

LEENA JONGPAIBOONKIT, PhD

CAREER HIGHLIGHTS

2019-present Medtronic

Principal R&D Engineer, Spine and Biologics

- Lead NPI effort and collaborate with cross-functional teams through ID2MR and Design Control Process
- Manage and perform gap analysis and risk assessment for MDT Biologic Synthetic Legacy Products Portfolio to meet EU MDR requirements
- Manage animal study and biocompatibility testing for NPI
- Serve as SME in key function and risk management activities
- Represent MDT on ASTM subcommittee E56 Nanotechnology and F04 Medical Devices for Surgery

2008-2019 Tissue Regeneration Systems, Inc. (TRS)

A start-up medical device company pioneering CMF and orthopedic implants.

Senior Biomaterials Engineer

Lead Biomaterials Engineer

Primary responsibility:

- Lead bioactive nanotechnology coating process including method development, implementation and validation for device manufacturing and research.
- Develop comprehensive workflow for product development and Design Control
- Experience in medical device development in all stages including Design Controls, ISO 13485, ISO 14971, risk assessments, equipment validation (IQ, OQ, PQ) and calibrations.
- Knowledge of applicable ASTM and ISO standards; FDA regulations and guidance.
- These efforts led to a success of TRS's first 510K approval for Cranial Bone Void Filler product in 2013.
- Serve as technical and regulatory subject matter expert for all testing performed by CRO and assists with the interpretation of test results and impact to the projects.
- Provide guidance in the development of product and selection of materials as well as establishing equivalency to ensure that released products meet biological safety requirements.
- Advise team on technical and scientific issues.
- Provide input to strategic business plan particularly on the technical/scientific content from surgeon advisory board for KOL opinion and collaborations.
- Manage and Implement Good Manufacturing Practices (GMP), and applicable Quality Systems.
- Manage 2 Class 7 cleanrooms.
- Lead the technology transfer to Johnson & Johnson/DePuy Synthes acquisition (40% of the company) in 2017 and Medtronic acquisition in 2019.

EDUCATION/TRAINING

University of Wisconsin, Biomedical Engineering Department

Research Associate

University of Michigan, Ann Arbor, MI

Ph.D. Materials Science and Engineering

Institute for Materials Research and Engineering (IMRE), Singapore

Summer Intern Researcher

Chulalongkorn University, Petroleum and Petrochemical College, Bangkok, Thailand

M.S., Chemical Engineering and Petroleum Technology

Stacie Institute for Molecular Sciences (SIMS), National Research Council of Canada (NRC), Ottawa, Canada

Visiting researcher

Chiang Mai University, Chiang Mai, Thailand

B.Sc., Industrial Chemistry, Minor Business Administration