



## Sangeeta Abraham, Ph.D., PMP, CQE

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### Professional Profile

Dr. Abraham's fields of expertise are focused on orthopaedics, orthobiologics, biomaterials, and translational research.

Dr. Abraham is an accredited Project Management Professional and has prior experience in managing large scale projects involving teams of people across multiple scientific and engineering disciplines. Dr. Abraham's project management experience includes leading multiple high performing, cross-functional, and interdisciplinary teams which impacted stakeholders within the pharmaceutical and medical device industries to deliver business, R&D, regulatory, and risk management strategies.

Dr. Abraham has supported medical device manufacturers in a variety of applications throughout the total product life cycle for Class I, II, and III medical devices. Her work includes, for example, providing design verification testing such as MRI safety labeling for medical devices, assessment of quality management systems and manufacturing lines, postmarket surveillance support, and reviewing and assembling regulatory submissions. She is knowledgeable with respect to a number of important industry standards and regulations impacting the medical device industry including ISO 13485, ISO 14971, 21 CFR 820, and 21 CFR 1271. She currently is an active member of the Orthopaedic Research Society and ASTM International's Tissue Engineered Medical Products Subcommittee. Dr. Abraham is proficient in running pre-clinical trials, animal surgical techniques, microCT analysis, histology, statistical analysis, failure analysis, and developing Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) protocols.

Prior to joining Exponent, Dr. Abraham earned her Ph.D. in Biomedical Engineering from a joint program at Rutgers University and the New Jersey Institute of Technology. During the course of her Ph.D. she worked with orthopaedic surgeons, business development teams, and engineers to develop new regenerative medicine technologies. Her research included the use of in vivo and in vitro models to assess the safety and efficacy of orthobiologic adjuncts, biomaterials, and pharmaceuticals.

Dr. Abraham has prior experience working in the private sector at Arthrex, Inc. with the Validation Engineering group. Here she gained skills for Class II and III medical device validation conforming to ISO 13485 standards. Dr. Abraham drafted and executed IQ/OQ/PQ protocols for equipment and processes adhering to cGMP and 21 CFR 820. Her primary focus here was to validate and incorporate new manufacturing processes into the current manufacturing system.

### Academic Credentials & Professional Honors

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

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

## Licenses and Certifications

Certified Quality Engineer (CQE)

Project Management Professional (PMP)

## Professional Affiliations

Orthopaedic Research Society

ASTM International

## 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

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, Arinze, 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, 2019-2020