# Catherine Trojanowski, MSc., P.Eng.

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## SKILLS

- **Regulatory knowledge**: medical device classification and databases, Pre-Submission Program requirements, standards and standardized testing, 21 CFR 820, ISO 10993, ISO 14971, 510(k), De Novo, PMA, IDE, HDE, post-approval studies, post-market surveillance, design verification and validation, as well as sterilization and labelling requirements.
- **Project management/planning**: supervising, mentoring, coordinating, cost estimation, budgeting, and scheduling.
- **Language skills**: strong written, oral, and interpersonal skills in English, working knowledge of Polish and French.
- Detail-oriented, client-centric, result-driven, excellent team player, well-organized, flexible, dependable, and self-motivated.

## EDUCATION

**JOHNS HOPKINS UNIVERSITY** Baltimore, MD, U.S.A.
**Master of Science in Engineering Degree** May 2022

- CGPA: 4.0.
- Major in Applied Biomedical Engineering (Translational Tissue Engineering focus).
- Advanced coursework in medical device regulation, rehabilitation engineering, biomaterials, immunoengineering, cell and tissue engineering, physiology, molecular biology, biomimetics, and mathematics. Enhanced understanding of mechanical design fundamentals through coursework and projects. Developed strong knowledge of medical device regulation.

**QUEEN'S UNIVERSITY** Kingston, ON, Canada
**Bachelor of Applied Science Degree** May 2017

- Major in Chemical Engineering (Biochemical Engineering focus).
- Relevant coursework included CAD modeling, statics and dynamics, structure and properties of materials, thermodynamics, fluid mechanics, electrical fields and circuits, statistics, differential and integral calculus, process control, and heat transfer.

## PROFESSIONAL EXPERIENCE

**PROCESS ENGINEER** Mississauga, ON, Canada
**Hatch Ltd.** June 2017 - Present

- Developed strong analytical and creative problem-solving skills while working on projects in various stages of the project lifecycle including conceptual, pre-feasibility, and feasibility studies, as well as detailed design and execution.
- Prepared technical specifications for equipment, evaluated bids to ensure compliance, and selected appropriate suppliers.
- Identified and evaluated possible risks of engineering strategies and suggested mitigation techniques to ensure public safety.
- Applied design control, change control, and engineering practices to support on time and on budget process development.
- Developed and reviewed engineering design deliverables including proposals, qualification documents, drawings, datasheets, specifications, engineering lists, design criteria, calculations, and summary reports. Prepared master and history files.
- Analyzed test protocols and reports to determine optimal equipment configurations and design processes.
- Collaborated with multidisciplinary design teams of 10 or more individuals and participated in client meetings.

**BIOMATERIAL HOST RESPONSE LABORATORY ASSISTANT** Kingston, ON, Canada
**Queen's University** September 2015 - April 2016

- Cultured NIH/3T3 fibroblast cells to make lysate and ran a Micro BCA assay to determine the protein concentration in the lysate. Cultured RAW-Blue cells and assisted in a QUANTI-Blue assay.
- Analyzed data from assays, performed dilution calculations, and read technical documents and protocol sheets.

## RELEVANT ACADEMIC WORK

**Regulation of Medical Devices,** Johns Hopkins University January 2022 - May 2022

- Solid understanding of design controls and risk management, and their influence on the medical device development process.
- Excellent understanding of the regulatory decisions required to assess the safety and effectiveness of new medical devices.
- In-depth knowledge of the 510(k) submission process and predicate devices. Reviewed applicable regulations and standards and used the 510(k) decision-making flowchart to make a determination of substantial equivalence.
- Strong understanding of IDE studies and PMAs, including scientific data required to determine safety and effectiveness.
- Used medical device databases to find relevant information required to classify and assess new medical devices.
- Familiar with ASTM standardized testing and Committee F04, the CDRH Standards Program, and the standards recognition process. Analyzed standards to predict outcomes of regulatory decisions.
- Determined required biocompatibility tests taking into consideration device modifications and the availability of predicates.

## REFERENCES

| Dr. Zane Wyatt | Dr. Arielle Drummond | Dr. John Hickey |
|---|---|---|
| zwyatt2@jhu.edu | adrummo9@jhu.edu | jwhickey@stanford.edu |