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.

- **Graduate Teaching Assistant – University of Galway (September 2024– September 2025)**
    1. Supervised student laboratory sessions and enforced GLP and biosafety compliance.
    2. Mentored 40 + students on analytical accuracy and data integrity
    3. Conducted supervised cell-culture research on MDA-MB-231 lines, optimising protocol for + 21 % live-cell yield.

- **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.