

MICHELLE CHUTKA

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Director of Engineering with 20 years of experience in medical device industry. Experienced leader providing oversight for three distinct product development engineering units: early-stage feasibility, first-generation product development, and product lifecycle engineering and sustaining engineering. Demonstrated successful product development portfolio management and financial analysis of new ventures. Established and grew company's R&D services branch to \$4M. Expertise and experience include Design Controls 21 CFR 820, Risk Management ISO 14971:2012, Quality Systems ISO 13485:2016, FDA and International Regulatory submission support, assessment and preparation (EU-MDR/APAC). Simultaneously provided education and mentorship to the students of the Purdue Community via a Continuing Lecturer appointment through the Davidson School of Chemical Engineering, Purdue University, in the topics of Medical Device Design and Development, Financial Analysis, and Project Management.

EDUCATION

AUGUST 2002-MAY 2003 M.S. CHEMICAL ENGINEERING

AUGUST 1999-MAY 2002 B.S. CHEMICAL ENGINEERING

UNIVERSITY OF MICHIGAN, ANN ARBOR, MI

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

Engineering Internship experiences include:

- Valeo Schalter und Sensoren, GmbH (Bietigheim-Bissingen, Germany, May 2003 - October 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)

CAREER SUMMARY

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 delivering on 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. Grew R&D services branch to \$4M in 2024.

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.

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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.

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

CONTINUING LECTURER (AUGUST 2019 – PRESENT)

Design lectures, projects, and discussions to advance student enrichment in the subject topics (ChE 59700: Medical Device Design, Financial Analysis and Project Management). 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 prep, especially for international students looking for domestic career opportunities.

SKILLS

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

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)

COMMUNITY LEADERSHIP

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