Timothy R. Morin

TJMorin@gmail.com | 860-944-9416

21 Oak Hill Road, Rocky Hill CT, 06067

Professional Experience

Medically Engineered FDA Solutions **April 2024- Current**

Founder and Principal Consultant

- Working with multiple companies, helping them evaluate/build/edit their QMS, DHF, and clinical trial/evidence development and management.
- Evaluating best regulatory options including pathway (finding predicate(s) if necessary)
- Developing appropriate submission documents for FDA and other regulatory bodies.
- Running a business, from marketing, quoting, invoicing, to performing the work required to support the clients.

Confinis *Senior Consultant* **October 2023-April 2024**

Mhetra (Confinis) *Senior Regulatory Advisor &* **June 2022- October 2023**

Medical device Engineering subject matter expert

- Guiding Medical Device and Drug companies on how to get market approval in the US, EU, and Internationally (FDA, EU MDR, etc).
- Correspondence with the FDA and Guidance on requirements and evidence to support regulatory burdens, including advice on how to comply with all regulations and standards including but not limited to: 21 CFR Part 820, ISO 13485, ISO 11608, ISO 14971:2019, 62366:2015, as well as many others.
- Guiding companies on or creating the most appropriate medical device documentation to support verification, validation, Engineering/usability reports or documentation needed for risk analysis, risk mitigation, product development, and process development, including FMEA's of all kinds, relying upon appropriate statistical analysis.

Cirtec Medical *Senior Process Design Engineer* **November 2019 – June 2022**

- Leading with a diverse cross-functional project team to ensure that designs meet user needs, and quality requirements, all while consider manufacturability.
- Analyzing product and process failures, performing troubleshooting, identifying root cause, and verifying corrective actions in a coherent and accurate engineering report including statistical evidence and techniques for management to use in decision making processes.
- Creating a database of project information and technical summaries related to each project that is easily understood and accessible to teammates allowing for aggressive timelines based on teamwork.
- Performing root cause analysis (RCA) using methods such as DOE, 5 whys, fishbone diagram, causal factor tree, Failure Modes, and Effects Analysis (FMEA), Fault Tree Analysis, Barrier Analysis, Change Analysis, etc.
- Designing manufacturing process instructions to help guide employees on more complex procedures and root cause analysis methodology.
- Relied upon as one of the subject matter experts in relation to class III implantable devices.

Medtronic *Senior Reliability Engineer (Contractor)* **February 2019 – November 2019**

- Perform workflow design, evaluation, testing, and logging anomalies of HUGO (Surgical Robot) while focusing on system performance.
- Guiding the decision-making process involving plans and assigning work, developing project tasks, managing responsibilities of personnel, and tracked deliverables for R&D projects, as well as performing, designing, validating, DHF, and maintaining component level testing.
- Completing Engineering Reports using Statistics and Minitab.
- Developing parts and drawings, using Creo software for machining and 3-D printing.
- Designing new test fixtures and software, to implement new technology (such as Universal Robots) to test product reliability
- Working with Vendors to supply the team with custom supplies to meet growing needs.

Physician Assistant **July 2016 – January 2019**

Timothy R. Morin
TJMorin@gmail.com | 860-944-9416
21 Oak Hill Road, Rocky Hill CT, 06067

Bay Path University *PA Graduate Student* **June 2013 – May 2016**
Hartford Hospital *Emergency Patient Care Associate* **October 2011 – November 2012**

Covidien *Quality Engineer* **July 2010 – August 2011**

- Writing and executing engineering tasks for the quality assurance laboratories involved in testing and releasing product conforming to Medical Device Regulations.
- Development of appropriate test methods for products following and aligning with industry standards, ensuring processes and procedures are in compliance with regulations.
- Validation and qualification of medical device manufacturing equipment using FDA and industry standard techniques, such as DFMEA and PFMEA.

Covidien *Manufacturing Engineer (Contractor)* **May 2010 – July 2010**

- Developed and performed validation CCR's, VMP's, IQ's, CQ's, OQ's, and PQ's.
- Designed manufacturing processes, procedures and production layouts for assemblies, equipment installation, processing, machining, and material handling.
- Identified and assessed suture defects, determined root causes, documented, and listed corrective actions.
- Designed arrangement of machines within plant suture facilities to ensure most efficient and productive layout adapting machine and equipment design to factory and production conditions.
- Collaborated with manufacturing and quality assurance teams to identify and resolve issues.
- Development of manufacturing processes that are applicable to statistical process control to provide guidance to engineering regarding design concepts and specifications required to best utilize equipment and manufacturing techniques
- Evaluation and purchasing of advanced equipment across multiple departments.

Supramagnetics *R&D Material's Engineer* **May 2009 – March 2010 R&D;**
Supramagnetics, *R&D Material's Associate Engineer* **June 2004 – May 2009**

- Mechanical testing, engineering analysis and design/development of superconducting wire, including finite element analysis (FEA).
- Proficient at hands-on advanced design, development, and analysis phases.
- Assess compounds for materials interchangeability and optimization.
- Recommend materials replacement options for cost reduction.
- Extensive prototyping to support new product proposals.
- Advanced wire swaging, pointing, assembly, extrusion, chemical etching, Electro/mechanical assembly, plastic injection modeling, CNC & CMM, with strict reliance on tolerance analysis.
- Experimentation with alternative lubricants to copper cladding and removal.
- Responsible for maintaining manufacturing equipment.

Education

Master of Science in Physician Assistant Studies **June 2013 – May 2016**
Bay Path University Physician Assistant Program; Longmeadow, MA
Master of Science in Molecular Cell Biology/Biomedical Engineering **August 2008 – December 2009**
University of Connecticut; Storrs, CT
GPA: 3.96
First Author in Experimental Cell Research publication; 2014
Bachelor of Science & Engineering in Biomedical Engineering
University of Connecticut; Storrs, CT **August 2003 – May 2007**
Minor in Materials Science Engineering & Mathematics

Scholarly Projects

Timothy R. Morin

TJMorin@gmail.com | 860-944-9416

21 Oak Hill Road, Rocky Hill CT, 06067

- Master's thesis on Cellular Mechanics including original research and in-depth evaluation of secondary research.
- Biomaterials engineering project: Designing a method for developing an advanced Hydroxyapatite biocompatible material for patient implantation.
- Tissue Engineering Project: Concept based project to develop an artificial tendon product, write a grant proposal and business plan.
- Senior Biomedical Engineering Design Project: Full year; Design through development of a surgical device, anesthesia monitoring system which transmits via Bluetooth to a surgeon's PDA, created a supporting manual, and a design report.

Clinical Experience

- Two months of operating room experience as primary and secondary assist. As well as clinical rotations in ambulatory medicine, women's health, inpatient care, emergency medicine, psychiatry, and pediatrics.
- Worked daily with physicians, patients, and colleagues at all levels within the medical field.
- Daily presentations on patient Diagnosis, Treatments, and Plans of Care.

Technical Competencies

- Computer Software: CAD (Solidworks), Agile, Creo, JAMA, JIRA, LabView, Matlab, CREO, MS Office, C++, Andor iQ 1.9, Motic, MS Project, Visio, Minitab.
- Computer hardware: Arduino, circuit board assembly, Nikon Eclipse Ti, and LCD programming.
- Machining: Lathe, Vertical and Horizontal Milling, Welding, screw threading, sawing, and extrusion.
- Technical writing: Engineering drawings, test method validation plan, laboratory procedures and reports.

Activities

- **Political Experiences:** Vice President, UConn Graduate Student Senate; Senator, UConn University Senate; Graduate Student Chair, Student Welfare Committee.
- **Volunteer Experiences:** Recreation consultant, Police Explorer, Shadowing in Operating Room, and Medical Engineering.