

Engineering & Scientific Consulting

Christie Bergerson, Ph.D.

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Professional Profile

Dr. Bergerson has a wide range of expertise including in vitro diagnostics, artificial intelligence in healthcare, and orthopedic medical devices. She has experience preparing applications and performing gap analyses for FDA, WHO and IVDR submissions, both on the hardware and the software side.

Dr. Bergerson participated in the development of the Quality Management System, developed verification and validation testing protocols, led Design of Experiment reviews, led verification and validation testing, composed technical reports for compliance with DHR/DMR regulations for FDA submissions, and participated in risk management activities.

Dr. Bergerson is knowledgeable of Software as a Medical Device regulations as well as the process for verification and validation of artificial intelligence/machine learning algorithms for submission to the FDA. She also led cross-functional design reviews for the mechanical, electrical, EMC and software teams and determined whether the path forward was technologically appropriate.

Dr. Bergerson has extensive experience with medical device quality systems and has led failure analysis efforts after a worldwide product launch. She has experience turning the Voice of the Customer into user requirements, then into product requirements down to detailed specifications, as well as performing gap analysis on product requirements and risk management documentation. Dr. Bergerson is well-versed in testing to ASTM standards, as well as developing justifiable modifications to accomplish target testing. As part of her experience in the medical device industry, Dr. Bergerson has designed, developed and implemented various sensing technologies and barcode readers using machine vision/computer learning algorithms for in vitro diagnostic and medical device applications which were ultimately cleared by the FDA, received a CE mark and were marketed worldwide.

Dr. Bergerson also has extensive experience working with proof of concept Total Knee Replacement components and conducting the testing necessary for a 510(k) submission to the FDA. This involved ASTM/ISO based testing of implant components, porous coating characterization based on ASTM standards, and designing a battery of tests with custom testing rigs for range of motion/constraint testing of the knee. In the regenerative medicine and materials characterization space, Dr. Bergerson worked to design and develop a PPF cuff for comminuted fractures of the long bones which had the appropriate mechanical environment for differentiation of stem cells into bone and tuned the degradation profile of the cuff such that it would biodegrade away after reformation of the bone. Dr. Bergerson led the effort to select the optimal nanoparticle concentration/composition for the PPF nanocomposite cuff material through extensive characterization testing, based both on ASTM standards and more customized approaches. The cuff geometry and manufacturing technique were optimized through the same type of characterization and in vivo testing was conducted using a six-camera motion capture system with gait analysis as the data of interest. She also has experience with cell culture, cardiovascular mechanics, tissue harvesting techniques and creating flow systems to mimic in vivo mechanical environments. Her

cardiovascular experience is both theoretical (i.e. study and mathematical description of the biomechanics of cardiovascular tissue) and experimental (i.e. setting up a flow system to replicate in vivo conditions experienced at different points in the vasculature, analysis of different strut types for stents).

Dr. Bergerson has experience working on several mechanics and biomechanics projects in microgravitybased applications. She was part of a team selected to develop a hands-free Heads Up Display based speech recognition system for the International Space Station, investigate thermal energy management in two phase flow based systems, analyze the mechanics for Protein Exchange Membrane fuel cells and develop a protein nanopore capable of analyte detection in microgravity in conjunction with NASA. The last project included testing the technology in microgravity aboard the DC-9 (a.k.a. Vomit Comet).

Dr. Bergerson has experience electrospinning nanofibers, including the creation of a custom electrospinning module for parallel fibers, coding in Python, C++, MATLAB and LabVIEW and investigating the constitutive relations of polymers to inform computational models of biodegradation. She developed the Biomechanical Experiential Learning Lab course and was faculty of record for Texas A&M University where she taught undergrads the fundamentals of experimental design their senior year.

Academic Credentials & Professional Honors

Ph.D., Biomedical Engineering, Texas A&M University, 2015

B.S., Biomedical Engineering, Texas A&M University, 2011

ISO Committee Member - Artificial Intelligence Standardization and Regulation

2020 Distinguished Alumni of TAMU Biomechanical Environments Lab Award

2015 U.S. Senator Phil Gramm Doctoral Fellowship for scholarly excellence as evidenced by teaching, research and mentoring

2013 P.E.O. Scholars Award given to the top 20 graduate students across North America

13 Abbott Excellence Awards given on the basis of outstanding research, leadership, technical communication or collaboration

Academic Appointments

Faculty of Record, Department of Biomedical Engineering, Texas A&M University, 2012 - 2014

Adjunct Professor, Engineering Management, Johns Hopkins University, 2021 to present

Invited Lectures:

Johns Hopkins, Whiting School of Engineering, 2021

Drexel University, Department of Biomedical Engineering, 2021

Texas A&M University, Department of Biomedical Engineering, 2021

University of Maryland, Department of Biomedical Engineering, 2021

Prior Experience

System Engineer, Abbott Laboratories, 2018-2019

System Verification Technical Lead, Abbott Laboratories, 2018

System Integration Specialist, Abbott Laboratories, 2015-2018

Research Assistant and Teaching Assistant, Texas A&M University, 2011-2015

Student Engineer, NASA's Space Engineering Institute, 2006 - 2011

Publications

Bergerson, Christie, Derek Holyoak, and Kevin Ong. January 2022. "US National Databases–Total Knee Arthroplasty: Lessons Learned." In Essentials of Cemented Knee Arthroplasty, edited by Erik Hausen and Klaus-Dieter Kühn. Springer, Berlin, Heidelberg, 2022. 447-462.

Bergerson, Christie, Elizabeth Groves and Maysam Gorji. December 2020. "Artificial Intelligence in Healthcare." In Software Engineering: Artificial Intelligence, Compliance, and Security, edited by Brian D'Andrade. New York: Nova Science Publishers.

Bergerson, Christie, Elizabeth Groves and Maysam Gorji. December 2020. "Artificial Intelligence and the Food and Drug Administration." In Software Engineering: Artificial Intelligence, Compliance, and Security, edited by Brian D'Andrade. New York: Nova Science Publishers.

Groves, Elizabeth, Christie Bergerson and Maysam Gorji. December 2020. "Artificial Intelligence." In Software Engineering: Artificial Intelligence, Compliance, and Security, edited by Brian D'Andrade. New York: Nova Science Publishers.

Bergerson, Christie, Danika Hayman, and James E. Moore, Jr. "Minimally Invasive Cardiovascular Technologies." Biomedical Technology and Devices, 2013. By Michael R. Moreno. 520-547.

Bergerson, C. M., & Moreno, M. R. (2013, June). Development of a Biodegradable Regenerative Implant for the Treatment of Long Bone Comminuted Fractures. In Summer Bioengineering Conference (Vol. 55607, p. V01AT17A004). American Society of Mechanical Engineers.

Hayman, D., Bergerson, C., Miller, S., Moreno, M., & Moore, J. E. (2014). The effect of static and dynamic loading on degradation of PLLA stent fibers. Journal of biomechanical engineering, 136(8).

Bonin, G. A., Baker, S. T., Davis, C. A., Bergerson, C. M., Hildebrandt, A. A., Hulse, D. A., ... & Saunders, W. B. (2014). In Vitro Biomechanical Comparison of 3.5 mm LC-DCP/Intramedullary Rod and 5 mm Clamp-Rod Internal Fixator (CRIF)/Intramedullary Rod Fixation in a Canine Femoral Gap Model. Veterinary surgery, 43(7), 860-868.

Presentations

Bergerson, CM. Automation of Wash Monitoring, Buffer Reconstitution and Sample Routing on the Alinity i System. Poster session presented at: AACC 2018, Aug 2; Chicago, Illinois.

Bergerson, CM. Evaluating Improvements in Predictive Instrument Monitoring and High Throughput Testing in an Integrated Immunochemistry Platform. Poster session presented at: AACC 2016, July 31st - August 1st; Philadelphia, PA.

Bergerson CM, Paulson Z, Davis CA, Sonoqui LG, Hunt J, Moreno MR. Proof of Concept Evaluation of a Novel TKR Tibial Tray Bone-Implant Interface. Poster session presented at: BMES 2014, Oct 22-25; San Antonio, Texas. *Reviewer's Choice Award

Bergerson CM, Khaled SZ, Fernandez-Moure JS, van Epps J, Weiner B, Tampieri A, Becker M, Tasciotti E, Moreno MR. Development of a Load-Bearing Regenerative Therapy for Comminuted Long Bone

Fractures. Poster session presented at: ASME 2013 Summer Bioengineering Conference. 2013 June 26-29; Sunriver, Oregon.

Fernandez-Moure, J. S., Chaudhry, A., Bergerson, C. M., Van Eps, J. L., Cabrera, F., Weiner, B. K., ... & Tasciotti, E. (2015). Platelet-rich plasma enhances mechanical properties of non-crosslinked acellular dermal matricies in rat model of ventral hernia repair. Journal of the American College of Surgeons, 221(4), S76.

Hayman D, Bergerson CM, Miller S, Moreno MR, Moore JE. The Effect of Static and Dynamic Loading on Degradation of PLLA Fibers. Poster session presented at: Applications for Modeling and Simulation. 1st Annual Frontiers in Medical Devices Conference. 2013 September 11-13; Washington D.C.

Davis CA, Baker ST, Bonin GA, Bergerson CM, Hildebrandt AA, Hulse DA, Kerwin SC, Saunders WB, Moreno MR. "In Vitro Biomechanical Comparison of LCDCP/rod and CRIF/rod Fixation in a Canine Femoral Gap Model." Poster Session presented at: BMES 2013 Annual Meeting. Sep 25-28, 2013. Seattle, WA

Additional Education & Training

Architecture of Complex Systems, MIT xPro Course

Models in Engineering, MIT xPro Course