

CURRICULUM VITAE

NOAH LERMER, PhD

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SUMMARY

Regulatory affairs scientist with expertise in clinical and molecular diagnostics, Six-Sigma practices, and reagent, assay, and instrumentation development. Over twenty years of experience in regulatory affairs, systems engineering, validation, development, and research groups of medical device manufacturers.

PROFESSIONAL EXPERIENCE

Director of Regulatory Affairs, New Products, Abbott Diagnostics, Abbott Park, IL, Sept 2022 to present

- Lead the new product development regulatory team.
- Oversee development and verification strategy of new clinical chemistry assays and immunoassays.
- Responsible for international and US FDA submissions for new assays.

Director of Regulatory Affairs, Immunoassays, Abbott Diagnostics, Abbott Park, IL, 2020 to Sept 2022

- Responsible for the Abbott Immunoassay portfolio.
- Supervise a team of regulatory leaders at four international and domestic sites.
- Manage technical files, international registrations for new products and on-market product modifications, emerging regulations (e.g. IVD-R, REACH), and product deficiencies.
- Oversee PMA product submissions to FDA: 30-day notices, 180-day supplements and annual reports.

Director of Regulatory Affairs, Clinical Chemistry, Abbott Diagnostics, Abbott Park, IL, 2015 to 2020

- Responsible for the Abbott Clinical Chemistry assays.
- Led the regulatory strategy and activities for the transfer of the clinical chemistry portfolio to a new instrument platform. Completed a US 510(k) submission for the instrument and representative assay (K170316). Obtained CLIA categorization and ability to market over 80 assays in the US following the Replacement Reagent policy. Supported world-wide product registrations.
- Managed a multisite regulatory team on new assay development, CAPA/on-market issues, and international regulatory submissions.

Director of Regulatory Affairs, Nanosphere, Northbrook, IL, 2014 to 2015

Sr. Manager of Regulatory Affairs, Nanosphere, Northbrook, IL, 2012 to 2014

- Primary FDA contact for 510(k) clearance of the Verigene Enteric Pathogen Nucleic Acid Test (K140083 and K142033) and the Verigene Respiratory Pathogens Flex Nucleic Acid Test (K143653).
- Led the submission of medical device recalls in compliance with 21CFR806.10.
- Responsible for support of international regulatory submissions (EU, MFDS, CFDA, PMDA).
- Provided regulatory guidance and review of validation studies supporting pre-market notification of molecular IVD tests.
- Key contributor to the preparation and clearance of 510(k)s for molecular diagnostic tests:

- Verigene Gram-Positive Blood Culture Nucleic Acid Test (K122514)
- Verigene *Clostridium difficile* Nucleic Acid Test (K123197)
- Verigene Gram Negative Blood Culture Nucleic Acid Test (K132843)
- Supported CE marking of IVD assays.

Process Improvement Consultant, Pacific Light Technologies, Portland, OR, 2011 to 2012

- Guided development activities (DOE's, process mapping, scale-up) to improve the synthesis and functional performance of fluorescent nanocrystals.

Professor of Chemistry, Okanagan College, Kelowna, BC, Canada 2011 to 2012

- Instructor of undergraduate chemistry.

Sr. Manager, Life Technologies, R&D / Manufacturing Sciences, Eugene, OR, 2010 to 2011

- Led a team of 4 Ph.D. and 2 M.A. level scientists.
- Led a process team to improve the synthesis of Cadmium Selenide quantum dot nanocrystals (Qdots) for use in next-generation DNA sequencing. Significantly increased the brightness (quantum yield, absorbance cross-section) and production stability of 655 and 705 nm emitting fluorescent quantum dots and Qdot conjugates.
- Project manager of a successful development effort to synthesize and scale-up Alexa Fluor organic dyes for use in DNA sequencing, with a significant (> \$4 million/yr) financial impact.

Principal Scientist, Roche Diagnostics, Technical Affairs Division, Indianapolis, IN, 2007 to 2009

- Project Leader for a new cleaning validation program in an FDA regulated environment.
- Directed studies into the sensitivity of clinical chemistry and immunodiagnostic assays to sources of contamination. These ranged from simple colorimetric assays and enzymatic assays for metabolite quantitation to microparticle assays for drug analysis and therapeutic drug monitoring.
- Led the analytical method development and validation of a Total Organic Carbon analyzer.
- Supervised a team of six scientists and engineers.
- Implemented changes in manufacturing operations to meet quality and cGMP requirements.

Staff Scientist, GE Healthcare / Amersham Biosciences, Tempe, Arizona, 2002 to 2007

Senior Scientist, Motorola Life Sciences (division purchased by Amersham), Tempe, Arizona 1999 to 2002

- Supervisor of a group of scientists, engineers, and technicians focused on improvement of mRNA expression assay performance, piezoelectric microdroplet generation, and DNA microarray production.
- Conducted DOE studies and implemented Six-Sigma practices for improved product quality and manufacturing throughput.
- Lead investigator for mRNA expression assay development on an automated hybridization system.
- Studied the role of fluid dynamics, molecular diffusion and reaction kinetics in the Codelink mRNA hybridization assay, and significantly reduced the assay target material requirements.
- Developed custom instrumentation for analysis of surface tension and electrostatic charge in microliter fluid volumes. Developed a process for hydrophobic coating of droplet dispense tips, giving improved microarray quality.

Scientist, Vysis Inc., Advanced Technology R&D Division, Downers Grove, Illinois, 1998 to 1999

- Developed techniques for the manufacture of microarrays of genomic DNA on chromium coated slides. Explored substrate surface modifications and developed a pneumatic non-contact robotic dispensing system.
- Assisted in the development and characterization of array-based comparative genomic hybridization (CGH) assays for detection of genetic aberrations.

Postdoctoral Fellow, Oak Ridge National Laboratory, Oak Ridge, Tennessee, 1995 to 1998

- Developed instrumentation for ultrasensitive laser induced fluorescence detection in electrostatically control microdroplets, using on-demand droplet generation, CW and pulsed Argon-ion laser excitation, and single-photon detection electronics.
 - Demonstrated single-molecule detection in streams of microdroplets.
 - Investigated cavity quantum electrodynamic effects in microdroplets.
- Supervisor: Dr. J.M. Ramsey.

Graduate Research Assistant, University of British Columbia, Vancouver, B.C., 1989 to 1995

- Investigated two-electron transitions in (e, 2e) electron scattering from atomic and molecular systems.
 - Designed, constructed and characterized a multichannel electron momentum spectrometer comprised of a vacuum system, electron beam and optics, energy analyzer, and position-sensitive detectors.
 - Implemented high-speed ECL and TTL nanosecond timing circuitry for coincidence event detection.
- Advisor: Professor C.E. Brion

EDUCATION

Doctor of Philosophy, Physical Chemistry, 1995

University of British Columbia, Vancouver, B.C., Canada

Dissertation: "Development and Application of a Momentum Dispersive Multichannel Electron Momentum Spectrometer"

Bachelor of Science (GPA 4.0), Chemistry, 1989

University of Lethbridge, Lethbridge, Alberta, Canada

HONORS AND AWARDS

- Abbott Laboratories RA Leadership Award, 2018
- Natural Science and Engineering Research Council (NSERC) Postdoctoral Fellowship, 1995-1997
- Bruker Spectrospin Scholarship in Chemistry, 1994
- NSERC Postgraduate Fellowship, 1989-1993
- Governor General's Silver Medal, University of Lethbridge, 1989
- Faculty of Arts and Science Gold Medal, University of Lethbridge, 1989

OTHER EXPERIENCE

- GE Six Sigma Green Belt Certified, 2006
- Training in Product Design Excellence, 2011
- Highly experienced with JMP statistical software
- Training in Analytical Biochemistry, Arizona State University (BCH 467), 2007

PUBLICATIONS

- “Homogeneous polymer-blend microspheres with tunable refractive index”, M. D. Barnes, C-Y. Kung, N. Lermer, K. Fukui, B. G. Sumpter, D. W. Noid, and J. U. Otaigbe, *Optics Letters*, **24**, 121-123 (1999).
- “Single-molecule analysis of ultradilute solutions using guided streams of 1- μ m water droplets”, C-Y. Kung, M. D. Barnes, N. Lermer, W. B. Whitten, and J. M. Ramsey, *Applied Optics*, **38**, 1481 - 1487 (1999).
- “Simulation of single-molecule photocount statistics in microdroplets”, S. C. Hill, M. D. Barnes, N. Lermer, W. B. Whitten, and J. M. Ramsey, *Analytical Chemistry*, **70**, 2964-2971 (1998).
- “Spatial photoselection of single molecules on the surface of spherical microcavities”, N. Lermer, M. D. Barnes, C-Y. Kung, W. B. Whitten, and J. M. Ramsey, *Optics Letters*, **23**, 951-953 (1998).
- “Probing single molecules in microcavities”, M. D. Barnes, N. Lermer, C-Y. Kung, W. B. Whitten, and J. M. Ramsey, *Proc. SPIE* **3270**, 182 (1988).
- “Confinement and manipulation of individual molecules in attoliter volumes” C-Y. Kung, M. D. Barnes, N. Lermer, W. B. Whitten, and J. M. Ramsey, *Analytical Chemistry*, **70**, 658 - 661 (1998).
- “Real-time observation of single-molecule fluorescence in microdroplet streams”, M. D. Barnes, N. Lermer, C-Y. Kung, W. B. Whitten, and J. M. Ramsey *Optics Letters*, **22**, 1265 - 1267 (1997).
- “High-Efficiency Molecular Counting in Solution: Single Molecule Detection Using Electrodynamically Focused Microdroplet Streams”, N. Lermer, M. D. Barnes, C-Y. Kung, W. B. Whitten, and J. M. Ramsey, *Analytical Chemistry*, **69**, 2115-2121 (1997).
- “A CCD-Based Approach to High-Precision Size and Refractive Index Determination of Levitated Microdroplets Using Fraunhofer Diffraction”, M. D. Barnes, N. Lermer, W. B. Whitten, J. M. Ramsey, *Review of Scientific Instruments*, **68**, 2287 - 2291 (1997).
- “Electron momentum spectroscopy of H₂ and D₂: Ionization to ground and excited final states”, N. Lermer, B.R. Todd, N.M. Cann, Y. Zheng, C. E. Brion, Z. Yang, E. R. Davidson, *Physical Review A*, **56**, 1393 (1997).
- “Electron Momentum Spectroscopy Experiments and Calculations for the Production of Excited States of He⁺ and H₂⁺”, N. Lermer, B.R. Todd, N.M. Cann, C.E. Brion, Y. Zheng, J.J. Neville, S. Chakravorty, E.R. Davidson, *Canadian Journal of Physics*, **74**, 748 (1996).
- “A High Sensitivity Momentum Dispersive Multichannel Electron Momentum Spectrometer for Studies in Experimental Quantum Chemistry”, B.R. Todd, N. Lermer, and C.E. Brion, *Review of Scientific Instruments*, **65**, 349-385 (1994).
- “Deconvolution of Fabry-Perot Spectra”, D.A. Naylor, N. Lermer, I. Furniss, *Infrared Physics*, **31**, 401-408 (1991).
- “Simulation of Finite Patches of Xenon on Graphite”, S. Suh, N. Lermer, S.F O’Shea, *Chemical Physics*, **129**, 273-284 (1989).

PATENTS

- “Preparation of Nanocrystals with Mixtures of Organic Ligands”, US Patent Application, J. Bartel, Y. Chen, N. Lermer, T. Carter, S. Sweeney, C. Teters, Filed 12/28/2010, Published 03/07/2019
- “Chamber Apparatus”, WO Patent 2008/002951, Kevin M. Reinhart, Solomon R. Pena, Roberta L. Druyor-Sanchez,,Noah Lermer, Tamma Kaysser-Kranich. Published 01/03/2008

SELECTED PRESENTATIONS

- “A Roadmap to Effective Cleaning Validation”, N. Lermer, T. Fugate, workshop presented at IVT Validation Week Conference, Philadelphia PA, Oct 21, 2008.
- “CodeLink™ multi-array bioarray system for focused and customized gene expression”, G. Kiser, R. Druyor-Sanchez, N. Lermer, S. Peña, T. Kaysser-Kranich, H. Samartzidou, presented at Molecular Medicine Tri-Conference, San Francisco, CA, Feb 22, 2006.
- “CodeLink™ Semi-Automated 16-Assay Bioarray Processing for Gene Expression Profiling”, R. Druyor-Sanchez, N. Lermer, G. Kiser, M. Ulepic, P. Kahn, R. Shippy, T. Sendera, H. Samartzidou, T. Kaysser-Kranich, presented at Chips to Hits 2005, Boston, MA, September 12, 2005.
- “CodeLink™ Custom Microarray Manufacturing Process Using Pre-Synthesized Oligos”, P. Kahn, B. Knipmeyer, N. Lermer, S. Pena, J. Fei, T. Wetteroth, N. Fuller, presented at Chips to Hits 2005, Boston, MA September 12, 2005.
- “Quantitation of sequence copy-number changes in genomic DNA through GenoSensor-based comparative genomic hybridization”, U.R. Müller, Y.P. Bao, D. Che, N. Lermer, W.R. Li, J. She, T. Ruffalo, A. Prokhorova, D. Lane, S. Seelig, presented at The Microarray Meeting (Nature Genetics), Scottsdale, AZ, September 23 1999.
- “Comparative Genomic Hybridization Arrays: Towards a “telomere chip”, C.M. Lese, X. Zhang, D. Pinkel, P. Bao, N. Lermer, D. Che, J. Shi, U. Müller, D.H. Ledbetter,” presented at Annual Meeting of the American Society of Human Genetics, San Francisco, CA, October 19, 1999.
- “Microarray based Detection of Single Copy Sequence Changes in Genomic DNA Advanced Technology”, Y. Bao, D. Che, N. Lermer, J. Shi, A. Prokhorova, U. Müller, presented at Annual Meeting of the American Society of Human Genetics, San Francisco, CA, October 19, 1999.
- “Attomolar detection limits in solution using microdroplet streams”, M. D. Barnes, N. Lermer, C-Y. Kung, W. B. Whitten, and J. M. Ramsey, presented at FACSS’98, Austin, TX, October 12, 1998 (invited).
- “Detection of Single Molecules in Microcavities”, N. Lermer, M. D. Barnes, C-Y. Kung, W. B. Whitten, and J. M. Ramsey, presented at American Chemistry Society National Meeting, Boston, MA, August 18, 1998.
- “Fluorescence lifetimes of oriented molecules in microspheres”, M. D. Barnes, C-Y. Kung, N. Lermer, W. B. Whitten, J. M. Ramsey, and S. Arnold, presented at Optical Society of America Spring Topical Meeting on Quantum Optoelectronics, Lake Tahoe, CA, March 20, 1997.
- “Electron correlation in He and H₂ studied by (e,2e) Spectroscopy”, N. Lermer, B. R. Todd, N. M. Cann, Y. Zheng, J. J. Neville, C. E. Brion, S. Chakravorty, E. R. Davidson, presented at The 8th International Congress of Quantum Chemistry, Prague, Czechoslovakia, July 1994.
- “Momentum profiles of the valence and core orbitals of atoms and small molecules measured with a high sensitivity momentum dispersive multichannel electron momentum spectrometer”, N. Lermer, B.R. Todd, C.E. Brion, presented at International Conference on the Physics of Electronic and Atomic Collisions ICPEAC XVIII, Aarhus, Denmark, July 1993.
- “The generalized van der Waals equation”, N. Lermer, S.F. O’Shea, The Third Chemical Congress of North America, Toronto, Ontario, 1988.