MICHELLE CHUTKA

West Lafayette, Indiana | 765.418.1524 | mchutka@purdue.edu | www.linkedin.com/in/michellechutka/

Visiting Professor; formerly Director of Engineering with 20 years of experience in medical device industry seeks contract or full-time opportunities to develop teams and advance projects. I am an experienced leader with previous oversight for three distinct product development engineering units: early-stage feasibility, first-generation product development, and product lifecycle engineering and sustaining engineering. Successful product development portfolio management and financial analysis of new ventures; established and grew company's R&D services branch. Managed multiple simultaneous projects for external partners ensuring value-added outcomes for all stakeholders.

CORE COMPETENCIES

- Design controls, V&V 21 CFR 820
- Risk management ISO 14971:2019
- Quality systems ISO 13485:2016
- Process validation and process development
- Animal tissue in med devices EN ISO 22442
- Financial analysis of new ventures
- Project management
- Tissue engineering
- Microsoft 365 collaboration suite
- R&D portfolio management

CAREER SUMMARY

DAVIDSON SCHOOL OF CHEMICAL ENGINEERING, PURDUE UNIVERSITY, WEST LAFAYETTE, IN (AUGUST 2019 – PRESENT)

VISITING ASSOCIATE PROFESSOR (MAY 2025-PRESENT)
CONTINUING LECTURER (AUGUST 2019 – APRIL 2024)
Design lectures, projects, and discussions to advance student enrichment in the subject topics (ChE 59700: Medical Device Design, Financial Analysis & Project Management, Marketing for Engineers; ChE 435: Senior Lab). Provide feedback on written assignments and oral presentations, assign final grades. Interface with students both in-person and virtually to accommodate learning styles. Mentor students on internship search and approach, career applications, and interview preparation, especially for international students looking for domestic career opportunities.

SYMBIOSIS CONSULTING, WEST LAFAYETTE, IN (SEPT 2024 – PRESENT)

PRESIDENT (SEPT 2024 – PRESENT)
Manage daily operations and client requests on research and advisement on topics ranging from manufacturing, design controls, risk analysis, product labeling, and tissue engineering constructs for medical devices. Generate white papers and serve as industry representative where requested.

COOK BIOTECH INCORPORATED, WEST LAFAYETTE, IN (JUN 2005 – SEPT 2024)

DIRECTOR OF PRODUCT ENGINEERING (JAN 2016 – SEPT 2024)
Direct and provide oversight to all stages of product development engineering from early feasibility engineering to sustaining engineering. Accountable to R&D budget, R&D services revenue projections, timeliness of new product launches. Responsible for evaluating financial viability of new ventures and developing product development portfolio.

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ENGINEERING PROGRAM MANAGER (JAN 2013 – DEC 2015)
Manage and lead a team in Product Development Engineering to develop medical devices utilizing a broad spectrum of base technologies from xenograph materials to bioresorbables. Areas of responsibility include personnel and resources management, research and feasibility engineering, design control, design verification and validation activities, risk management, and post-production design engineering.

ENGINEERING PROGRAM LEADER (JAN 2009 – DEC 2012)
Advance new technology platform for applications in a multitude of disease states through process development and scale up and achieving clinical trial readiness.

PROCESS ENGINEERING LEADER (JAN 2008 – JAN 2009)
Serve as technical lead in a team focused on rapidly developing processes to transfer new products from the development phase to manufacturing.

PROCESS ENGINEER (JUN 2005 – DEC 2007)
Support process development and process risk analysis activities for medical devices in the development phases. Perform process validations and process scale up.

EDUCATION

Master of Science (MS) in Chemical Engineering, University of Michigan Ann Arbor, MI 2003
Bachelor of Science (BS) in Chemical Engineering, University of Michigan Ann Arbor, MI 2002

Professional-focused master's program with emphasis on gaining industry experience, collaboration opportunities, and practical insights. Specific industry concentration in Pharmaceutical Engineering. Engineering internships included:

- Valeo Schalter und Sensoren, GmbH (Bietigheim-Bissingen, Germany, May 2003 – Oct 2003)
- Eli Lilly (Indianapolis, IN, May 2002 - August 2002)
- Independent Engineering Labs, Incorporated (iEL) (Jackson, MI, May 2001 - January 2002)
- Valeo Automotive (Auburn Hills, MI, May 2000 - August 2000)

PATENTS/PUBLICATIONS

U. S. Patent 10,973,856: "ECM implant compositions and methods", April 13, 2021.
U. S. Patent 9,827,271: "Methods and Devices for Lung Volume Reduction with Extracellular Matrix Material", November 28, 2017.
Crapo PM, Wang Y. Small intestinal submucosa gel as a potential scaffolding material for cardiac tissue engineering. *Acta Biomater*. 2010;6(6):2091–2096. (Featured in acknowledgements).

ORGANIZATIONAL LEADERSHIP

- Research Review Committee Member: LittleStar ABA Therapy, West Lafayette, IN
- Purdue Staff Representative Club Officer: Purdue Archery Club
- Local Community Sponsor: Wabash River Runners Club, Lafayette Area Aquatics Masters, Indiana Bass'N Gals