting Scientist, University of Illinois, Chemistry Department
Responsibilities – Assist teaching Chem 332 (Organic Chemistry for non-chemistry majors). Organize and taught special topics courses for senior level students for "Biopharmaceutical and Pharmaceutical Discovery and Product Development", and "Medical Device Product Development". Mentored graduate student and postdoctoral fellows doing research in polymers that can inhibit amyloid protein aggregation.
Accomplishments – Created and taught three special topics courses in pharmaceutical discovery and product development, in medical device product development, and in pharmaceutical impurities. Assisted teaching organic chemistry for non-chemistry majors. Provided mentorship to grad student who demonstrated synthesis of a polymer that could inhibit amyloid aggregation, published orginal findings in JACS article.

1/12 – 1/15 — WCBP conference. WCBP is an international conference

for biopharmaceuticals (recombinant therapeutic proteins, monoclonal antibodies, vaccines, blood derived proteins, cell and gene therapies) which is co-sponsored by CASSS and by FDA.

1/12 – 1/14 Workshop Industry Co-chair
Responsibilities - Co-chaired the workshops along with second industry co-chair and co-chairs from FDA CDER and from FDA CBER. Led planning committee tasks for selecting workshop topics, finding workshop leads, and conducting workshops at the conference.
Accomplishments – Sixteen workshops successfully organized each year. Introduced alternate "speed dating" workshop format that has become effective and popular format for engaging participants.

1/14 – 1/15 Industry Chair
Responsibilities – Chaired the conference along with chairs from FDA CDER and from FDA CBER. Led planning committee tasks for selection of plenary sessions relevant to current issues in biopharmaceutical product development, finding co-chairs for each of the plenary sessions, finding speakers for each of the plenary sessions, delivering opening remarks, and moderating the conference.
Accomplishments – Conference held January 27-29, 2015 with over 600 attendees. Nine plenary sessions successfully organized and presented. 91% of respondents to survey rated the conference as relevant or extremely relevant to their job responsibilities.

8/94 – 7/13 Baxter Healthcare Corp.
All Baxter product development activities that I was involved was conducted under cGMP using corporate and division quality systems and SOPs.

2011 – 2013 Sr. Director, R&D, Technology Resources, Medical Products
Responsibilities – Global Analytical Method Development and Validaton. Managed 29 scientists in US and Europe who conducted studies for analytical method life cycle management, extractable / leachable for Baxter containers, USP and EP compendial tracking and compliance, China R&D. Managed budget responsibility and forecast. Interfaced with project management office for personnel resourcing, project timelines, and project tracking. Interfaced with global regulatory affairs, quality and manufacturing organizations. Member of Technology Resouces Sr Management Team reporting to VP R&D Technology Resources.
Accomplishments – Met division needs for analytical method development and validation for current and new products globally. Evaluated and interfaced with CROs to provide analytical method and characterization additional resources to meet division demand for extractale / leachable testing as well as other analytical method needs. Arranged for CRO in-sourcing of personnel to supplement work in Baxter laboratories. Several analytical method development and validation projects were performed by CRO in India to demonstrate that they could conduct cGMP studies comparable to studies done in our laboratories. Developed and trained China R&D group to have SOP and quality systems similar to US. China

R&D group demonstrated capability of formulation, analytical method, and process development of parenteral drug products through submission of regulatory files to China FDA.

2005 – 2011 Sr. Director, R&D, Pharmaceutical R&D, Medication Delivery
Responsibilities – Analytical Method Development and Validation. Managed 15 scientists responsible to analytical method development for new parenteral drug products and lifecycle support of current products. USP compliance for Baxter global products. Budget responsibility for department operating and capital budget. Project management of analytical method responsibilities on Baxter and client projects. Interface with regulatory affairs, quality and manufacturing organizations. Assisted business development to work with external corporate clients interested in developing IV parenteral formulations on their drugs in Baxter ready-to-use containers.
Accomplishments – Met analytical method needs of Baxter generic and enhanced generic ready-to-use IV infusion products. Besides development of analytical methods for product controls, also characterized new small molecule impurities and developed control measures consistent with ICH and FDA guidance. Wrote analytical method sections of dossier for FDA filing. Kept Baxter Medication Delivery division current on USP compendial changes. Managed interface with China R&D group to begin training on formulation, analytical method development and process development of IV infusion products. Selected and managed CROs that were able to relieve capacity contraints on analytical method development and validation. Assumed interim duties as VP Product Development during extended medical leave. Interim duties included leading development projects for formulation and analytical, coordinating with other R&D functions and commercial functions, and management of expense and capital budget. Led the integration R&D formulation and analytical method product development functions from New Providence and Cherry Hill into Round Lake.

2002 – 2004 Sr. Director, Research and Development, Renal Pharmaceuticals
Responsibilities – Product Development for Recombinant Erythropoietin-*omega* (Epo omega). Led CMC product development team to take in-licensed technology for Epo omega and produce cGMP product. Team was cross-divisional including Renal, Bioscience and Technology Resources divisions. Overall budget supervision for CMC product development.
Accomplishments – Baxter licensed this product from small company. Performed due diligence to understand design history and product development path/requirements. Redeveloped baby hamster kidney (BHK) cell bank from original recombinant seed to fully compliant cGMP master cell bank and working cell banks. Conducted ICH compliant molecular biology characterization of the cell bank using external CROs. Constructed commercial scale manufacturing facility in Ireland adjacent to Baxter plant. Worked with external CROs to validate virus removal

process. Plant was validated with multiple scale runs, approved by Irish Medical Board, and used to produce full commercial scale batch of recombinant Epo omega. Analytical methods were transferred to manufacturing plant and validated. Epo omega batches were characterized for protein structure and glycosylation pattern to be comparable to previous batches of Epo omega and natural human erythropoietin. External CMO selected for formulation, fill, finish of pre-filled syringes for finished drug product. Worked with entire development team for presentations to EMEA Scientific Advice Working Party. Worked with the development team to prepare a detailed MS project management plan. Worked with the development team to create and present to a scientific advisory board of external experts. Baxter decided not to pursue clinical trials and product development. Outlicensing data room was created for potential acquisition partners.

1998 – 2002 Director, Chemical Sciences, Hemoglobin Therapeutics

Responsibilities – Analytical method development and validation, biochemical characterization of recombinant hemoglobin, chemical modification of recombinant hemoglobin, and stability testing. Managed 25 scientists. Managed departmental budget for operating and capital budget. Project managed tasks for department consistent with the overall project timeline. Interacted with process development, pre-clinical testing, molecular biology, protein chemistry, quality assurance, clinical / medical affairs, and regulatory affairs departments. Member of Sr. management team.

Accomplishments – Participated in the overall team effort to successfully engineer recombinant human hemoglobin (rHb) in E. coli expression systems to reduce nitric oxide binding thirty fold while maintaining normal oxygen binding. Developed and validated analytical methods for endotoxin and pyrogen detection. Developed and validated analytical methods for product control of drug substance and drug product. Developed synthesis process for bis-maleimide PEG used for crosslinking rHb, transferred synthesis to CMO. Developed and validated bioanalytical methods and transferred to clinical CRO for phase I trials. Participated in writing CMC and bioanalytical sections of dossier for IND to FDA.

1997 - 1998 Director, Analytical Research and Testing, Blood Substitutes Div.

1994 - 1997 Manager, Analytical Research and Testing, Blood Substitutes Div.

Responsibilities – Analytical method development and validation and stability testing. Managed 15 scientists. Project managed tasks for department consistent with overall project timelines. Interacted with process development, quality assurance, pre-clinical testing, clinical/ medical affairs and regulatory affairs departments. Member of Sr. management team.

Accomplishments – Validated methods to ICH, FDA, and EMEA guidance standards. Supported process development and manufacturing for production of clinical batches and troubleshooting problems. Supported construction and validation of commercial scale manufacturing facility.

Transferred analytical methods to commercial scale manufacturing facility. Participated in writing Phase III IND for FDA and EMEA clinical trials. Participated in FDA and in EMEA presentations for product development advice.

10/78 - 8/94 Abbott Laboratories, Abbott Diagnostics Division, Abbott Park, IL

1993 - 1994 Project Manager for Extramural Research Activities (Diagnostics Division R&D)
Responsiblities – Track external research activities that could lead to new clinical diagnostic methods. Provide scientific support for business development groups.

1990 - 1993 R&D Manager (Diagnostics Division R&D).
Responsibilities – New biochemical markers of disease. Manage 15 scientists. Budget management for department operating and capital budgets. Project manage internal R&D activities. Coordinate internal work with external academic and CRO investigators.
Accomplishments – Developed, validated, and proved clinical applicability of clinical diagnostic assays for homocysteine, high sensitivity C-reactive Protein, Troponin. Investigated other bioanalytical method for Alzheimer' Disease and other disease states.

1989 - 1990 R&D Manager (Venture Business Unit)
1987 - 1989 R&D Manager (Consumer Diagnostics venture).
Responsibility – Develop over-the-counter clinical diagnostic methods. Support marketing and general manager to evaluate and prepare for commercial opportunity for consumer diagnostic tests. Manage 10 scientists. Manage operating and capital budget.
Accomplishments –Developed home pregnancy test, step test. Methods evaluated for glucose test, diet test.

1984 - 1987 R&D Manager (Therapeutic Drug Monitoring business unit)
Responsibilities – R&D product development and Rare Reagent Manufacturing. Manage up to 75 scientists, technicians, and engineers. Budget responsibility for operating and capital budget. Manage departments responsible for chemical synthesis, antibody development, assay development and optimization, software development, clinical trials, and rare reagent (antibody and drug-tracer) manufacturing. Project manage development of new assay development. Project management of development tasks.
Accomplishments – Increased number of new therapeutic drug monitoring assays, abused drug methods, and clinical chemistry methods from 23 to 52 total assays. Redeveloped monoclonal antibody for theophylline drug monitoring method. No off market days due to rare reagent supply for approved clinical test methods. Introduced abused drug assays to TDx instrument system.

1983 - 1984 R&D Lab Manager (Diagnostics Division R&D)
1980 - 1983 Section Head (Diagnostics Division R&D)
Responsibilities – Investigate new technologies for clinical diagnostics systems. Mange department of 12 scientist. Budget management for operating and capital budget.
Accomplishments – Developed field effect transistors (FET) as sensors for detecting and quantitating clinically significant analytes, e.g. glucose, sodium, potassium, in blood and other body fluids. Collaborated with academic institutions to learn process for constructing FETs. Construct an in-house facility for manufacturing pilot batches of FETs. Invented membrane technologies for selective measurement of body fluid components including enzymes and organic ionophore molecules.

1978 - 1980 Project Manager and Lead Scientist (Diagnostics Division R&D)
Responsibilities – Develop clinical chemistry assays for glycosylated hemoglobin. Manage one technician. Develop and transfer manufacturing process for assay kit. Conduct clinical trial of glycosylated hemoglobin method.
Accomplishments – Automated glycosylated assay developed on Abbott ABA automated clinical analyzer. Developed and manufactured reference standards and assay kit. 510k filed and approved by FDA for clinical chemistry assay. Product approved by Japanese ministry of health and launched in Japan.

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. Native flavin was removed for enzyme and modified flavin was substituted. Modified enzymes were studied by Michaelis-Menton kinetics, rapid kinetics, and thermodynamic studies to determine chemical mechanisms.

Professional Organization Achievements:

Industry Mentor for Editekk Inc team for NSF I-CORPS program, April 3 – May 16, 2017.

Proposed and organized symposium, "*Protein Aggregates in Monoclonal Antibody Products: Lessons learned in quantitating sub-visible particles*" at AAPS National Meeting, November 13-17, 2016.

Member planning committee for AAPS National Biotech Conference (2014 – 2015).

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.

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

"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.

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

CASSS associate director, January 2010 – present.

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

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

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.

NIH Study Section reviewer for Musculskeletal Tissue Engineering, July 11-12, 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 Musculoskeletal Tissue Engineering, March 17-18, 2005.

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

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 and co-chair at Barnett Institute conference on Immunogenicity Testing for Therapeutics, September 30 – October 1, 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 at Barnett Institute conference on Immunogenicity Testing for Therapeutics, February 9-10, 2004. Topic: "Immunogenicity of Chemically Modified Proteins".

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

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

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

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

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

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

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

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

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

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.

Y. Song, P. Cheng, L. Zhu, E.G. Moore, J.S. Moore "Multivalent Macromolecules Redirect Nucleation-Dependent Fibrillar Assembly into Discrete Nanostructures" (2014) J Am Chem Soc 136:5233-5236.

Y. Song, E.G. Moore, Y. Guo, J.S. Moore "Polymer−Peptide Conjugates Disassemble Amyloid β Fibrils in a Molecular-Weight Dependent Manner" (2017) J Am Chem Soc 139:4298−4301.

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.