15235 Alton Parkway, Suite 120
Irvine, CA 92618

FELICIA L. SVEDLUND, PH.D.
SENIOR CONSULTANT

flsvedlund@engsys.com

Dr. Svedlund's expertise encompasses the design, testing, and manufacture of medical devices and the materials from which they are constructed; failure analysis and non-destructive examination of medical devices and the multi-factorial assessment of their performance; and evaluation of medical device design, testing, manufacturing, risk management, postmarket surveillance, and regulatory 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"). Dr. Svedlund is well-versed in the design, function, preclinical testing, manufacturing, regulatory approval, and commercialization of medical devices, owing to her extensive education, training, and experience in the field of medical devices. With over 13 years of employment in the realms of materials science and engineering, biomaterials, and biomedical engineering, Dr. Svedlund possesses a comprehensive understanding of the complexities involved in the development and application of medical devices.

Dr. Svedlund's unique approach to failure analysis and evaluation of explanted medical devices sets her apart in the industry. She 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). Her expertise extends to various categories of medical devices and surgical instruments, including orthopaedic devices like total knee arthroplasty, total hip arthroplasty, and spinal implant devices, as well as interventional cardiology devices, surgical coagulation and cutting devices, implantable birth control devices, and feminine hygiene products.

Dr. Svedlund has direct experience and training in the assessment of medical devices and other components and products using X-ray imaging and micro-computed tomography (micro-CT). Her training and expertise encompass micro-CT technique development for high-resolution scanning, minimization of CT artifacts, high-quality scanning of mixed-material devices and samples, and scanning of biological tissues. 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. In her doctoral research, Dr. Svedlund synthesized and characterized multivalent conjugate molecules of a peptide growth factor conjugated to a polymer backbone chain to investigate their impact on the apoptosis of cardiac cells under hypoxic conditions. Additionally, she has experience in the culture of mammalian and human cell lines, including embryonic and induced pluripotent stem cells and in vitro assays for examining cell viability, proliferation, and function.

Areas of Specialization

Medical Devices
Medical Investigation
Polymers & Composites
Metals
Risk Analysis
Design Analysis
Intellectual Property
Inspection Services

May 2024

Education

Ph.D. Materials Science and Engineering, University of California, Berkeley, 2016
M.S. Materials Science and Engineering, University of California, Berkeley, 2016
B.S. Materials Science and Engineering (Biomaterials specialization, minor in Sales Engineering, Summa Cum Laude), University of Florida, 2010

Professional Affiliations

Biomedical Engineering Society (BMES)
Regulatory Affairs Professional Society (RAPS)
ASM International
ASTM International

Honors & Awards

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

Positions Held

Simple HealthKit, Fremont, CA

Program Manager, September 2023 – February 2024

Exponent, Inc., Menlo Park, CA

Managing Scientist, March 2019 – August 2023
Senior Associate, March 2018 – March 2019
Associate, July 2016 – March 2018

University of California, Berkeley, CA

ARCS and NSF Graduate Fellow and Graduate Student Instructor, August 2010 – June 2016

Continued Education and Certifications

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

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

Publications

Bowers M, Ganot G, Malito L, Kondori B, Ezechukwu A, **Svedlund F**, James B. Failure Analysis of Medical Devices. Journal of Failure Analysis and Prevention. 2022 Feb;22(1):154-80.

Bowers M, Ganot G, Malito L, Kondori B, Ezechukwu A, **Svedlund F**, James B. “Failure Analysis of Medical Devices.” (Book Chapter) ASM Handbook - Analysis and Prevention of Component and Equipment Failures. 2021;11A:736-753.

Feuerstadt P, Aroniadis OC, **Svedlund FL**, Garcia M, Stong L, Boules M, Khanna S. Heterogeneity of randomized controlled trials of fecal microbiota transplantation in recurrent Clostridioides difficile infection. Digestive Diseases and Sciences. 2021;1-8.

Ong K, **Svedlund FL**, Feature Article, Expert Insights: “A Picture Is Worth a Thousand Words—Using Imaging to Support Your Case,” DRI Rx for the Defense, Volume 28, Issue 1, March 13, 2020.

Zbinden A, Browne S, Altiok EI, **Svedlund FL**, Jackson WM, Healy KE. Multivalent conjugates of basic fibroblast growth factor enhance in vitro proliferation and migration of endothelial cells. Biomaterials Science. 2018;6(5):1076-1083.

Svedlund FL, Altiok, EI, Healy KE. Branching Analysis of Multivalent Conjugates Using Size Exclusion Chromatography-Multiangle Light Scattering. Biomacromolecules. 2016;17(10):3162-3171.

Svedlund FL. Synthesis and Characterization of Multivalent Conjugates. Ph.D. Dissertation, University of California, Berkeley, May 2016.

Altiok EI, Santiago-Ortiz JL, **Svedlund FL**, Zbinden A, Jha AK, Bhatnagar D, Loskill P, Jackson WM, Schaffer DV, Healy KE. Multivalent hyaluronic acid bioconjugates improve sFlt-1 activity in vitro. Biomaterials. 2016 Jul 31; 93:95-105.

Ma Z, Wang J, Loskill P, Huebsch N, Koo S, **Svedlund FL**, Marks NC, Hua EW, Grigoropoulos CP, Conklin BR, Healy KE. Self-organizing human cardiac microchambers mediated by geometric confinement. Nature Communications. 2015 Jul 14; 6:7413.

Jha AK, Mathur A, **Svedlund FL**, Ye J, Yeghiazarians Y, Healy KE. Molecular weight and concentration of heparin in hyaluronic acid-based matrices modulates growth factor retention kinetics and stem cell fate. Journal of Controlled Release. 2015 Jul 10; 209:308-316.

Thula TT, **Svedlund FL**, Rodriguez DE, Podschun J, Pendi L, Gower LB. Mimicking the Nanostructure of Bone: Comparison of Polymeric Process-Directing Agents. 2010 Dec 27; 3(1):10-35. **(*Polymers* Best Paper Award 2015, First Prize Article Award)**

Presentations

Khanna S, Aroniadis OC, Garcia M, **Svedlund FL**, et al. Mo1951 Reporting of Randomized Controlled Trial Methodological Characteristics of Fecal Microbiota Transplantation (FMT) for Recurrent Clostridioides Difficile Infection (rCDI). Gastroenterology. 2020;158(6):S-990-S-991.

Feuerstadt P, Aroniadis OC, **Svedlund FL**, et al. Mo1950 Heterogeneity of Randomized Controlled Trials of Fecal Microbiota Transplantation (FMT) in Recurrent Clostridioides Difficile Infection: A Systematic Review. Gastroenterology. 2020;158(6):S-990.

Svedlund FL, Sanchez H. Seeing Things More Clearly: Using CT Scans for Evidence Evaluation. PLAC Technology in Litigation Webinar Series, August 2019.

Svedlund FL, Sanchez H, Greene MC. Seeing Things More Clearly: Using X-rays and CT Scans in Product Liability Evaluations. The Florida Liability Claims Conference, June 2019.

Svedlund FL. Advanced Radiological Imaging Techniques for Product Evaluation. International Association of Defense Counsel (IADC) Midyear Meeting, February 2019.

Svedlund FL, Sanchez H. Seeing Things More Clearly: Using CT Scans for Evidence Evaluation. Webinar Presentation for Exponent, November 2018.

Svedlund FL, Jha A, Healy KE. Multivalent Conjugates of Mechano-Growth Factor with Cardioprotective Effects. First Annual ARCS Scholar Symposium, May 2015.

Svedlund FL, Altiok E, Zbinden A, Healy KE. SEC-MALS Characterization of Hyaluronic Acid-Based Multivalent Conjugates. Wyatt Technology's San Francisco Bay Area Protein and Biotech User Meeting, February 2015.

Svedlund FL, Wang J, Lin J, Healy KE. A Synthetic, Micropatterned Culture Surface for Embryonic Stem Cells. Annual Meeting of the Biomedical Engineering Society, October 2012.

Svedlund FL, Wang J, Lin J, Healy KE. A Simple, Synthetic, Micropatterned Surface for Embryonic Stem Cell Culture. Annual Meeting of the Polymer Networks Group, August 2012.

Svedlund FL, Irwin EF, Wang J, Healy KE. A Synthetic, Micro-patterned Surface for Embryonic Stem Cells. Spring Meeting of the Materials Research Society, April 2012.

Selected Project Experience

Medical Device Design, Manufacturing, and Regulatory Affairs

Dr. Svedlund routinely conducts assessments of activities throughout the medical device total product lifecycle, including regulatory submissions, device history files, verification test reports, clinical study reports, risk management activities, Instructions for Use and product labeling, manufacturing records, complaints and medical device reporting, and CAPAs and recalls. These assessments include analysis of processes and documentation for consistency with FDA regulations and guidance, as well as industry standards. Selected project examples are as follows:

- 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

Dr. Svedlund has extensive experience conducting failure analysis investigations of medical devices, as well as imaging, chemical, and mechanical analysis of medical devices and other materials and components. Dr. Svedlund specializes in non-destructive analysis techniques, especially micro-computed tomography (micro-CT), for the assessment of one-of-a-kind evidence in failure analysis investigations. Dr. Svedlund draws on her depth of education and experience in materials characterization techniques when conducting these investigations. Selected project examples are as follows:

- 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

Dr. Svedlund routinely conducts literature reviews and authors reports and publications with the findings in support of product development, device testing, and failure investigations. Selected project examples are as follows:

- 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.