

Exponent®
Engineering & Scientific Consulting


# Alexis Sauer-Budge, Ph.D.

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## Professional Profile

Alexis Sauer-Budge, Ph.D., is a principal scientist in Exponent's Biomedical Engineering & Sciences practice, focusing on in vitro diagnostics (IVDs), microbiology, biological contamination investigations, and contamination control for regulated products. Her expertise includes IVD technical due diligence, microbiological contamination consulting, cleaning and disinfection of reusable medical devices, microbial risk assessment, biological asset loss investigations, and expert support for litigation and insurance matters.

Dr. Sauer-Budge helps clients identify biological materials, determine their source and persistence, evaluate contamination and product quality risks, and address challenges involving pharmaceuticals, medical devices, biotechnology products, and consumer products. Her expertise is founded on interdisciplinary training in chemistry and biophysics and more than 25 years of experience applying microbiology, molecular biology, and analytical science to real-world product and manufacturing challenges.

Throughout her career, Dr. Sauer-Budge has led multidisciplinary teams of scientists and engineers in the development, evaluation, and investigation of diagnostic technologies, biomedical products, and manufacturing processes. She specializes in determining what biological materials are present, where they originated, how they behave in complex environments, and how they interact with products, surfaces, and materials. Her understanding of molecular structure-function relationships, microbial proliferation and persistence, contamination pathways, analytical characterization, and product design enables clients to address challenges involving diagnostics, contamination control, product quality, cleaning and disinfection, and biological risk.

Before joining Exponent, Dr. Sauer-Budge led the Biomedical and Biotechnology Group at the Fraunhofer Center for Manufacturing Innovation at Boston University, where she directed multidisciplinary teams of scientists and engineers developing diagnostic technologies, medical devices, laboratory automation systems, and biomedical instrumentation. She managed translational research programs spanning early-stage technology development through scale-up, manufacturing, and FDA readiness, helping clients bridge the gap between academic innovation and commercial products.

Earlier in her career, she worked at BioScale on the commercialization of a BioMEMS sensing platform for clinical diagnostics and food safety applications. Her doctoral research at Harvard University focused on single-molecule DNA sequencing technologies that later contributed to the development of nanopore sequencing platforms.

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## In Vitro Diagnostics Consulting

Dr. Sauer-Budge provides consulting support across the total product lifecycle for in vitro diagnostics (IVDs), from early-stage technology development through regulatory submission, commercialization, and postmarket investigations. Her experience encompasses molecular diagnostics, immunoassays, microbiology assays, sample preparation technologies, microfluidic systems, laboratory instrumentation, and bioanalytical methods.

Dr. Sauer-Budge assists clients with technical due diligence for acquisitions and investments, assay development and optimization, design and manufacturing investigations, regulatory strategy, and diagnostic test failure analysis. Drawing upon her background in chemistry, biophysics, and molecular biology, she evaluates the scientific principles underlying assay performance, including biomolecular interactions, surface chemistry, analytical sensitivity and specificity, and system-level design considerations. She works with medical device, biotechnology, and diagnostic companies to address technical, quality, regulatory, and litigation-related questions involving diagnostic technologies.

## Microbiology, Biological Materials & Contamination Investigations

Dr. Sauer-Budge assists clients in investigating microbiological contamination events involving pharmaceuticals, medical devices, biotechnology products, consumer products, and laboratory environments. She helps organizations identify contaminating organisms and biological materials, determine contamination sources and transmission pathways, evaluate the extent and significance of contamination, and assess potential impacts on product quality, safety, and regulatory compliance.

Dr. Sauer-Budge's experience includes investigations involving bacteria, fungi, viruses, biofilms, mold, and human-derived biological materials, as well as environmental monitoring excursions, contamination control failures, and unexpected biological residues. Dr. Sauer-Budge applies microbiological, molecular biological, and analytical techniques to support source attribution, root-cause investigations, microbial risk assessments, and scientifically defensible decision-making in quality, regulatory, litigation, and insurance matters.

## Cleaning, Disinfection & Contamination Control

Dr. Sauer-Budge helps clients evaluate strategies to prevent, control, and mitigate microbiological contamination in regulated products and manufacturing environments. Her work includes scientific assessment of cleaning and disinfection chemistries, contamination control programs, reusable and reprocessed medical device reprocessing, remediation approaches, and microbial risk assessments.

Drawing upon her expertise in microbiology, chemistry, and biological-material interactions, Dr. Sauer-Budge evaluates factors that influence microbial survival, persistence, and removal, including biofilms, surface properties, disinfectant mechanisms, environmental conditions, and use-related factors. She helps clients assess whether cleaning and disinfection approaches are appropriate for their intended application, investigate contamination control failures, evaluate microbial risks, and develop scientifically supported contamination mitigation strategies for pharmaceuticals, medical devices, biotechnology products, and consumer products.

## Microbial-Material Interactions & Antimicrobial Technologies

Dr. Sauer-Budge assists clients in understanding how microorganisms interact with materials, surfaces, products, and built environments. Her expertise draws on training in chemistry and biophysics, including the molecular and surface interactions that influence microbial adhesion, biofouling, persistence, survival, and removal. She evaluates factors affecting microbial behavior on materials, including surface chemistry, material composition, environmental conditions, and the presence of antimicrobial coatings or treatments.

Dr. Sauer-Budge supports the development, assessment, and investigation of antimicrobial technologies, contamination-resistant materials, and products intended to reduce microbial growth, persistence, or transmission. Her work integrates findings from laboratory studies, scientific literature, and real-world evidence to assess how experimental observations translate to practical use environments, recognizing that laboratory models cannot fully replicate the complexity and variability of real-world conditions. She helps clients understand the scientific basis for microbial persistence, evaluate the strengths and limitations of antimicrobial strategies, and address technical, regulatory, quality, and litigation-related questions involving medical devices, pharmaceuticals, consumer products, and biotechnology applications.

**Technical Investigations, Insurance & Litigation Support**

Dr. Sauer-Budge assists clients in investigating biological incidents, product quality issues, contamination events, and losses involving biological materials. She conducts root-cause investigations, evaluates scientific evidence, assesses causation, interprets laboratory findings, and helps organizations understand the implications of biological data for products, manufacturing operations, research activities, and commercial losses.

Dr. Sauer-Budge's experience includes investigations involving microbial contamination, biological materials, research laboratory incidents, freezer failures, and damage to biologics, drugs, vaccines, and other temperature-sensitive materials, as well as technical consulting in matters involving medical devices, diagnostics, and consumer products. Drawing upon her expertise in microbiology, molecular biology, chemistry, contamination investigations, and microbial risk assessment, she helps clients determine contamination sources, assess biological damage, evaluate competing technical explanations, and establish the most scientifically supported root cause of an event for regulatory, insurance, and litigation-related proceedings.

## Academic Credentials & Professional Honors

Ph.D., Biophysics, Harvard University, 2002

M.S., Chemistry, Stanford University, 1997

B.S., Chemistry, Stanford University, 1996

## Academic Appointments

Adjunct Associate Professor, Biomedical Engineering, Boston University, 2017-2018

Adjunct Research Assistant Professor, Biomedical Engineering, Boston University, 2009-2017

## Prior Experience

Senior Research Scientist, Fraunhofer Center for Manufacturing Innovation, 2007-2017

Director of Microbial Assay Development, BioScale, Inc., 2005-2007

Senior Scientist, BioScale, Inc, 2003-2005

Consultant, Eagle Research and Development, 2000-2003

Research Assistant, Hauser Chemical Research, 1993-1995

## Professional Affiliations

Association for Diagnostics & Laboratory Medicine (ADLM)

Northeast Branch - American Society for Microbiology (ASM)

## Patents

US11331659B2 “Pipetting Devices and Methods of Using the Same.” 5/17/2022, A. Sauer-Budge, H. Wirz, S.J. Brookfield, N. Pollock, R. Janzen.

US11337586B2 “Retractable endoscopic suction tube” 5/24/2022, A. Devaiah, A. Sharon, A. Sauer-Budge, H. Wirz, Y. Yang, S. Van Der Kemp, D. Echeverria

US9611501B2 "Method and Device for Rapid Detection of Bacterial Antibiotic Resistance/Susceptibility" 4/4/2017, A. Sauer-Budge, A. Sharon, M. Kalashnikov, H. Wirz.

US9046483B2 "Characterization of individual polymer molecules based on monomer-interface interactions." 6/2/2015, T. Denison, A. Sauer-Budge, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

US8986528B2 "Characterization of individual polymer molecules based on monomer-interface interactions." 3/24/2015, T. Denison, A. Sauer-Budge, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

US9199250B2 "Disposable Separator/Concentrator Device and Method of Use." 12/1/2015, A. Sharon, A. Sauer-Budge, A. Size, H. Wirz.

US8227261B2 "Methods and apparatus for assay measurements." 7/24/2012, B. Masters, M. Miller, A. Sauer-Budge.

US7632638B2 "Methods and apparatus for detecting viruses using an acoustic device." 12/15/2009, A. Sauer-Budge, B. Masters, M. Miller, M. Lundstrom.

US7629137B2 "Methods and apparatus for detecting bacteria using an acoustic device." 12/8/2009, A. Sauer-Budge, E. Fitch, B. Masters, M. Miller, M. Lundstrom.

US6673615B2 "Characterization of individual polymer molecules based on monomer-interface interactions." 1/6/2004, T. Denison, A. Sauer, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

US6362002B1 “Characterization of individual polymer molecules based on monomer-interface interactions." 3/26/2002, T. Denison, A. Sauer, J. Golovchenko, A. Meller, E. Brandin, D. Branton.

## Publications

Coombs, C. Rodriguez-Quijada, J.O. Clevenger, A.F. Sauer-Budge. 2023. Current Understanding of Potential Linkages between Biocide Tolerance and Antibiotic Cross-Resistance. Microorganisms 11(8): 2000.

Spink, S., F. Teng, V. Pera, H. Peterson, T. Cormier, A. Sauer-Budge, D. Chargin, S. Brookfield, A. Eggebrecht, N. Y. Ko, and D. Roblyer. 2021. High optode-density wearable diffuse optical probe for monitoring paced breathing hemodynamics in breast tissue. J Biomed Opt 26(6).

Wirz, H., S. Teufelhart, C. McBeth, R. Gyurko, S. Dibart, and A. Sauer-Budge. 2020. Design and ex vivo characterization of narrow implants with custom piezo□activated osteotomy for patients with substantial bone loss. Clinical and Experimental Dental Research. 6(3): 336-344.

Sauer-Budge, A. F. 2019. New technologies for the rapid identification of drug-resistant bacteria. TechConnect Briefs:310-313.

Gladman, A. S., M. Garcia-Leiner, and A. F. Sauer-Budge. 2019. Emerging polymeric materials in additive manufacturing for use in biomedical applications. 6(1):1-20.

Gutermuth, A., J. Maassen, E. Harnisch, D. Kuhlen, A. Sauer-Budge, C. Skazik-Voogt, and K. Engelmann. 2019. Descemet's Membrane Biomimetic Microtopography Differentiates Human Mesenchymal Stem Cells Into Corneal Endothelial-Like Cells. Cornea 38(1):110-119.

Fernandez-Carballo, B. L., C. McBeth, I. McGuiness, M. Kalashnikov, C. Baum, S. Borros, A. Sharon, and A. F. Sauer-Budge. 2018. Continuous-flow, microfluidic, qRT-PCR system for RNA virus detection. Anal Bioanal Chem 410(1):33-43.

Ganser, P., C. Baum, D. Chargin, A. F. Sauer-Budge, and A. Sharon. 2018. A practical approach for the optimization of channel integrity in the sealing of shallow microfluidic devices made from cyclic olefin polymer. Biomed Microdevices 20(2):24.

Kalashnikov, M., J. C. Lee, and A. F. Sauer-Budge. 2018. Optimization of Stress-Based Microfluidic Testing for Methicillin Resistance in *Staphylococcusaureus* Strains. Diagnostics (Basel) 8(2).

Sauer-Budge, A. F., S. J. Brookfield, R. Janzen, S. McGray, A. Boardman, H. Wirz, and N. R. Pollock. 2017. A novel device for collecting and dispensing fingerstick blood for point of care testing. PLoS One 12(8):e0183625.

Kalashnikov, M., M. Mueller, C. McBeth, J. C. Lee, J. Campbell, A. Sharon, and A. F. Sauer-Budge. 2017. Rapid phenotypic stress-based microfluidic antibiotic susceptibility testing of Gram-negative clinical isolates. Sci Rep 7(1):8031.

McBeth, C., A. Gutermuth, J. Ochs, A. Sharon, and A. F. Sauer-Budge. 2017. Automated Tissue Dissociation for Rapid Extraction of Viable Cells. Procedia CIRP 65:88-92.

Kulik, M., J. Ochs, N. König, C. McBeth, A. Sauer-Budge, A. Sharon, and R. Schmitt. 2017. Parallelization in Automated Stem Cell Culture. Procedia CIRP 65:242-247.

McBeth, C., J. Lauer, M. Ottersbach, J. Campbell, A. Sharon, and A. F. Sauer-Budge. 2017. 3D bioprinting of GelMA scaffolds triggers mineral deposition by primary human osteoblasts. Biofabrication 9(1):015009.

Teng, F., T. Cormier, A. Sauer-Budge, R. Chaudhury, V. Pera, R. Istfan, D. Chargin, S. Brookfield, N. Y. Ko, and D. M. Roblyer. 2017. Wearable near-infrared optical probe for continuous monitoring during breast cancer neoadjuvant chemotherapy infusions. J Biomed Opt 22(1):14001.

Campbell, J., C. McBeth, M. Kalashnikov, A. K. Boardman, A. Sharon, and A. F. Sauer-Budge. 2016. Microfluidic advances in phenotypic antibiotic susceptibility testing. Biomed Microdevices 18(6):103.

Boardman, A. K., W. S. Wong, W. R. Premasiri, L. D. Ziegler, J. C. Lee, M. Miljkovic, C. M. Klapperich, A. Sharon, and A. F. Sauer-Budge. 2016. Rapid Detection of Bacteria from Blood with Surface-Enhanced Raman Spectroscopy. Anal Chem 88(16):8026-8035.

Premasiri, W. R., J. C. Lee, A. Sauer-Budge, R. Theberge, C. E. Costello, and L. D. Ziegler. 2016. The biochemical origins of the surface-enhanced Raman spectra of bacteria: a metabolomics profiling by SERS. Anal Bioanal Chem 408(17):4631-4647.

Fernandez-Carballo, B. L., I. McGuiness, C. McBeth, M. Kalashnikov, S. Borros, A. Sharon, and A. F. Sauer-Budge. 2016. Low-cost, real-time, continuous flow PCR system for pathogen detection. Biomed

Microdevices 18(2):34.

Keenan, M., C. Howard, T. Tate, I. McGuiness, A. Sauer-Budge, J. Black, U. Utzinger, and J. K. Barton. 2016. Design of an everting balloon to deploy a microendoscope to the fallopian tubes. SPIE BiOS: Photonic Therapeutics and Diagnostics XII. SPIE.

Teng, F., T. Cormier, A. Sauer-Budge, and D. M. Roblyer. 2016. A wearable optical device for continuous monitoring during neoadjuvant chemotherapy infusions. SPIE BiOS: Optical Diagnostics and Sensing XVI: Toward Point-of-Care Diagnostics. SPIE.

Campbell, J., N. Pollock, A. Sharon, and A. F. Sauer-Budge. 2015. Development of an automated on-chip bead-based ELISA platform. Anal Methods 7(19):8472-8477.

Campbell, J., I. McGuinness, H. Wirz, A. Sharon, and A. F. Sauer-Budge. 2015. Multimaterial and Multiscale Three-Dimensional Bioprinter. Journal of Nanotechnology in Engineering and Medicine 6(2):021005-021007.

Boardman, A. K., J. Campbell, H. Wirz, A. Sharon, and A. F. Sauer-Budge. 2015. Rapid microbial sample preparation from blood using a novel concentration device. PLoS One 10(2):e0116837.

Rosen, J. E., A. Size, Y. Yang, A. Sharon, and A. Sauer-Budge. 2015. Artificial hand for minimally invasive surgery: design and testing of initial prototype. Surg Endosc 29(1):61-67.

Briggs, J. C., O. A'amar, I. Bigio, J. E. Rosen, S. L. Lee, A. Sharon, and A. F. Sauer-Budge. 2014. Integrated Device for in Vivo Fine Needle Aspiration Biopsy and Elastic Scattering Spectroscopy in Preoperative Thyroid Nodules. Journal of Medical Devices 8(2):021003-021006.

Kalashnikov, M., J. Campbell, J. C. Lee, A. Sharon, and A. F. Sauer-Budge. 2014. Stress-induced antibiotic susceptibility testing on a chip. J Vis Exp (83):e50828.

Byrnes, S., A. Fan, J. Trueb, F. Jareczek, M. Mazzochette, A. Sharon, A. F. Sauer-Budge, and C. M. Klapperich. 2013. A Portable, Pressure Driven, Room Temperature Nucleic Acid Extraction and Storage System for Point of Care Molecular Diagnostics. Anal Methods 5(13):3177-3184.

Boardman, A. K., S. Allison, A. Sharon, and A. F. Sauer-Budge. 2013. Comparison of anti-fouling surface coatings for applications in bacteremia diagnostics. Anal Methods 5(1):273-280.

Sauer-Budge, A. F., A. K. Boardman, S. Allison, H. Wirz, D. Foss, and A. Sharon. 2013. Materials and Surface Properties Optimization to Prevent Biofouling of a Novel Bacterial Concentrator. Procedia CIRP 5:185-188.

Mirsky, P., A. Chatterjee, A. F. Sauer-Budge, and A. Sharon. 2012. An automated, parallel processing approach to biomolecular sample preparation. J Lab Autom 17(2):116-124.

Kalashnikov, M., J. C. Lee, J. Campbell, A. Sharon, and A. F. Sauer-Budge. 2012. A microfluidic platform for rapid, stress-induced antibiotic susceptibility testing of Staphylococcus aureus. Lab Chip 12(21):4523-4532.

Wirz, H., A. F. Sauer-Budge, J. Briggs, A. Sharpe, S. Shu, and A. Sharon. 2012. Automated production of plant-based vaccines and pharmaceuticals. J Lab Autom 17(6):449-457.

Premasiri, W. R., A. F. Sauer-Budge, J. C. Lee, C. M. Klapperich, and L. D. Ziegler. 2012. Rapid bacterial diagnostics via surface enhanced Raman microscopy. Spectroscopy (Springf) 27(6):s8-31.

Campbell, J., P. Mirsky, A. Chatterjee, A. Sharon, and A. F. Sauer-Budge. 2012. A semi-automated liquid handler for parallel sample preparation. Biotech International (May / June):23-25.

Gruentzig, A. W., C. M. Klapperich, A. Sharon, J. Braman, A. Chatterjee, and A. F. Sauer-Budge. 2011. A new DNA extraction method for automated food analysis. Analytical Methods 3:1507-1513.

Sauer-Budge, A. F., and A. Sharon. 2011. Editorial for the special issue of RCIM on translational research—Where engineering meets medicine. Robotics and Computer-Integrated Manufacturing 27(2):235-236.

Size, A., A. Sharon, and A. Sauer-Budge. 2011. An automated low cost instrument for simultaneous multi-sample tissue homogenization. Robotics and Computer-Integrated Manufacturing 27(2):276-281.

Sauer-Budge, A.F., P. Mirer, A. Chatterjee, N. Pollock, C. Klapperich, and A. Sharon. Integrated lab-on-a-chip Influenza diagnostic designed for low cost manufacturing. Techworld 2010, 2010. Anaheim, CA.

Chatterjee, A., P. L. Mirer, E. Zaldivar Santamaria, C. Klapperich, A. Sharon, and A. F. Sauer-Budge. 2010. RNA isolation from mammalian cells using porous polymer monoliths: an approach for high-throughput automation. Anal Chem 82(11):4344-4356.

Sauer-Budge, A. F., P. Mirer, A. Chatterjee, C. M. Klapperich, D. Chargin, and A. Sharon. 2009. Low cost and manufacturable complete microTAS for detecting bacteria. Lab Chip 9(19):2803-2810.

Sauer-Budge, A. F., J. A. Nyamwanda, D. K. Lubensky, and D. Branton. 2003. Unzipping kinetics of double-stranded DNA in a nanopore. Phys Rev Lett 90(23):238101.

Sauer-Budge, A. and Branton, D. (2002). "Unzipping Double-Stranded DNA Molecule by Molecule through a Nanopore." Thesis presented to Harvard University in partial fulfillment of the requirements for the degree of Doctor of Philosophy in Biophysics. October.

Sauer, A. and Zare, R. (1997). "The Interaction Of Peptide Nucleic Acid With Complementary Single-Stranded DNA And Double-Stranded DNA In The Development Of A Genetic Screening Protocol" Thesis presented to Stanford University in partial fulfillment of the requirements for the degree of Master of Science in Chemistry. June.

**Presentations**

Bell-Moss, K., Clevenger, J., Sauer-Budge, A. (2023) Webinar. “There are chemicals in my chemicals!”

Sauer-Budge, A. (2021) Panel speaker “Wonder Women (and Men) – Lessons Learned in the Pandemic Trenches” DRI Women in the Law Seminar.

Sauer-Budge, A., Bergerson, C. (2021) Webinar. “The Latest in COVID-19 Testing: Where We Are and Where We Are Going.”

Khanolkar, A., Walder, T., Sauer-Budge, A. (2020) Panel speaker “Material Innovations Driving Innovation & Quality Manufacturing” Conference Track: Product Development Innovation, BIOMEDigital 2020.

Sauer-Budge, A., Bergerson, C., and Lipp, J. (2020) Webinar. “COVID-19 Diagnostic Tests: Perspectives from the Scientific, Regulatory, and Legal Communities.”

Sauer-Budge, A. (2020) Panel speaker “Product Liability and the Coronavirus.” American Bar Association (ABA) Women in Products Liability Virtual Regional CLE Program.

Sauer-Budge, A. (2019) Track Chair. “Panel: How Miniaturization is Driving Design in Top Medical Device Categories” BIOMEDevice Boston, Track A: Product Development, Boston, MA.

Sauer-Budge, A. (2017) Invited talk. "Rapid Sample to Answer Antibiotic Susceptibility Testing for Bacteremia" Lab-on-a-Chip & Microfluidics World Congress 2017, San Diego, CA.

Sauer-Budge, A. (2017) Invited talk. "Automated tissue dissociation for rapid extraction of viable cells" CIRP Biomanufacturing, Chicago, IL.

Kalashnikov M, Mueller M, McBeth C, Lee JC, Sharon A, Sauer-Budge, A. (2017) Poster "Phenotypic stress-based antibiotic susceptibility testing of Gram-negative clinical isolates" Gordon Research Conference, Microfluidics, Italy.

Sauer-Budge, A. (2017) Invited talk. "Assay development while designing for manufacturing" Microfluidics 8.4, Boston, MA.

Sauer-Budge, A. (2017) Invited talk. "Plasma surface modifications for microfluidic and diagnostic devices" PlasmaTreat Open House.

Sauer-Budge, A. (2017) Invited talk. "Empowering Rapid Diagnostics with Sample Preparation Methodologies" Sample Prep, Washington DC.

Sauer-Budge, A. (2016) Invited Talk. "Rapid phenotypic methods for diagnosing infections and antibiotic susceptibility testing" BioDefense Global Summit, Baltimore, MD.

Sauer-Budge, A. (2015) Invited Talk. "Isolation of Dilute Pathogens from Blood" Select Bio Circulating Biomarkers World Congress 2015, Boston, MA.

Sauer-Budge, A. (2015) Invited Talk. "Rapid sample preparation of viable bacteria directly from blood specimens" Sample Prep 2015. Bethesda, MD.

Sauer-Budge, A. (2015) Invited Talk. "Rapid phenotypic methods for diagnosing infections and antibiotic susceptibility testing." AACC Emerging Clinical & Laboratory Diagnostics: Pushing the Envelope, Los Angeles, CA.

Kalashnikov M, Campbell J, Hanelt I, Lee J, Sharon A, Sauer□Budge AF. (2014) Invited Poster. "Enhanced microfluidic platform for stress□induced rapid antibiotic susceptibility testing." AACC Emerging Clinical & Laboratory Diagnostics Conference, San Jose, CA.

Sauer-Budge, A (2014) Invited talk. "Design for low cost manufacturing of point of care microfluidic devices", SLAS 2014, San Diego, CA.

Sauer-Budge, A (2013) Invited talk. "Rapid Bacterial Sample Preparation from Blood", Sample Prep 2013, San Diego, CA.

Sauer-Budge, A (2013) Invited talk. "Automated on-chip bead-based ELISA", Sample Prep East, Boston, MA.

Sauer-Budge, A (2012) Invited talk. "Innovations at the Intersection of Mechanical Engineering and Life Sciences", Boston University Mechanical Engineering Department Seminar Series, Boston, MA.

Sauer-Budge, A. (2012) Invited talk. "Development of a point-of-care rapid and sensitive bacteremia diagnostic," AACC Oakridge 2012, San Jose, CA.

Sauer-Budge, A (2012) Invited talk. "Isolation of dilute bacteria from blood for rapid diagnostics", Sample Prep 2012, San Diego, CA.

Kalashnikov, M., Campbell, J., Lee, J.C., Sharon, A., Sauer-Budge, A.F. (2012) Poster presentation. "Rapid, Stress-Induced Antibiotic Susceptibility on a Chip". IEEE Micro- and Nano-engineering

conference, Maui, HI.

Campbell J, Sauer-Budge AF, and Sharon A. (2012) Poster presentation. "Research at the Intersection of Life Sciences and Engineering: Developing Microfluidic Platforms for Diagnostic Applications". Gordon Research Conference: Bioanalytical sensors, Newport, RI.

Kalashnikov MK, Lee JC, Sharon A, and Sauer-Budge AF. (2012) Poster presentation. "Microfluidic platform for stress-induced rapid antibiotic susceptibility testing". AACC Oakridge 2012, San Jose, CA.

Sauer-Budge, A (2009) Invited talk. "Microfabricated tools for programming live neural pathways", Neural Restoration Workshop, Washington D.C.

Sauer-Budge, A. (2008) Invited talk. Boston University Biomedical Engineering Department Seminar Series. "Integrating microfluidic sample preparation and molecular diagnostics into a low cost disposable device"

Sauer-Budge, A. (2005) Invited talk to the NIH Viral Load Working Group, NIH, Bethesda, MD, November.

Sauer-Budge, A., Nyamwanda, J., Lubensky, D. K. and Branton, D. (2003). "Progress towards Nanopore-based single molecule sequencing: The Unzipping of Double-Stranded DNA Forced through a Nanopore Measured at the Single Molecule Level." BioMEMS, The Knowledge Foundation, Cambridge, MA.

Sauer, A., Dulay, M.D., and Zare, R. (1996). "Kinetic Studies of Mixed Base PNA-DNA Hybridization with Capillary Electrophoresis and Laser Induced Fluorescence Detection" Johnson Symposium for Organic Chemistry, Stanford University.

## Project Experience

### In Vitro Diagnostics Consulting

- Performed independent technical and regulatory due diligence of an in vitro diagnostic (IVD) startup on behalf of a private equity firm and strategic medical device investor, evaluating technology readiness, assay performance, development risks, manufacturing considerations, regulatory strategy, and commercialization potential.
- Conducted technical, quality, manufacturing, and supply-chain assessments of multiple point-of-care COVID-19 diagnostic companies on behalf of a nonprofit organization evaluating investment opportunities to accelerate deployment of diagnostic testing technologies.
- Advised diagnostic developers on assay architecture, biomolecular interactions, surface chemistry approaches, and platform design considerations, helping teams evaluate tradeoffs between analytical sensitivity, specificity, manufacturability, and product development timelines.
- Investigated alleged shipping-related damage to commercial molecular diagnostic products by evaluating retained manufacturing samples and test performance data, demonstrating consistency with labeled product specifications and claimed performance.
- Supported development of verification and validation strategies for in vitro diagnostic products, including test plan development, technical report preparation, regulatory documentation, and Instructions for Use (IFU) content supporting regulatory submissions.
- Advised a pharmaceutical company on companion diagnostic development strategy, evaluating regulatory pathways and commercialization timelines across the United States, European Union, and United Kingdom. Reviewed and compared potential diagnostic development partners,

assessed advantages and limitations of laboratory-developed test (LDT) and IVD approaches, and supported strategic decision-making for companion diagnostic implementation.

### Microbiology, Biological Materials & Contamination Investigations

- Led a multidisciplinary root-cause investigation of recurrent mold contamination within a pharmaceutical manufacturing facility following repeated environmental monitoring excursions and product-related findings. Developed a structured Ishikawa-based investigation framework encompassing approximately 70 potential root causes and more than 200 investigative activities, ultimately identifying primary and contributing factors related to contamination sources, disinfectant failures, cleaning practices, environmental monitoring programs, data trending, and corrective action processes.
- Investigated reports of microbiological contamination associated with a recalled liquid pharmaceutical product. Conducted microbiological testing and scientific evaluation of retained samples and available evidence to assess the validity of contamination allegations and the potential relevance of microbiological findings to product quality concerns.
- Led a contamination investigation involving intermittent bacterial contamination of a consumer product manufacturing process. Identified a contamination source associated with a biofilm within a water system component, evaluated contamination pathways and control measures, assessed formulation-dependent microbial survivability, and helped narrow the scope of potentially affected products based on microbial risk.
- Applied microbiological, biochemical, and analytical chemistry techniques to identify unknown biological materials associated with consumer products, personal injury claims, and product-related investigations. Utilized complementary biological and analytical methods to characterize materials, determine likely origins, and evaluate their relevance to the questions under investigation.
- Confirmed the presence of blood residues within consumer product materials using targeted biological testing methods and assisted clients in determining the source and significance of the findings.

### Cleaning, Disinfection & Contamination Control

- Evaluated persistent contamination findings observed during postmarket studies of a reusable medical device. Assessed clinical study design, reprocessing instructions, cleaning and disinfection procedures, validation data, device design features, and user training materials. Identified opportunities to improve device reprocessing effectiveness and demonstrated how differences in study design could substantially influence reported contamination rates and comparisons across competing products.
- Conducted microbial risk assessments for medical devices used in home, point-of-care, and hospital environments, evaluating how differences in use conditions, users, contamination opportunities, and clinical settings influence infection risk and contamination control requirements.
- Evaluated cleaning and disinfection approaches intended for home use on consumer products and textiles. Assessed the effectiveness of soap and water, 70% isopropyl alcohol, laundering, and heat-based treatments against bacterial pathogens and coordinated additional testing of viral pathogens through external laboratories.
- Assessed the effectiveness of a wide range of disinfectant products and chemistries intended for control of SARS-CoV-2. Performed detailed evaluations of disinfectant mechanisms of action,

published efficacy studies, EPA List N designations, viral properties, and product formulations to assess the scientific basis for antiviral performance claims and likely effectiveness under intended use conditions.

- Evaluated the mechanisms of action of disinfectants, antiseptics, and antibiotics, and critically assessed scientific literature addressing potential relationships between biocide tolerance and antibiotic resistance. Integrated microbiological, mechanistic, and real-world evidence to help clients understand the strengths, limitations, and practical implications of available data.

### Microbial-Material Interactions & Antimicrobial Technologies

- Conducted a comprehensive scientific evaluation of SARS-CoV-2 persistence on surfaces and in aerosols, integrating findings from laboratory stability studies, environmental sampling studies, virology, surface chemistry, and microbial ecology literature. Assessed the impact of material type, environmental conditions, viral structure, and surface interactions on viral persistence, while evaluating how laboratory model systems compare to real-world environments and identifying factors that can lead laboratory studies to overestimate persistence under practical use conditions.
- Evaluated antimicrobial coatings and surface treatments using standardized microbiological test methods, including ISO 22196, to assess antibacterial performance and support optimization of material properties, antimicrobial effectiveness, and product development strategies.
- Assessed antimicrobial coatings applied to textile materials using ISO 20743 methodologies to evaluate antimicrobial performance and support development of products designed to reduce microbial growth under expected use conditions.
- Evaluated how changes in epoxy formulation and material properties influenced microbial adhesion and persistence before and after cleaning cycles. Assessed the relationship between surface characteristics, cleaning processes, and microbial attachment to support development of contamination-resistant materials.
- Characterized antibiotic susceptibility profiles of microorganisms contained within a probiotic formulation by evaluating susceptibility to clinically relevant antibiotics and comparing results against CLSI interpretive criteria. Assessed organism-specific resistance patterns and their relevance to a clinical case involving antimicrobial treatment decisions.

### Technical Investigations, Insurance & Litigation Support

- Assessed the impact of an unexpected freezer excursion on lipid nanoparticle (LNP) formulations and other pharmaceutical materials following loss of temperature control. Conducted on-site inspections and analytical testing to evaluate changes in particle size and other critical characteristics relevant to product performance, stability, and potential commercial impact.
- Evaluated the effects of inappropriate storage conditions on temperature-sensitive clinical products following a refrigeration failure and subsequent exposure to elevated temperatures. Assessed available stability data, product specifications, Instructions for Use (IFUs), and published scientific literature to evaluate potential impacts on biologics, chemotherapy agents, small-molecule drugs, and supporting clinical materials.
- Assessed damage resulting from a water intrusion event affecting a research and development facility that included manufacturing operations for molecular diagnostic assays and instrumentation. Evaluated scientific assets, stage of technology development, commercial value,

and replacement considerations to support assessment of losses involving developmental technologies and laboratory infrastructure.

- Conducted root-cause investigations and scientific evaluations related to consumer products recalled for microbiological contamination. Reviewed microbiological findings, clinical information, product testing data, and scientific literature to assess potential relationships between identified microorganisms and reported injuries and to evaluate the strength of the available evidence supporting causation.
- Evaluated the potential impact of freeze-thaw excursions on vaccine stability following a temperature control event. Assessed thermal tracking records, regulatory and scientific literature, clinical trial data, product stability information, and functional testing results to determine the likelihood of degradation, impacts on product performance, and remaining storage life of affected materials.

## Advisory Appointments

Senior Advisor, Fraunhofer USA Science and Technology Advisory Council

Ad Hoc Scientific Advisor for FIND Diagnosis for All

## Editorships & Editorial Review Boards

Robotics and Computer-Integrated Manufacturing, Editor for Special Issue on "Translational Research - Where Engineering Meets Medicine" (2011).

## Peer Reviews

**Journals**

Lab On A Chip

Scientific Reports

Bioengineering

PLOS One

Antibiotics

ASME Journal of Nanotechnology in Engineering and Medicine

RSC Advances

**NIH Review Panels**

NIH Neurological Sciences and Disorders C (NSD-C), 2023, 2024

NIH / NIBIB ZEB1 OSR-D (M1) POCTRN Centers Review, 2023.

NIH Center for Scientific Review Enabling Bioanalytical and Imaging Technologies (EBIT), Standing member, 2017 - 2021

NIH Center for Scientific Review EBIT, Ad hoc reviewer, 2016

NIH Center for Scientific Review Clinical Research and Field Studies (CRFS), Ad Hoc Reviewer, 2016

NIH/NIAID ZAI1 RRS-M (C2), Contracts Sample Preparation, 2015

NIH/NIAID ZAI MM-1 (M1), Development of Sample Sparing Assays for Monitoring Immune Responses, 2015

NIH ZRG1 F130C 20, Center for Scientific Review Special Emphasis Panel, Fellowships, 2015

NIH /NIAID ZAI1 ALW0M (J1), NIAID Clinical Trial Planning Grant (R34), 2015

NIH/NIGMS ZGM1 BBCB-A(BI), Biomedical Instrumentation Special Emphasis Panel (SEP), 2014

NIH/NIMH ZMH1 ERB-L (04), BRAIN Initiative Review Special Emphasis Panel (SEP), 2014

NIH Center for Scientific Review CRFS, Ad Hoc Reviewer, 2014

NIH/NIAID ZAI MFH-M (J1), Partnerships for Diagnostics to Address Antimicrobial Resistance of Select Bacterial Pathogens, 2014

NIH/NIGMS ZGM1 BBCB-A (BT), Biomedical Instrumentation Special Emphasis Panel (SEP), 2013

NIH/NIAID ZAI-LG-M-J1, Partnerships for Biodefense (Diagnostics), 2012

NIH/NHLBI SBIR Contract Proposals: Phase 2, Protein Capture Agents for Cardiovascular Research, 2011

NIH/NIAID U.S. India Bilateral Collaborative Research Partnerships (CRP) for Prevention of HIV/AIDS and Co-Morbidities, 2010

NIH/NIAID ZAI1 LG-M (J3) Partnerships for Biodefense (Diagnostics), 2010

NIH/NHLBI SBIR Contract Proposals: Phase 1 Protein Capture Agents for Cardiovascular Research, 2010