



CONSULTANT PROFILE

Michelle Chutka

Full Name:

Michelle Chutka

Title / Role:

Consultant

Areas of Expertise:

- 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
- Applied AI in med device & pharma

Professional Summary:

I am an experienced leader with previous oversight for three distinct product development engineering units with a medical device manufacturer: early-stage feasibility, first-generation product development, and product lifecycle and sustaining engineering. I've demonstrated successful product development portfolio management and financial analysis of new ventures as well as established and grew the company's R&D services branch. I enjoy providing my experiences in both design control and process/manufacturing to ensuring value-added outcomes for all stakeholders.

Key Competencies:

- Achieved transfer to manufacturing for 15+ distinct Class II Med Devices
- Lean Manufacturing review and optimization
- Curriculum and skills analysis, training program development

Industry Experience:

- Med Devices: 20 years
- Consulting: 3 years
- Biopharma: 2 years
- Educational Programs: 8 years

**Selected Achievements / Project Experience:**

- 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.
- 3 pre-sub FDA interactions for 510k and clinical trials
- Heartland Bioworks EDA Grant: Faculty Representative, Subawardee, BioTrain Program

Education & Certifications:

- M.S Chemical Engineering, University of Michigan, 2003
- B.S Chemical Engineering, University of Michigan, 2002

Regulatory / Technical Expertise (if relevant):

- ISO 13485
- ISO 14971:2019
- EN ISO 22442

Languages:

- English – Fluent
- French – Conversational
- German – Conversational

Availability:

Project-based availability.

Location / Willingness to Travel:

West Lafayette, IN. Willing to travel for short assignments; hybrid arrangement for long-term assignments.

Contact / Booking:

mc@plenumconsult.com