Felicia L. Svedlund, Ph.D.

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Brillouin

PROFESSIONAL PROFILE

Dr. Svedlund is a biomedical engineering and materials science expert with more than 15 years of experience. Through her diverse experience in biomaterials and biomedical engineering, she has expertise in material failure analysis, mechanical behavior of materials, material selection and design, material characterization, biomaterials, material chemistry, and tissue engineering and regenerative medicine. Dr. Svedlund routinely provides expert analysis in support of product liability and intellectual property litigation matters. Her unique approach to forensic analysis of medical devices incorporates a multi-factorial approach, considering device factors (e.g., explanted device inspections/functional evaluations and review of design, manufacturing, regulatory, and postmarket surveillance documents), as well as patient and surgical factors (e.g., interpretation of medical histories, radiographs, and patient anatomy/biomechanics). Dr. Svedlund is well-versed in the total product lifecycle of medical devices, including design, testing, risk management, manufacture, regulatory approval, commercialization, and postmarket surveillance. She routinely performs evaluation of medical device documentation to ensure compliance with Quality System Regulation (QSR), U.S. Food and Drug Administration's (FDA) requirements and guidance documents, and consensus standards, such as American Society for Testing and Materials (ASTM) and International Organization of Standardization (ISO). Her expertise extends to various categories of medical devices, including orthopedic implants, interventional cardiology devices, surgical robotics, surgical tools and instruments, mobility aids, ventilators, wearable defibrillators and cardiac monitors, drug delivery devices, and women's health products.

POSITIONS

Brillouin Consulting — **San Francisco, CA**
Senior Manager — May 2026 - Present
Biomedical Engineer with a failure analysis focus in materials science and engineering, biomaterials, and medical devices. Focus in litigation matters as an expert witness.

Engineering Systems Inc. — **Oakland, CA**
Senior Consultant — May 2024 - April 2026
Biomedical engineering, materials science and engineering, biomaterials, and medical devices expert focused on support for industrial life sciences and medical device manufacturer clients, as well as expert analysis for product liability and intellectual property litigation matters. Served as a member of the leadership team focused on building Biomedical Engineering and Life Sciences as a new practice area within the firm.

Simple HealthKit — **Fremont, CA**
Program Manager — Sep 2023 - Feb 2024
Led all Program Management efforts across the organization, including new product development for lab developed test (LDT)/in-vitro diagnostic (IVD) products and customer-tailored programs. Facilitated cross-functional collaboration and communication between R&D, operations, product science, product management, engineering, regulatory and quality, design, marketing, business development, and executive leadership teams. Facilitated the development and implementation of document control and quality management system procedures in cooperation with Regulatory and Quality group. Led regular conversations with medical advisors to receive input and approval for clinical aspects of products and product road mapping. Conducted road mapping and strategic planning for new product development activities

Exponent, Inc. **Menlo Park, CA**
Managing Scientist, Senior Associate, Associate Jul 2016 - August 2023
Contributed as a testifying expert, technical lead, and individual contributor to hundreds of projects at all stages of the product lifecycle for medical device and life sciences products including, orthopedic implants, robotic surgery instruments and accessories, interventional cardiology devices, electrosurgical instruments, wearable cardiac defibrillators, inferior vena cava filters, and women's health products. Assessment of medical device design, testing, manufacturing, risk management, postmarket surveillance, and regulatory documentation to ensure compliance with Quality System Regulation, FDA requirements and guidance documents, and consensus standards. Specialized in failure analysis and multi-factorial assessment of the performance of medical devices. Employed an arsenal of non-destructive and destructive characterization techniques to discover failure modes, including imaging techniques, mechanical analyses, chemical analyses, and metrology techniques, with a particular expertise in micro-CT imaging and analysis. Developed laboratory test plans and designed experiments, including design and fabrication of custom test fixtures.

ACADEMIC CREDENTIALS

University of California, Berkeley **Berkeley, CA**
Ph.D., Materials Science and Engineering 2016

University of California, Berkeley **Berkeley, CA**
M.S., Materials Science and Engineering 2016

University of Florida **Gainesville, FL**
B.S., Materials Science and Engineering (Biomaterials specialization, minor in Sales Engineering, Summa Cum Laude) 2010

TEACHING EXPERIENCE

- Graduate Student Instructor, University of California, Berkeley
  - Undergraduate Course: Biological Performance of Materials, 2011 and 2015
  - Undergraduate Course: Stem Cells and Technologies, 2015
  - Graduate Course: Stem Cells and Directed Organogenesis, 2014

CONTINUING EDUCATION

- Regulatory Affairs Certificate: Medical Devices – Regulatory Affairs Professional Society (RAPS), Online University Certificate Program, 2021
- Industrial X-Ray Technical Training Course, Advanced CT (CT Level II) – North Star Imaging, Rogers, Minnesota, 2018
- Master Diver – Scuba Schools International (SSI), 2020
- Enriched Air Nitrox Level 2 (40%) – Scuba Schools International (SSI), 2019
- Diver Stress & Rescue – Scuba Schools International (SSI), 2012
- Advanced Scuba Diver – National Association of Underwater Instructors (NAUI), 2010
- Scuba Diver – National Association of Underwater Instructors (NAUI), 2010

PROFESSIONAL AFFILIATIONS/HONORS

- Biomedical Engineering Society (BMES)
- Regulatory Affairs Professional Society (RAPS)
- ASM International
- ASTM International
- National Science Foundation (Graduate Research Fellowship, 2012-2015)
- Achievement Rewards for College Scientists (ARCS) (Fellowship, 2010-2012)
- National Defense Science and Engineering (Graduate Fellowship, awarded 2012)
- National Science Foundation (Materials World Network Scholarship, 2009)

PROJECT EXPERIENCE

Medical Device Design, Manufacturing, and Regulatory Affairs

- Assessment of design defect claims for a broad range of medical devices through review and analysis of Design Control (21 CFR 820.30) documents, regulatory submissions, risk analyses, and postmarket surveillance activities. Devices include total hip replacements, total knee replacements, fracture fixation plates, rods, and screws, spinal implant devices, percutaneous coronary intervention (PCI) devices including guide wires, catheters, stents, angioplasty balloons, and embolic protection filters, inferior vena cava (IVC filters), surgical instruments, wearable cardiac defibrillators, and ventilators.
- Reconstruction of Design History Files for an IVC filter product line following an acquisition. The product had been developed several decades prior, and most institutional knowledge was lost during the acquisition. We were provided with a large quantity of disorganized documents from storage and tasked with assessing the contents of the documents and reconstructing the content of the Design History Files for each of the products.
- Analysis of lot-specific manufacturing records, as well as Device Master Records (DMR) and manufacturing processes to assess manufacturing defect claims for a broad range of medical devices.
- Review and analysis of the manufacturing processes and documentation for a feminine hygiene product related to claims of a foreign object found within the product.
- Developed an SOP to serve as a qualified vendor of computed tomography (CT) services as part of an inspection step in the manufacturing process for a robotic surgery tool in the event of downtime of the CT equipment at the manufacturer's facility.

Laboratory Assessment of Medical Devices and Materials

- Retrieval analysis of numerous medical devices per ISO 17025 accredited methods.
- Contact angle measurements to understand material surface properties (e.g., cleanliness, effect of surface treatments or coatings, adhesiveness) of various materials and components conducted per ISO 17025 accredited methods.
- Fractographic analysis of medical devices composed of titanium, cobalt-chromium, and stainless-steel alloys.
- Chemical and imaging analysis following simulated aging for degradation of polymeric vaginal mesh.
- Trackability testing of guide wires to assess coating materials.
- Mechanical assessment of the insertion force for tissue anchor devices.
- Computed tomography (CT) assessment of albuterol inhalers' actuation, flow path, and potential clogging.
- Computed tomography (CT) assessment of fretting and corrosion in taper junctions of modular total hip replacement devices.
- Computed tomography (CT) analysis of wear on bearing surfaces of retrieved medical devices as part of postmarket surveillance activities.
- Computed tomography (CT) assessment of quarantined lots of robotic surgery tools to identify units with a missing component.
- Computed tomography (CT) analysis of the three-dimensional spatial relationship of components in a radiofrequency ablation probe to support intellectual property infringement and invalidity analyses.
- Identification of foreign objects found within feminine hygiene and food products.
- Non-destructive investigation of cup-neck impingement of a total hip arthroplasty device, including computed tomography (CT) analysis of the volume of material loss and transfer due to impingement and chemical analysis of the material transfer.
- Non-destructive investigation of an embolic protection system, including computed tomography (CT) analysis of the size and spatial relationship of the filter and associated guide wire to assess a claim that the filter fell off the end of the guide wire.

Clinical Literature Reviews

- Literature reviews and analysis of testing methodologies for various medical devices, including IVC filters and gastric balloons.
- Literature review on the clinical experience for various IVC filter devices from multiple manufacturers to assess the reporting frequency for different adverse events and to compare the performance of different filter designs.
- Literature review on the clinical experience and reporting frequency of fracture of modular total arthroplasty devices from multiple manufacturers.
- Literature review on the development and regulatory history of IVC filters to provide context in assessing adverse events related to retrievable as compared with non-retrievable IVC filters.
- Literature review on the heterogeneity of current methods for fecal microbiota transplant (FMT) procedures, which was published as a review article and presented in two poster presentations.

PUBLICATIONS

- "Failure Analysis of Medical Devices," Bowers M, Ganot G, Malito L, Kondori B, Ezechukwu A, Svedlund F, James B., Journal of Failure Analysis and Prevention, 22(1):154-80.12(6), pp.617-623, 2022.
- "Failure Analysis of Medical Devices (Book Chapter)," Bowers M, Ganot G, Malito L, Kondori B, Ezechukwu A, Svedlund F, James B., ASM Handbook – Analysis and Prevention of Component and Equipment Failures. 11A:736-753, 2021.
- "Heterogeneity of randomized controlled trials of fecal microbiota transplantation in recurrent Clostridioides difficile infection," Feuerstadt P., Aroniadis, O.C., Svedlund, F.L., Garcia, M., Strong, L., Boules, M., Khanna, S., Digestive Diseases and Sciences, 1-8, 2021.
- "A Picture is Worth a Thousand Words-Using Imaging to Support Your Case – Feature Article, Expert Insights," Ong, K., Svedlund, F.L., DRI Rx for the Defense, Volume 28, Issue 1, March13, 2020.
- "Multivalent Conjugates of Basic Fibroblast Growth Factor Enhance in Vitro Proliferation and Migration of Endothelial Cells" Zbinden, A., Browne, S. Altiok, E.L., Svedlund, F.L., Jackson, W.M., Healy, K.E., Biomaterials Science, 6(5): 1076-1083, 2018.
- "Branching Analysis of Multivalent Conjugates Using Size Exclusion Chromatography-Multiangle Light Scattering," Svedlund, F.L., Altiok, E.L., Healy, K.E., Biomacromolecules, 17(10):31623171, 2016.
- "Synthesis and Characterization of Multivalent Conjugates," Svedlund, F.L., Ph.D. Dissertation, University of California, Berkeley, May 2016.
- "Multivalent Hyaluronic Acid Bioconjugates Improve sFlt-1 Activity in Vitro," Altiok, E.L., Santiago-Ortiz, J.L., Svedlund, F.L., Zbinden A., Jha, A.K., Bhatnagar, D. Loskill, P. Jackson, W.M., Schaffer, D.V., Healy, K.E., Biomaterials, 93:95-105, 2016.
- "Self-organizing Human Cardiac Microchambers Mediated by Geometric Confinement," Ma, Z., Wang, J., Loskill, P., Huebsch, N., Koo, S., Svedlund, F.L., Marks, N.C., Hua, E.W., Grigoropoulos, C.P., Conklin, B.R., Healy, K.E., Nature Communications, 6:7413, 2015.
- "Molecular Weight and Concentration of Heparin in Hyaluronic Acid-based Matrices Modulates Growth Factor Retention Kinetics and Stem Cell Fate," Jha, A.K., Mathur, A., Svedlund, F.L., Yeghiazarians, Y., Healy, K.E. Journal of Controlled Release, 209:308-316, 2015.
- "Mimicking the Nanostructure of Bone: Comparison of Polymeric Process-Directing Agents," Thula, T.T., Svedlund, F.L., Rodriguez, D.E., Podschun, J., Pendi, L., Gower, L.B., Polymers (Polymers Best Paper Award 2015-First Prize Article Award), (1): 10-35, 2010.

PRESENTATIONS

- "Guest Lecture on Real-World Applications of Biomaterials and Biomedical Engineering," Svedlund, F.L., Principles and Applications of Biomaterials Course, California Polytechnic State University, 2025.
- "Scary, Dirty, and Misunderstood Words in Medical Device Litigation," Svedlund, F.L., DRI Drug and Medical Device Seminar 2025.
- "Mo1951 Reporting of Randomized Controlled Trial Methodological Characteristics of Fecal Microbiota Transplantation (FMT) for Recurrent Clostridioides Difficile Infection (rCDI)," Khanna, S., Aroniadis, O.C. Garcia, M., Svedlund, F.L. et al., Gastroenterology, 158(6)S-990-S-991, 2020.
- "Mo1950 Heterogeneity of Randomized Controlled Trials of Fecal Microbiota Transplantation (FMY) in Recurrent Clostridioides Difficile Infection: A Systematic Review," Feuerstadt, P., Aroniadis, O.C. Svedlund, F.L. et al., Gastroenterology, 158(6)S-990, 2020.
- "Seeing Things More Clearly: Using CT scans for Evidence Evaluation," Svedlund, F.L., Sanchez, H., PLAC Technology in Litigation Webinar Series, 2019.
- "Seeing Things More Clearly: Using X-rays and CT scans in Product Liability Evaluations," Svedlund, F.L., Sanchez, H., Greene, M.C., The Florida Liability Claims Conference, 2019.
- "Advanced Radiological Imaging Techniques for Product Evaluation," Svedlund, F.L., International Association of Defence Counsel (IADC) Mid-year Meeting, 2019.
- "Seeing Things More Clearly: Using CT scans for Evidence Evaluation," Svedlund, F.L., Sanchez, H., Webinar Presentation for Exponent, 2018.
- "Multivalent Conjugates of Mechano-Growth Factor with Cardioprotective Effects," Svedlund, F.L., Jha, A., Healy, K.E., First Annual ARCS Scholar Symposium, 2015.
- "SEC-MALS Characterization of Hyaluronic Acid-Based Multivalent Conjugates," Svedlund, F.L., Altiok, E., Zbinden, A., Healy, K.E., Wyatt Technology's San Francisco Bay Area Protein and Biotech Use Meeting, 2015.
- "A Synthetic, Micropatterned Culture Surface for Embryonic Stem Cells," Svedlund, F.L., Wang, J., Lin, J., Healy, K.E., Annual Meeting of Biomedical Engineering Society, 2012.
- "A Simple, Synthetic, Micropatterned Surface for Embryonic Stem Cell Culture," Svedlund, F.L., Wang, J., Lin, J., Healy, K.E., Annual Meeting of Polymer Networks Group, 2012.
- "A Synthetic, Micropatterned Surface for Embryonic Stem Cells," Svedlund, F.L., Irwin, E.F., Wang, J., Healy, K.E., Spring Meeting of the Materials Research Society, 2012.