Gregory M. McLaughlin
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Summary
I wish to be a major scientific contributor in a company that requires a proven veteran scientist with a broad analytical skill set and sound judgment who understands and can independently tailor his work towards business objectives. My ideal situation would be any combination of "hands on" method development/validation experimentation, working on a team of dedicated, bright minds from a variety of backgrounds, and mentoring junior scientists. I have over 30 years of experience with all facets of analytical techniques (from instrument design to rapid method development/validation); yet have stayed current with instruments and data manipulation/management packages. I am willing to relocate for the right organization.

Experience:

West Palm Beach Analytical Development (WPBAD) 3/10 - Present
CEO/Chief Analytical Development Scientist of a new development company that has developed, optimized and validated over 300 chemical analysis methods for a wide variety of dosage forms (tablets, capsules. oral, , inhalation/respiratory, suppositories, transdermal, topical, & ophthalmic) and the associated performance testing (stability, dissolution, ACI & NGI). Method development projects have included a wide array of compounds, including: antibiotics, steroids, prostaglandin-like drugs, proteins, peptides, DNA, stimulants, opiates, antidepressants, antihistamines, anti-inflammatories, diuretics, anti-hypertensives, antibiotics, catecholamines, antithyroid agents, polymers, additives, sympathomimetic agents, adrenergic receptor blockers, beta blockers, ophthalmics, surfactants, amino acids, narcotics, anesthetics, diabetes therapies, chiral compounds, PAHs, PCBs, and chemical/environmental molecules. Commonly used techniques include: HPLC, GC, IC, UV/Vis, dissolution, fluorometry, FTIR, ICP, AA, GFAA, TGA, DSC, polarimetry, KF, and limited GC/MS & LC/MS.

Expertise includes method development, method validation/transfer, de-formulation, combination therapy assays, residual solvents/OVI, extractables/leachables, stability indicating assays, forced degradation, reference standard characterization, comparative studies, counterfeit product evaluation, medical device analysis, isolation and identification of impurities and degradation products, and semi-preparative HPLC scale-up and collection. Additional expertise includes developing instrumental validation protocols (HPLC, GC, IC, ICP, UV/Vis, and other instruments) and training in method development (MD), method validation, method transfer, stress studies, laboratory instrument qualification (DQ, IQ, OQ, and PQ); introduction to HPLC, HPLC MD, GC, CE MD, UV/Vis, FTIR, TGA, DSC, ICP, AA/GFAA, pH meters, and balances.

Pearl Therapeutics, Inc. 7/08 - 3/10
Staff Scientist that developed, optimized, and validated methods on inhalable drug therapies and NGI extracts. Inhalable drug classes included muscarinic anticholinergics, beta2-adrenergic receptor agonists, glucocorticoids, and substituted phosphatidylcholines. Developed methods for complex low level mono/bi/tri component inhalable drugs that in one case resulted in baseline separation of two APIs, 18 related substances, and an additional >20 unknowns. Separated and identified more than 10 previously unknown impurities and degradation products, extractables/leachables, and NGI coating impurities. Developed methods for detecting NGI coating impurities, degradation studies, sample preparation schemes that lead to ID of numerous previously unknown impurities and formation of hierarchal polymers that lead to understanding of mass balance.

Irvine Pharmaceutical Laboratories (A.K.A. - Irvine Analytical Laboratories) 5/01 – 7/08
Principal Scientist & Group Leader that has developed, optimized and validated over 75 chemical analysis methods for a wide variety of dosage forms (oral, inhalation/respiratory, suppositories, transdermal, topical, & ophthalmic) and the associated performance testing (stability, dissolution, ACI & NGI). Method development projects have included a wide array of compounds, including: antibiotics, steroids, prostaglandin-like drugs, proteins, peptides, stimulants, opiates, antidepressants, antihistamines, anti-inflammatories, diuretics, anti-hypertensives, antibiotics, catecholamines, antithyroid agents, polymers, additives, sympathomimetic agents, adrenergic receptor blockers, beta blockers, ophthalmics, surfactants, amino acids, narcotics, anesthetics, diabetes therapies, & chiral compounds.
Commonly used techniques include: HPLC, GC, IC, UV/Vis, dissolution, fluorometry, FTIR, ICP, AA, GFAA, TGA, DSC, polarimetry, KF, and limited GC/MS & LC/MS. Specialties included de-formulations, residual solvents/OVI, extractables/ leachables, stability indicating assays, forced degradation, reference standard characterization, comparative studies, counterfeit product evaluation, medical device analysis, isolation/identification of impurities and degradation products, semi-preparative HPLC scale-up and collection, instrument validation protocols (HPLC, GC, ICP, and other instruments), and researched and implemented a instrument control/data management system for all chromatography systems (Chromeleon® by Dionex controlled more than 75 Agilent, Waters, Dionex and other brand HPLCs and GCs). Played a pivotal role for the

company in preparing for successful FDA audits. Coordinated developed and delivered sales training on stability and other subject. Interviewed key major pharmaceutical and medical device manufacturer personal (CEOs, presidents, VPs, R&D directors, and a variety of scientists) and wrote major market research proposals for future product introductions/positioning.

Frost & Sullivan (Healthcare – Pharm./Med. Devices, San Jose, CA) 12/99 - 10/00
Account Manager & Market Research Consultant that successfully developed strategic account management program for company to focus efforts on major pharmaceutical and medical device manufacturing companies. Typical studies involved varying disciplines and subject matter (e.g. chemotherapy, radiopharmaceuticals, anti-infectives, stem cells, recombinant proteins, glaucoma treatments, MRI, CT scanners, automated clinical analyzers, CME training internet sites, hyperbaric chambers, emergency resuscitator devices, & many others).

Rheodyne (LabPRO HPLC Automation Products, Rohnert Park, CA) 8/97 - 11/99
Marketing Manager who developed strategies to identify HPLC automation opportunities in HPLC/MS, column switching multidimensional chromatography and "customer focused solutions." Devised and co-presented more than 50 OEM and distributor presentations on HPLC automation (technical capabilities & applications) in universities, industrial accounts, and trade shows. Investigated and specified regulatory products concerned with GXP/ISO/Compliance/Validation. Defined product requirements (12 automated switching and injection modules, multi-dimensional HPLC system, GUI, Windows control software) and lead development on MS interface.

Dionex Corporation (CE and Bio-HPLC, Sunnyvale, CA) 8/92 - 8/97
Senior Product line Manager who conducted independent method development research into many different areas of CE and HPLC (including: proteins, drugs, DNA, chiral analytes, inorganic ions, pesticides, dyes, surfactants). Presented >100 scientific talks, posters, papers, and CE/HPLC presentations at major/minor scientific meetings, universities, trade shows & dealers on CE, IC, carbohydrate analysis, DNA and method validation. Taught advanced CE courses at Pittsburgh Conference and EAS. Developed instrumental validation program for HPLC/IC products.

Beckman Instruments, Inc. (Multiple Divisions & Locations) 12/78 - 7/92
Sr. Sales Representative (5 months) - Successfully sold/supported Beckman bioresearch equipment at UCSF (chromatography & data systems, UV/VIS, LS, AAA, oligonucleotide syn. protein sequencers/synthesizers, and LIMS).
Area Sales Support Manager (13 months): Responsible for hiring, development, and management of group of eight technical specialists (HPLC/CE/ LIMS, UV/VIS, LS, robotics, and consumables) with the goal of increasing technical proficiency and selling skills of sales force in the region of Maine to Virginia. Created a 4 day DNA training program for the sales force that educated on basic molecular biology techniques (including PCR, agarose electrophoresis, dot blots, & cloning), bio-molecular instrumentation (DNA sequencing & DNA synthesis), market opportunities and competition . Created a 3 day HPLC training program for the sales force to enhance technical competence. Developed national technical education program for bioresearch salesforce. Taught Advanced CE/HPLC courses at PittCon and EAS symposia.
CE Product Line Manager (4.5 years): Identified, planned, & guided CE market opportunities to achieve the #1 position worldwide. Researched, designed, and delivered >50 lectures, posters, and presentations on CE and HPLC. Conducted research in many areas of CE and HPLC separations (mobility, viscosity, pH, temperature, & ionic effects and novel stationary phase research: free solutions, coated capillaries, & gels).
Sr. Sales Representative (4.5 years): Turned my key account (University of Wisconsin-Madison) into Beckman's 2nd largest account in the world in under 5 years (300% growth).
HPLC Area Manager & Technical Specialist (4.5 years): Supported the HPLC product line inclusive of: sales calls, providing regional expertise on HPLC, competitive monitoring, method development, instrument design/modification for special projects (e.g. Post column reactors, AAA/peptide/protein purification, valve switching schemes, lab data system/LIMS interfacing, on line process monitors, drug dissolution, PAH/carbamate analyzers, ion chromatography, etc.), sales/customer training course development, seminars/scientific lectures, and troubleshooting). Developed more than 100 HPLC applications to support various Beckman customers in areas ranging from peptide mapping, protein purification, DNA, amino acids, catecholamines, steroids, phospholipids, leokotrienes, fatty acids, vitamins, carbohydrates, PAHs, pesticides, and polymers. Designed and built a completely automated amino acid analyzer (with post column ninhydrin/OPA tagging) & protein/peptide purification system (with simultaneous collection and fluorescamine tagging). Supported customers on HPLC method problems on a variety of chemicals and biochemicals. Recorded the highest HPLC sales volume for any region worldwide. Produced and executed the first Beckman HPLC training program for customers. Devised/taught >50 HPLC courses including the Northern New Jersey ACS HPLC courses (2 years).

Monsanto Company (R&D, St. Louis, MO) 1/78 - 12/78
Sr. Technologist - Developed HPLC and GC methods for a catalyst research group (Bisphenolic sulfonate polymer intermediates, phosphonate herbicides, synthetic amino acids, and organometallics). Saved over $280M by developing a novel assay that detected major impurities in a new synthetic route thought to have significantly improved yield in a process that would have been otherwise scaled up into a new plant. Designed, fabricated, and modified HPLC instruments (e.g., post column reactors, valve switching schemes, on line catalytic process monitors, & etc.).

Mallinckrodt Chemicals (R&D, St. Louis, MO) 4/73 - 12/77
Sr. Technologist - Developed all HPLC methods for highest performing division of company (Acetaminophen process, p-aminophenol process, narcotics, opiates and specialty chemicals/drugs/intermediates). Designed and fabricated from components eleven analytical and two prep HPLC's for the R&D group. Defended the company in an EPA lawsuit ($12M) by successfully designing a model and sampling system for monitoring aniline and ethylene dichloride emissions.

McDonnell Douglas Corporation (St. Louis, MO) 1/67 - 4/73
Sr. Technologist - Independently developed methods for analyzing complex samples/unknowns and drafted government reports in corporate analytical chemistry laboratory using many different instrument techniques (e.g., GPC, GC, IR, UV/VIS, AAA, TGA, DSC, TMA, NMR, GC/MS, IR, FTIR, & Raman). Designed and developed an ellipsometer to measure thin films for Skylab. Developed and fabricated an H_2 leak detector after Cape Canaveral disaster. Co-patent holder for chemical treatment of high temperature aircraft radome materials. Interfaced and designed computer programs to automate IR and UV/VIS analyses. Developed methods, analyzed samples, and drafted government reports on numerous types of materials (boron & graphite composites, adhesives, space shields, ceramic composite armor, windshield materials, and other plastics).

Education: Chemistry Major, University of Missouri at St. Louis, 1972 (Completed 127 Semester Hours)

COURSE INSTRUCTOR
H. Issaqs and G. McLaughlin "Separation of Proteins, Peptides and Small Molecules by CE", Pittsburgh Conference of Analytical Chemistry and Applied Spectroscopy, New Orleans and Orlando ('96-'97)
Course - G. McLaughlin, "Analytical Capillary Electrophoresis-Advanced Topics", 33-35th Annual Eastern Analytical Symposium and Exposition, Somerset, NJ ('94-'97)
H. Issaqs, G. McLaughlin, and J. Olechno "HPCE-Biological Methods Development", Pittsburgh Conference of Analytical Chemistry and Applied Spectroscopy, New Orleans ('95)
Course - J. Olechno and G. McLaughlin, "Analytical Capillary Electrophoresis", 32nd Annual Eastern Analytical Symposium and Exposition, Somerset, NJ ('93)
Course - G. McLaughlin and J. Giles, "Modern Concepts in High Performance Liquid Chromatography", North Jersey Chapter ACS Short Courses, Farleigh Dickinson University, Madison, NJ ('82-'83)

SELECTED PUBLICATIONS
- Book Chapter - G. M. McLaughlin, K. W. Anderson, and D. K. Hauffe, "Peptide Analysis by CE: Methods Development and Optimization, Sensitivity Enhancement Strategies, and Applications", in "High Performance Capillary Electrophoresis: Theory, Techniques, and Applications", Khaledi, M.G. (Editor), (ISBN 0_471_14851_2) New York: John Wiley & Sons, 1998.
- G. M. McLaughlin, A. Weston, and K. D. Hauffe, "Capillary electrophoresis methods development and sensitivity enhancement strategies for the separation of industrial and environmental chemicals", in "J. Chromatogr. B Biomedical Sciences and Applications (Special Issues), Vol. 706, no. : Polymer and Biopolymer Separations by Chromatography and Capillary Electrophoresis", Krstulovic, A.M., (Editor) Amsterdam: Elsvier, 1996.
- G. M. McLaughlin, R. M. McCormick, D. C. Siu, W. A. Ausserer, K. Srinivasan, J. Horvath, and K. W. Anderson, "Better CE Protein and Peptide Separations Through Better Chemistry - Part 1, Use of Buffer Additives", J. Chromatogr., (1996).
- G. M. McLaughlin, R. M. McCormick, D. C. Siu, W. A. Ausserer, K. Srinivasan, J. Horvath, and K. W. Anderson, "Better CE Protein and Peptide Separations Through Better Chemistry - Part 2, Use of Coated Capillaries", J. Chromatogr., (1997).
- G. McLaughlin, R. Palmieri, and K. Anderson, "Benefits of Automation in the Separation of Biomolecules by HPCE", Techniques in Protein Chemistry II, J. Villafranca, ed., Academic Press, Inc., New York, 1991, pp. 3-19.
- G. McLaughlin, J. Nolan, J. Lindahl, R. Palmieri, K. Anderson, S. Morris, J. Morrison, and, T. Bronzert, "Pharmaceutical Drug Separations by HPCE: Practical Guidelines", J. Liq. Chromatogr. 15 (6&7) 961- 1021 (1992).

SELECTED LECTURES AS INVITED SPEAKER

- G. McLaughlin, J. Schibler, D. Fan, and D. Gragg, "Making Quantitative Capillary Electrophoresis Practical via Correction Software", The Pittsburgh Conference of Analytical Chemistry and Applied Spectroscopy, Chicago, IL (1996).
- G. McLaughlin, J. Schibler, D. Fan, and D. Gragg, "Improving Precision and Accuracy with Software-Based .Chromatography Signal Filtering", The Pittsburgh Conference of Analytical Chemistry and Applied Spectroscopy, Chicago, IL (1996).
- G. M. McLaughlin, A. Weston, and K. D. Hauffe, "Applications of Capillary Electrophoresis in the Industrial and Environmental Chemistry Laboratory", 8th Symposium on HPCE, FL (1996).
- G. M. McLaughlin "Intelligent Use of CE Instrumentation to Improve Methods Development Time, Speed of Analysis, Analyte Sensitivity, and Resolution of Biomolecules", 7th Frederick Conference on CE, Frederick, MD (1996).
- G. McLaughlin, J. Stillian, V. Baretto, M. Marucco, and M. Wojtisik, "Design and Optimization of Capillary Electrophoresis with Suppressed Conductivity Detection", The Pittsburgh Conference of Analytical Chemistry and Applied Spectroscopy, Chicago, IL (1996)
- G. McLaughlin, K. Srinivasan, J. Horvath, L. Bao, R. Rocklin, J. Stillian, and N. Avdalovic., "CE Coming to Age_ An Exciting Technology for the Separation of Biomolecules", 1st Latin American Symposium on Biomedical, Biopharmaceutical, and Industrial Applications of CE, Santiago, Chile (1995).
- G. M. McLaughlin, K. Srinivasan, J. Horvath, and M. l Bello, "Better CE Protein and Peptide Separations Through Better Chemistry- Part III, Physical Parameter Measurement and Reaction Monitoring", 6th Frederick Conference on CE, (1995).
- G. McLaughlin, R. McCormick, K. Anderson, and W. Ausserer,"CE: A Versatile and Powerful Tool for Protein, Peptide, and Amino Acid Chemistry _ Part I and Part II", Seminário sobre Análise de Aminoácidos em Alimentos e Outros Materiais Biológicos ITAL, Campaniris University, Sao Paulo, Brazil (1994).
- G. McLaughlin, "Application of HPLC for Carbohydrate Analysis", Conference on Analysis of Carbohydrates- University of Sao Paulo, Sao Paulo, Brazil (1994).
- G. McLaughlin, "Ion analysis and organic applications by CE", Conference on Analysis of Petroleum Products- Intevep, SA." Caracas, Venezuela (1994).
- G. M. McLaughlin, R.M. McCormick, D.C. Siu, K.Srinivasan, and K. W. Anderson, "Better CE Protein and Peptide Separations Through Better Chemistry ", 5th Frederick Conference on Capillary Electrophoresis, Frederick, MD (1994).
- G. McLaughlin and K. Anderson, "Optimization of Chiral Separations Using HPCE, 32nd Annual Eastern Analytical Symposium and Exposition, Somerset, NJ (1993).
- G. McLaughlin, K. Anderson, D. Siu, and A. Burquist, "High Performance Capillary Electrophoresis: A Powerful and Versatile Tool for Protein Chemistry", ISPPP'93, San Francisco, CA (1993).
- G. McLaughlin and K. Anderson, "Chiral CE Methods Optimization of Pharmaceutical Drugs", 4th Frederick Conference on Capillary Electrophoresis, Frederick, MD (1993).
- G. McLaughlin, M. Shifen, and K. Anderson, "Recent developments in Modern Capillary Electrophoresis", 5th Bejing Conference and Exhibition on Instrumental Analysis, Bejing, China (1993).
- G. McLaughlin, K. Ulfelder, K. Anderson, and H. Schwartz, "Methods Development Optimization for Pharmaceutical Drugs and Metabolites", Amer. Assoc. of Pharm. Sci. Meeting, Las Vegas, NV (1990).
- G. McLaughlin, R. Nelson, K. Anderson, and R. Palmieri, "HPCE Experimental Parameter Optimization for Analysis of Pharmaceutical Drugs and Metabolites", The Pittsburgh Conference of Analytical Chemistry and Applied Spectroscopy, Chicago, IL (1991).

Other Posters (more than 50 total at analytical chemistry meetings) on wide range of topics including: chiral CE methods development and optimization, CE data analysis software, protein and peptide separations, control of electrokinetic injection and mobility correction, pharmaceutical method development using CE, CE of physiological compounds using fluorescence detection, use of CE buffer modifiers for enhanced sensitivity, factors that Effect quantitation in HPCE, and numerous HPLC applications on a broad variety of analytes.

ADDITIONAL PUBLIC LECTURES:

- Delivered more than 50 HPLC valve and automation talks in universities, industrial accounts, trade shows, major OEM accounts and dealers for Rheodyne L.P. (1997-1999)
- Delivered more than 100 CE, IC, carbohydrate. DNA, and validation talks in universities, industrial accounts, trade shows, and dealers for Dionex Corporation and more than 250 HPLC, CE, LS, UV/Vis, Protein/Peptide, software/automation DNA, and AAA talks in universities, industrial accounts, trade shows, and dealers for Beckman Instruments.