



Exponent®
Engineering & Scientific Consulting

Michael Frohbergh, Ph.D.

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Professional Profile

Dr. Frohbergh works closely with his clients from strategic planning and experimental design/testing through risk analysis and regulatory considerations. His expertise focuses on medical device biological safety, biocompatibility, risk and quality management, experimental design, and remediation management.

Dr. Frohbergh's technical background is in regenerative medicine with a concentration in bone and cartilage, natural and synthetic biomaterials, in vivo biocompatibility and analysis of medical devices and implantable materials. He specializes in physical, chemical and mechanical characterization of biomimetic materials and tissue scaffolds and pre-clinical evaluation for tissue interaction and integration and performance. He also has extensive experience with 3D printing and additive manufacturing for biomedical applications and small animal models for wound healing, histology, cell and molecular biology techniques.

Dr. Frohbergh is a certified biological safety specialist and a certified ISO 13485 lead auditor. He supports his clients in quality and risk management of medical devices, including ISO 10993, ISO 14971, 21 CFR 820, 21 CFR 1271 and regulation EU 2017/745 (MDR). He also currently holds an adjunct professor position for the department of Biomedical Engineering, Science and Health Systems at Drexel University, where he has lectured on the regulatory issues and FDA framework related to stem cell therapies. He is also a member of the External Advisory Board (EAB) for the Department of Bioengineering at Temple University.

Prior to joining Exponent, Dr. Frohbergh earned his Ph.D. at Drexel University where his work focused on developing and characterizing an electrospun, crosslinked chitosan/hydroxyapatite scaffold for non-load bearing cranial bone regeneration, as well as its in vivo performance to induce wound healing. He then worked as a postdoctoral fellow at Icahn School of Medicine at Mount Sinai Hospital in the department of Genetics and Genomic Sciences where he evaluated articular cartilage repair using enzymatically treated cells in rodent models. While at Mount Sinai, he developed their rodent osteochondral defect model and protocol. He also worked on rare lysosomal storage disease mechanisms including mucopolysaccharidosis (MPS) and Farber disease. He was also involved in helping to develop the Mt. Sinai Institute of Technology (MSIT) and a mentor/assistant for the Design, Technology and Entrepreneurship (DTE) graduate classes.

Academic Credentials & Professional Honors

Ph.D., BIOMEDICAL SCIENCE, Drexel University, 2012

B.A., Chemistry and Biochemistry, LaSalle University, 2007

International Cartilage Repair Society Postdoctoral Travel Award

LaSalle University Founder's Scholarship

Licenses and Certifications

ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

Certified Biological Safety Professional (CBSP)

Certified ISO 13485 Medical Device Management Systems Lead Auditor

ISO 14971:2019 - Application of risk management to medical devices

Academic Appointments

External Advisory Board (EAB), Temple University, Department of Bioengineering, 2018 - present

Adjunct Faculty, Drexel University, School of Biomedical Engineering, Science & Health Systems, 2016 - present

Lectures

Hazard Analysis During Design, School of Biomedical Engineering, Science and Health Systems, Drexel University Medical Device Development lecture, May 2024

Bioprinting, School of Biomedical Engineering, Science and Health Systems, Drexel University Biomedical Additive Manufacturing lecture, August 2023

Hazard Analysis During Design, School of Biomedical Engineering, Science and Health Systems, Drexel University Medical Device Development lecture, May 2023

Additive Manufacturing, Tissue Engineering, and Point-of-Care, School of Biomedical Engineering, Science and Health Systems, Drexel University Biomedical Additive Manufacturing lecture, November 2022

Hazard Analysis During Design, School of Biomedical Engineering, Science and Health Systems, Drexel University Medical Device Development lecture, May 2022

Additive Manufacturing and Regenerative Medicine, School of Biomedical Engineering, Science and Health Systems, Drexel University Biomaterials lecture, August 2021

A Career in Engineering and Scientific Consulting, School of Biomedical Engineering, Science and Health Systems, Drexel University Biomaterials lecture, November 2020

Additive Manufacturing and Tissue Engineering, School of Biomedical Engineering, Science and Health Systems, Drexel University Biomedical Additive Manufacturing lecture, August 2020.

Stem Cell Therapies for Tissue Engineering Applications: An FDA Update and Introduction to Regulatory Affairs School of Biomedical Engineering, Science and Health Systems, Drexel University Tissue Engineering lecture, March 2018

Stem Cell Therapies for Orthopedic Applications: Hard vs. Soft Tissues School of Biomedical Engineering, Science and Health Systems, Drexel University Tissue Engineering lecture, March 2017

Professional Affiliations

ASTM Working Group F04

Society for Biomaterials

International Cartilage Regeneration & Joint Preservation Society

Standards Coordinating Body (Regenerative Medicine)

Patents

Frohbergh ME and Lelkes PI. New PCT Patent Appl. No. PCT/US11/55209, filed October 7, 2011 (Claims priority to U.S. Prov'l Appl. No. 61/390,918, filed October 7, 2010). Title: Electrospun Mineralized Chitosan Nanofibers Crosslinked With Genipin For Bone Tissue Engineering.

Publications

Putnam MD, Rau A, Frohbergh M, Ong K, Bushelow M, and Blauth M. Comparing the Volume of Vascular Intersection of Two Femoral Neck Fracture Fixation Implants Using In Silico Technique. Orthopedic Trauma Association International. 2023 May 4; 6(2 Suppl): e256.

Holyoak DT, Andreshak TG, Hopkins TJ, Brook AL, Frohbergh ME, Ong KL. Height restoration and sustainability using bilateral vertebral augmentation systems for vertebral compression fractures: a cadaveric study. Spine J. 2022 Dec;22(12):2072-2081.

Meng L, Frohbergh M, Villarraga M, Sundaram S, Roffidal T, Fodor W. Biomechanics of Regenerated Esophageal Tissue Following the Implantation of a Tissue Engineered Cellspan™ Esophageal Implant. Journal of Biomechanics. 2022 Jul; 140:111162

Benetatos N, Frohbergh M, Abraham S, Ong K. Development and Regulation of Innovations: In the Current State of Facts vs. Public Opinions, the Truth Does Not Always Prevail. Food and Drug Law Institute Newsletter. 2020.

Guevara-Morales J, Frohbergh M, Castro-Abril H, Vaca-Gonzalez J, Barrera L, Garzon-Alvarado D, Schuchman E and Simonaro C. Growth Plate Pathology in the Mucopolysaccharidosis Type VI Rat Model – An Experimental and Computational Approach. Diagnostics. 2020 May; 10(6): E630

Hirsch JA, Chandra RV, Carter NS, Beall D, Frohbergh M, Ong K. Number Needed to Treat with Vertebral Augmentation to Save a Life. American Journal of Neuroradiology. 2020 Jan; 41(1): 178-182

Schachtner J, Frohbergh M, Hickok N, Kurtz S. Are Medical Grade Bioabsorbable Polymers a Viable Material for Fused Filament Fabrication? Journal of Medical Devices. 2019 Sep; 13(3): 0310081-310085

Ong KL, Beall DP, Frohbergh M, Lau E and Hirsch JA. Were VCF Patients at Higher Risk of Mortality Following the 2009 Publication of the Vertebroplasty "Sham" Trials? *Osteoporosis International*. 2018 Feb; 29(2): 375-383.

Ong KL, Frohbergh M, Stevenson J and Constance J. Postmarket Surveillance: The Truth is Never Simple (Parts 3- Legal Issues). Medical Device and Diagnostic Industry Newsletter. 2016.

Ong KL, Frohbergh M, Stevenson J and Constance J. Postmarket Surveillance: The Truth is Never Simple (Parts 2- Manufacturer Considerations). Medical Device and Diagnostic Industry Newsletter. 2016.

Ong KL, Frohbergh M, Stevenson J and Constance J. Postmarket Surveillance: The Truth is Never Simple (Parts 1- Regulatory Requirements). Medical Device and Diagnostic Industry Newsletter. 2016.

Simonaro CM, Tomatsu S, Sikora T, Kubaski F, Frohbergh M, Guevara JM, Wang RY, Vera M, Kang JL, Smith LJ, Schuchman EH and Haskins ME. Pentosan Polysulfate: Oral Versus Subcutaneous Injection in Mucopolysaccharidosis Type I Dogs. PloS one. 2016; 11 (4): e0153136.

Frohbergh ME, Guevara JM, Grelsamer R, Barbe M, He X, Simonaro CM and Schuchman EH. Acid Ceramidase Treatment Enhances the Outcome of Autologous Chondrocyte Implantation in a Rat Osteochondral Defect Model. Osteoarthritis and Cartilage. 2016; 24 (4): 752-62.

Frohbergh ME, Katsman A, Mondrinos MJ, Stabler CT, Hankenson KD, Oristaglio JT and Lelkes PI. Osseointegrative Properties of Electrospun Hydroxyapatite-Containing Chitosan Nanofibrous Scaffolds. Tissue Eng Part A. 2015; 21 (5-6): 970-81.

Frohbergh M, Ge Y, Mang FL, Karabul N, Solyom A, Lai A, Iatridis J, Schuchman EH and Simonaro CM. Dose Responsive Effects of Subcutaneous Pentosan Polysulfate Injection in Mucopolysaccharidosis Type VI Rats and Comparison to Oral Treatment. PloS one. 2014; 9 (6): e100882.

Frohbergh ME, Katsman A, Botta GP, Lazarovici P, Schauer CL, Wegst UG and Lelkes PI. Electrospun Hydroxyapatite-Containing Chitosan Nanofibers Crosslinked with Genipin for Bone Tissue Engineering. Biomaterials. 2012; 33 (36): 9167-78.

Review Articles / Book Chapters

Frohbergh ME, He X and Schuchman EH. The Molecular Medicine of Acid Ceramidase. Biol Chem. 2015; 396 (6-7) : 759- 765.

Frohbergh ME and Lelkes PI. Biomimetic Scaffolds for Craniofacial Bone Tissue Engineering: Understanding the Role of the Periosteum. Book chapter from A Tissue Regeneration Approach to Bone and Cartilage Engineering, Zreiqat H, Dunstan C and Rosen V, 147 - 162, 2014.

Frohbergh ME, Newman P, Simonaro CM and Zreiqat H. Bone Tissue Engineering Nanomedicine Approach. Encyclopedia of Molecular Cell Biology and Molecular Medicine. 2015; 1: 153-178.

Conference Presentations and Abstracts

Smith B, Gupta C, Albert D, Frohbergh M, Siskey R. Bone ingrowth fixation of Gription™ S Porous Coating. Poster Presentation. International Society for Technology in Arthroplasty, August 2024.

Holyoak D, Andreshak T, Hopkins T, Brook A, Frohbergh M, Ong K. Height restoration and sustainability with bilateral vertebral augmentation for vertebral compression fractures. Podium Presentation, Society of Interventional Radiology, Boston, MA, 2022.

Holyoak D, Andreshak T, Hopkins T, Brook A, Brasher M, Tsitsios D, Watson H, Frohbergh M, Ong K. Height restoration and sustainability using bilateral vertebral augmentation for vertebral compression fractures. Poster Presentation, Orthopaedic Research Society, Tampa, FL, 2022.

Binzak Blumenfeld B, Mendoza M, Frohbergh M, Sheers N, Berg E. Key Issues in Regenerative Medicine Regulation and Approval. Virtual Panel, FDLI Annual Meeting. Panelist. May 18, 2021

Robertson B, Frohbergh M, Stabler C, Siskey R. Adding Automated Colony Counting to Mask BFE Testing. Virtual Presentation, ASTM F04 / F23 Virtual Workshop, American Society for Testing and Materials, Headquarters, West Conshohocken, Pennsylvania, September 9-10, 2020.

Stabler C, Frohbergh M, Robertson B, Siskey R. Using Bacterial Filtration Efficiency to Assess Reprocessing Methods for Face Masks. Virtual Presentation, ASTM F04 / F23 Virtual Workshop, American Society for Testing and Materials, Headquarters, West Conshohocken, Pennsylvania,

September 9-10, 2020.

Frohbergh M, Daley E, Paredes J, Siskey R. How Does Bacterial Concentration Affect Bacterial Filtration Efficiency? Virtual Presentation, ASTM F04 / F23 Virtual Workshop, American Society for Testing and Materials, Headquarters, West Conshohocken, Pennsylvania, September 9-10, 2020.

Siskey R, Frohbergh M, Toner A, Berg-Johansen B, Svedlund F, Basgul C and Kurtz S. 3D Printing Process Validation. Podium presentation, NIST AM BENCH, National Institute of Standards and Technology (NIST) Headquarters, Gaithersburg, Maryland, June 18-21, 2018.

Yenner E, Kumar K, Wetknight D, Neiman A, Wanico N and Frohbergh M. 3D-Printed Polylactic Acid Scaffolds for Regenerative Implant Integration Applications. Panel Speaker and Poster No. P-59. Society for Biomaterials Annual Meeting and Exposition, Atlanta, GA, April 11-14, 2018

Ong K, Beall D, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty sham trials? Poster No. P380, 85th Annual Meeting of the American Academy of Orthopaedic Surgeons, New Orleans, LA, March 6-10, 2018.

Ong K, Beall D, Frohbergh M, Lau E, Hirsch J. How many VCF patients were exposed to elevated mortality risk from the diminution in vertebral augmentation referrals? ePoster No. 592, 43rd Annual Scientific Meeting of the Society of Interventional Radiology, Los Angeles, CA, March 17-22, 2018.

Ong K, Beall D, Frohbergh M, Lau E, Hirsch J. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty sham trials? Poster No. 1057, 43rd Annual Scientific Meeting of the Society of Interventional Radiology, Los Angeles, CA, March 17-22, 2018.

Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty sham trials? Digital Poster No. 4087, 2017 Congress of Neurological Surgeons Annual Meeting, in Boston, MA, October 7-11, 2017.

Schuchman EH, Frohbergh M, Guevara JM, He X, DeAngelis V, Simonaro CM. Cartilage and Bone Disease in a Mouse Model of Farber Lipogranulomatosis and Response to Treatment. *Molecular Genetics and Metabolism*. 2016; 117 (2): S103.

Frohbergh M, Guevara J, Grelsamer R, Scuchman EH and Simonaro CM. Acid Ceramidase Treatment Enhances the Effect of Autologous Chondrocyte Implantation in a Rat Osteochondral Defect Model. *International Cartilage Repair Society World Congress*. 2015; Panel Speaker.

Simonaro CM, Tomatsu S, Ge Y, Meng F, Frohbergh M, Haskins ME, Ruane T, Wang RY, Vera M, Solymon A, Schuchman EH. Pentosan Polysulfate: New Mechanistic Insights and Treatment of the Mucopolysaccharidoses. *Molecular Genetics and Metabolism*. 2015; 114 (2): S106-7.

Simonaro C, Frohbergh M, Ge Y, Meng F, DeAngelis V, Karabul N, Solymon A, Schuchman E. THU0361 Bone and Joint Disease in Mucopolysaccharidosis Involves Tlr4-Related Inflammation and Improves Upon Treatment with Pentosan Polysulfate. *Annals of Rheumatic Diseases*. 2014; 73 (Suppl 2): 307.

Simonaro C, Frohbergh M, Ge Y, Meng F, Schuchman E. A63: Treatment of Arthritis in Animal Models of the Mucopolysaccharidoses Using a Novel Anti-Inflammatory Drug, Pentosan Polysulfate. *Arthritis & Rheumatology*. 2014; 66 (S3): S93.

Simonaro C, Frohbergh M, Ge Y, Meng F, DeAngelis V, He X, Schuchman EH. Comparison of Subcutaneous and Oral Pentosan Polysulfate Treatment in a Rat Model of Mucopolysaccharidosis Type VI. *Molecular Genetics and Metabolism*. 2014; 111 (2): S98.

Frohbergh ME, Sachot S, Ge Y, He X, DeAngelis VA, Schuchman EH, Simonaro CM. A Novel Use for Acid Ceramidase in Cell-Based Therapies for Degenerative Joint Diseases. *International Cartilage Repair*

Society World Congress. 2013; Panel Speaker

Frohbergh ME, Katsman A, Botta G and Lelkes PI. Electrospun Mineralized Chitosan Scaffolds as a Bioactive Aide in the Osseo-Integration of Autograft Substitutes. Biomedical Engineering Society Annual Fall National Meeting. 2011; Panel Speaker

Frohbergh ME, Katsman A, Botta G, Wegst U, Schauer C, Lelkes PI. Electrospun Mineralized chitosan nanofibers as a bioactive scaffold for craniofacial regeneration. Drexel University College of Medicine, October 6, 2011.

Frohbergh ME, Katsman A, Botta G, Lelkes PI. Mineralized Chitosan nanofibrous scaffolds for bone tissue engineering. Drexel University, Philadelphia, PA, April 8, 2011.

Frohbergh ME, Katsman, Lelkes PI. Electrospun mineralized chitosan fibers for bone tissue engineering. Drexel University College of Medicine, Philadelphia, PA, October 7, 2010.