ANTHONY MAGUIRE

BIOTECH TECHNICAL WRITER – ELI LILLY
QC ANALYST – TEVA

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PERSONAL PROFILE

- 1+ Years proven hands-on industry experience working as a Biotech Technical Writer for Eli Lilly, in addition to working as a QC Analyst for Teva Pharmaceuticals.
- Strong background in raw material, in-process and finished product testing in accordance to SOPs, cGMP and GLP.
- Relevant experience in cGMP documentation & compliance, deviations, validations and change controls.
- Hands-on Python, MATLAB, R, Polymath, Materials Studio, PyMOL/QuteMol and LaTeX experience.
- Exposure to Machine Learning and Crystallization Kinetics for the creation of ANNs on MATLAB and Python.
- Graduated with a BSc. in Industrial Biochemistry in the University of Limerick, Ireland (Grade – 2.1).
- Currently looking for an opportunity to excel in a challenging working environment & become a valuable asset to the team.

EXPERIENCE

BIOTECH TECHNICAL WRITER

Eli Lilly Kinsale Ltd | Eli Lilly and Company
Oct 2021 – Present

Documentation & Compliance

- Responsible for the design, generation and updating of facility/process SOPs & Work Instructions (WIs), Production Master Batch Records (MBRs), Operations Area Logbooks, Training Documentation, EHS System Documentation, and PQ Protocols.
- Authoring Process Validation Protocols, Reports, in addition to writing and reviewing Protocols for Production support activities.
- Fundamentals in Process & Quality Risk Assessments, and Product Impact Assessments.
- Design and generation of DQ, IQ, OQ, PQ Protocols.
- Act as Procedure Coordinator for the completion of routing new and revised Procedures, Training Courses, Batch Records and Compliance Documents.

Production, Quality & Operations Support

- Collaborate with management and supervisory personnel from Production, Quality & Operations to resolver product quality and non-conformance issues.
- Liaising with Upstream, Downstream & Media/Buffer Process Teams for successful implementation of new and revised process procedures, WIs, MBRs, in addition to other relevant cGMP documentation.
- Assist site management in investigation reports, authoring quarterly/annual summaries and metrics, in addition to ensuring cGMP and regulatory compliance is consistently enforced.

QC ANALYST

Tosara Pharma Ltd | Teva Pharmaceuticals
Jan 2020 – Sep 2020

Testing

- Responsible for preparation and testing of raw materials, in-process and finished product testing to ensure conformance with quality standards.
- Preparation of technical documents for results of laboratory experiments.
- Use of SAP for results of testing and material management.
- Aid in the execution of closures of deviations/LIRs, CAPA, and change controls.
- Provide support to MFG Teams by performing shift-work as required.
- Calibration & troubleshooting of equipment.

Documentation & Compliance

- Ensuring experiments are completed in accordance to SOPs, GLP and cGMP.
- Writing SOPs, dealing with LIRs and stock management of chemicals needed for the QC lab.
- Development of SOPs & WIs for specific laboratory tasks, exposure to MSDS and CoAs of chemicals & disposal of chemical waste in accordance to EHS.
- Support Quality management in the implementation of QMS systems, in addition to data analytics for performance feedback and related activities.

Project Management

- Improving & digitising raw material sample retention system, and QC documentation archiving.
- Changing and updating relevant SOPs for the improved systems, DCR form requests, implementing required training to relevant operators.
- Liaising with external companies for storage of documents / excess materials.

RELEVANT SKILLS

- Experience in the design, generation and updating of SOPs, WIs, MBRs, Logbooks, Training Documentation, EHS System Documentation
- Fundamental knowledge in Six Sigma Tools, Kaizen Methodology, FDA & EMA Regulations, and Quality Management Systems (QMS)
- Strong Quality orientation with incremental ability to focus on details and adherence to standards
- Proficient laboratory skills and analytical methods for greater efficiency in testing, in addition to competency in the closure of LIRS, CAPA, and change controls whilst ensuring compliance to cGMPs
- Use of HPLC & Gas Chromatography, Wet chemistry analysis, bioinformatic tools, UV–Vis, FTIR, SDS–PAGE/Gel Electrophoresis, Western Blotting, Mass Spectroscopy, troubleshooting and diagnostics
- Hands–on Python, MATLAB, R, Polymath, Materials Studio, PyMOL/QuteMol and LaTeX experience
- Advanced in Microsoft Office Applications, SAP, Regulus, FOX IA and Trackwise/Trackwise Harmony
- Highly proficient problem solving and communication skills
- Competent teaching ability from providing a lecture in 'Immuno and DNA Diagnostic Techniques (ZIKV)'

EDUCATION

BSC. INDUSTRIAL BIOCHEMISTRY
University of Limerick
Aug 2017 – Aug 2021

- Modules included
  - Analytical Chemistry, Bioprocess Engineering, Safety & Industry, Quality Management, Bioinformatics and Chemometrics, etc.
- Second Class Honours Grade 1, 2.1.
- QCA – 3.01.

LEAVING CERTIFICATE
St. Colman's College
Sep 2012 – May 2017

- Completed 7 honours.
- Achieved 445 points.

THESIS / PUBLICATION

MODELLING THE CRYSTALLIZATION KINETICS OF ORGANIC COMPOUNDS USING ARTIFICIAL NEURAL NETWORKING/ BACKPROPAGATION ANN FOR CRYSTALLIZATION KINETICS OF ORGANIC COMPOUNDS

- In–depth knowledge of Machine Learning and Crystallization Kinetics
- Fundamentals in effective Crystallization Process Development and Crystallization Data Analytics
- Proficient in creating neural networks on Python and Matlab
- Proficient in LaTeX for publishing professional scientific papers
- Nominated for Best Thesis in the Department of Chemical Sciences UL 2021
- Thesis: Modelling the Crystallization Kinetics of Organic Compounds Using Artificial Neural Networking
- Pending Publication: Backpropagation ANN for Crystallization Kinetics of Organic Compounds

REFERENCES

Eli Lilly and Company
Supervisor: Susan Foster

Teva Pharmaceuticals
Manager: Arul Viswanathan

University of Limerick
FYP Advisor: Vasanth Kannuchamy

References available upon request.