

GARY D. FLETCHER, Ph.D.

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R&D ENGINEERING PRODUCT DEVELOPMENT EXECUTIVE | IP EXPERT WITNESS

Entrepreneurial executive with expanding R&D roles in business, technology, and new product development leadership and execution, building and guiding teams in both Fortune 500 and startup companies. Yale Ph.D. in physics with proven record of leadership in creating innovative new businesses and products in healthcare, medical devices, diagnostics, life, materials, and optical sciences.

- **New Product Development and R&D Leadership** - Managing, planning, budgeting, financing, recruiting, and leading internal and external research and product development programs in medical device, diagnostics, optical devices, point-of-care and blood sample testing; championing technology development and product development stage-gate process implementation.
- **New Business and Technology Due Diligence** - Strategic assessment, customer discovery, ideation, product design, usability, technology assessment, business development, and marketing of new products and business opportunities.
- **Strategic Innovation** – Building and communicating business strategy and technology cases; identifying industry trends, technology trends, market trends, translating into business development, technology roadmaps, implementing product portfolio management.
- **IP Assessment & Development** - Defining intellectual property strategy, conducting due diligence, implementing a major IP portfolio in start-up new technology company, negotiating licensing agreements, Expert Witness, 23 issued patents.

PROFESSIONAL EXPERIENCE

RnDDx SOLUTIONS LLC, Media, PA (2015 – present)

Founder & Principal – Expert Witness in Medical Device Patent Litigation | Medical Device Business & Product Development Consultant

- Expert Witness in medical device patent litigation involving mechanical engineering, blood collection, blood separation, and blood preparation for clinical diagnostics, and cell and platelet therapy.
 - Successfully represented respondents as Expert Witness in International Trade Commission, Inv. No. 337-TA-1147, providing expert opinion on infringement, validity, and enforceability of US patent; included two declarations for Markman hearing, expert witness report, rebuttal expert report, 9-hour deposition, expert witness statement and rebuttal statement. The technical case was so strong that Complainant withdrew complaint and requested stay of hearing. (2019)
 - Retained as Expert Witness for the defendant in a patent dispute before the USDC in Delaware, involving four patents in the area of blood collection and processing. Reviewed drafts of Petition for IPR; informed defendant's counsel that arguments presented in draft

- IPR Petition were weak. I was not asked to prepare an IPR Expert Declaration, nor did I review the final IPR Petition. (2020)
- Retained as Expert Witness for the defendant in a patent infringement case before USDC in Delaware, involving two patents in the area of medical diagnostic testing fluidic systems and methods of sample processing, and point-of-care diagnostic fluidic systems and uses. I reviewed prior art, and the plaintiff dismissed their suit. (2020)
 - Retained as Expert Witness for the defendant in a patent infringement case before USDC in Western District of Texas, involving two patents in the area of preparing blood samples for analysis of circulating nucleic acids using chemical agents that inhibit blood cell lysis. I prepared a declaration supporting defendant's responsive claim construction brief, and I was deposed by plaintiff regarding the declaration. (2021)
 - Retained as Expert Consultant for counsel developing patent litigation strategy for client in glucose monitoring space. Prepared Expert Declarations for two filed IPR Petitions, IPR2022-00605 & IPR2022-00637, for Petitioner, Dexcom, Inc. The PTAB granted institution of IPR2022-00605 and denied institution of IPR2022-00637 (2022). Deposed regarding my expert declaration in IPR2022-00605. Prepared and deposed on my supplemental declaration in IPR2022-00605. Prepared opening expert report regarding patent invalidity in patent infringement case before USDC in Delaware, and I was deposed on my opening expert report regarding patent invalidity. (2023)
 - Retained as Expert Consultant for counsel developing patent litigation strategy for client selling lancets for glucose testing (2022). Prepared Expert Declarations in support of defendant's opening and responsive claim construction briefs in patent infringement case before USDC in Central District of California, Western Division.
- Expert video commentary for episode of Advancements TV with Ted Danson, discussing engineering challenges in developing comprehensive point-of-care testing systems, for point-of-care testing diagnostic company. <https://vimeo.com/508612748#t=2m15s> to 02m48s.
 - Consultant to startup medical device company, providing product development and product optimization of chemical attributes of blood separation devices.
 - Consultant advisor to startup medical device company, providing business & product development expertise and competitive analysis in blood separation devices for point-of-care testing.
 - Consultant to startup medical diagnostics company, providing technical due diligence, product design, development, and testing of blood sampling methods.
 - Consultant to startup medical device company developing blood microcollection device and diagnostics, providing expertise in the field of blood diagnostic products and services.
 - Consultant to startup medical device company developing blood collection device, providing project management and product advisory services.
 - Consultant to Fortune 100 Healthcare Provider, delivered Point-of-Care-Testing Growth Opportunity Assessment and Emerging Technology Landscape, with actionable targets.
 - Lean Startup Coach within Program Management Office of Fortune 1000 data analytics company, developing repeatable Lean Startup process around Customer Discovery and Validation, training materials for workshops.
 - Mentored four early stage companies, building business models, plans, and funding presentations.
 - Guided technology companies through Lean Startup, Business Model Canvas, and national NSF I-Corps business development efforts.
 - Conducted customer discovery, built business models and case, developed investor presentations, performed due diligence, set up operations, and initiated licensing negotiations with academic inventors, for U. of Pennsylvania life sciences startup developing super-resolution fluorescent microscopy for cell analysis.
 - Maven consultations
 - Phone consultation for confidential entity regarding emerging companies and technologies in in vitro diagnostics and point-of-care diagnostics and needs for outsourced contract design, development, and manufacturing.

- Phone consultation for confidential entity regarding cell therapy workflow, specifically, the upstream cell isolation, characterization, and activation portion of the workflow.
- Guidepoint consultations
 - Phone consultation for confidential entity regarding remote blood collection devices.
 - Phone consultation for confidential entity regarding biospecimen users and purchasers.
 - Phone consultation for confidential entity regarding remote blood collection space.
 - Phone consultations for confidential entity regarding medical device supply chain and product development.
 - Phone consultation for confidential entity regarding microfluidics and medical devices.
 - Phone consultation for confidential entity regarding healthcare in vitro diagnostics.
 - Survey for confidential entity regarding medical technology OEMs.
- Gerson Lehrman Group consultations
 - Completed survey on MedTech Services for confidential entity
- Reviewer for NSF SBIR/STTR Phase I and Phase II proposals

RAVEN BIOMATERIALS LLC, Pennington, NJ (2020 – present)

Founder -- biotech startup developing greatly improved cell separation / enrichment processes for cell therapy manufacturing, cell-based diagnostics, protein and vaccine manufacturing.

- Conducted customer discovery, built business models and case, developed investor presentations, performed due diligence, set up laboratory and operations, conducted proof of feasibility experiments, developed patent strategy.

BECTON DICKINSON, Franklin Lakes, NJ (2004 – 2014)

BD is a global medical technology company with products in drug delivery, life sciences tools, and disease management in diabetes, women's health and cancer, and infection control.

Leader, Technology Innovation, R&D (2010 – 9/2014)

Responsible for identifying adjacent business opportunities, building compelling business cases, and leading product development in new business spaces. Moved into this role to address critical need to identify higher growth business opportunities for low-single-digit growth business.

- Developed and executed two adjacent market business plans and technology strategies, achieving \$2M internal investment for medical device technology development, in: 1) Tissue collection and preservation for improved cancer diagnostics; and 2) Point of care blood collection and diagnostic testing, managing consultants and partnerships in microfluidics technologies.
- Led product development of first tissue collection product to manufacturing release.
- Initiated customer discovery, developed Key Opinion Leader relationships with surgical and clinical pathologists and Point of Care Coordinators to understand cancer diagnostic and blood testing needs. Set up expert focus group panels at international conferences.

Technology Leader, Advanced Technology, R&D (2006 – 2010)

Moved into new innovation strategy role; charged with identifying and leading technology and product development of new-to-business concepts to reinvigorate core business.

- Developed business unit technology and innovation strategy.
- Developed and led technology scouting, due diligence, and innovation processes for new medical devices.
- Completed "deep dive" technology assessment in blood fractionation technologies, leveraging and contracting academic experts in materials and fluidics; led development effort assessing primary blood separation technologies. Effort to develop rapid noncentrifugal blood separation challenging and continues to present.

Director, Core Technologies, R&D (2004 – 2006)

Based on interest and experience in medical device product development, hired at Director level into Preanalytical [Vacutainer] business at BD to bring innovative new product development leadership and vision to legacy business.

- Reporting to VP R&D, led 5-member technology development group, executing technology strategy to support medical device blood specimen collection and preservation business.
- Built team key technical capabilities to support innovation of current and next generation products; interfacing R&D with clinical affairs, regulatory, Program Management Office.
- Led R&D teams resolving manufacturing problems in core plastic blood collection products, identified and solved vendor plastic materials changes, material coatings changes, manufacturing process changes.
- Led Business Unit R&D rollout of Technology Development stage-gate process, initiated prior to formal New Product Development stage-gate process, to reduce technology risk in New Product Development.
- Taught, on ongoing basis, 2-day BD University course on “Managing for Performance Excellence” to managers.

SARNOFF CORPORATION, Princeton, NJ (2001 – 2004)

Sarnoff [previously RCA Laboratories, now part of SRI] was a contract research laboratory executing both government and commercial research and new product development contracts in hardware, software, image analysis, and market analysis. Hired to expand Sarnoff’s commercial medical device and diagnostic product development contract business, and to create patentable internal product development capabilities which could be licensed or spun-out as startup companies.

Technical Manager, Healthcare Products (2001 – 2004)

- Reporting to Technical Director, directed 12-member multidisciplinary group as product development program manager of new painless minimally invasive blood glucose monitor; achieved successful spinout as medical device startup. Managed 8-month, \$2M budget.
- Functionally manage 7-member scientific and engineering staff involved in multiple medical device product development contracts.
- As Co-Principal Investigator, prepared successful Department of Homeland Security research grant funding product development for rapid detection of airborne biological weapons, based on electrostatic particle collection and Raman spectroscopy detection.

CYTOMETRICS, INC., Philadelphia, PA (1996 – 2001)

Cytometrics was a medical imaging and diagnostic startup commercializing a platform miniature optical reflectance microscope for human in vivo assessment of circulation perfusion and noninvasive measurement of whole blood count parameters, using hemoglobin optical absorption spectroscopy.

Vice President, Advanced Technology (1998 – 2001)

Asked to lead innovative team developing additional clinical applications for the platform optical imaging instrument in circulation perfusion assessment.

- Reporting to CEO, led team of five scientists evaluating technical feasibility of new product concepts, identified new applications of core technology, and assessed competitive technology.
- Managed the development of a novel noninvasive technology platform, achieving product introduction 18 months after concept definition.
- Led research, medical imaging analysis, and clinical groups, demonstrating clinical efficacy of noninvasive blood analysis and microcirculation imaging instrument, generating \$41M in capital for continued development.
- Managed company intellectual property portfolio, resulting in filing of 14 major patent applications.

- Developed corporate R&D strategy. Negotiated external university research contracts and funding, resulting in 10 study reports and 8 manuscripts submitted for publication. Directed technical consultants.
- Collaborated in the ISO implementation and manufacturing start-up.

Vice President, Engineering (1996 – 1998)

Hired as employee #6 to lead product development and build the product development team for the core noninvasive WBC [whole blood count] application.

- Reporting to CEO, led optical, mechanical, electrical, software image analysis, and clinical team, and developed product prototypes.
- Built a high-performance team of scientists and engineers with a driven-to-execute innovation culture
- Led research, development, and clinical testing of 4 generations of prototype video reflectance microscopes for noninvasive blood analysis, resulting in performance improvements and sensor miniaturization, which generated \$10M in angel investment for continued development.

BIOCONTROL TECHNOLOGY, INC., Indiana, PA (1996)

Biocontrol Technology was established medical device company developing noninvasive glucose measurement based in near infrared skin reflectance spectroscopy. Hired to lead product development.

Manager, Engineering (1996)

- Reporting to President, managed 25 electrical, mechanical, optical, and software engineers developing noninvasive glucose sensor utilizing diffuse reflectance near-infrared spectroscopy.
- Led cross-functional teams to refocus technical effort, resulting in greater interaction between engineering, research, data analysis, clinical, and manufacturing departments and faster sensor performance improvements.

ANDROS, INC., Berkeley, CA (1993-1996)

Andros, Inc. was an OEM supplier of gas analysis instruments based on infrared absorption spectroscopy to the automotive and medical device markets. I was hired to expand development of new anesthetic and respiratory gas analyzers.

Senior Physicist and Manager, Advanced R&D (1993-1996)

- Reporting to VP Engineering, managed development of nondispersive infrared [NDIR] absorption anesthetic and respiratory gas analyzers, resulting in new OEM agreements with medical patient monitoring companies.
- Assessed and tested biomedical and automotive sensor technologies, including low cost gas analyzer based on quenching of fluorescent radiation excited by blue LEDs, and portable gas analyzer based on solid-state IR sources and nonimaging IR optics.

MEASUREX CORPORATION, Cupertino, CA (1991-1993)

Measurex Corporation provided process control sensors and instrumentation for the pulp and paper, and plastics industries. I was hired to develop and commercialize new infrared and x-ray sensor technology.

Staff Physicist (1991-1993)

- Reporting to Manager of Sensor Engineering, developed, field tested, and released to manufacturing new IR moisture sensor for paper industry use, requiring fewer calibrations and generating greater customer acceptance.
- Researched and led customer acceptance tests of 10 and 30 keV x-ray sensors as thickness monitors, generating new sales in aluminum industry.

LAWRENCE LIVERMORE NATIONAL LABORATORY, Livermore, CA (1986-1991)

LLNL is a Department of Energy national lab dedicated to research and development of energy, weapons, laser, defense, and biological technologies. I was hired into the Physics Department to understand and develop rapid laser and x-ray technologies.

Physicist (1986-1991)

- Designed and fielded subnanosecond time-resolving crystal x-ray spectrometers to measure temperature and density of laser-produced plasmas, which provided data for modeling and development of x-ray lasers.
- Formulated new nuclear test experiment, involving 2-dimensional x-ray imaging.

UNIVERSITY OF VIRGINIA, Charlottesville, VA (1983-1986)

Assistant Professor of Physics and Research Associate in Physics (1983-1986)

- Reporting to Prof. Daniel Larson, mentored seven graduate students, resulting in 6 peer-reviewed publications.
- Designed and executed precision measurements in high field nuclear magnetic resonance spectroscopy of laser optically pumped atomic rubidium and laser photodetachment studies of atomic negative ions confined in Penning trap, discovering new effects.
- Taught undergraduate introductory physics laboratory course.

YALE UNIVERSITY, New Haven, CT (1976-1983)

Research Assistant in Physics (1976-1983)

- Under the direction of Prof. Vernon Hughes and Prof. Michael Lubell, upgraded experimental lab, measured spin dependence in electron-hydrogen atom collisions, wrote dissertation and 4 peer-reviewed publications.

EDUCATION

Doctor of Philosophy in Physics, Yale University, New Haven, CT, 1983

Master of Philosophy in Physics, Yale University, New Haven, CT, 1978

Bachelor of Arts in Physics and Mathematics, DePauw University, Greencastle, IN, 1976

HONORS

1999 -- Cytometrics Founders' Award, "for outstanding contributions to the furtherance of Cytometrics' mission."

1975 -- Elected to Phi Beta Kappa, with 4.0 GPA

PROFESSIONAL ACTIVITIES

Member, American Association for Clinical Chemistry (AACC)

Member, American Chemical Society (ACS)

Member, Biomedical Engineering Society (BMES)

PUBLICATIONS

1. G.D. Fletcher et al., "Measurement of Spin-Exchange Effects in Electron-Hydrogen Collisions: 90° Elastic Scattering from 4 to 30 eV," Phys. Rev. Lett. **48**, 1671, (1982).

2. T. J. Gay, G. D. Fletcher, M. J. Alguard, V. W. Hughes, P. F. Wainwright, and M. S. Lubell, "Measurement of spin-exchange effects in electron-hydrogen collisions: Further studies of impact ionization," Phys. Rev. **A 26**, 3664 (1982).
3. G.D. Fletcher et al., "Experimental study of spin-exchange effects in elastic and ionizing collisions of polarized electrons with polarized hydrogen atoms," Phys. Rev. **A 31**, 2854 (1985).
4. G. D. Fletcher, T. J. Gay, and M. S. Lubell, "New insights into Mott-scattering electron polarimetry," Phys. Rev. **A 34**, 911 (1986).
5. S.J. Lipson, G.D. Fletcher, and D.J. Larson, "Observation of Quadrupole and Dipole Diamagnetic Shifts in Atomic Ground State Hyperfine Structure, Phys. Rev. Lett. **57**, 567 (1986).
6. R.E. Elmquist, C.J. Edge, G.D. Fletcher, and D.J. Larson, "Observation of Resolved Zeeman Thresholds in Photodetachment in a Magnetic Field," Phys. Rev. Lett. **58**, 333 (1987).
7. G.D. Fletcher, S.J. Lipson, and D.J. Larson, "Observation of a Magnetic Field Dependent g-Factor Ratio," Phys. Rev. Lett. **58**, 2535 (1987).
8. R. Trainham, G.D. Fletcher, N.B. Mansour, and D.J. Larson, "Photodetachment Threshold Shift in a Strong Laser Field," Phys. Rev. Lett. **59**, 2291 (1987).
9. N. B. Mansour, G. D. Fletcher, and D. J. Larson, "Laser photodetachment spectroscopy of S- near the D1 threshold," Phys. Rev. A **35**, 2321 (1987).
10. R Trainham, G D Fletcher and D J Larson, "One- and two-photon detachment of the negative chlorine ion," Journal of Physics B **20**, L777 (1987).

CONFERENCE ORGANIZER

- **D2H2 [Distributed Diagnosis and Home Healthcare] Conference**, Program Committee, Session Organizer and Session Chair, Chair—Home Devices, April 2006.
- **NIST Cross-Industry Issues in Nanomanufacturing**. Workshop Organizer, Plenary Speaker, and Report Co-author; Organized and chaired session – "Surfaces, Interfaces, and Non-bonded Interactions of Nanomaterials." Plenary Speaker – "Pharmaceuticals and Medical Devices." May 2008. http://www.nist.gov/mml/upload/nano_small_web-4.pdf

CONFERENCE PROCEEDINGS

1. Rusty Trainham, G. D. Fletcher and D. J. Larson, "Laser photodetachment spectroscopy of the negative chlorine ion," AIP Conf. Proc. **146**, 385 (1986); <http://dx.doi.org/10.1063/1.35750>
2. O. Genzel-Boroviczeny, A. G. Harris, G. D. Fletcher, and F. Christ, "Non-invasive determination of hemoglobin in neonates with orthogonal polarization spectral (ops) imaging," Pediatric Research **47**(4), 332A–332A (2000). Part 2 Suppl. S.

COINVENTOR ON GRANTED PATENTS

EP1983891B1	System and method for blood collection devices
EP2986220B1	Biological fluid collection device and biological fluid collection and testing system

EP2986221B1	Biological fluid sampling device
EP2986222B1	Biological fluid sampling transfer device and biological fluid separation and testing system
EP2986223B1	Blood sampling transfer device
EP2986383B1	Biological fluid separation device and biological fluid separation and testing system
EP2986384B1	Biological fluid sampling transfer device and biological fluid separation and testing system
EP3169236B1	Lancet device with first-drop removal
EP3513727B1	Biological fluid sampling device
EP3598944B1	Lancet device with first-drop removal
US 9,380,972	Biological Fluid Collection Device and Biological Fluid Collection and Testing System
US 9,380,973	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US 9,408,568	Biological Fluid Sampling Device
US 9,549,700	Biological Fluid Sampling Transfer Device and Biological Fluid Separation and Testing System
US 9,724,690	Blood Collection Device, Method, and System for Using the Same
US 9,743,876	Lancet Device with First-Drop Removal
US 9,808,192	Biological fluid sampling transfer device and biological fluid separation and testing system
US 10,154,808	Biological fluid separation device and biological fluid separation and testing system
US 10,194,851	Blood sampling transfer device and blood separation and testing system
US 10,342,471	Biological fluid transfer device and biological fluid sampling system
US 10,682,085	Lancet Device with First-Drop Removal
US 10,791,975	Biological fluid transfer device and biological fluid sampling system
US 10,925,530	Blood Sampling Transfer Device