

Patricia K. Thewes

307 Jasmine Avenue
Monrovia, CA 91016
pkthewes@gmail.com
310-968-1322 (c)

CAREER SUMMARY

Over Fourteen years of pharmaceutical industry-related experience. A strong Quality Assurance experience performing internal and external audits, dealing with FDA, State and other regulatory agency auditors, managing training programs, document control, CAPA investigations, batch record review and all compliance related issues. An extensive background in Regulatory Affairs, Quality Control, method development, validation, and final release responsibility and testing of Pharmaceutical medical devices, solid and liquid dosage formulations, testing and approving bulk API's, and the ability to perform IQ, OQ, and PQ validation protocols. Vast experience with the implementation of 21CFR 210-211, 820 and Part 11 protocols, and use of USP monographs, and in-house method developed techniques. A solid background with data acquisition systems: Agilent ChemStation, Waters Millennium 32, and Bruker NMR spectroscopy software. Experience conducting cGMP and GLP, ISO 13485 audits, implementing, USP regulations, ICH analytical validation and stability guidelines, conduct technology transfers, developing and implementing a vendor qualification program. A successful record utilizing project management in pharmaceutical and fine chemical production cross-functional teams.

INSTRUMENTATION Solid background performing analysis using HPLC, NMR, FT-IR, KF, UV-Vis, Endotoxin (both gel clot and Kinetic Turbidometric), aseptic technique, and titration methods (standard and potentiometric), as well as GC Analysis Software experience beyond acquisition systems includes Trackwise, ISOTrain, Microsoft Word, Excel, and PowerPoint.

PROFESSIONAL EXPERIENCE

Sterigenics, Ontario, CA

1/2009- 3/2011

QA Manager

- Manage all aspects of Quality Assurance for facility, including official correspondence with the FDA, management review meetings, and serving as Ontario facility's Quality Management Representative.
- Administer the maintenance of the Quality management systems and ensures facilities compliance to Sterigenics' procedures.
- Supervise interface with Sales, Operations, Engineering and Corporate Staff, as well as customers and government personnel.
- Direct activities related to corrective actions and preventive action (CAPA), deficiency program, complaints and training activities.
- Manage Quality department staff which includes oversight of Validation and Calibration activities.
- Certified ISO 13485 Lead Auditor with experience leading audits of other Sterigenics Facilities (internal audit program).
- Coordination and supervision of customer audits, FDA audits, ISO (13485:2003 and 9001:2000) audits, and vendor audits.
- Facility resource for FDA, ISO, EN and other Quality Management System requirements.

Genchem, Brea, CA

1/2008- 11/2008

Manager of RA/QA

- Managed all aspects of Regulatory Affairs and Quality Assurance for company, including official correspondence with the FDA, management review meetings, and serving as Genchem's management with Executive responsibility.
- Administered the maintenance of the Quality management systems and ensures firm's compliance to the established system.
- Strengthened the Device History Record (DHR) documentation system.
- Supervised the maintenance and revision of the company's Device Master Record and approved final Batch Record Review for release.
- Conducted internal and external regulated quality management system audits, and responded to audit findings from regulatory agencies and customer audits.
- Improved the quality management system and firm's compliance to FDA standard.

Watson Laboratories, Corona, CA

01/2005-01/2008

Laboratory Training Supervisor

- Supervised a staff of 7 Trainers/Scientists and Department coordinators to provide all training on new and revised SOPs/test methods, safety training, cGMP training per 21 CFR 210 and 21CFR 211, refresher training sessions and all new hire training for LabOps.
- Represented the Laboratory Operations Training Department in cross-functional meetings.
- Serve as lead investigator during Out of Specifications, OOS, investigations; and implement corrective actions.

Patricia K. Thewes

- Collaborated with Senior Lab management and QA to address internal customer requests and maintain open lines of communications.
- Facilitated continuous compliance through the improvement of the training program and material.
- Instrumental in establishing and executing a department wide implementation of Structured-on-the-Job-Training (SOJT) training program for LabOps (160 individuals).
- Maintained a weekly training compliance score of 100% for the LabOps.
- Conducted training sessions for continuous improvements and personnel developmental needs.
- Work with QC Managers, Senior Management and QA to insure adherence to and improvement of all internal documentation.
- Represented the training department on the steering committee for the implementation of the new LIMS system.

Nektar Therapeutics, Huntsville, AL **QC Supervisor (Quality Control Dept)**

07/1997-01/2005

- Supervised a staff of 10 analytical chemists and technicians in the Intermediate and Final product QC department; queue samples, facilitate the completion of final product and in-process sample analysis and report the results.
- Organized the technical transfer of analytical methods from Analytical Research and Development (AR&D) to the Intermediate and Final product QC department and conduct the necessary personal training.
- Coordinated the scheduling of testing / instrument time to insure efficiency and meeting of metric timelines.
- Served as lead investigator during OOS investigations; when applicable conduct necessary training and / or implement corrective action.
- Maintained tracking system for productivity reports; includes daily reporting of sample status to QC Manager, and any other relevant internal customer.
- Daily interactions with manufacturing and QA to maintain open lines of communications.
- Promoted a strict compliance to Nektar policies and procedures.
- Facilitated continuous improvement in compliance areas and QC processes.
- Work to improve efficiency in the lab by suggestion and implementation of new process systems.
- Trained external customers, coordinating and implementing technology transfers to their facilities.
- Work with QC Manager and QA to insure adherence to and improvement of all internal documentation.
- Maintained high level of integrity and accountability within the QC department.
- Executed analytical testing and release approval for polyethylene glycol (PEG) derivatives for in-process and final product testing utilizing extensive use of NMR (300 MHz and 400MHz), HPLC (normal phase, reversed phase, gel permeation chromatography, ion exchange, derivatization methods), GC, FT-IR, and label claim confirmation, prior to finished product release.
- Performed Endotoxin assays on water and final product samples using both gel clot and kinetic turbidometric techniques.
- Provided raw materials analysis utilizing an Agilent UV-Vis 8453 spectrophotometer and a Mattson FT-IR, classical wet chemistry methods (manual and potentiometric titration using a Mettler DL-55 autotitrator), as well as, other approved Nektar methods.
- Trained new employees on all methods and instruments.
- Performed Stability Study analysis.
- Executed internal and external audits and responded to external audit concerns.
- Wrote Certificates of Analysis; also wrote and reviewed Standard Operating Procedures.
- Assisted with development and validation of analytical methods for QC.
- Implemented setup of a new Quality Control laboratory as well as assessed and implemented new systems for QC lab.

Vintage Pharmaceuticals, Huntsville, AL **Chemist (Quality Control Dept)**

10/1996-07/1997

- Provided analytical testing for raw materials, in-process, final product, and stability samples of generic drugs in compliance with USP and ICH guidelines using Waters HPLC with Millennium 2.15, IR, UV and GC.
- Performed water analysis and validation for the Purified Water System, implementing new USP procedures for testing purified water and the purchase and installation of new equipment.
- Assisted microbiology lab on finished product, stability samples, and PET (Preservative Effectiveness Testing).
- Coordinated and assigned purified water testing analysis.

EDUCATION

Bachelor of Science – Biochemistry in Chemistry (ACS certified) and Biological Sciences.
1996, University of Alabama in Huntsville, Huntsville, Alabama
Certificate of Pharmaceutical Engineering, 2007 Cal State Fullerton
Certified ISO 13485 Lead Auditor, 2010 BSI