

EXPERIENCE

**Boston
Scientific
Corporation
May 2009 –
April 2013**

Supervisor (May 2009 – Oct 2009)

Quality Engineer I (Oct 2009 – Jun 2011)

Quality Engineer II (Jun 2011 – Apr 2013)

Operations Quality Engineering Excellent (OQEE)

- CAPA (Corrective and Preventative Actions) owner: performed investigation to determine root cause of repeated non-conforming event (NCE), implement corrective actions, and perform verification of effectiveness while meeting companywide cycle time goals.
- Closure of MGOAL: transferred methods to new laboratory, performed method performance and review training, completed testing and closure of batch records
- Non-conforming events: analyzed trends in non-conformances, reviewed investigation documentation for conformance to Standard Operating Procedures (SOPs)
- Lean Culture Facilitator: participate and instruct during rollout of Principles of Lean throughout the company; worked with IQA, Metrology/Equipment Engineering and Quality Systems/OQEE

Maple Grove Operations Analytical Laboratory (MGOAL) Quality Assurance (QA)

- Raw Data/Documentation Reviewer: assure cGMP and SOP compliance of testing
- MGOAL Practice vs. procedure Assessor
- Validation Support: review software change control executions
- Internal/External Audit Support: review documentation, support backroom activities and perform internal assessments
- Investigator: initiated documentation for investigations, such as Out Of Specification(OOS) / Out Of Trend (OOT), deviations and quality incident reports

MGOAL Laboratory Information Management System (LIMS)

- Certified LIMS Administrator: perform administrative duties to support system users
- Validation Support: execute and review test cases to support system enhancements
- LIMS Trainer: educate QA and QC system users on use and efficiency in LIMS

Incoming Quality Assurance (IQA)

- IQA Inspection Reviewer: assure Current Good Manufacturing Practices (cGMP) compliance to material specification/drawing requirements
- Investigate NCE in support of IQA Engineers
- Risk Based Incoming Acceptance Expert: revise matrix and implement changes to gain efficiency
- Annual Supplied Data (SD) Audit Lead: assure compliance, as well as revisions to the SD matrix.
- Trend and Track Resources: evaluate Work In Progress (WIP) of blocked/unblocked components, plus daily receipts and releases
- Change Control Team Lead: manage document revisions per issues, risk and potential Value Improvement Projects (VIPs)
- Oversee Equipment Compliance: assure calibration and maintenance tracking per SOP
- Good Documentation Practices (GDP) Trainer: IQA and within cGMP facilities
- QA Right First Time (RFT): maintained RFT goals for observations of all QA reviewed documents

**Élan
Pharmaceuticals
Jan 2008-Feb
2009
On Assignment
Lab Support at
Élan**

Associate Manager Documentation

Analytical Development and Quality Control

- Raw Data/Documentation Reviewer: assured cGMP and SOP compliance of pre-clinical, clinical, method qualification/validation, and characterization development studies
- Trainer of Good Laboratory Practices (GLP)/Good Manufacturing Practices (GMP): trained and provided guidance to analysts on GLP/GMP documentation

Quality Assurance Research Associate

Quality Assurance Operations

- Quality Control (QC) and Analytical Development Data Reviewer: assured cGMP compliance
- Basic cGMP Compliance Trainer: provided training and guidance to operations and QC labs
- Production Facility Documentation Reviewer: assured conformity to SOPs and cGMPs
- QA Internal Audit Support: internal audits and regulatory inspections
- Development Product Support: assisted in review of document changes and change control

Boston Scientific Corporation
Jun 2004 – Sep 2007
Aerotek at BSC
Jun 2004 – Dec 2004

Quality Control Specialist II
MGOAL Testing Experience

- Analytical Testing: performed testing of raw materials, in process solutions, and drug eluting stents, commercial and experimental, in a cGMP regulated laboratory
- Operated Lab Instrumentation/Software: Waters High Performance Liquid Chromatography (HPLC), Waters Gel Permeation Chromatography (GPC), and ThermoNicolet Fourier Transform Infrared Spectroscopy (FT-IR) employing Waters Millennium, Waters Empower, and Omnic software
- Authored planned and unplanned Deviations, OOS reports, and laboratory Investigation reports
- Clean Room Experience: weighed drug substance by analytical balance in an isolator

Leadership Experience

- Kinetic Dug Release (KDR) Team Lead: Coordinated testing and independent review by 5-6 analysts while maintaining lab wide cycle time goals
- Styrene Isobutyl Styrene (SIBS) Team Lead: Coordinated testing by 3-5 resources and independent review to complete required methods while maintaining lab wide cycle time goals
- Analytical Reference Standards Designee: Performed monthly audit of analytical reference standards, documented all audit observations/reconciliation, and performed training for all laboratory personnel
- Qualified Trainer: KDR, Material ID by FT-IR, Molecular Weight Distribution by GPC, Weights and Dilutions, and clean room/isolator procedures
- Operations Analytical Laboratory Stability Designee: Followed stability protocols to coordinate analytical testing of raw materials and finished goods, including tracking sample receipt, testing, and disposition

3M Company
May 2001 – Dec 2003
Pace Analytical Services
May 2002 – Dec 2003

Lab Analyst I
Analytical Research and Development

- Testing and Formulation: Drug substances in meter dose inhalers in a cGMP regulated laboratory
- Software: Waters Millennium, ACD Labs (NMR software)
- Synthesis: Performed synthesis of novel excipients for use in pharmaceutical formulations. Performed synthesis of pharmaceutical degradation molecules
- Analytical Testing: Anderson Cascade Impactor, Aerodynamic Particle Size Tests, ELSD-HPLC and UV-HPLC
- Research: Performed excipient studies for pre-formulation of biologically active molecules.

Technical Aide
Synthetic Research and Development

- Synthesis: Performed synthesis of organic compounds for use in horticulture testing
- Performed synthesis of derivatives of currently used pharmaceutical molecules
- Analytical Testing: TLC, ¹H and ¹³C-NMR
- Research: Worked with phage display technologies for isolation of genetic sequences in bacteria

EDUCATION

University of St. Thomas, St. Paul, MN
Degree Earned: Bachelor of Arts
Major: Chemistry

SKILLS/TRAINING

- Kaizen, 5S, and Lean Culture training and execution experience
- Data Management: Organize and maintain spreadsheets to track samples and data flow throughout the *Operations Analytical Laboratory* in a format that makes information easily extractable for reporting
- LabWare LIMS v6 Certified Administrator