Alexander Averin

First-Class MSc Biotechnology Graduate | ISO 13485/14971 Certified | Six Sigma Yellow Belt | Aspiring Quality Engineer

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Professional Summary

First-Class MSc Biotechnology graduate and Medtronic Quality Operator with hands-on experience in ISO 13485/GMP manufacturing. Proven record in root cause analysis, process validation support, and non-conformance documentation. Six Sigma Yellow Belt and ISO 13485/14971 certified, combining biological science precision with engineering-grade quality assurance. Focused on validation, risk-based quality, and continuous improvement within regulated med-tech manufacturing. Dedicated to ensuring product reliability, compliance, and patient safety through disciplined execution of validation, risk management, and quality engineering principles.

Education

MSc in **Biotechnology** (First class honours)– University of Galway 2024-2025
BSc in **Biomedical Science** (First class honours) – University of Galway 2020-2024

Professional Experience (Quality and Research)

- **Manufacturing Quality Technician – Medtronic, Galway (March 2025– September 2025)**
  1. **Operated in ISO 13485 Class 7** cleanrooms, maintaining 100% documentation accuracy
  2. Conducted visual inspections for defects, assembly integrity, and part conformity.
  3. Performed in-process quality checks, documentation review, and lot traceability under regulated manufacturing procedures.
  4. Utilised precision instruments and followed Standard Operating Procedures **(SOPs)** to ensure batch conformity and reliability.
  5. Collaborated with quality engineers to identify non-conformities and contribute to **root cause analyses (RCA)** for process improvement.
  6. **Maintained 5S standards**, safety compliance, and cross-trained in quality documentation to support continuous improvement initiatives.
  7. Monitored and recorded machine parameters, including UV intensity, speed, and cycle settings to ensure **process stability and compliance** with defined specifications

- **Post-graduate researcher (June 2025- September 2025)**
  1. Led an MSc project on bacterial histidine acid phosphatase (HAP) phytases using large-scale bioinformatics and phylogenetic analysis.
  2. Curated a 400 + sequence dataset from NCBI, UniProt, and AnnoTree; performed MAFFT alignments and IQ-TREE phylogeny reconstruction.
  3. Produced a first-class thesis demonstrating precision in data curation, analysis, and result interpretation.

- **Laboratory Assistant – University of Galway (September 2024– September 2025)**
  1. Calibrated and operated analytical laboratory equipment
  2. Prepared buffers and carried out analytical techniques like Elisa, HPLC, PCR, blotting all in GLP enviroment
  3. Assisted professors in experimentations and mentored students

- **Undergraduate Researcher – University of Galway (2 months)**

1. Conducted Supervised research on MDA-MB-231 cancer cell lines
2. Utilized laminar flow hoods and gained proficiency in cell culturing
3. Improved a laboratory protocol to yield extra 21.35 % live cell count

Core Competencies

- **Six Sigma:** White and Yellow Belt certified (CSSC); practical experience applying DMAIC and 5S methodologies for continuous improvement and deviation prevention.

- **Quality Management Systems (QMS):** Trained in system structure, document control, and non-conformance management; applied QMS principles during Medtronic operations and academic research documentation.

- **Good Manufacturing Practice (GMP):** Distinction-level module complemented by hands-on experience in ISO 13485 cleanrooms at Medtronic, ensuring full compliance in batch documentation, traceability, and inspection workflows.

- **Good Laboratory Practice (GLP):** Applied through laboratory supervision as Graduate Teaching Assistant and postgraduate researcher, ensuring precision, reproducibility, and traceable experimental data.

- **ISO Standards:** Certified in ISO 13485, ISO 14971, and ISO 9001; practical familiarity with risk management, quality audits, and regulated manufacturing frameworks.

- **Programming & Automation:** Python, R, and Bash for data processing, automation, and analysis; GitHub portfolio includes machine-learning and AI-based tools.

- **Software & Design:** SolidWorks, AutoCAD, and Excel (advanced macros, pivot tables) for process visualization and data trending.

- **Technical Communication:** Skilled in scientific and regulatory writing; authored first-class MSc thesis demonstrating structured reporting and GLP-compliant documentation.

Technical & Quality Engineering skills

Programming & Data: Python (automation, visualization, API parsing), R (statistical analysis, ggplot2), Bash (pipelines), Git (version control), Excel (macros, pivot tables).

Quality & Regulatory Systems: GMP, GLP, ISO 13485 / 14971 / 9001, Six Sigma (White & Yellow Belt), QMS documentation, root cause analysis (RCA), CAPA awareness.

Laboratory Techniques: Microscopy, ELISA, mammalian cell culture, spectrophotometry, centrifugation, protocol optimization, visual inspection in ISO 13485 cleanrooms.

Design & Software: SolidWorks, AutoCAD, Canva, Adobe Illustrator (scientific posters, figures).

Soft Skills

Leadership: Served as Class Representative for both BSc and MSc cohorts, coordinating communication between 100+ students and faculty.

Communication: Developed through teaching, tutoring, and public STEM outreach; able to explain complex concepts with clarity and precision.

Analytical Problem-Solving: Adapted and optimised research protocols, improving experimental reproducibility and data quality.

Process Improvement: Applied Six Sigma and 5S principles in both academic and industrial settings to enhance efficiency and compliance.

Creativity & Initiative: Participant in Medtronic Hackathon and the Ideas Lab start-up incubator.