

Exponent®
Engineering & Scientific Consulting

Sangeeta Abraham, Ph.D., PMP, CQE

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Professional Profile

Dr. Abraham is a biomedical engineer, a licensed Project Management Professional (PMP) and a Certified Quality Engineer (CQE) with expertise in quality and risk management within the medical device, pharmaceutical, and human cells, tissues, and tissue-based products (HCT/Ps) industries. Since joining Exponent Dr. Abraham has consulted for companies on numerous projects related to product development, manufacturing, quality management, risk management, regulatory affairs, postmarket activities, and failure analysis. She has served as a subject matter expert for a variety of products spanning Class I (*e.g.*, adult portable bed rails), Class II (*e.g.*, endotracheal tubes), and Class III (*e.g.*, neurostimulators) medical devices as well as HCT/Ps (*e.g.*, bone grafts).

Dr. Abraham has been a member of professional and standards organizations throughout her career, including the Orthopaedic Research Society (ORS), ASTM International (formerly American Society for Testing and Materials), Standards Coordinating Body (SCB), the Project Management Institute (PMI), the American Society for Quality (ASQ), and on professional committees within the Food and Drug Law Institute (FDLI). While serving as a member with ASTM and SCB she has participated in drafting, reviewing, and implementing various technical standards, including those for tissue-engineered medical products (TEMPs), implantable fibrous scaffolds, and MRI safety and compatibility of medical devices. In addition to the standards she has drafted or reviewed, Dr. Abraham is knowledgeable with respect to a number of other important industry standards and regulations impacting the medical device industry including ISO 13485, ISO 14971, 21 CFR 820, and 21 CFR 1271.

Currently, Dr. Abraham holds a position on West Chester University's Biomedical Engineering Industrial and Professional Advisory Board (WCU IPAB) and has been a board member since 2019. During this time WCU IPAB has helped establish a Biomedical Engineering undergraduate degree program by providing guidance on the academic curriculum. In addition to establishing the new Biomedical Engineering program, WCU IPAB also played an integral role in the program's ABET accreditation.

Prior to joining Exponent, Dr. Abraham worked for a medical device manufacturer within the Validation Engineering department. Here, she was responsible for developing and executing various process and equipment validations for implants and surgical instruments and served as the lead validation engineer for activities related to the integration of a new multifunctional piece of manufacturing equipment into the existing production line.

Dr. Abraham has a Doctor of Philosophy (Ph.D.) in Biomedical Engineering from a joint program between the New Jersey Institute of Technology and Rutgers University. Her research was focused on orthopaedics, orthobiologics, biomaterials, and translational research. During the course of her Ph.D. she collaborated with orthopaedic surgeons, industry teams, and engineers to develop and study new regenerative medicine technologies. The research included the use of *in vivo* and *in vitro* models to assess the safety and efficacy of orthobiologic adjuncts, biomaterials, and pharmaceuticals in bone regeneration.

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Academic Credentials & Professional Honors

Ph.D., Biomedical Engineering, Rutgers University, 2016

B.S., Biological Engineering, University of Florida, 2009

Licenses and Certifications

ASQ Certified Quality Engineer (CQE)

Project Management Professional (PMP)

Professional Affiliations

Orthopaedic Research Society

ASTM International

Food and Drug Law Institute

Standards Coordinating Body

Languages

Tamil

Patents

Lin, S.S., Paglia, D.N., O'Connor, J.P., Benevenia, J., Wey, A., Subramanian, S., Chirachella, P., Vives, M.J. Insulin-Mimetics as Therapeutic Adjuncts for Bone Regeneration. U.S. Patent No. 9,999,636 B2, June 19th, 2018.

Publications

Kadkoy Y, Abraham SS, Michael P, Tazin T, Wetterstrand C, O'Connor P. Novel approaches to correlate computerized tomography imaging of bone fracture callus to callus structural mechanics. Bone Reports 2023; 19:101726.

Abraham S, Vives N, Cottrell JA, Mitchell A, Lin HN, Effiong L, Iqbal E, Jingar N, Kim B, Shah N, Munoz W, Chaudhary SB, Lin SS, Benevenia J, O'Connor JP. Local insulin application has a dose-dependent effect on lumbar fusion in a rabbit model. Journal of Tissue Engineering and Regenerative Medicine; 2021.

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 Update Magazine; 2020.

Koerner J, Vives M, O'Connor JP, Chirichella P, Breitbart E, Chaudhary S, Uko L, Subramanian S, Benevenia J, Lin S. Zinc has insulin-mimetic properties which enhance spinal fusion in a rat model. The Spine Journal; 2016.

Mitchell AM, Kim BD, Engler SS, Subramanian S, Uhrich KE, O'Connor JP. Use of salicylic acid polymers and BMP-2 to promote bone regeneration in rabbit parietal bone defects. Journal of Bioactive and Compatible Polymers; 2015.

Subramanian S, Mitchell AM, Yu W, Engler SS, Uhrich KE, O'Connor JP. Salicylic acid-based polymers for guided bone regeneration using BMP-2. Tissue Engineering Part A; 2015.

O'Connor JP, Manigrasso MB, Kim BD, Subramanian S. Fracture healing and lipid mediators. BoneKEy Reports 2014; 3.

Conference Papers

Subramanian S, Schussler S, Bakhtina A, Lin S, Arinzeh, T. A nanocomposite scaffold for bone tissue engineering. 62nd Annual Orthopaedic Research Society Meeting, Orlando, FL, March 5-8, 2016.

Vives MJ, O'Connor JP, Subramanian S, Cottrell JA, Chaudhary S, Shah NP, Munoz III W, Lin SS. Local insulin application has a dose-dependent effect on lumbar fusion in a rabbit model. 62nd Annual Orthopaedic Research Society Meeting, Orlando, FL, March 5-8, 2016.

Conference Posters

Abraham SS, Kadkoy Y, Cottrell JA, O'Connor JP. Correlating Fracture Callus MicroCT Data to Mechanical Properties. 65th Annual Orthopaedic Research Society Meeting, Austin, TX. February 2-5, 2019.

Cottrell JA, Vives MJ, Lin SS, Abraham SS, Uko L, O'Connor JP. Locally applied immediate release insulin has a dose-responsive effect on posterolateral lumbar fusion in a rabbit model. 62nd Annual Orthopaedic Research Society Meeting, Orlando, FL, March 5-8, 2016.

Subramanian S, Mitchell AM, Engler SS, Uhrich KE, O'Connor JP. The use of BMP-2 and novel polymers for guided bone regeneration. 60th Annual Orthopaedic Research Society Meeting, New Orleans, LA, March 15-18, 2014. Also 2nd Annual Musculoskeletal Repair and Regeneration Symposium, Bronx, NY, October 10, 2013.

Presentations

Abraham S, Benetatos N, Frohbergh M, Ong, K. Development and Regulation of Innovations: In the Current State of Facts vs. Public Opinions, the Truth Does Not Always Prevail. Panel discussion, Food and Drug Law Journal 2019 Symposium, Washington D.C., 2019.

Advisory Appointments

Board Member, Biomedical Engineering Industrial and Professional Advisory Board, West Chester University, 2019-present