

QUALITY ASSURANCE ASSOCIATE

Summary

Enthusiastic Chemist eager to pursue a lasting career in the Agriculture industry.

Detail-oriented Chemist with expertise in the instrumentation, physical and wet chemistry, and formulation as well as coordinating testing and development.

Highlights

- HPLC
- GC
- FTIR
- UV-Vis
- Physical Chemistry techniques
- GMP/GCP

Accomplishments

Led the pre-formulation and formulation development of a topical cream and gel for psoriasis which successfully entered clinical trials.

Experience

01/2011 to Current

Quality Assurance Associate Company Name i¼ City , State

- Preparation, configuration, execution and authoring of reports for IQ, OQ and PQ protocols for Labware LIMS and Trackwise Systems
- Managed quality systems change control, site training, deviation and CAPA compliance programs for Eisai. Other responsibilities include:
- Administration and development in Trackwise, Plateau Learning Management System and Labware LIMS systems
- QA oversight on all validation activities for Plateau Learning Management System
- Deviation investigations, CAPA and SOP review for site engineering automation systems
- Developed and provided training on local and global change management, cGMP and deviation/CAPA compliance processes to site personnel
- Reviewed and approved Master Batch Records (MBRs) and Lot Packaging Records (LPRs) for commercial batch release.
- Work within QA audit department for regulatory site audits and assist in responding to regulatory inspection observations.
- Support the Clinical organization by providing oversight to the clinical lot record packaging, specifically, review and provide a disposition decision for packaged clinical trial material.

01/2005 to 01/2011

Senior Researcher Formulation Company Name i¼ City , State

- Lead formulation chemist in the design and execution of development programs to deliver specific topical and lyophilized product attributes.
- Designed studies to substantiate formulation excipient choice, use levels and desired product aesthetic attributes
- Responsible for preclinical and toxicology study drug product manufacture and testing
- Generated and interpreted study data to determine physicochemical stability
- Drug excipient compatibility studies and other relevant studies, including solubility/pH-solubility profiles, pK_A, partition coefficient studies during formulation development process Communicated formulation development program status, goals and timelines to senior management by:
- Writing detailed technical reports on completed formulation development programs and periodic reports of on-going programs
- Performed a bi-monthly series of technical presentations to the product development group and regularly presented data at monthly local project team meetings
- Scale-up process development of cream formulation and lyophilized parental formulations.
- Assisted in the preparation of the Chemistry, Manufacturing & Control(CMC) sections of IND, ANDA and NDA submissions
- Evaluated clinical and scientific literature to identify potential product differentiators and new product opportunities
- Employed chromatography, spectroscopy and spectrophotometry techniques.

01/2003 to 01/2005

Quality Control Chemist Company Name i¼ City , State

Responsible for performing dissolution testing, content uniformity, acid resistance and assay of solid oral dosage products in a cGMP environment

Managed the stability program for all oral solid dose products

Performed USP-NF Compendial testing to ensure raw material compliance utilizing analytical and wet chemistry techniques

Investigated out of specification and out of trend data with appropriate CAPA.

Authoring and technical review of analytical SOPs

01/2001 to 01/2003

Quality Control/ Analytical Chemist Company Name i¼ City , State

- Responsible for performing physical and chemical cGMP testing of ophthalmic formulations

- Responsible for performing physical and chemical CGMP testing of pharmaceutical formulations
- Performed raw material, in process and finished product testing as well as method transfers to Quality Control
- Developed and validated stability indicating compendial and non-compendial analytical methods in accordance with ICH and FDA guidelines

01/1998 to 01/2001

Chemist / Supervisor Company Name i¼ City , State

- Supervision of a busy contract laboratory
- Responsible for running, developing and validating methods for wet chemistry and ICP, AA and GFLAA instruments
- Responsible for preparation of reports and communication of results to customers

01/1995 to 01/1997

Chemist Company Name i¼ City , State

Performed toxicological screening and conformational studies using GC/MS on horse serum and urine for illegal or banned drugs and their metabolites

Conducted both qualitative and quantitative analysis.

Education

2014

Master of Science : Chemistry University of North Carolina i¼ City , State , US

1996

Bachelor of Science : Forensic Science Michigan State University i¼ City , State , US

Presentations

Performed a quarterly series of technical presentations to the product development group and regularly presented data at monthly local project team meetings.

Presented data and formulation recommendations to senior leadership

Skills

HPLC, GC, Physical Chemistry, UV/VIS