

CURRICULUM VITAE

PROFILE

Mary Johnson

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PROFESSIONAL SUMMARY

Recent MSc graduate in Bioprocess Engineering with a strong academic background in Biopharmaceutical Science, driven to contribute to quality assurance and compliance in the pharmaceutical and biotechnology sectors. Equipped with in-depth knowledge of GMP, GLP, HPRA, FDA, and EMA guidelines such as EudraLex volume 4, with hands-on experience gained through internships and research projects. Proficient in developing and maintaining quality systems, managing deviations, CAPAs, conducting risk assessments, and ensuring adherence to rigorous regulatory standards. Recognized for effective communication skills, keen attention to detail, and a proactive mindset geared toward continuous improvement. Eager to leverage my technical skills and regulatory knowledge to support the production of safe and effective biopharmaceutical products in a dynamic and growth-oriented company.

EDUCATION & QUALIFICATIONS

Master of Science in Bioprocess Engineering

Dublin City University, Dublin, Ireland

September 2023 – September 2024 | GPA: 2.1

Key Modules: Introduction to Bioprocess Engineering, Fundamentals of Bioprocess Engineering, Recombinant DNA Technology, Regulatory Affairs for Biotechnology Products, Animal Cell Culture Technology, Bioreactor Design, Modelling and Monitoring, Biopharmaceutical Industry Regulation and Management, Bioprocessing Laboratory Formulation and Delivery of Biopharmaceuticals, Biopharmaceutical Facility Design and Operation, Bioprocess Scale Up and Technology Transfer, Bioseparations, and Bioprocess Engineering Project.

Bachelor of Science (Hons) in Biopharmaceutical Science

Dundalk Institute of Technology (DKIT), Ireland

2022 – 2023 | Second Class Honours

Key Modules: Upstream and Downstream processing, Biopharmaceutical Analysis, Ethical Biomolecular Therapeutics & Bioinformatics, Recombinant Drug Manufacturing, project Design & Statistics and Biopharma Research Project

Bachelor of Science in Pharmaceutical Science

Dundalk Institute of Technology (DKIT), Ireland

2019 – 2022 | Second Class Honours

Key Modules: Chemistry Biology, Mathematics, Excel Spreadsheets, Health and safety, physics, Introduction to Organic Chemistry Biochemistry, Analytical Science, Pharmaceutical Microbiology, Molecular Biology, Statistics & data analysis, Pharmaceutical chemistry & Pharmaceutical processing.

RELATED EXPERIENCE

Bioprocessing Intern

National Institute for Bioprocessing Research and Training (NIBRT), Dublin, Ireland

March 2024

- Monitored bioprocess parameters, ensuring compliance with GMP.
- Assisted in quality control, including reviewing data and documentation to meet regulatory guidelines
- Prepared and operated bioreactors while maintaining precise records of deviations, and corrective actions.
- Adhering to Aseptic processing, Data integrity, and GDP guidelines

Laboratory Assistant

DKIT Smooth Muscle Research Lab, Dundalk, Ireland

Oct 2022 – March 2023

- Managed GLP-compliant documentation, waste disposal, and equipment calibration.
- Conducted and documented DNA extraction and PCR, ensuring all activities met quality standards.
- Supported Technician on research initiative by correct disposal of biological, chemical, glass and plastic waste in appropriate containers.

3-month summer internship in a laboratory during degree course: Cell culture, quality control techniques, using biochemical equipment • Teamwork within a lab of eight people.

Projects

Master's Thesis: "The use of AI in the Manufacturing of Antibodies and Cell-Based Biotherapeutics. Supervised by Dr. Paul Leonard

- Explored AI-driven advancements in biotherapeutic production, including quality control and process optimization.
- Collaborated with cross-functional teams to present findings, demonstrating effective communication and knowledge-sharing.

Undergraduate Research Project: cAMP-mediated regulation of tracheal tone

- Designed and Conducted experiments to investigate the regulation of tracheal tone mediated by cAMP. The project focused on exploring downstream pathways by employing pharmacological modulators targeting the Epac (exchange factor directly activated by cAMP 1) pathway and the protein kinase A (PKA) pathway.
- Analyzed data and presented findings at the DKIT Annual Research Symposium.

RELATED Project

Designed and conducted experiments: culturing cells, construction of AAV vectors Interpretation and analytical skills, accuracy, and precision data analysis.

Wrote up and presented work to the department: Self-driven and motivated, communication skills (writing and presenting)

Voluntary work experience : Worked on a conservation project, Teamworking and co-operation, Good laboratory practice e.g., wearing of PPE, safety goggles, gloves, and laboratory coat.

Optimization of Fermentation Conditions for Enzyme Production

- Focused on regulatory requirements for enzyme production, contributing to an understanding of documentation and compliance processes

key Skills & Competencies

- **Technical Skills:** Cell culture, Fermentation, Bioreactor operation, Protein purification, Aseptic techniques, Protein A chromatography, Ultrafiltration & Diafiltration Ion-Exchange chromatography, HPLC, PCR, and spectrophotometry.
- **Quality Assurance & Compliance:** In-depth understanding of GMP and biopharmaceutical regulatory standards (EMA, FDA, HPRA). Experienced in creating and reviewing quality documentation, managing deviations, and ensuring compliance with quality systems.
- **Risk Management:** Familiar with supply chain risk registers and the oversight of supply chain risks, capable of providing support to mitigate potential issues.
- **Regulatory Change Management:** Experience supporting regulatory change management and ensuring alignment with compliance requirements.
- **Analytical & Problem-Solving Skills:** Strong analytical background with a keen eye for detail and a methodical approach to identifying improvements in processes.
- **Communication & Teamwork:** Excellent written and verbal communication skills, with experience collaborating across teams and providing feedback for continuous improvement.
- **Adaptability & Continuous Learning:** Committed to developing technical and regulatory expertise to support evolving industry demands.
- **Software Proficiency:** Microsoft Office Suite, and data analysis tools. Excel functions such as Pivot Tables, Minitab, and LabScribe2.

Professional Affiliations

- Member of the Biotechnology Industry Organization (BIO)
- Member of the Parental Drug Association (PDA)
- Member of the Engineers Ireland

VOLUNTARY EXPERIENCE

Parental Drug Association 2023-2024

Enhanced association visibility and coordinated events to support member engagement and development.

Mature Students Society, DkIT 2019 –2022

- Developed a marketing strategy to grow membership from 5 in the first year to 63 currently.
- Planned weekly activities and recorded action points for delivery with fellow members.

Cell Explorer, Science Educational Outreach Programme, DkIT November 2019

- Volunteered during science week, as a tutor to 4th and 5th class students from different primary schools in Louth on scientific techniques such as extracting DNA from a banana.

HOBBIES, INTERESTS, ACHIEVEMENTS & AWARDS

- **DkIT Elevate Award:** In recognition of my voluntary participation with DkIT Mature Student Society.
- **Fundraising:** Helped raise over €2000 for the Kevin Bell Repatriation Fund and €500 for Crumlin Children's Hospital.
- **Running:** Member of Friends Athletics Running Club and run twice weekly. Member of DKIT GYM, enjoy making friends and , travelling, and dancing.

References : Available upon request.

